STANDARD OPERATING PROCEDURES

FOR

INFECTIOUS DISEASES INSTITUTE

RESEARCH ETHICS COMMITTEE

(IDI REC SOPs)

Version 2.0, 14 July 2020

Table of Contents

LIST OF ABBREVIATIONS

ADE	Adverse Drug Event/Experience
AE	Adverse Event
CGMP	Current Good Manufacturing Practice
CIOMS	Council for International Organizations of Medical Science
CRF	Case Report Form
CRO	Contract Research Organizations
DSMB	Data Safety and Monitoring Board
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IBC	Institutional Biosafety Committee
ICF	Informed Consent Form
ICH	International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) & GCP Guidelines
IDE	Investigational Device Exemption
IDI	Infectious Diseases Institute
IDMC	Independent Data Monitoring Committee
IND	Investigational New Drug
IVD	In Vitro Diagnostic
NBC	National Biosafety Committee
NDA	National Drug Authority
OHRP	Office for Human Research Protections (former OPRR
PHI	Protected Health Information
PI	Principal Investigator
PMA	Premarket Approval (Application)
QA	Quality Assurance
QC	Quality Control
REC	Research Ethics Committee

SAE	Serious Adverse Event
SOP	Standard Operating Procedure
UNCST	Uganda National Council for Science and Technology

FOREWORD

Oversight of research involving human participants requires specialized knowledge which includes; regulatory requirements, Good Clinical Practice (GCP), and medical ethics. Institutions are obliged to establish an institutional culture where studies are conducted in an ethical and scientifically rigorous manner and where safeguards to humans who participate in clinical studies are of paramount importance. Ensuring an institutional culture of research excellence begins with the establishment of operational policies and Standard Operating Procedures (SOPs) that address the regulatory requirements, ethical conduct and sound implementation of all research conducted on human research participants.

An ethically responsible researcher is expected to carry the dual burden of advancing knowledge that can improve the human condition or generate new knowledge and, at the same time, to recognize the absolute imperative to treat human research participants with the utmost care and respect. Institutions and society as a whole who expect to benefit from research should be expected to share in the responsibility of conducting ethical clinical research.

This burden also falls on REC members. They are expected to act as gatekeepers to check the research enterprises that investigate new therapies, interventions, and to advance knowledge of the basics of biological and behavioral mechanisms. They are expected to share the responsibility of protecting research participants of this research.

Uganda's National Guidelines for Research Involving Humans as Research Participants require that a Research Ethics Committee (REC) must have written SOPs; and activities of the REC are conducted as per written SOPs.

These SOPs and other document shall standardize and guide the operations of the REC in line with the national and international research regulations and guidelines, and application of day-to-day operations of the REC.

These SOPs are based on current regulations, ethical principles, and guidelines for the protection of the human research participants. The SOPs should be reviewed every after 3 years or whenever necessary to ensure that they are aligned with the current legislation and/or regulations.

These SOPs state what the IDI REC requires to guide review and the ethical conduct of research involving human participants.

ORGANIZATION OF THIS SOP MANUAL

This manual is organized in 9 sets of SOPs, as follows:

SOP 1: REC General Administration

These sets of SOPs include REC's responsibilities that guide the activities of protocol review, study monitoring, maintenance of SOPs, training, staff and investigators management, and conflicts of interest. These activities form the regulatory framework of a human participant protection.

SOP 2: REC Organization

These sets of SOPs describe the composition and management of the REC.

SOP 3: Functions and Operations

These sets of SOPs detail the procedures to ensure that the REC meets its regulatory mandate to oversee research. It includes SOPs for submission requirements, determining and documenting research that is exempt from REC review, meeting administration, and documentation.

SOP 4: Review of Research

These sets of SOPs contain procedures for initial review and continuing review of research. This section describes the criteria for approval, the methods employed to assure adequate review and the actions the REC may take as a result of such review.

SOP 5: Reviews of Studies involving Vulnerable Populations

These sets of SOPs contain the SOPs for research that involves vulnerable populations and for types of research that require additional considerations by the REC, such as clinical trials involving investigational medical devices and prospective research in emergency and refugee settings, among others.

SOP 6: REC Communication and Notification

These sets of SOPs contain the SOPs to ensure timely and adequate notification of REC decisions regarding research projects to Investigators and other entities that may have an interest in the outcome of REC review.

SOP 7: Informed Consent

These sets of SOPs focus on the general requirements for informed consent and documentation of the informed consent process, exemptions to informed consent process or documentation, and the assent of minors. It also includes template consent forms and checklists of required and optional elements of consent.

SOP 8: Responsibilities of Investigators and Sponsors

These sets of SOPs provide instructions to Investigators and Sponsors regarding the REC's requirements for Investigators, from initial submission through continuing review and study completion.

SOP 9: Quality Assurance

These sets of SOPs include checklists and procedures to ensure adequate and consistent procedures by REC staff and key members in order to ensure that the REC meets a high standard of performance, and to prepare the REC for audits by regulatory agencies,

Each SOP consists of the following parts;

1. **Background** - Elucidates the IDI REC's guiding principle for an area of IDI REC activity.
2. **Scope** – Defines the extent of the SOP.
3. **Responsibility** – Lists the positions responsible for ensuring that the SOP is carried out.
4. **Applicable Regulations and Guidelines** – Cites the National Guidelines for Research Involving Humans as Research Participants, 2014, National Drug Authority Act (insert year), WHO Guidelines on Standards of Ethical Review, ICH GCP Guidelines, and any other guideline.
5. **References to Other Applicable SOPs** – Lists other related SOPs.
6. **Attachments** – Lists the forms, templates, checklists and/or documents available to integrate the procedures into the daily operations of the IDI REC and ensure compliance.
7. **SOP flow charts:** Describes the details of individuals and daily activities of REC administrator and members to carry out the requirements of the SOP.

Finally, this SOP Manual contains an extensive library of attachments, which include narrative guidelines, checklists, logs and other forms. The forms are either *controlled* or *non-controlled* – controlled forms contain information that becomes part of the record of the REC's review and determinations. Non-controlled forms are management tools that are designed to facilitate day-to-day operations. These forms are not considered part of the permanent record.

SOP 1: SOPS ON GENERAL ADMINISTRATION OF THE IDI REC

SOP 1.1 MAINTENANCE OF STANDARD OPERATING PROCEDURE (SOP)

1.1.1 BACKGROUND

In reference to regulations and guidelines of Uganda National Council for Science and Technology (UNCST), National Drug Authority (NDA) and the International Conference on Harmonization (ICH), supported by institutional policies, ensures that the rights and welfare of human research participants of such research will be overseen and protected in a uniform manner, regardless of changes in personnel. Written procedures must be in place to ensure the highest quality and integrity of the review and oversight of research involving human research participants and for the adequate documentation of such oversight. Standard Operating Procedures (SOPs) provide the framework for the ethical and scientifically sound conduct of human research.

SPECIFIC PROCEDURES

1.1.1.1 REVIEW, REVISION AND APPROVAL OF SOPS

a) Changes to regulations, national guidelines, or research practice as well as the policies and procedures of the Infectious Diseases Institute Research Ethics Committee may require a new SOP or a revision to a previously issued SOP.
b) SOPs will be reviewed by the REC at intervals and when necessary but not longer than 3 years.
c) Approval of new or revised SOPs is required by the REC Chairperson.
d) Documentation of reviews and approval is required by signature of the Chair and Secretary of the IDI REC.

1.1.1.2 SOP DISSEMINATION AND TRAINING

a) When a new or revised SOP is approved, it will be disseminated to the appropriate REC members, individuals and research departments as detailed in form 101-F.
b) Training will be provided to REC members and administrative staff on any new or revised policy. Evidence of training must be documented and filed with the IDI REC Administrator.
c) Each new IDI REC member or staff employee must acquaint himself/herself with all applicable SOPs prior to undertaking any responsibilities. Evidence of training must be documented and filed with the IDI REC Administrator.

1.1.1.3 FORMS

Forms are used to;

a) Ensure that SOPs are integrated into the daily operations of research and reviewed throughout the IDI REC system.
b) Enable IDI REC staff to manage review, tracking, and notification functions consistently.

2.1.2 SCOPE

These SOPs apply to IDI REC members, Investigators and staff.

2.1.3 RESPONSIBILITY

a) The Chairperson and Secretary are responsible for signing off new and revised SOPs.
b) The REC Administrator and members are responsible for establishing and periodically reviewing and suggesting modifications in the SOPs (as found appropriate).

2.1.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research involving Humans as Research Participants, of July 2014,
b) National Drug Authority (NDA) act and Research Registration and Clearance Policy and Guidelines of July 2016.

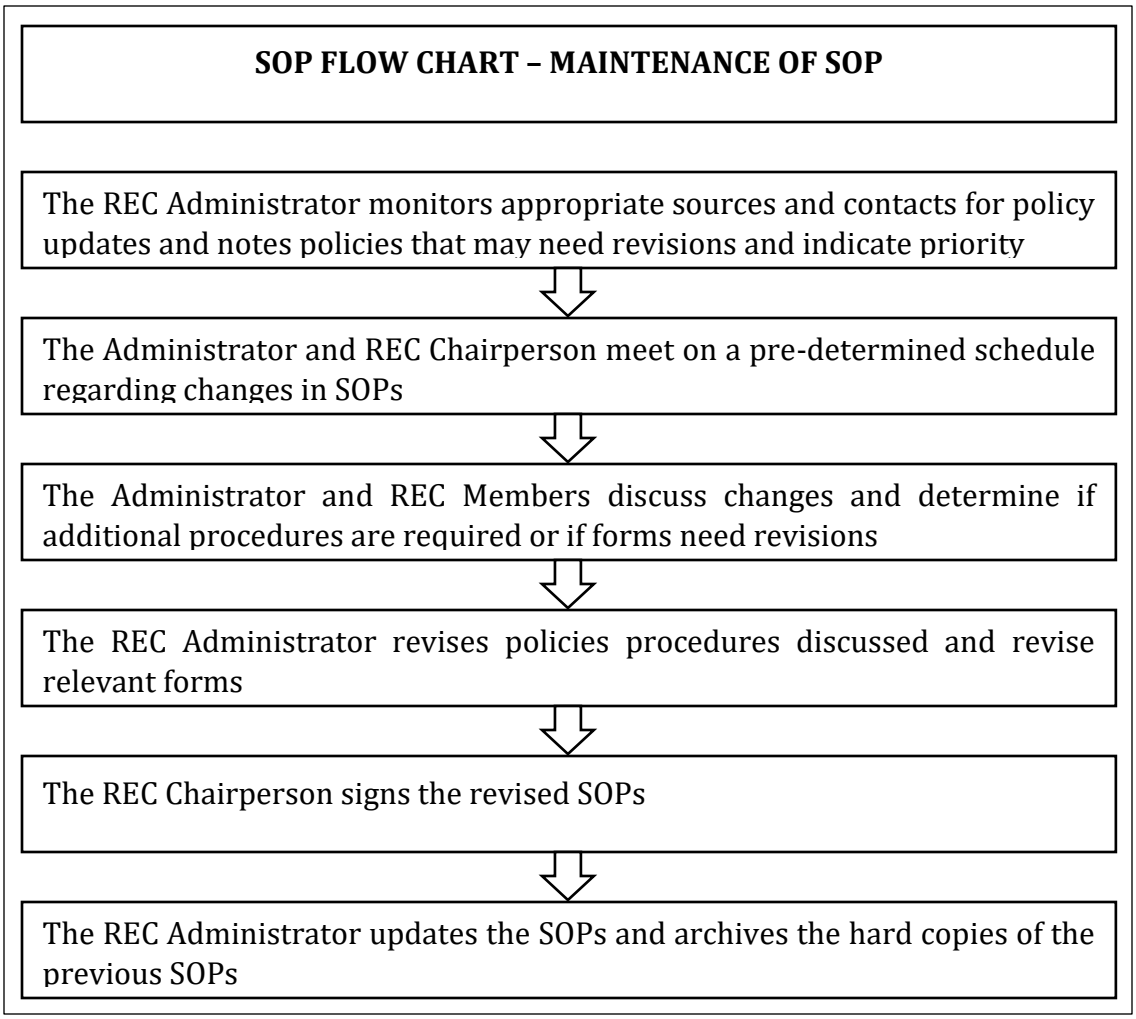
1.1.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

1.1.6 ATTACHMENTS

a) Form 1.1A: SOP Revision Worksheet
b) Form 1.1B: SOP Review Meeting Template Form.
c) Form 1.1C: SOP Revision Log
d) Form 1.1D: Forms Revision Log Form.
e) Form 1.1E: SOP Template
f) Form 1.1F: Notification of SOP Change

1.1.7 SOP FLOW CHART


SOP FLOW CHART – MAINTENANCE OF SOP
The REC Administrator monitors appropriate sources and contacts for policy updates and notes policies that may need revisions and indicate priority
The Administrator and REC Chairperson meet on a pre-determined schedule regarding changes in SOPs
The Administrator and REC Members discuss changes and determine if additional procedures are required or if forms need revisions
The REC Administrator revises policies procedures discussed and revise relevant forms
The REC Chairperson signs the revised SOPs
The REC Administrator updates the SOPs and archives the hard copies of the previous SOPs

SOP 1.2 TRAINING AND EDUCATION

1.2.1 BACKGROUND

Training of REC administrator and members is critical if the REC is to fulfill its mandate to protect the rights and welfare of research participants in a consistent manner throughout the Ugandan research community. REC members and administrators charged with the responsibility for reviewing, approving, and overseeing research involving humans should receive detailed training in the regulations, guidelines, ethics and policies applicable.

All REC members and administrators are required to undertake training in human research protection at least once every two years. The actions of Committee and the administrative staff relating to their responsibilities to protect human research participants of research will not be measured or evaluated in terms of institutional or financial goals.

SPECIFIC PROCEDURES

1.2.1.1 TRAINING

a) IDI research management level staff and members of REC who are overseeing research involving humans, as defined in national guidelines, that is managed, funded, or taking place in an entity under the jurisdiction of the Trustees of UNCST will receive initial and ongoing training regarding the responsible review and oversight of research and these policies and accompanying procedures. Such training will include, but not limited to

   i. Good Clinical Practice (GCP),
   ii. Human Participants Protection (HSP)

b) Each member of the REC will be required to update their training in GCP at least once every two years, and their HSP training at least once every year.

c) REC Administrator establishes the educational and training requirements for;

   i. REC members and nominated administrators who review research involving human research participants and who perform related administrative duties.
   ii. Initial and ongoing training is provided and documented by this Infectious Diseases Institute through the REC mechanism.

d) Members of the REC will participate in initial and continuing training in areas relevant to their responsibilities.

e) The Chairperson will receive additional training in areas relevant to his/her additional responsibilities.

f) REC administrator will receive initial and continuing training in the areas relevant to their responsibilities, including all Standard Operating Policies and Procedures (SOP)

g) REC members and administrators will be encouraged to attend workshops and other educational opportunities focused on REC functions. The Infectious Diseases Institute will support such activities to the extent possible and as appropriate to the responsibilities of members and staff.

1.2.1.2 DOCUMENTATION

Training and continuing education shall be documented and added to the records of each REC member as described in these SOPs.

1.2.2 SCOPE

These SOPs apply to REC members and administrative staff

1.2.3 RESPONSIBILITY

a) REC chairperson in collaboration with REC administrator is responsible for establishing, conducting and/or supervising all relevant training programs for REC members and administrators.
b) The REC Chairperson (or designee) in consultation with IDI leadership is responsible for guiding the development of REC member training programs.

1.2.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research Involving Humans as Research Participants, 2014 Section 4 Subsection 4.3.
b) WHO Guidelines on Standards of Ethical Review
c) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) GCP Guidelines.

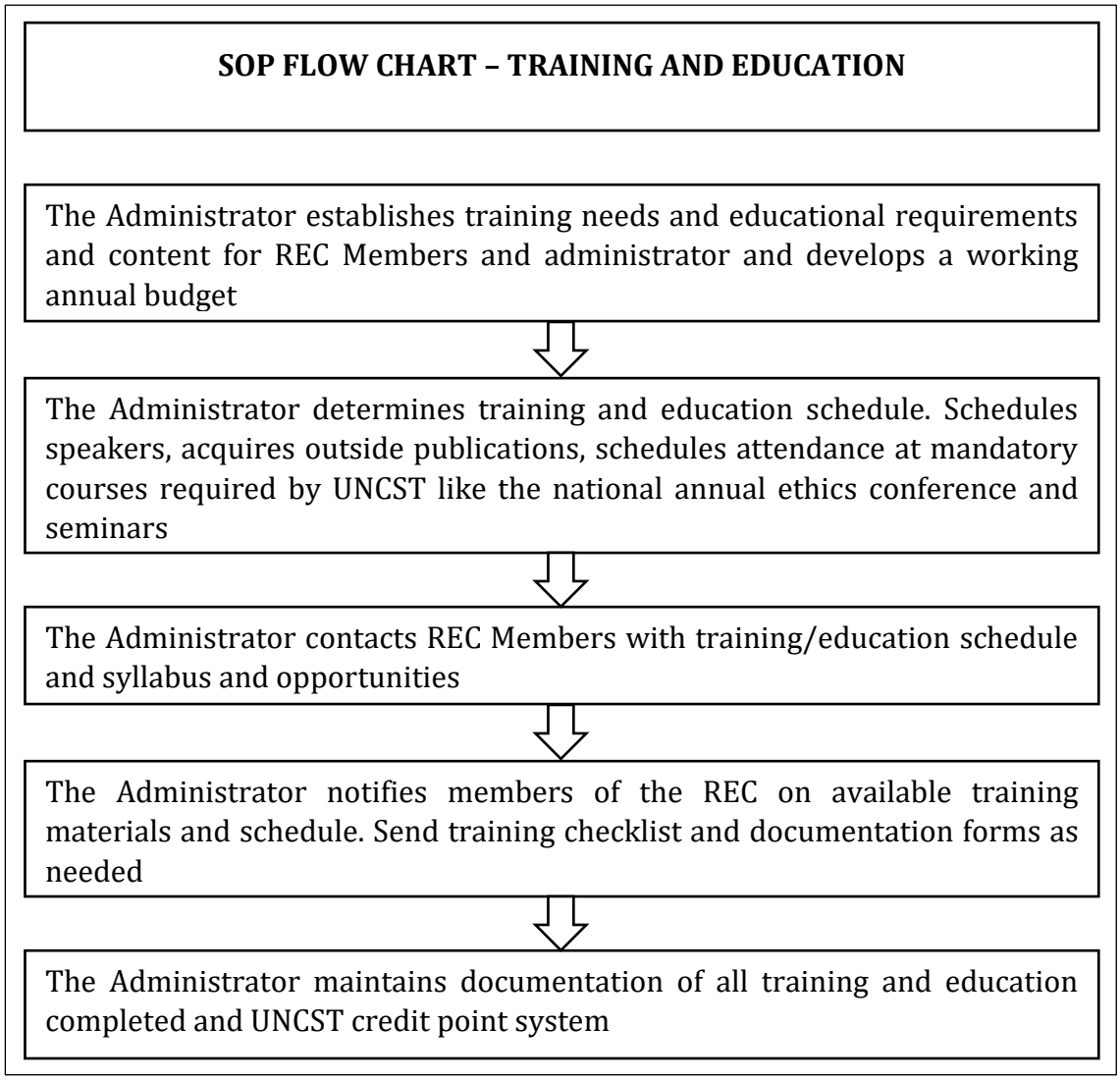
1.2.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

1.2.6 ATTACHMENTS

a) Form 1.2 A Bibliography & Resource List
b) Form 1.2 B Training Checklist and Documentation – REC Members.
c) Form 1.2 C Training Checklist and Documentation –REC administrators

1.2.7 SOP FLOW CHART



SOP 1.3 MANAGEMENT OF REC PERSONNEL

1.3.1 BACKGROUND

REC administrators provide consistency, expertise, and administrative support to the REC and serve as a daily link between the REC and the research community. Thus, REC staff are the most vital component in the effective operation of REC's human research participants' protection program. Therefore, the highest level of professionalism and integrity on the part of REC members is expected.

SPECIFIC PROCEDURES

1.3.1.1 JOB DESCRIPTIONS AND PERFORMANCE EVALUATIONS

a) REC members and administrators shall have a description of the responsibilities. The performance of each member and staff shall be reviewed in line with performance SOP member Position.

b) The REC administrator's performance shall be evaluated by the chairperson and nominated REC members in line with IDI Human resource manual.

1.3.1.2 HIRING AND TERMINATING REC MEMBERS AND ADMINISTRATIVE STAFF

We shall follow the IDI human resource manual on recruitment, termination and motivation

1.3.1.3 DELEGATION OF AUTHORITY OR RESPONSIBILITY

Delegation of specific functions, authorities, or responsibilities by the Chairperson to an REC member shall be documented.

1.3.2 SCOPE

These policies and procedures apply to REC members and Administrative staff.

1.3.3 RESPONSIBILITY

a) The IDI Executive Director shall be responsible for appointing the REC Chairperson and other REC members.
b) The IDI Human Resources Department shall be responsible for hiring and evaluating the ongoing performance of the REC administrative staff.
c) The REC Chairperson (or designee) is responsible for providing input on the ongoing performance of the REC Administrator using IDI human resource performance measurement.

1.3.4 APPLICABLE REGULATIONS AND GUIDELINES

IDI Human Resource Manual

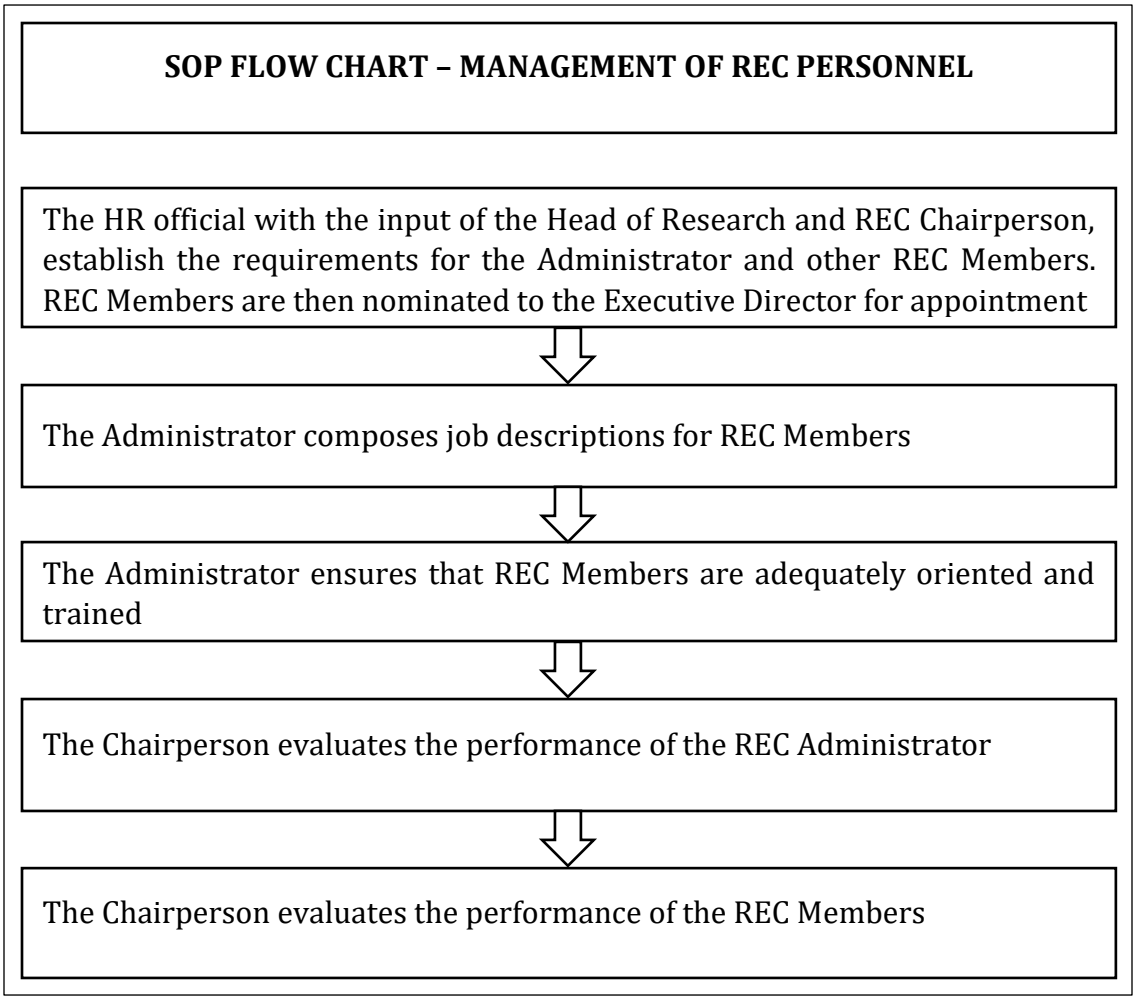
1.3.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

1.3.6 ATTACHMENTS

Form 1.3A REC Administrator Functions

1.3.7 SOP FLOW CHART



SOP 1.4 CONFLICT OF INTEREST

1.4.1 BACKGROUND

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest (CoI) should be minimized whenever possible and effectively managed and disclosed.

SPECIFIC PROCEDURES

1.4.1.1 DEFINITION OF A COI

A conflict of interest is defined as a close personal or professional association with the submitting Investigator(s); direct participation in the research (e.g., protocol development, Principal or Co-investigator); or any significant financial interest in the sponsoring company defined as (example, Uganda Shillings 2,000,000 or 5% ownership). For REC members, the REC Chairperson or his/her designee has the authority to determine when CoI exists as defined by institutional policy and to impose and enforce disciplinary action in the event that CoI is not disclosed. For Investigators, the REC has the authority to determine when CoI exists as defined in these policies and to impose and enforce appropriate penalty in the event that CoI is not disclosed by investigator(s).

1.4.1.2 MANAGEMENT OF COI

a) All investigators and REC members must disclose conflicts of interest (as defined by IDI SOPs) to the REC chairperson.

b) For Investigators that have not completed IDI financial disclosure of interest form, they will complete the REC CoI declaration form

c) Each potential conflict will be reviewed on an individual basis.

d) The REC may require that conflicts be disclosed in the informed consent, that the investigator excuses him/herself as the principal investigator, or from the study entirely.

e) The REC also requires that REC members that have a CoI on any protocol to be reviewed, that conflicts be disclosed to the REC prior to the protocol being reviewed, and that the REC member excuses him/herself from reviewing that protocol, but the member may be invited to provide additional information about the protocol.

1.4.1.3 DISCLOSURE AND DOCUMENTATION OF FINANCIAL INTEREST AND COI

a) No regular or alternate member may participate in the initial or continuing review of any research project in which the member has a conflict of interest, except to provide information as requested.
b) It is the responsibility of each voting member or alternate member of the REC to disclose any CoI in a study submitted to REC and recuse him or herself from

reviewing and voting.

c) The procedures for recusal of REC members, including the Chairperson, from deliberating/voting on all protocols for which there is a potential or actual financial conflict of interest are detailed in SOP REC Meeting Administration.

1.4.1.4 EDUCATION AND TRAINING IN COI

REC members and administrators are required to participate in education and training activities related to financial conflict of interest issues including those required by their institution.

1.4.2 SCOPE

These SOP apply to all REC members and administrative staff.

1.4.3 RESPONSIBILITY

a) The IDI head of research or his/her designee is responsible for articulating and enforcing the conflict of interest policy (CoI) at IDI.
b) The REC Administrator is responsible for monitoring the CoI status and disclosures of REC members.
c) REC Chairperson (or designee) is responsible for identifying CoI disclosures before beginning every REC meeting.
d) (REC Administrator is responsible for documenting all CoI disclosures in REC meeting minutes.

1.4.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research Involving Humans as Research Participants, 2014 Section 4 Subsection 4.3-part e
b) WHO Guidelines for Ethical Review of Biomedical Research

1.4.5 REFERENCES TO OTHER APPLICABLE SOPs

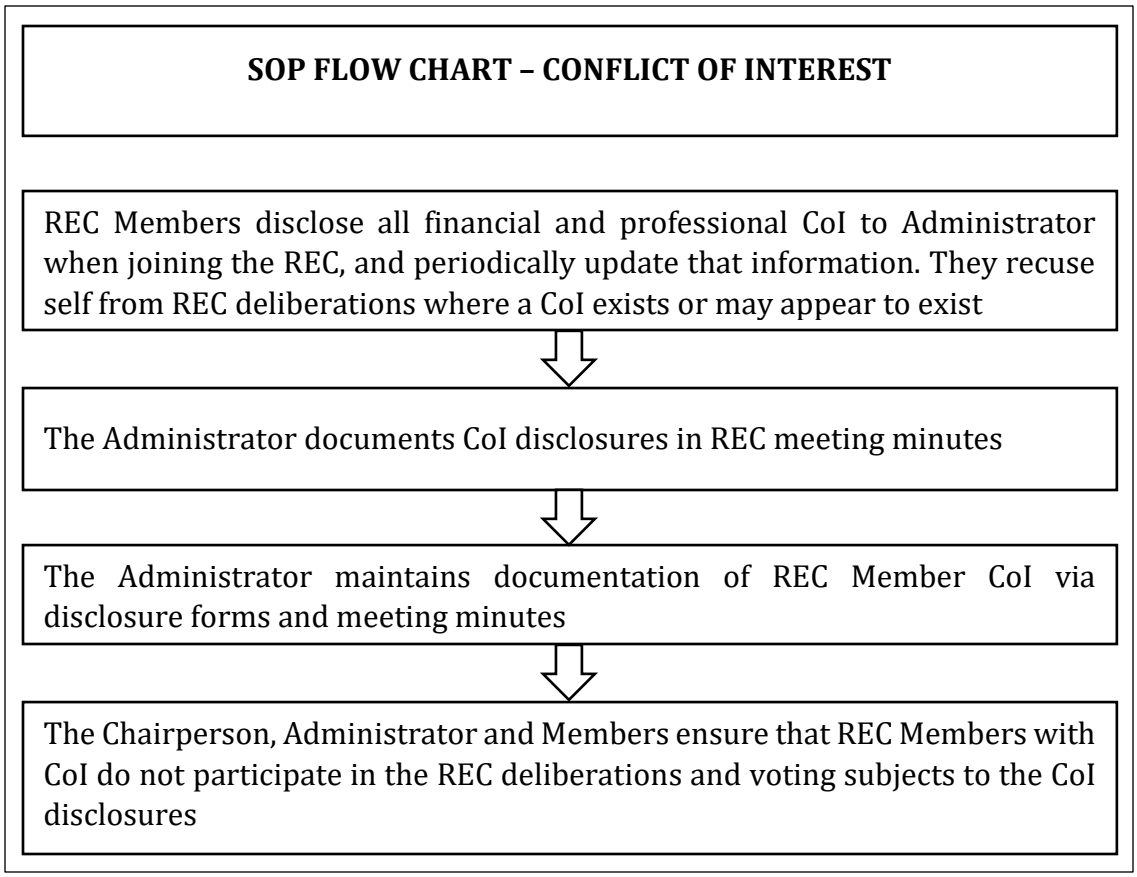
This SOP affects all other SOPs.

1.4.6 ATTACHMENTS

a) Form 1.4 A: REC Member Recusal Agreement

b) Form 1.4 B: Definitions Relating to REC Member Recusal Agreement

1.4.7 SOP FLOWCHART


SOP FLOW CHART – CONFLICT OF INTEREST
REC Members disclose all financial and professional CoI to Administrator when joining the REC, and periodically update that information. They recuse self from REC deliberations where a CoI exists or may appear to exist
The Administrator documents CoI disclosures in REC meeting minutes
The Administrator maintains documentation of REC Member CoI via disclosure forms and meeting minutes
The Chairperson, Administrator and Members ensure that REC Members with CoI do not participate in the REC deliberations and voting subjects to the CoI disclosures

SOP 1.5 SIGNATORY AUTHORITY

1.5.1 BACKGROUND

The REC Chairperson (or designee) is authorized to sign the documents in connection with the review and approval of research projects involving the use of humans as research participants, which have been reviewed and approved pursuant to UNCST policies and procedures. This procedures applies to all staff of the REC. In all cases individuals must sign their name and no other and indicate their title under their signature.

SPECIFIC PROCEDURES

1.5.1.1 AUTHORIZATION FOR SIGNATORY AUTHORITY

Authorization to sign documents which is not described in this SOP may be made in writing by the REC Chairperson.

1.5.1.2 RESULTS OF REVIEWS, ACTIONS AND DECISIONS

The results of reviews and actions taken by the REC, either by the full REC or by expedited review, that grant or may appear to grant Investigators with initial or continuing approval of research, training or educational projects involving human research participants, may be signed by designated REC staff members.

1.5.1.3 ROUTINE INTERNAL CORRESPONDENCE

Any action, letters, memos or emails between the REC, and/or members or staff of IDI that provides information concerning the review of research protocols by the IDI member which do not imply or appear to imply approval of this activity, may be signed by designated REC administrators.

1.5.1.4 CORRESPONDENCE WITH EXTERNAL AGENCIES

Any letters, memos or emails sent to agencies of the Uganda government, funding agencies (whether private or public) or their agents will be signed by the REC Chairperson.

1.5.1.5 DECISIONS MADE BY CHAIRPERSON

Any letters, memos or email sent representing the decision or opinions of the Chairperson of the REC or his/her respective designees, as long as such correspondence does not imply review and approval of research may be signed by designated REC staff member.

1.5.2 SCOPE

This SOP apply to all REC members and administrator

1.5.3 RESPONSIBILITY

a) The REC and REC chairperson is responsible for establishing the overall procedure for delegating signatory authority.

b) REC Administrator is responsible for implementing and controlling signatory authority delegations.
c) REC Chairperson, members staff are responsible for adhering to REC signatory authority SOP

1.5.4 APPLICABLE REGULATIONS AND GUIDELINES

This SOP is applicable to all the relevant SOP

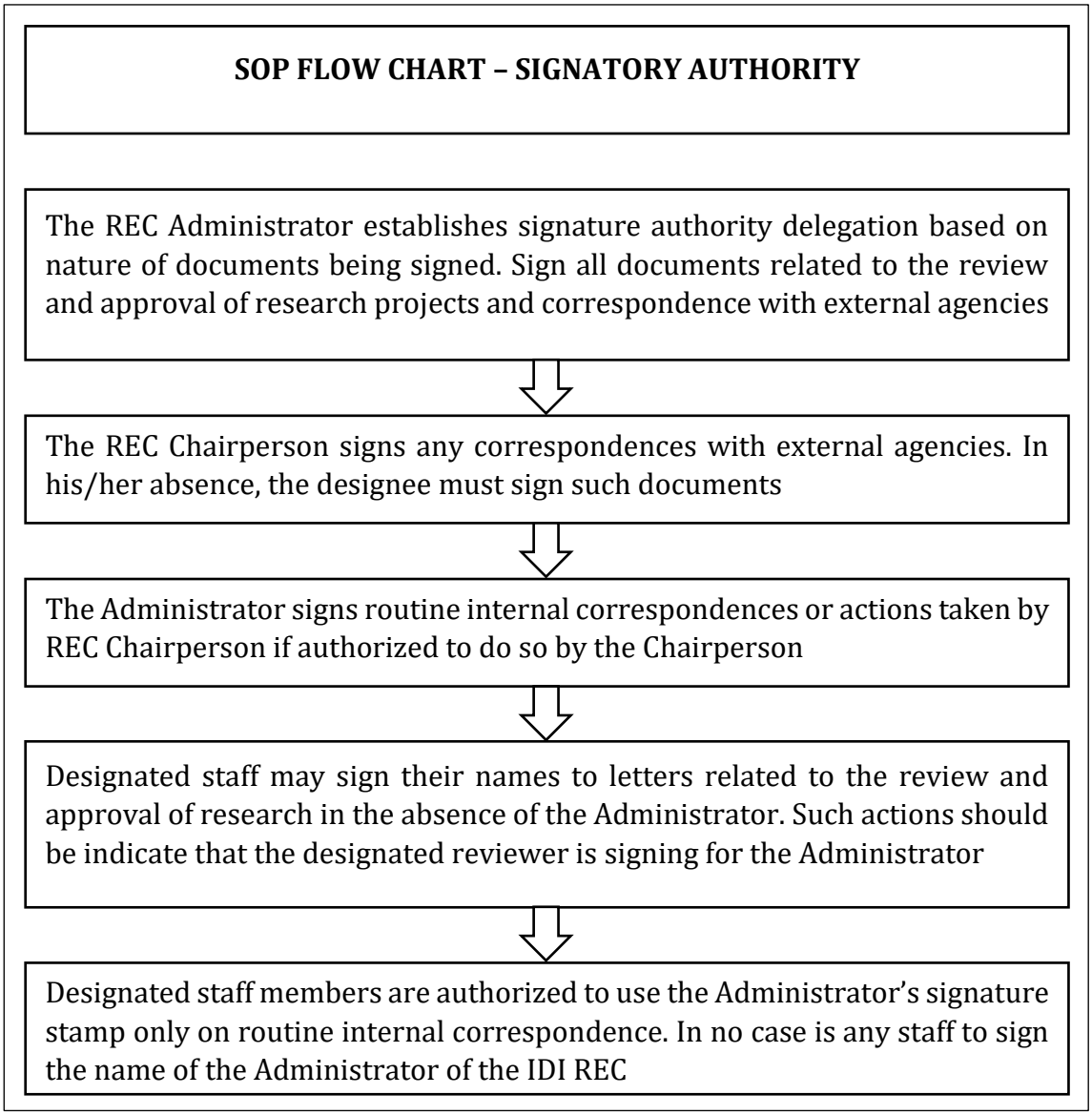
1.5.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

1.5.6 ATTACHMENTS

Form 1.5A: Definitions Relating to Signatory Authority

1.5.7 SOP FLOW CHART



SOP 2: SOPS ON ORGANIZATION OF THE IDI REC

SOP 2.1 COMPOSITION OF THE IDI REC

2.1.1 BACKGROUND

The REC shall be able to ascertain the acceptability of proposed research in terms of national regulatory framework, applicable law, and standards of professional conduct and practice. It shall promote respect for its advice and counsel in safeguarding the rights and welfare of human research participants.

Therefore, the REC shall consist of at least five regular, voting members. Qualified persons from multiple professions shall be considered for membership. REC membership shall not consist entirely of men or of women.

IDI will make every effort to have a diverse membership appointed to the REC, within the scope of available expertise needed to conduct its functions.

SPECIFIC PROCEDURES

2.1.1.1 MEMBERSHIP SELECTION CRITERIA

a) The members of the REC shall be sufficiently qualified through experience and expertise, for reviewing research proposals in terms of regulations and guidelines, applicable law and standards of professional conduct and practice, and UNCST commitments. Therefore, the REC shall include persons knowledgeable in these areas. The membership shall be diverse, so selection shall include consideration of ethnicity, gender, cultural backgrounds, clinical experience, healthcare experience and sensitivity to such issues such as community attitudes to assess the research submitted for review.

b) There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be at least one member who has no affiliation with IDI, either self or family member. There shall be at least one member who is a licensed physician.

2.1.1.2 COMPOSITION OF THE REC

a) **Regular members:** The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the REC. Regular members must include:

b) **Scientific members**: Most RECs include physicians and PhD level scientists. Such members satisfy the requirement for at least one scientist. When a REC encounters studies involving science beyond the expertise of the members, the IDI REC may co-opt a member to assist in the review, as provided by the National Guidelines on Research Involving humans as Research Participants. However, when clinical trials are reviewed, the convened meeting must include a licensed physician member.

c) **Nonscientific member:** The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not solely in medical or scientific areas.

d) **Representatives of special groups of participants:** When certain types of research are reviewed, REC members or co-opted members who are knowledgeable about the concerns of certain groups may be required. For example, if IDI REC reviews research involving prisoners, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group must be included on the REC.

e) **Chairperson:** The REC Chairperson should be a highly respected individual, from outside IDI, fully capable of managing the REC and the matters brought before it with fairness and impartiality.

f) **Special Co-opted members:** The Chairperson may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REC. These individuals will not vote with the regular and alternate members of the REC and their presence or absence will not be used in establishing a quorum for a REC meeting. Co-opted members will be used at the Chairperson's discretion, or if requested by the full REC. All co-opted members will be asked to sign a Conflict of Interest Statement, and co-opted members with access to confidential information will be asked to sign a Confidentiality Agreement.

g) **The co-opted** member may be asked to participate via a teleconference or attend the REC meeting to lend his/her expertise to the discussions. Co-opted members will not vote.

2.1.1.3 APPOINTMENT OF REC MEMBERS

a) The appointing authority of REC members will be the IDI Executive Director.

b) At his/her discretion, he/she may perform this responsibility in consultation or advise from existing REC members.

2.1.2 SCOPE

This SOP applies to the membership of REC.

2.1.3 RESPONSIBILITY

a) The IDI Executive Director is responsible for ensuring that the REC has adequate resources to identify and recruit qualified potential members.

2.1.4 APPLICABLE REGULATIONS AND GUIDELINES

National Guidelines for Research Involving Humans as Research Participants Section 4 Subsection 4.3

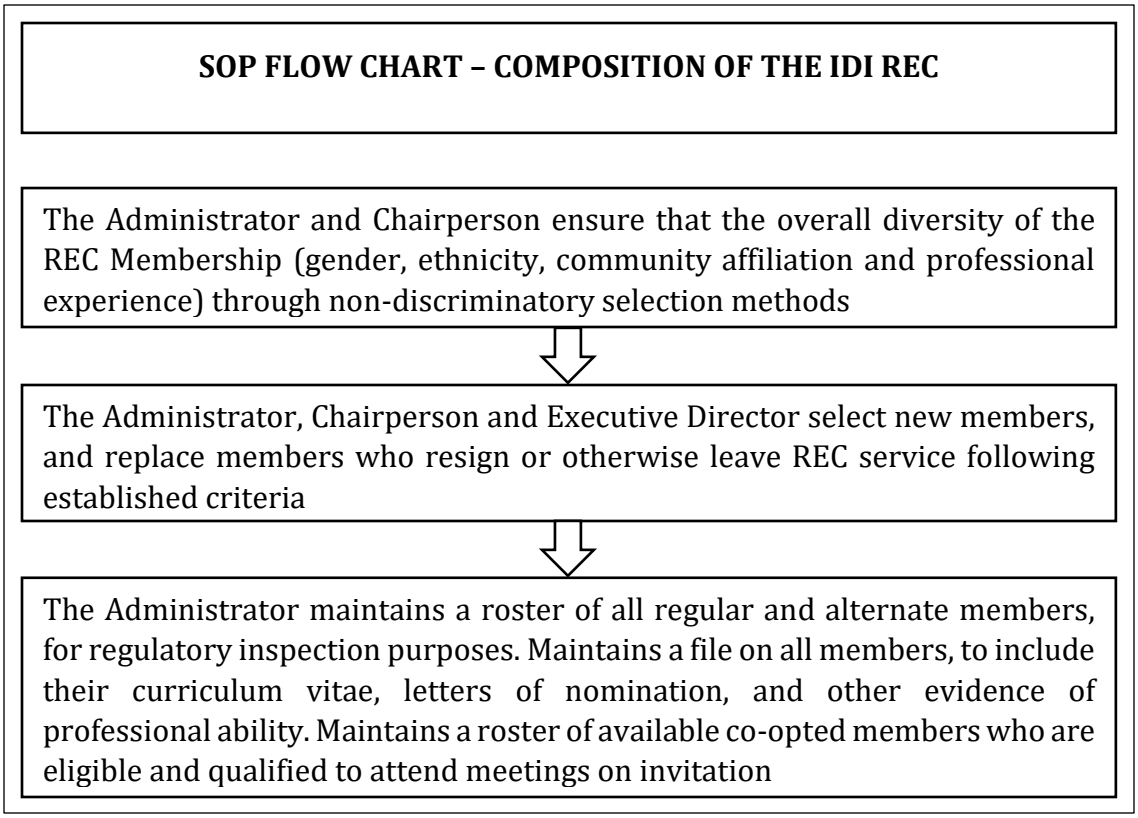
2.1.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

2.1.6 ATTACHMENTS

Form 2.1A: IDI REC Member Details

2.1.7 SOP FLOWCHART



SOP 2.2 MANAGEMENT OF THE IDI REC

2.2.1 BACKGROUND

The management of the membership of the IDI REC and oversight of member appointments, REC related activities, communications, and other administrative details are the responsibility of the REC Administrator.

SPECIFIC PROCEDURES

2.2.1.1 TERM

Members, including the Chairperson, will serve on the REC for a term of *three (3)* years. Reappointment for additional terms may occur, upon satisfactory service.

2.2.1.2 APPOINTMENTS

The IDI Executive Director in consultation with the REC Chairperson, and other REC members; has the authority to appoint members to the IDI REC. Members will be

solicited from qualified individual's resident in Uganda.

2.2.1.3 RESIGNATIONS AND REMOVALS

A member may resign before the conclusion of his/her term. The vacancy will be filled as quickly as possible. A member may be removed from the REC by the IDI Executive Director for a reasonable cause.

2.2.1.4 COMPENSATION

All REC members shall be paid a fixed transport and facilitation allowance at rates determined by the REC from time to time. Co-opted members shall receive the same fixed transport and facilitation allowance as the other regular members of REC for only the meetings that they may attend. Co-opted members shall be paid an amount determined by the REC on a case-by-case basis.

2.2.2 SCOPE

This SOP applies to all REC members.

2.2.3 RESPONSIBILITY

a) The REC Administrator is responsible for day-to-day management of the activities of the REC.

b) The REC Chairperson (or designee) is responsible for management of the activities of the REC members relevant to meeting conduct and review of research.

2.2.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research Involving Humans as Research Participants, Subsection 4.3 h)

b) International Ethical Guidelines for Biomedical Research Involving Human Participants

c) UNCST Act (CAP 209)

2.2.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

2.2.6 ATTACHMENTS

a) Form 2.2A: New Member Information Packet Checklist

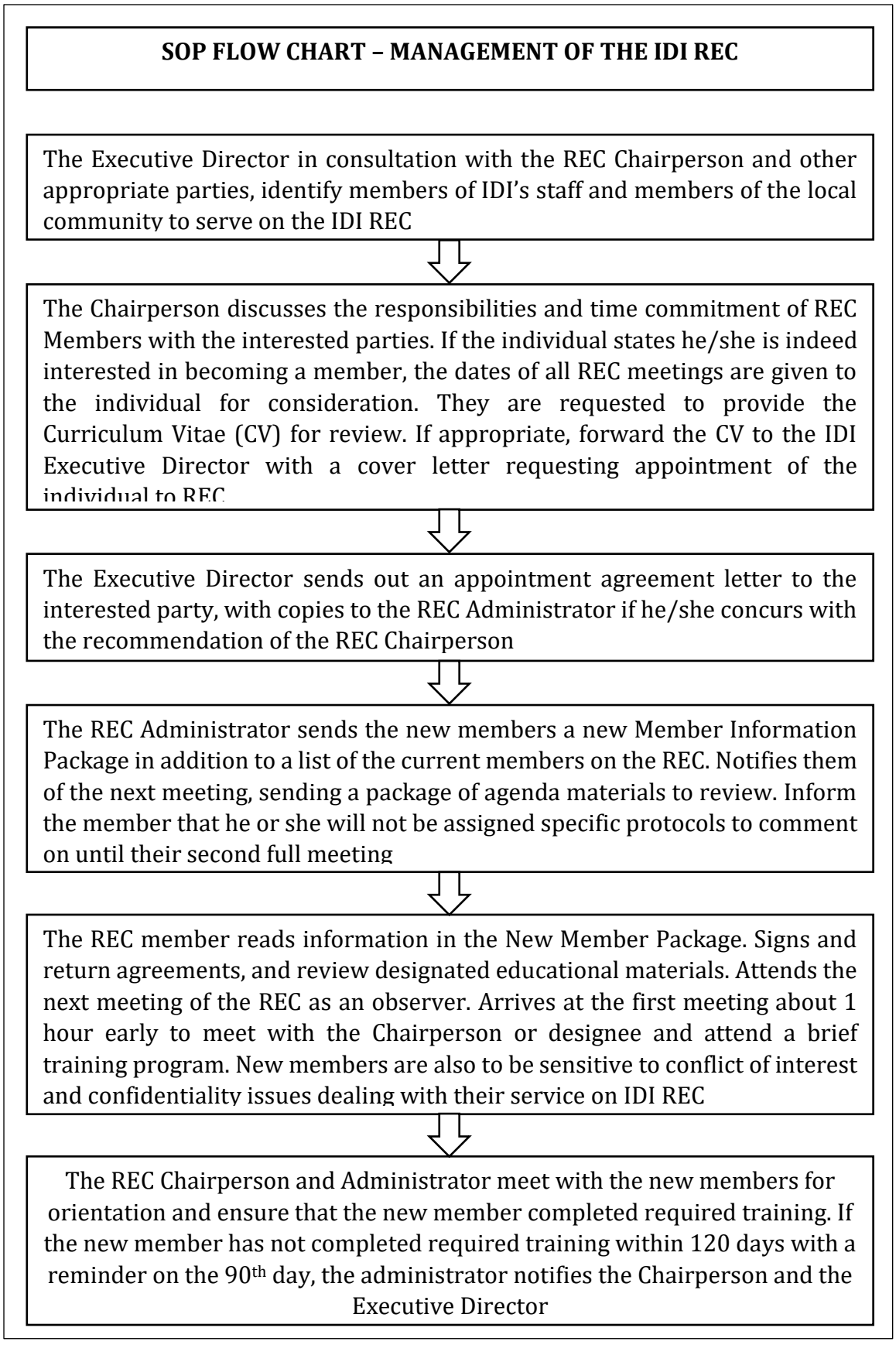
b) Form 2.2B: New Member Welcome Letter

c) Form 2.2C: REC Appointment Agreement

d) Form 2.2D: REC Member Confidentiality Agreement

e) Form 2.2E: Member Documentation Checklist

2.2.7 SOP FLOW CHART



SOP 2.3 DUTIES OF IDI REC MEMBERS

2.3.1 BACKGROUND

Each REC member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as research participants. The REC member must understand that he or she is not serving on the IDI REC to expedite the approval of research, but to be a gatekeeper between the Investigator and the research participants. In order to fulfill their duties, REC members are expected to be versed in regulations and guidelines governing human research participants' protection, biomedical and behavioural research ethics, and the policies of UNCST relevant to human research participant's protection.

SPECIFIC PROCEDURES

2.3.1.1 DUTY TO IDI

The IDI REC is an accredited institutional Research Ethics Committee. Although REC members' decision-making regarding REC review is independent, members must not allow their own interest or that of their institution/department to supersede their duty to protect the rights and welfare of research participants.

2.3.1.2 TERM OF DUTY

REC members and Chairperson are expected to commit to a 3-year term and, during that time, to fulfill certain duties. These duties will be described prior to appointment and each REC member is expected to fully understand the duties of REC members prior to accepting appointment as a REC member.

SPECIFIC DUTIES

2.3.1.3 REGULAR MEMBERS:

a) **Community representative(s)**: Members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

b) **Non-scientific members:** Nonscientific members are expected to provide input on areas relevant to their knowledge, expertise and experience, professional and otherwise. For example, members who are bioethicists should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Non-scientific members should advise the REC if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of research participants.

c) **Scientific members:** Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IDI REC if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of research participants.

d) **Chairperson**: In addition to the above responsibilities (relevant to the member's capacity), the Chairperson shall chair meetings of the IDI REC. Chairperson performs or delegates to an appropriate voting REC member expedited review when appropriate. He/she is empowered to suspend the conduct of a research study deemed to place individuals at unacceptable risk, pending IDI REC review. The Chairperson is also empowered, pending IDI REC review, to suspend the conduct of a study if he/she determines that an Investigator is not following IDI REC's requirements. The committee will appoint a Vice Chairperson to assist or act on behalf of the Chairperson in particular IDI REC matters and at REC meetings, either as a general procedure, or on a case-by-case basis. The Chairperson also may delegate any of his/her responsibilities as appropriate to other qualified individual(s). Such documentation must be in writing and maintained by the REC Administrator.

e) The task of making the IDI REC a respected part of the institutional review community will fall primarily on the shoulders of these individuals. The IDI REC should be fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

2.3.1.4 PRIMARY AND SECONDARY REVIEWERS

In addition to the duties described in the above section, each REC member will be expected to act as a Primary or Secondary Reviewer for assigned studies at convened meetings. The Primary Reviewer presents his or her findings resulting from review of the application materials and provides an assessment of the soundness and safety of the protocol and recommends specific actions to the IDI REC. He or she leads the IDI REC discussion of the study. The Primary Reviewers may be required to review additional material requested by IDI REC for the purpose of study approval. The Secondary Reviewer, if assigned, adds to the discussion, as necessary.

2.3.2 SCOPE

This SOP applies to all IDI REC Members.

2.3.3 RESPONSIBILITY

a) REC Administrator is responsible for clearly articulating all IDI REC members' duties to REC members.

b) IDI REC Members are responsible for fulfilling their duties as specified.

2.3.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research Involving Humans as Research Participants, 2014 Section 4

b) WHO Guidelines for Ethical Review of Biomedical Research

2.3.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

2.3.6 ATTACHMENTS

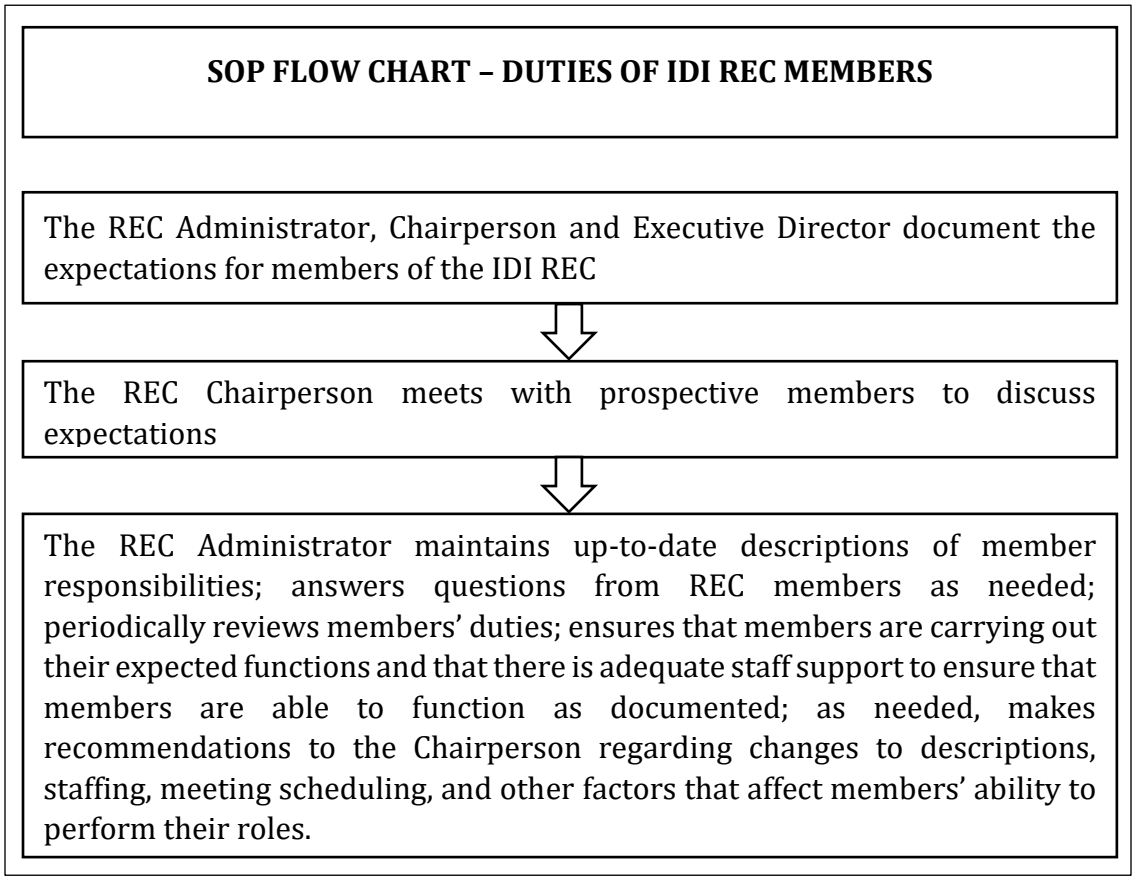
a) FORM 2.3A: Member Responsibilities - Regular Member

b) FORM 2.3B: Member Responsibilities – Chairperson

c) FORM 2.3C: Member Responsibilities - Alternate Member

d) FORM 2.3D: Member Responsibilities - Reviewer Duties

2.3.7 SOP FLOW CHART



SOP 3: SOPS ON FUNCTIONS AND OPERATIONS OF THE IDI REC

SOP 3.1 RESEARCH SUBMISSION REQUIREMENTS

3.1.1 BACKGROUND

IDI REC members often rely solely on the documentation submitted by Investigators for initial and continuing review. Therefore, these materials must provide REC members with enough information about the study to assess if it adequately meets the IDI REC's criteria for approval. A submitted protocol will be scheduled for REC review when the REC Administrator has determined that the information and materials submitted present an adequate description of the proposed research.

SPECIFIC PROCEDURES

3.1.1.1 SUBMISSION REQUIREMENTS FOR INITIAL REVIEW

Investigators applying for initial approval of a proposed research protocol must submit:

a) IDI REC Investigator's Agreement (Form 3.1A)

b) Research Project Proposal Form B(Form 3.1B)

c) Research protocol with version and date

d) Investigators' CVs (should highlight Investigator's qualifications, experience, ethics training completed and license, as appropriate)

e) Investigator Brochure, or device specifications (where applicable)

f) Questionnaires, case report form(s) & assessment instruments, interview guides (as appropriate)

g) Proposed informed consent document(s) and relevant delivery materials.

h) Proposed participant instructions

i) Any other supporting material, such as examples of recruitment advertising, etc.

j) A description of the consenting process or a copy of the investigative site's Standard Operating Procedures for obtaining informed consent.

In addition, applicants <u>shall</u> be required to submit:

k) Financial disclosure statement

l) Case report form

m) Documentation that the study has been reviewed and approved by other committees charged with oversight of research at the relevant institution.

n) A Material Transfer Agreement (where applicable)

o) Knowledge of local law requirements when applicable.

3.1.1.2 SUBMISSION REQUIREMENTS FOR CONTINUING REVIEW

During the approval period, Investigators must submit documentation to inform the IDI REC about changes in the status of the study including, but not necessarily limited to:

a) Deviations from the protocol (protocol violations)

b) Reports of serious or unexpected adverse events

c) For IND / IDE studies, reports of serious or unexpected adverse events that occur during the approval period as required by UNCST and NDA Guidelines

d) Changes to the status of Principal or Co-investigators

3.1.1.3 PROGRESS REPORT AND/OR REQUEST TO RENEW REC APPROVAL

Sixty (60) days prior to IDI REC approval expiration date, Investigators requesting renewal of an approved research project must submit:

a) A completed Continuing Review Report and Renewal Request (Form 4.4A).

b) All the required materials that are indicated on the form are also required prior to review.

3.1.1.4 ACTION TAKEN IF DOCUMENTATION IS NOT ADEQUATE OR ADDITIONAL INFORMATION IS REQUIRED

If the REC staff determine that the submitted documents are not adequate, Investigators may be required to submit additional information, or explain the details of the study. No incomplete submission will be reviewed by the REC.

3.1.2 SCOPE

This SOP applies to all research submitted to IDI REC.

3.1.3 RESPONSIBILITY

a) The REC Administrator is responsible for maintaining current research submission requirements for interested Investigators and for preliminary triage of non-routine submissions.

b) The REC Administrator is responsible for preparing member review materials and reviewing submission elements.

c) The REC Administrator is responsible for submission receipt, tracking and acknowledgements.

3.1.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research involving Humans as Research Participants, 2014 Section 4 Subsection 4.8

b) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) & GCP Guidelines

3.1.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

3.1.6 ATTACHMENTS

a) FORM 3.1A: IDI REC Submission face sheet

b) FORM 3.1B: study summary form

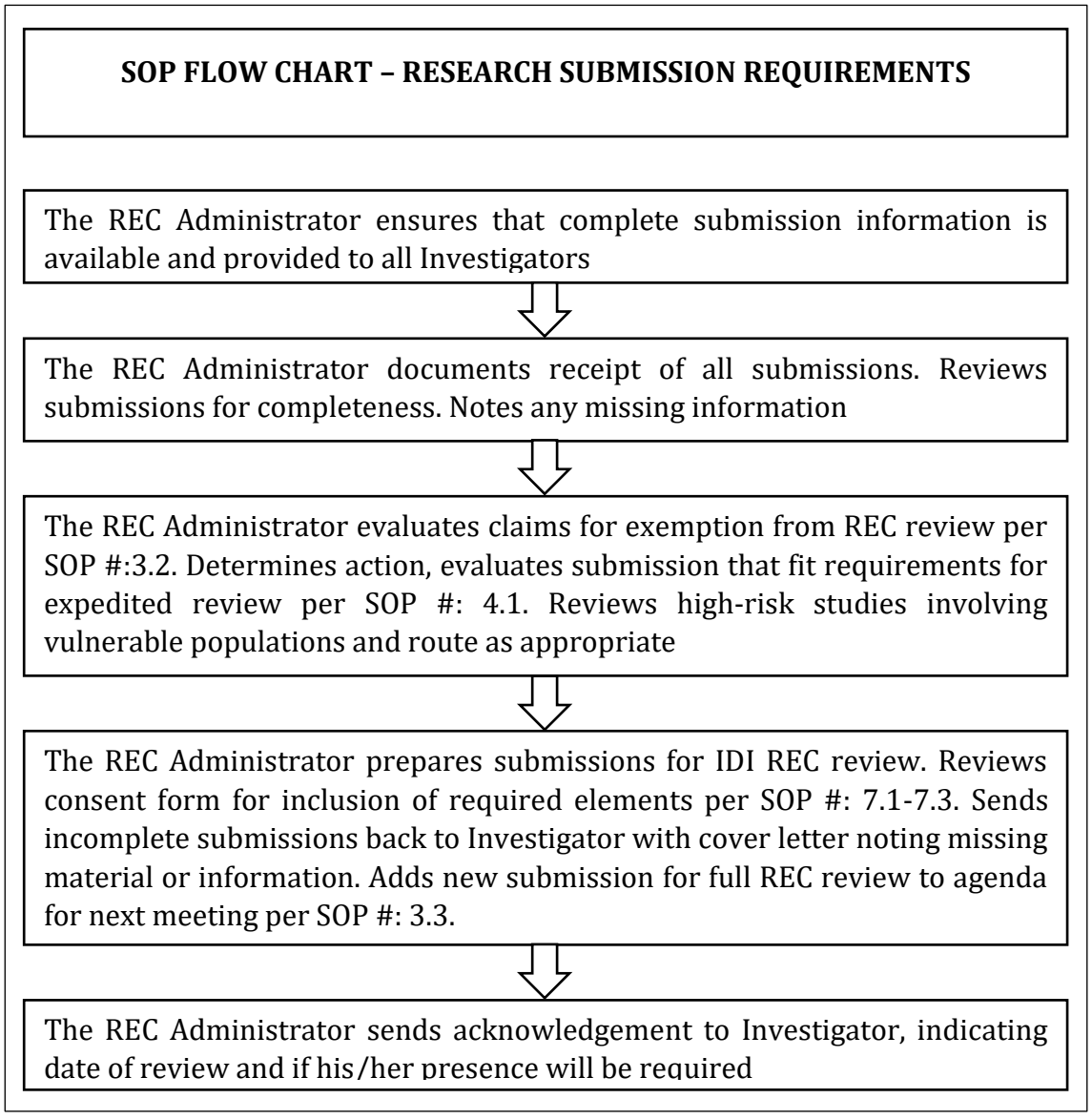
c) FORM 3.1C: IDI REC Submission Checklist (Staff)

d) FORM 3.1D: Acknowledgement/Request for Additional Information

e) FORM 3.1E: Investigator delegation of responsibility

f) FORM 3.1F: Study submission-additional study location

3.1.7 SOP FLOW CHART



SOP 3 .2 RESEARCH EXEMPT FROM IDI REC REVIEW

3.2.1 BACKGROUND

This SOP defines the steps to be followed to exempt a research protocol involving human participants from REC review. This SOP is consistent with the Uganda National Council for Science and Technology (UNCST) regulatory guidelines in Section 4 sub-section 4.5.3. Determination of exemption must be based on regulatory criteria and documented by the REC.

Research categories outlined below shall be exempted from REC review:

1. Proposed research using publicly available unlinked data that does not identify individuals or communities.
2. A research requiring emergency use of a test investigational product/device provided that such as emergency use is reported to the REC within 7 calendar days. Any subsequent use of the investigational product/device at the organization shall be participant to REC approval.

SPECIFIC PROCEDURES

a) An Investigator shall submit a request for REC review exemption application together with a full package of research documents to the REC.
b) The REC staff will review the submitted package for completeness and note any missing information.
c) REC staff shall document receipt of REC review exemption application and notify the Investigator when his/her protocol will be reviewed. The REC shall review the application and determine whether the proposed research project satisfies requirements for exemption from REC review, and will, thereafter, grant exemption.

3.2.2 SCOPE

This SOP applies to Investigator claims for exemption from IDI REC review.

3.2.3 RESPONSIBILITY

a) IDI REC Chair is responsible for evaluating submissions that claim exemption from REC review.

b) IDI REC Chairperson (or designee) is responsible for providing consultation in the review of claims of exemption.

3.2.4 APPLICABLE REGULATIONS AND GUIDELINES

National Guidelines for Research involving Humans as Research Participants, 2014 Section 4 Subsection 4.5.3

3.2.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs

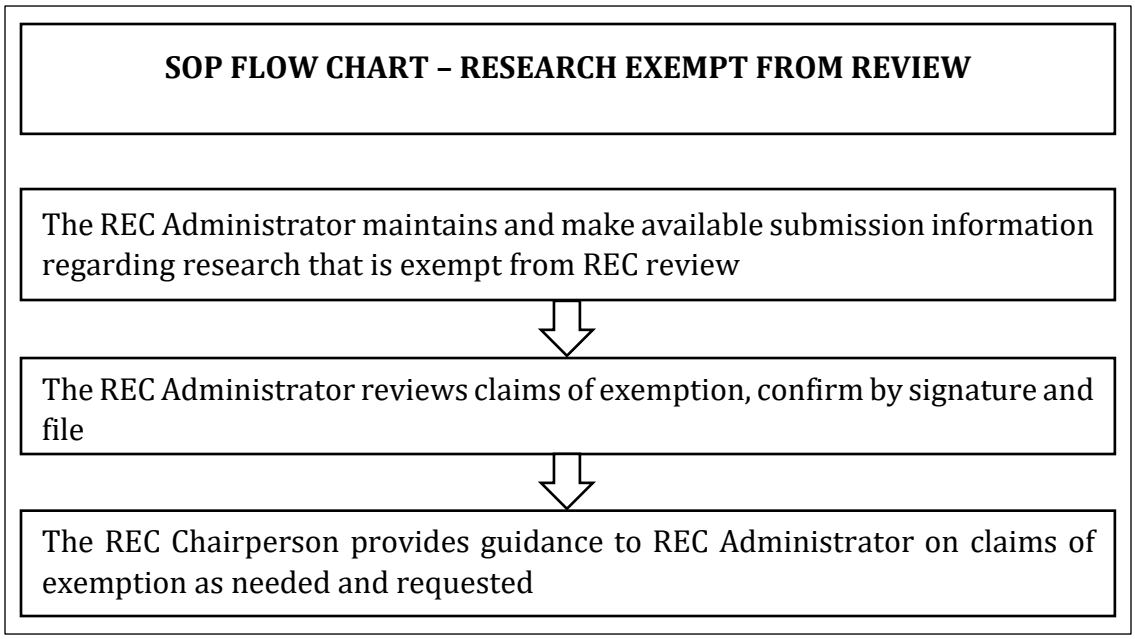
3.2.6 ATTACHMENTS

a) Form 3.2A Exemption Screening Questions

b) Form 3.2B Claim of Exemption

c) Form 3.2C Claim of Exemption Checklist for administrator

3.2.7 SOP FLOW CHART



SOP 3.3 IDI REC MEETING ADMINISTRATION

3.3.1 BACKGROUND

Except when an expedited review procedure is used, the IDI REC will review proposed research at convened meetings at which a quorum is present. IDI REC will meet *monthly*, or at some other frequency determined by REC Chairperson and the REC Administrator.

SPECIFIC PROCEDURES

3.3.1.1 QUORUM AND PRIMARY REVIEWERS

a) A minimum quorum shall be 50% plus one of the REC members.

b) A quorum consists of regular and/or their alternate members and includes at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are of the community.

c) When a clinical trial is reviewed, there shall be at least one member who is a physician.

d) The alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above.

e) Special co-opted(s) will not be used to establish a quorum.

f) If a member abstains from voting, the member may be used to establish a quorum.

g) If a member recuses him/herself from deliberations and voting, the member may be used to establish quorum for the duration of review of the item from which the member is recused.

h) A member experiencing a CoI must recuse him/herself.

i) Prior to the meeting, the Chairperson or REC Administrator will designate primary reviewers for each research proposal. The primary and secondary reviewer's duties are described in SOP 2.3

3.3.1.2 MEETING MATERIALS SENT PRIOR TO IDI REC MEETINGS

a) All REC members will be sent study documentation required for review 2 weeks prior to the meeting to allow time for adequate review.

b) Agenda: a meeting agenda will be prepared by the REC Administrator or designee and distributed to REC members prior to each meeting. A copy of the agenda and attached materials will be maintained on file with the meeting minutes. The meeting agenda will remind members to declare any potential CoI they may have with research that is about to be reviewed at the outset of each meeting.

c) The Chairperson will ask for a declaration of such conflict at the beginning of the meeting and this will be incorporated in the minutes of the meeting. The REC minutes should also specifically reflect such recusals as they occur during meetings.

3.3.1.3 REVIEWER MATERIALS:

All REC members will receive:

a) A completed IDI REC Research Proposal Form, Investigator's Agreement Form with a signature page and conflict of interest statement

b) Proposed informed consent document(s) and/or script as appropriate

c) Protocol Review Worksheet: Regular Reviewer (Form 4.2C)

Primary reviewers will receive:

a) Full Investigator's or Sponsor's protocol

b) A completed IDI REC Research Proposal Form, Investigator's Agreement Form with a signature page and conflict of interest statement

c) Proposed informed consent document(s) and/or script as appropriate

d) Copies of surveys, questionnaires, or videotapes

e) Copies of letters of assurance or cooperation with research sites

f) Investigator Brochure (where applicable)

g) Advertising intended to be seen or heard by potential participants, including email solicitations and physician letters

h) Protocol Review Worksheet: Primary Reviewer (Form 4.2A) or Protocol Review Worksheet (Social): Primary Reviewer (Form 4.2B) and Informed Consent Checklist (Form 7.1A)

i) IDI REC Review of Sponsor-Approved Informed Consent Documents for Sponsor-Supported Multi-center Clinical Trials: If available, for Sponsor-supported multi-center clinical trials the IDI REC must receive and review a copy of the Sponsor-approved sample informed consent document and the full Sponsor-approved Investigator's protocol as a condition for review and approval of the local informed consent document. Any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document must be justified in writing by the Investigator, approved by the IDI REC, and reflected in the REC minutes.

3.3.1.4 MINUTES

a) The national guidelines for the protection of human research participants require that "Minutes of a REC meetings shall be in sufficient detail to show attendance at the meeting; conflict of interest declared; actions taken by the REC; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution." These requirements are minimal. Good minutes should enable a reader who was not present at the meeting to determine exactly how and with what justification the REC arrived at its decisions.

b) Recording: The REC Administrator will take minutes of each meeting using IDI REC Agenda/Minutes Template (Form 3.3A). Minutes will be written in sufficient detail to show the following:

   i. Meeting attendance; including status of each attendee (regular member, co-opted, etc.), and conflicts of interest, if any;

   ii. Actions taken by the IDI REC on each agenda item requiring full REC action, including, the basis for requiring changes in or disapproving the research; Summary of the discussion of controversial issues and resolution;

   iii. Voting results, including number for, against and members who recused themselves and reason for recusal.

c) Approval: Draft minutes will be distributed to members two weeks before the next

REC meeting for review and approval at the next meeting.

d) Corrections requested by the REC will be made by the REC Administrator or designee and the minutes will be printed in final form and made available to members at the following meeting.

e) The Chairperson of the REC shall sign and date final, approved minutes.

f) The REC Administrator will maintain copies of the minutes, as well as the agenda and pertinent materials on file (see SOP #: 3.5).

g) A majority of members must vote in favor of an action for that category of action to be accepted by the REC. Only regular and alternate members acting in place of absent regular members may vote. The vote will be recorded in the minutes. Members with a conflict of interest will recuse themselves from the discussion and voting and such will be noted in the minutes.

3.3.1.5 TELEPHONE USE

a) Convened meeting using speaker phone: Should a member not be able to be physically present during a convened meeting, but is available by telephone/any other media, the meeting can be convened using a speakerphone. The member who is not physically present will be connected to the rest of the members via speakerphone. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by such speakerphone call may vote, provided they have had an opportunity to review all the material the other members have reviewed.

b) Meetings Conducted Via Telephone Conference Calls: On occasion, meetings may be convened via a telephone conference call. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place - "telephone polling" (where members are contacted individually) will not be accepted as a conference call.

c) Members not present at the convened meeting, nor participating in the conference call may not vote on an issue discussed during a convened meeting (no voting by proxy).

3.3.1.6 VOTING

a) REC members vote upon the recommendations made by the primary reviewers according to the criteria for approval (see SOP #s: 4.2 and 4.4).
b) Members also will determine level of risk, the frequency of review for each protocol, monitoring of the investigative site, and whether third party assessment and follow-up will be needed.
c) If an IDI staff member is serving on the REC as a voting member that staff member will not be responsible for any administrative functions during that meeting. Specifically, he or she will not take minutes.

3.3.2 SCOPE

This SOP applies to all research submitted to the IDI REC.

3.3.3 RESPONSIBILITY

a) The REC Administrator is responsible for IDI REC meeting procedural conduct and documentation.

b) The REC Chairperson (or designee) is responsible for IDI REC meeting review conduct and leadership.

3.3.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research involving Humans as Research Participants, 2014 Section 4, Subsection 4.5.1 part a, b , Subsection 4.6 part c

b) WHO Guidelines for Ethical Review of Biomedical Research

c) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) & GCP Guidelines

3.3.5 REFERENCES TO OTHER APPLICABLE SOPs

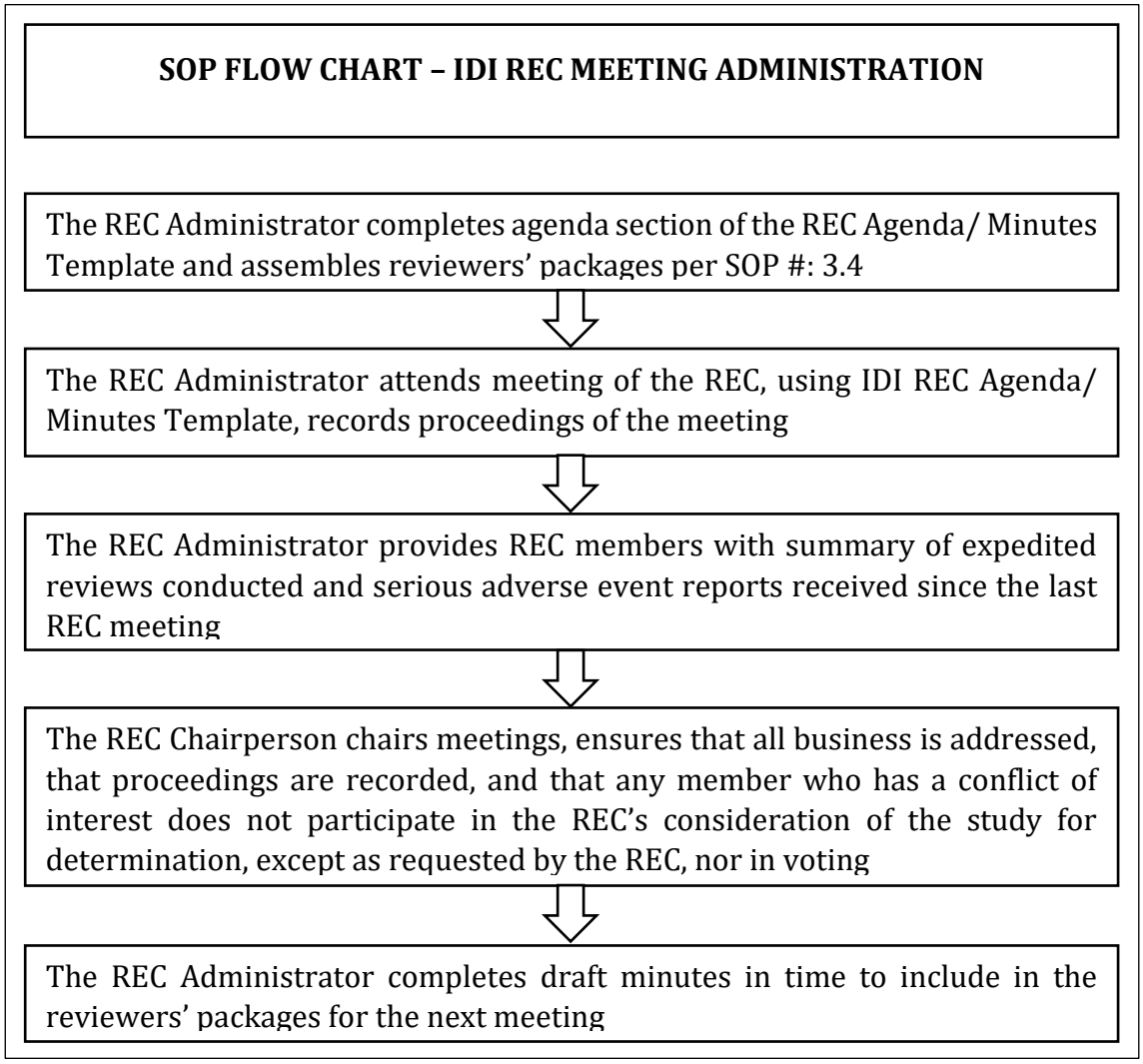
This SOP affects all other SOPs.

3.3.6 ATTACHMENTS

a) Form 3.3A: IDI REC Agenda/Minutes Template

b) Form 3.3B: Report of IDI REC Activities Since the Last Meeting

3.3.7 SOP FLOW CHART



SOP 3.4 ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS

3.4.1 BACKGROUND

The efficiency and effectiveness of the IDI REC is supported by administrative procedures that ensure that IDI REC members not only have adequate time for thorough assessment of each proposed study, but that the documentation they receive is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions.

SPECIFIC PROCEDURES

a) **Exemptions:** The REC Administrator will review Claims for Exemption submitted by Investigators in consultation with the REC Chairperson. Such Claims of Exemption will be logged and filed.

b) **Incomplete Submissions:** Incomplete applications will not be accepted for

review until the Investigator has provided all necessary materials as determined by the REC Administrator. The REC Administrator will notify the submitting Investigator to obtain any outstanding documentation or additional information before the application is scheduled for review.

c) **Scheduling for Review:** Complete applications that appear to meet qualifications for expedited review will be submitted to the Chairperson or his/her designee. If a submission meets expedited review requirements, the review will be performed as described in SOP # 4.1 (Expedited Review). All other applications will be placed on the agenda for the earliest meeting possible for review by the full IDI REC as described in SOP #: 3.3 (IDI REC Meeting Administration).

d) **Distribution to Members Prior to REC Meetings:** Copies of application materials described in SOP #: 3.1 (Research Submission Requirements) will be distributed to all REC members, generally at least ten (10) working days prior to the meeting. Each regular member of the IDI REC, and any alternate members attending the meeting in place of a regular member, will receive a copy of the initial application material. Co-opted members will only receive copies of material that pertain to their requested input. The originals of submission materials will be retained in the REC Office and available for the REC meeting.

e) **Confidentiality:** All material received by the IDI REC will be considered confidential and will be distributed only to meeting participants (regular members and special co-opted members) for the purpose of review. All application materials will be stored in a REC study file with access limited to REC members and administrative staff. Co-opted members and visitors will be expected to sign Confidentiality Agreements (Form 2.2D - IDI REC Member Confidentiality Agreement).

3.4.2 SCOPE

This SOP applies to all research submitted to the IDI REC.

3.4.3 RESPONSIBILITY

a) REC Administrator is responsible for conducting appropriate assessment of submissions for triage purposes and provision of complete review material packets to REC members and other relevant parties.

b) REC Chairperson (or designee) is responsible for supporting and assisting the REC Administrator in submission triage activities.

3.4.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research involving Humans as Research Participants, 2014 Section 4, Subsection 4.5.3, Subsection 4.3 part I, Subsection 4.5.2

b) WHO Guidelines for Ethical Review of Biomedical Research

c) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) GCP Guidelines

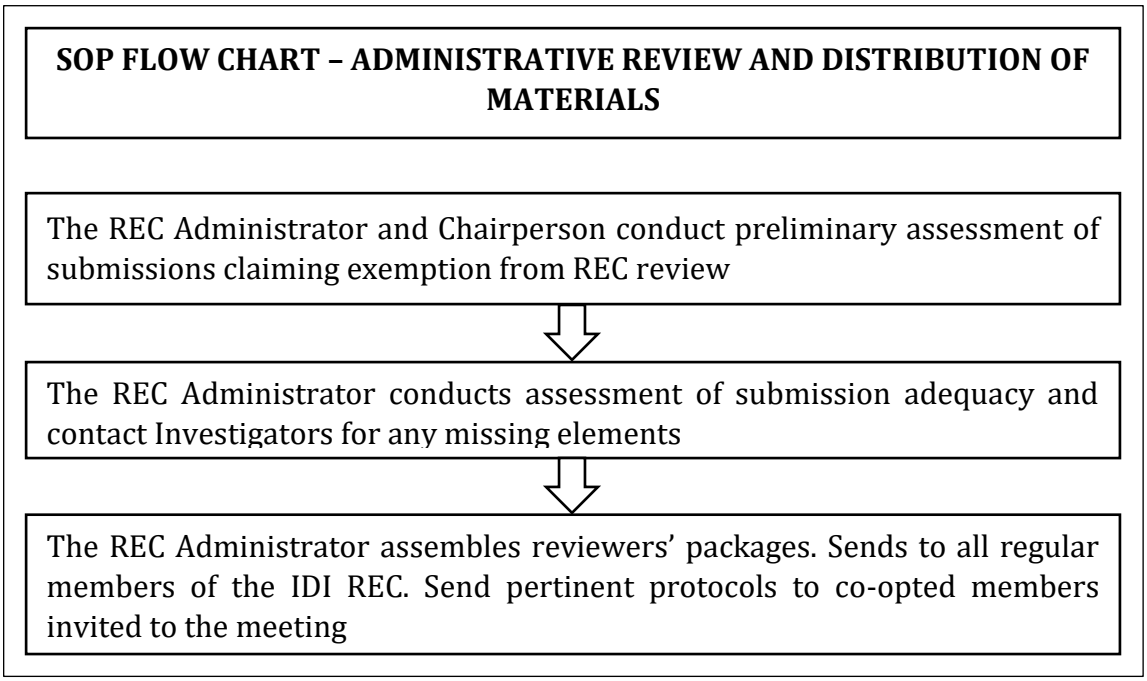
3.4.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

3.4.6 ATTACHMENTS

Form 3.4A Distribution Checklist

3.4.7 SOP FLOWCHART



SOP 3.5 DOCUMENTATION AND DOCUMENT MANAGEMENT

3.5.1 BACKGROUND

The IDI REC's files must be maintained in a manner that maintains a complete history of all REC actions related to review and approval of a protocol, including continuing reviews, amendments and adverse event reports. All records regarding a submitted study (regardless of whether it is approved) must be retained in an appropriate manner as required by regulatory requirements and/or IDI data protection policy.

Records must be accessible for inspection and copying by authorized representatives of the Sponsor, funding agency, regulatory agencies and institutional auditors at reasonable times and in a reasonable manner.

SPECIFIC PROCEDURES

3.5.1.1 DOCUMENT RETENTION

In line with the National Guidelines for Research involving Humans as Research

Participants sub-section 4.6 b., IDI REC office must retain all records regarding a research application for five (5) years after completion of the research. However, records will be retained longer if required (e.g., NDA requires clinical trial records to be kept for 20 years). Records may be preserved in hard copy, or electronic form.

3.5.1.2 STUDY-RELATED DOCUMENTS:

Adequate documentation of each IDI REC activity will be prepared, maintained and retained in a secure location. Retained documents include:

a) Copies of all original research protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, progress reports submitted by Investigators, and reports of adverse events occurring to research participants and reported deviations from the protocol.

b) Agendas and minutes of all REC meetings.

c) Copies of all submitted monitoring reports, site visit reports and other continuing review activities.

d) Copies of all correspondence between the REC and the Investigators.

e) Statements of significant new findings provided to research participants.

f) Reports of any complaints received from research participants.

3.5.1.3 REC ADMINISTRATION DOCUMENTS

The IDI REC office must maintain and retain all records regarding REC administrative activities that affect review activities for least five (5) years.

i) Rosters of regular and alternate REC members identified by name, earned degrees, representative capacity, and indications of experience sufficient to describe each regular and alternate member's chief anticipated contribution to the REC's deliberations; and any employment or other relationship between each member and IDI REC and/or the IDI (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid co-opted).

ii) Alternate members shall be included on the roster. In addition to the above information, the roster shall indicate the regular member for whom the alternate may substitute.

iii) Current and obsolete membership rosters will remain in the IDI REC Office and then archived according to IDI data protection policy.

iv) The roster of REC members must be submitted to UNCST and the US Office of Human Research Protection (OHRP) or similar regulatory body.

v) Any changes in IDI REC membership must be reported to the head of the department or agency supporting or conducting the research, unless the department or agency has accepted the existence of a Federal Wide Assurance (FWA) or its equivalent.

vi) Maintain current and obsolete copies of the Standard Operating Procedures.

vii) Delegation of specific functions, authorities, or responsibilities by the REC Chairperson must be documented in writing and filed in the IDI REC Office.

3.5.1.4 DESTRUCTION OF COPIES

All material received by the IDI REC, which is considered confidential and in excess of the required original documentation and appropriate controlled forms, will be collected at the end of the meeting and destroyed by a method deemed appropriate by the REC Administrator.

3.5.1.5 ARCHIVING AND DESTRUCTION

After 5 years, all documents and materials relevant to IDI REC determinations will be archived according to IDI data protection policy. Archiving procedures of the IDI will determine when such archived records may be destroyed.

3.5.2 SCOPE

This SOP applies to all controlled documents used in the submission, initial review, and continuing review of research submitted to the IDI REC.

3.5.3 RESPONSIBILITY

REC Administrator is responsible for maintaining complete files on all research reviewed by or submitted to IDI REC and for all applicable regulatory compliance requirements.

3.5.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research involving Humans as Research Participants, 2014 Section 4 subsection 4.6

b) WHO Guidelines for Ethical Review of Biomedical Research

c) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) & GCP Guidelines

3.5.5 REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

3.5.6 ATTACHMENTS

a) Form 3.5A Study Folder Content Checklist

b) Form 3.5B Archiving Procedure Checklist

3.5.7 SOP FLOWCHART

SOP FLOW CHART – DOCUMENTATION AND DOCUMENT MANAGEMENT

The REC Administrator ensures that the study information is entered in the database upon receipt of a new study. Creates a file label, organize submitted material in the order as described in SOP #: 3.1 for administrative intake of new studies

The REC Administrator ensures that all records regarding a submitted study (regardless of whether it is approved) are retained in an appropriate manner as required by regulatory requirements and/or IDI data protection policy. Ensures that all records are accessible for inspection and copying by authorized representatives of the Sponsor, funding department or agency, national and institutional auditors at reasonable times and manner

The REC Administrator ensure that the REC's electronic system and records are maintained in a manner that contains a complete history of all IDI REC actions related to review and approval of a protocol, including continuing reviews, amendments and adverse event reports

The REC Administrator with the assistance from the Information Services staff, oversee computerized systems used to generate documentation, track submissions and studies, and communicate with Investigators to ensure that systems are validated and are in compliance with applicable regulations, as regards design and validation. Ensures that all REC administrative staff are trained on the proper use of all electronic systems used to document study review and compliance activities. Maintains specific operations and procedures manuals to train staff and assure consistency of operations

The REC Administrator oversees the security of the electronic system by conducting appropriate reviews of electronic data and audit trails at designated time periods. Maintains appropriate security methods such as issuance and revision of ID/passwords, to ensure limited access to secure areas. If user ID/password combination are used, they will be changed at appropriate intervals, and invalidated, stolen, lost or otherwise compromised user ID/password combinations will be replaced with a new combination

SOP 4: SOPS ON REVIEW OF RESEARCH DOCUMENTS

SOP 4.1 EXPEDITED REVIEW

4.1.1 BACKGROUND

An expedited review procedure consists of a review of research involving humans as research participants by the Chairperson of REC or by one or more experienced reviewers designated by the Chairperson from among members of the REC. The categories of research that may fall under this consideration include research activities that (1) present no more than minimal risk to human research participants, and (2) involve only procedures listed in one or more of the specific categories listed in the national guidelines for research involving Humans as Research Participants, 2014 section 4.5.2.

SPECIFIC PROCEDURES

4.1.1.1 DEFINITION OF MINIMAL RISK

Minimal risk is defined as "...the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in routine medical, dental, or psychological examination of healthy persons".

4.1.1.2 CAUTIONS

a) The activities listed should not be deemed to be of minimal risk simply because they are included on the list of eligible research. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human research participants.

b) The expedited review procedure may not be used where identification of the research participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Furthermore, the expedited review procedure may not be used for classified research involving human research participants.

4.1.1.3 AUTHORITY OF THE IDI REC CHAIRPERSON

The Chairperson (or designee) may exercise all of the authorities of the REC, except that he/she may not disapprove the research proposal. A research proposal shall be disapproved only after review by the full IDI REC.

4.1.1.4 NOTIFICATION OF THE IDI REC

When the expedited review procedure is used, all regular members shall be informed of actions taken by the REC Chairperson at the next convened meeting.

4.1.1.5 DOCUMENTATION

If the study qualifies for expedited review, the REC Chairperson or designee will document his/her determination of risk.

The minutes will include documentation of the studies that were reviewed via expedited review and any issues resolved relating to questions that the designate REC reviewers by the chairperson had concerning the research reviewed.

4.1.1.6 ADDITIONAL ITEMS THAT MAY BE REVIEWED BY THE CHAIRPERSON OR DESIGNEE

a) **Conditional approval pending minor revisions, clarification**: Revisions to consent documents and other documentation or clarifications submitted as a result of full REC review and as a condition to final approval. Final approval will be issued provided that the revisions, documentation or clarifications do not indicate or result in a change to the study or change the risk/benefit ratio.

b) **Continuing review**: The REC Chairperson may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Any protocol revision that entails more than a minimal risk to the research participants must be reviewed by the full IDI REC at a convened meeting.

c) Revisions to informed consent documents that entail minor changes that do not affect the rights and welfare of study participants, or do not involve increased risk or significant changes in study procedures.

d) **Serious adverse event and safety reports**: A qualified staff person will triage serious adverse event reports (including IND safety reports) according to pre-established criteria. The Chairperson or designee will review those reports deemed significant. If the Chairperson feels that action is needed to protect the safety of research participants due to the nature or frequency of reported adverse events, he/she may take such action to the full REC or designated subcommittee, which will review the adverse events and study in question to determine action, if any, by the REC. The REC Chairperson acting for the REC will review summaries of safety reports and serious adverse events as soon as possible.

e) **Advertisements:** The REC Chairperson or designee may approve new or revised recruitment advertisements or scripts.

f) **Translations:** Translations of consent documents will also be submitted for REC approval and will be reviewed in an expedited manner. There are two options available to obtain approval of translated consent forms.

    i. The IDI REC approved consent form is translated by the Sponsor or site and submitted to the REC.

    ii. The Investigator (or Sponsor) may submit the REC approved version of the informed consent form to certified translator.

4.1.2 SCOPE

This SOP applies to all research proposals submitted to the IDI REC that qualifies for expedited review.

4.1.3 RESPONSIBILITY

a) REC Administrator is responsible for:

   i) Screen and identifying submissions that qualify for expedited review.

   ii) Providing a summary of proposal(s) that went through the expedited review mechanism at convened REC meetings.

b) REC Chairperson (or designee) is responsible for conducting expedited review.

4.1.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research involving Humans as Research Participants, 2014 Section 4 subsection 4.5.2

b) WHO Guidelines for Ethical Review of Biomedical Research

c) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) & GCP Guidelines

4.1.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other relevant SOPs.

4.1.6 ATTACHMENTS

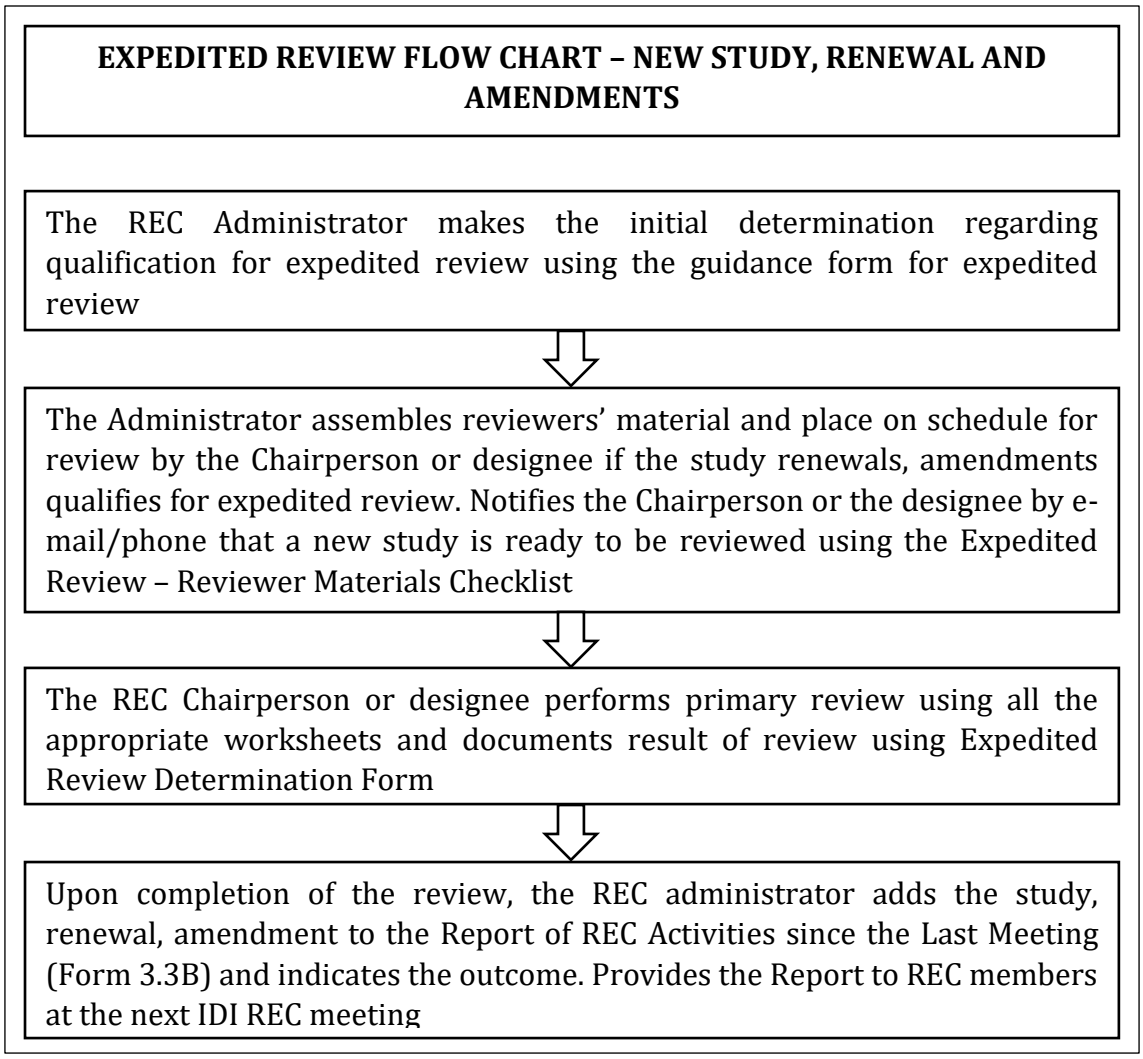
a) Form 4.1A Determination of Qualification for Expedited Review

b) Form 4.1B Guidance – Expedited Review

c) Form 4.1C Expedited Review - Reviewer Materials Checklist

d) Form 4.1D Expedited Review Determination

4.1.7 SOP FLOW CHART



SOP 4.2 INITIAL REVIEW – CRITERIA FOR IDI REC APPROVAL

4.2.1 BACKGROUND

All research proposals that plan to enroll human research participants must comply with Uganda's National Guidelines for Research Involving Humans as Research Participants and any other criteria that is unique to UNCST's system. They must adhere to the bio-ethics principles of justice, beneficence, non-maleficence and autonomy.

SPECIFIC PROCEDURES

4.2.1.1 MINIMAL CRITERIA FOR APPROVAL OF RESEARCH PROPOSAL

a) Risks to participants are minimized:

   i) By using procedures that are consistent with sound research design and which do not unnecessarily expose research participants to risk, and

   ii) Whenever appropriate, by using procedures already being performed on the research participants for diagnostic or treatment purposes.

b) Risks to research participants are reasonable in relation to anticipated benefits, if any, to research participants, and the importance of the knowledge that may be expected to result.

    i) In evaluating risks and benefits, the REC review mechanism will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that research participants would receive even if not participating in the research). The REC should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the scope of its responsibility.

c) Selection of research participants is equitable.

    i) In making this assessment the REC review mechanism should take into account the purposes of the research project and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

d) Informed consent will be sought from each prospective research participant or the research participant's legally authorized representative, in accordance with and to the extent required by appropriate national regulations and guidelines.

e) Informed consent will be appropriately documented as required by national regulations and guidelines.

f) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of research participants.

g) Where appropriate, there are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of data

h) When some or all of the, research participants such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for research participants found at international sites, additional safeguards must have been included in the study and in the REC review process, to protect the rights and welfare of these research participants.

i) Studies are reviewed at periods appropriate to the degree of risk research participants are exposed to due to their participation in the study, but at least annually.

4.2.1.2 OTHER CRITERIA

The REC may require verification of information submitted by an Investigator. The need to verify any information will be determined by the REC at a convened meeting. The purpose

of the verification will be to provide necessary protection to research participants when deemed appropriate by the REC.

The criteria used to determine whether third-party verification is required may include:

i) Investigators that conduct studies that involve a potential high risk to research participants,

ii) Studies that involve vulnerable populations,

iii) Investigators that conduct studies that involve large numbers of research participants, and

iv) Investigators selected at the discretion of the REC.

Projects that need third party verification from sources other than the Investigator that no material changes have occurred since previous REC review is determined, will have such assessment performed as necessary.

4.2.1.3 RELIANCE ON OTHER RECS FOR REVIEW AND APPROVAL OF RESEARCH CONDUCTED IN UGANDA.

Under authority granted by the UNCST, the REC may enter into joint review arrangements, rely upon the review of another UNCST accredited REC, or make similar arrangements for avoiding duplication of effort.

4.2.2 SCOPE

This SOP applies to the REC administrator and all members and to research proposals submitted to the REC for review.

4.2.3 RESPONSIBILITY

a) REC Administrator is responsible for ensuring that REC reviewers have all the tools and resources needed to complete proposal reviews.

b) REC Chairperson (or designee) is responsible for providing REC members adequate submission review training and ongoing guidance, and for selecting primary and secondary reviewers with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the REC.

c) REC Reviewer(s) is responsible for conducting a thorough review and making all appropriate approval recommendations for consideration by the REC.

4.2.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research Involving Humans as Research Participants, 2014 section 4 Subsection 4.7

b) WHO guidelines for Ethical Review of Biomedical Research

c) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) GCP Guidelines

4.2.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other relevant SOPs.

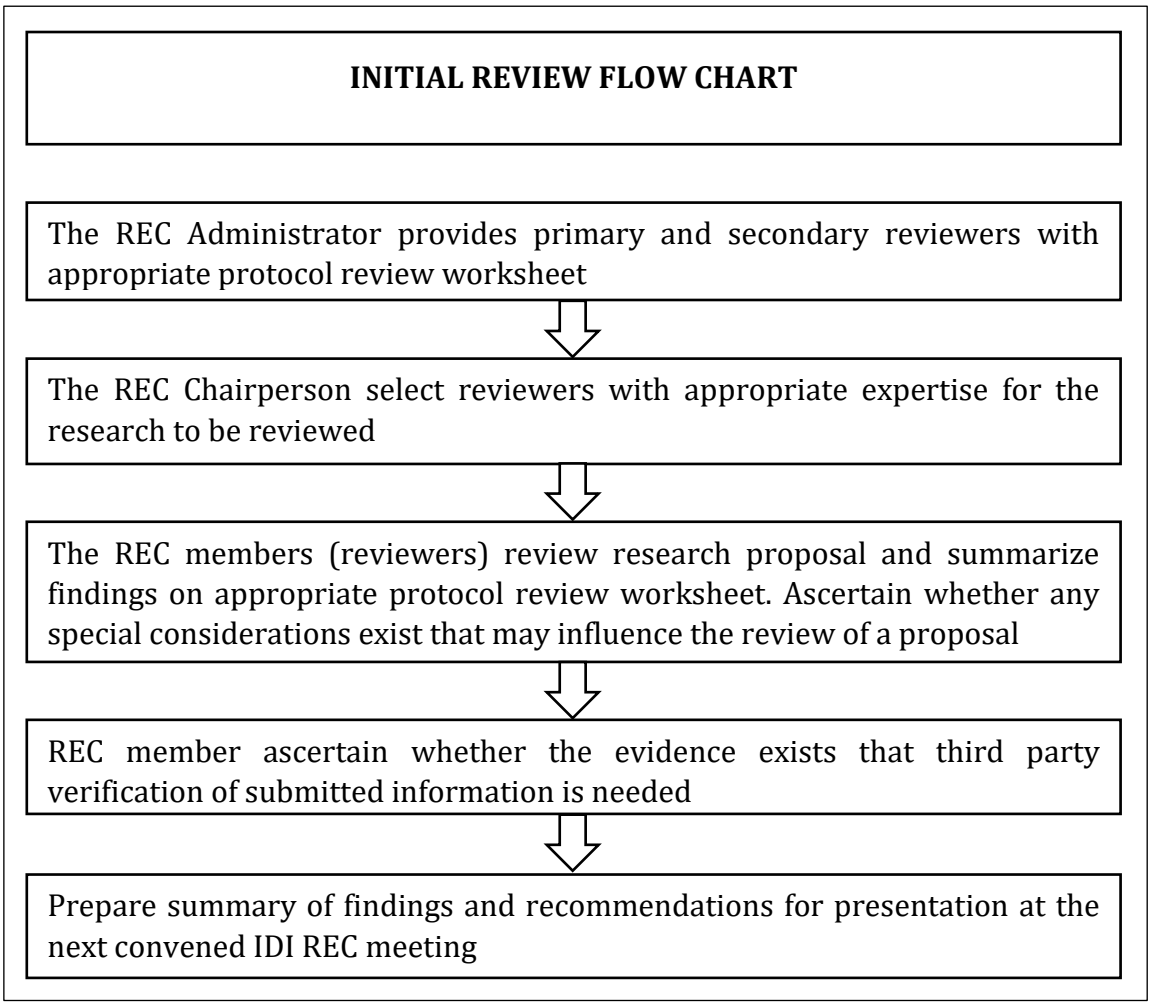
4.2.6 ATTACHMENTS

a) Form 4.2A Protocol Review Worksheet: Primary Reviewer

b) Form 4.2B Protocol Review Worksheet (Social): Primary Reviewer

c) Form 4.2C Protocol Review Worksheet: Regular Reviewer

4.2.8 SOP FLOW CHART



SOP 4.3 CONTINUING REVIEW – ON GOING RESEARCH PROJECTS

4.3.1 BACKGROUND

No Investigator has absolute right to conduct a research project within his/her institution. Rather, it is a privilege granted by society as a whole and the UNCST in particular.

IDI REC approval may be withdrawn at any time if warranted by the conduct of the research project. The national regulations and guidelines authorize REC to establish procedures for

the concurrent monitoring of research activities involving human research participants. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. All research involving human participants must be reviewed no less than once per year. REC approval for the conduct of a study may be withdrawn if the risks to the research participants are determined to be unreasonably high, for example, more than an expected number of adverse events, unexpected serious adverse events; or evidence that the Investigator is not conducting the investigation in compliance with REC approved research proposal or national guidelines. Such findings may result in more frequent review of the study to determine if approval should be withdrawn or enrollment stopped until corrective measures can be taken or the study terminated.

Continuing review includes, but may not be limited to the following activities:

a) Site Visits and Third Party Verification

b) Review of Serious and Unexpected Adverse Events

c) Amendments

d) Review of Significant New Findings

e) Reports from Employees, Staff and Faculty

f) Noncompliance

SPECIFIC PROCEDURES

4.3.1.1 SITE VISITS AND THIRD PARTY VERIFICATION:

The IDI REC has the authority to observe, or have a third party observe, the informed consent process of research it has approved, and to verify that the study is being conducted as required by the REC and within the Institutional policies and procedures and site-specific procedures, as appropriate. REC administrator or members may perform site visits or use another party, either affiliated or not with the UNCST, to verify information in the study application, or in any interim or continuing review submissions. The criteria for selecting Investigators to be visited may include:

a) Investigators who conduct studies that involve a potential high risk to research participants,

b) Studies that involve vulnerable populations,

c) Investigators who conduct studies that involve large numbers of research participants and

d) New investigators with limited research experience

e) Investigators selected at the discretion of the REC.

Other means of verification include questionnaires sent to investigative staff to verify information submitted by the Investigator. Sponsors may be asked to submit copies of

monitoring reports, or may be requested to complete a questionnaire regarding the protocol and/or the investigative site.

Investigators may be asked to submit copies of signed informed consent forms or other documents to ensure their compliance with IDI REC requirements. The REC may conduct interviews with screened and/or enrolled research participants as deemed necessary.

4.3.1.2 SERIOUS AND UNEXPECTED ADVERSE EVENTS

Research participant safety is of the greatest importance for both the individual participant and the goals of the clinical study. If the event is serious and unexpected, prompt reporting to the Sponsor and to REC is mandatory. Reports will be reviewed by the REC Chairperson or designee. If the Chairperson or designee determines that action may be needed to protect the safety of research participants due to the nature or frequency of reported adverse events, he/she may take such action and/or the full REC or designated subcommittee will review the adverse events and study in question to determine action, if any, by the REC. The REC, or designated subcommittee will review summaries of all safety reports and serious adverse events as soon as possible at a convened meeting.

4.3.1.3 UNANTICIPATED PROBLEMS

All unanticipated problems must be reported promptly to the REC. An unanticipated problem is defined as any unforeseen event or events that may involve risks or affect the safety or welfare of research participants or others, or that may affect the integrity of the research. Examples of an unanticipated problem include, but are not limited to: difficulty recruiting participants, higher than expected adverse events, higher than expected participant dropout rate, higher than expected protocol deviation rate, loss of multiple staff members, injury to a staff member while conducting study-related procedures, or participants' difficulty understanding the informed consent.

4.3.1.4 AMENDMENTS

Changes in approved research proposal, during the period for which approval has already been given, may not be initiated without prior REC review (full or expedited review, as appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human research participants. Investigators or Sponsors must submit requests for changes to the REC Administrator in writing. Upon receipt of the protocol change, the Chairperson or designee, with assistance of the REC Administrator, will determine if the revision meets the criteria for minimal risk. If the change represents more than a minimal risk to research participants, it must be reviewed and approved by the REC. Minor changes, involving no more than minimal risk to the participant, will be reviewed by the expedited review procedure (SOP #: 4.1 - Expedited Review).

4.3.1.5 SIGNIFICANT NEW FINDINGS

During the course of a study, the REC may review reports generated from a Data and Safety Monitoring Board (DSMB), adverse event reports, current literature, and other sources to ascertain the status of the study and assess whether or not the risk/benefit balance is still acceptable. The REC will determine whether or not new information need to be conveyed to

research participants in the current studies and those in similar studies under the jurisdiction of the REC, or if a segment of the population may be bearing an undue burden of research risk or being denied access to promising therapy.

4.3.1.6 REPORTS FROM EMPLOYEES, STAFF AND FACULTY

It is the responsibility of the REC administrator and members to act on information or reports received from any source that indicate a study being conducted at any facility under the jurisdiction of the REC could adversely affect the rights and welfare of research participants.

4.3.1.7 ENSURING PROMPT REPORTING OF ANY SERIOUS OR CONTINUING NONCOMPLIANCE WITH APPLICABLE REGULATIONS OR THE REQUIREMENTS OR DETERMINATIONS OF THE IDI REC:

All credible reports of inappropriate involvement of human research participants in research projects approved by the REC must be investigated by the REC Chairperson or designee and referred to the REC. The results of the investigation will be reported to the UNCST Executive Secretary, Regulatory authorities or Sponsors may also be notified in writing. Such reports of noncompliance may come from any source including REC members, investigators, research participants, institutional personnel, the media, anonymous sources or the public. The REC has the authority to suspend or terminate approval of research project that is not being conducted in accordance with the REC SOPs, approved research proposal, noncompliance with national regulations, or has been associated with unexpected serious harm to research participants. All such suspension and or terminations will be reported to the UNCST, sponsors, funding and regulatory agencies in writing.

4.3.1 SCOPE

This SOP applies to research proposal (s) submitted to the IDI REC.

4.3.2 RESPONSIBILITY

a) REC members are responsible for establishing the processes for conducting ongoing reviews of research projects.

b) REC Chairperson (or designee) is responsible for preliminary assessments of adverse events, significant new findings and the need for third party verification.

4.3.3 APPLICABLE REGULATIONS AND GUIDELINES

a) National guidelines for Research Involving Humans as Research Participants, 2014, Section 4 subsection 4.9 part a, subsection 4.5.5,

b) WHO guidelines for Ethical Review of Biomedical Research

c) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) & GCP Guidelines

4.3.4 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other relevant SOPs.

4.3.5 ATTACHMENTS

a) Form 4.3A Site Visit Confirmation Letter

b) Form 4.3B Site Visit Worksheet

c) Form 4.3C Site Visit Report

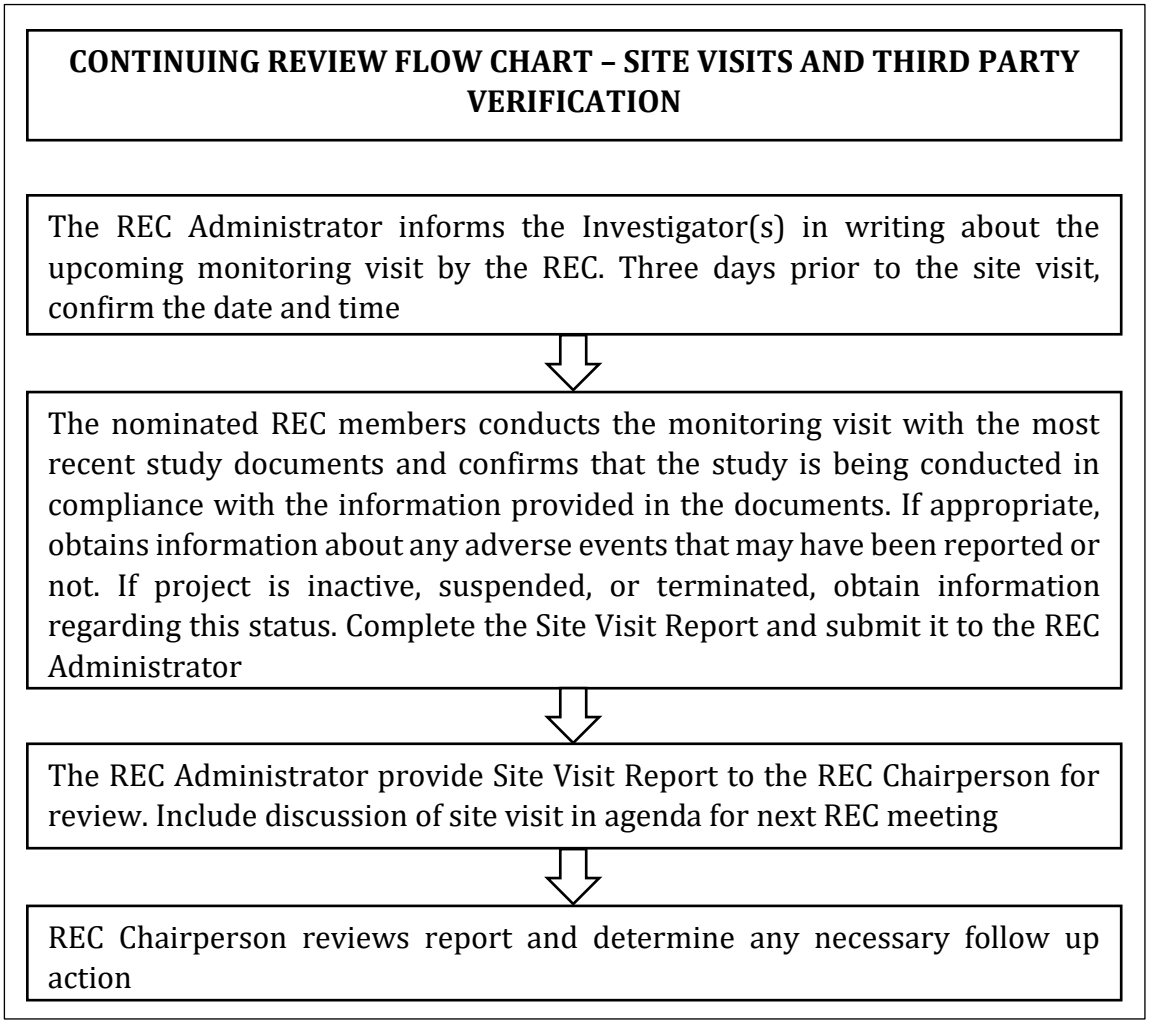
d) Form 4.3D Serious Adverse Event Report

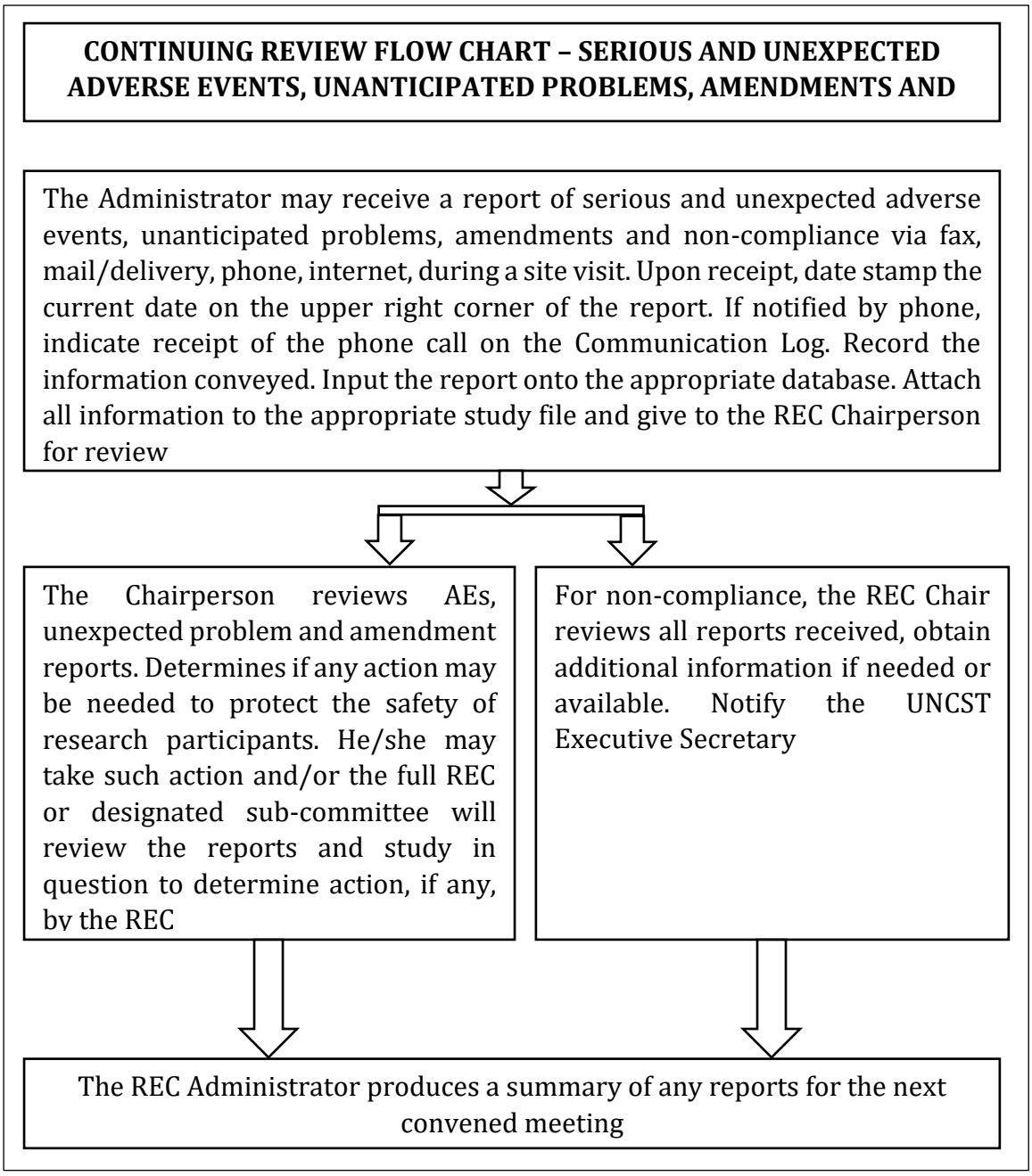
e) Form 4.3E Adverse Event Report Review Form

f) Form 4.3F Significant New Findings Review

g) Form 4.3G Amendment Submission Form

4.3.6 SOP FLOW CHART





SOP 4.4 CONTINUING REVIEW – CRITERIA FOR RENEWAL

4.4.1 BACKGROUND

The IDI REC conducts continuing review of research projects taking place within its jurisdiction at intervals appropriate to the degree of risk, but not less than once per year.

SPECIFIC PROCEDURES

4.4.1.1 INTERVAL FOR REVIEW FOR PURPOSES OF RENEWAL

The REC must conduct continuing review of protocols for purposes of renewal of the REC approval period, at intervals appropriate to the degree of risk, which is determined at the initial review, but not less than once per year. “Not less than once per year" means that the research must be reviewed on or before the one-year anniversary of the previous REC review date, even though the research activity may not have begun until sometime after REC gave its approval. Investigators are required to submit a periodic report prior to the expiration of the study or as specified by the REC, but at least annually. The report should normally be filed 60 days before the study approval period ends.

4.4.1.2 EXTENSIONS OF APPROVAL PERIOD

There is no grace period extending the conduct of the research beyond the expiration date of REC approval. Extensions beyond the expiration date will not be granted. If Continuing Review Report forms and other requested progress reports are not received as scheduled, the Investigator must suspend the study, including study enrollment and data collection until reports are reviewed and approved. However, if the Investigator is in communication with the REC, the Continuing Review Report or other report is forthcoming, and in the opinion of the REC, humans participating in such a study would suffer a hardship if medical care were discontinued, appropriate medical care may continue beyond the expiration date for a reasonable amount of time. However, new research participants cannot be enrolled. The REC will address on a case-by-case basis those rare instances where failure to enroll new research participants would seriously jeopardize the safety or wellbeing of an individual. Prospective research data cannot be collected, and no procedures that are only being performed for the purposes of the protocol may be performed until a Continuing Review Report or other progress report is reviewed and approved.

4.4.1.3 CRITERIA FOR RENEWAL

Continuing review must be substantive and meaningful. When considering whether or not to renew a study, the REC revisits the same criteria used to grant initial approval. Therefore, the REC (or the reviewers for protocols reviewed under an expedited procedure) must determine that:

a) The risks to research participants continue to be minimized and reasonable in relation to the anticipated benefits;
b) The selection of research participants continues to be reasonable in relation to anticipated benefits;
c) Informed consent continues to be appropriately documented;

Additionally, there are:

d) Provisions for safety monitoring of the data,

e) Protections to ensure the privacy of research participants and confidentiality of data, and

f) Appropriate safeguards for vulnerable populations.

Because it may be only after research has begun that the real risks can be evaluated and the preliminary results used to compute the actual risk/benefit ratio; the REC can then

determine whether or not the study can be renewed at the same risk/benefit ratio, or if new information has changed that determination.

In order to determine the status of the study, the following will be revisited:

a) ***Consent document:*** Each member of the REC shall review the currently approved consent document and ensure that the information is still accurate and complete. Any significant new findings that may relate to the research participant's willingness to continue participation should be provided to the research participant in an updated consent document.

b) ***Current approved protocol including any amendments to protocol since initial review:*** A copy of the protocol will be sent to the primary reviewer of the continuing review. Amendments and addenda to a research protocol should be submitted as generated during the course of the study. They also may be submitted at the time of continuing review. A separate cover letter describing the change and all appropriate documentation (approved consent form) must accompany the continuing review application.

c) ***Continuing REC review is required as long as individually identifiable follow- up data are collected on research participants enrolled in protocols*.** This remains the case even after a protocol has been closed at all sites and protocol-related treatment has been completed for all research participants. These renewal requests may qualify for expedited review.

d) ***Continuing review of DSMB-monitored clinical trials:*** The REC may rely on a current statement from the DSMB indicating that it has reviewed study-wide adverse events, interim findings and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the REC. However, the REC must still receive and review reports of local, on-site unanticipated problems involving risks to research participants or others and any other information needed to ensure that its continuing review is substantive and meaningful.

e) ***Progress report:*** All REC members shall receive a progress report prepared and submitted by the Investigator along with the number of research participants entered to date and since the last review. The progress report shall summarize adverse event experiences, amendments and new Conflict of Interest (CoI) disclosure as applicable, and provide a reassessment of the risk-to-benefit ratio. (see available progress report format)

f) Possible Outcomes of Continuing Review: As an outcome of continuing review, the REC may require that the research be modified or halted altogether. The REC may need to impose special precautions or relax special requirements it had previously imposed on the research protocol.

g) Expedited Review for Renewal: A protocol that was originally reviewed using the expedited review procedure may receive its continuing review on an expedited basis. Additionally, a standard-review protocol that had no accrual during the previous period, or which has not been awarded funding, or which remains open

only for data analysis may be reviewed using an expedited review. When conducting research under an expedited review procedure, the REC Chairperson or designated REC member conducts the review on behalf of the full REC using the same criteria for renewal as stated in section 1.3 of this SOP. If the reviewer feels that there has been a change to the risks or benefits, he or she may refer the study to the full REC for review.

4.4.2 SCOPE

This SOP applies to all research proposals submitted to the REC.

4.4.3 RESPONSIBILITY

REC Administrator is responsible for establishing and implementing processes for making research proposal renewal decisions.

4.4.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National guidelines for Research Involving Humans as Research Participants, 2014 Section 4 subsection 4.9 part a, b, c

b) WHO guidelines for Ethical Review of Biomedical Research

c) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) & GCP Guidelines

4.4.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other relevant SOPs.

4.4.6 ATTACHMENTS

a) Form 4.4A Continuing Review Report / Renewal Request

b) Form 4.4B Continuing Review Worksheet

4.4.7 SOP FLOW CHART

CONTINUING REVIEW FLOW CHART – CRITERIA FOR RENEWAL

During the last week of each month, the Administrator generates a summary from the database for the entire month of studies with IDI REC approvals due to expire in 5 weeks

⇩

The Administrator contacts the Investigator/Contact Person at least 4 weeks prior to the expiration date to advise that the research study is about to lapse and remind them of the materials required for submission. Record the telephone notification per SOP #: 6.1.

⇩

During the second and last weeks of each month, generate a summary for the entire month of the Continuing Reviews due to expire in 3 weeks and the corresponding suspension letters from the database per SOP #: 6.1. The Investigator must submit a Continuing Review Form to the IDI REC within 2 weeks to expiration date. Fax/mail/e-mail the Notice of Study Suspension to the Investigator/Contact Person per SOP #: 6.1.

⇩

If a Continuing Review is not received, the Administrator distributes the existing materials in a package to the primary reviewer(s) designating the information as incomplete due to a lack of response from the Investigator. Place the Continuing Review on the agenda (under a separate section titled Lapsed Continuing Review with Incomplete Information) prior to the expiration date

⇩

The REC Members will review the report and associated materials to determine the status of continuation of the study

⇩

The Administrator notifies the Investigator the outcome of the review. If the IDI REC does not re-approve the research by the specific expiration date, the research suspension letter is sent per SOP #: 6.1. Coordinate faxing or emailing the approval letter to the Investigator

SOP 4.5 STUDY COMPLETION

4.5.1 BACKGROUND

The completion or termination of the study is a change in activity and must be reported to the REC. Although research participants will no longer be "at risk" under the study, a final report/notice to the REC allows it to close its files as well as providing information that may be used by the REC in the evaluation and approval of related studies.

SPECIFIC PROCEDURES

4.5.1.1 DETERMINING WHEN A PROJECT CAN BE CLOSED

a) When individually identifiable follow-up data are no longer being collected on research participants enrolled in protocols and analysis that could indicate new information is complete, the study may be closed.

b) Multi-site studies may be closed when the Investigator submits his or her final report.

4.5.1.2 COMPLETION REPORTS

Completion reports should be submitted within 90 days after completion or termination of the study. Completion reports may be submitted in a written format that provides adequate information about the study. Completion reports may be submitted by the Investigator's designee at the investigative site. The REC Administrator will review all reports of study completion and, if needed, request further information from the Investigator to clarify any questions that may arise. A listing of closed studies will be presented to the REC at the next meeting, and copies of the Completion Report and supplementary information are made available to the REC members upon request.

4.5.2 SCOPE

This SOP applies to all research proposals submitted to the REC.

4.5.3 RESPONSIBILITY

REC Administrator is responsible for ensuring all study completion documentation is received, reviewed, presented to the REC, and filed appropriately.

4.5.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National guidelines for Research Involving Humans as Research Participants, 2014 Section 4.5.6

b) WHO Guidelines for ethical review of biomedical research

c) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) GCP Guidelines

4.5.5 REFERENCES TO OTHER APPLICABLE SOPs

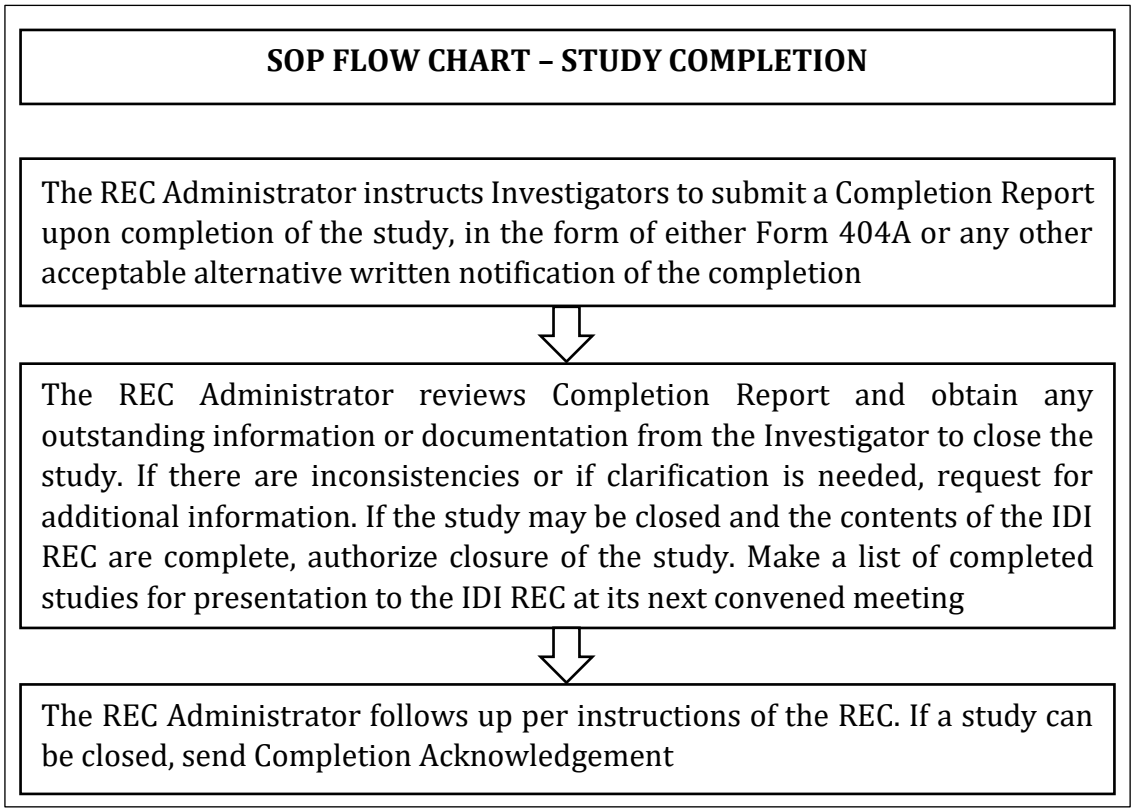
This SOP affects all other relevant SOPs.

4.5.6 ATTACHMENTS

a) Form 4.4A Continuing Review Report / Renewal Request

b) Form 4.4B Continuing Review Worksheet

4.5.7 SOP FLOW CHART



SOP 4.6 CATEGORIES OF ACTION

4.6.1 BACKGROUND

As a result of its review, the REC shall approve or disapprove the proposed research proposal, or to specify modifications required to secure REC approval of the research proposal. Except when the expedited review procedure is used, these actions will be taken by a vote of a majority of the regular and alternate members present, except for those members present but unable to vote in accordance with REC's conflict of interest policies. When reviewed via expedited review, the Chairperson or designee can take any of the following actions except to disapprove a study.

SPECIFIC PROCEDURES

4.6.1.1 DETERMINATIONS

The REC may make one of the following determinations as a result of its review of research proposal submitted for initial review or for continuing review:

a) ***Approval:*** The protocol and accompanying documents are approved as submitted. Final approval will commence on the day the study is approved by an action of the convened REC or Chairperson or designee and expire within one (1) year of the meeting date, but not later than the day preceding the date of review. Approvals are always considered conditional. The conditions for continued approval, and the time frame (if any) within which they must be met will be clearly stated in the approval letter. If the conditions of the approval are not met, approval may be withdrawn.

b) ***Withheld Approval****:* Minor modification of, or addition to, a protocol or accompanying document(s) is required. Changes will be voted upon during REC's meeting, as well as the terms of approval. The Investigator will be informed in writing of the required changes and requested information and must provide the REC with the changes or information. The REC Chairperson or his/her designee has the authority to review the information via expedited review unless the REC requires that the material or information be reviewed by the full REC, the primary reviewer or another individual delegated by the REC to review the response. Upon satisfactory review, approval will be issued as of the date that the requested information or materials are approved. However, the expiration date of REC approval will be based on the anniversary date of the initial REC review. Research participants must not be recruited into the study until final approval has been issued.

c) ***Tabled:*** Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the Sponsor and/or Investigator.

d) ***Disapproval:*** The proposal fails to meet one or more criteria used by the REC for approval of research. Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the REC.

4.6.2 SCOPE

This SOP applies to all research submitted to the REC.

4.6.3 RESPONSIBILITY

a) REC Chair (or designee) is responsible for ensuring that all REC decisions and actions are based on institutional and regulatory requirements.

b) REC Chairperson (or designee) is responsible for ensuring the appropriateness of all REC decisions and actions.

4.6.4 APPLICABLE REGULATIONS AND GUIDELINES

National guidelines for Research Involving Humans as Research Participants, 2014 Section 4.5.1 part d.

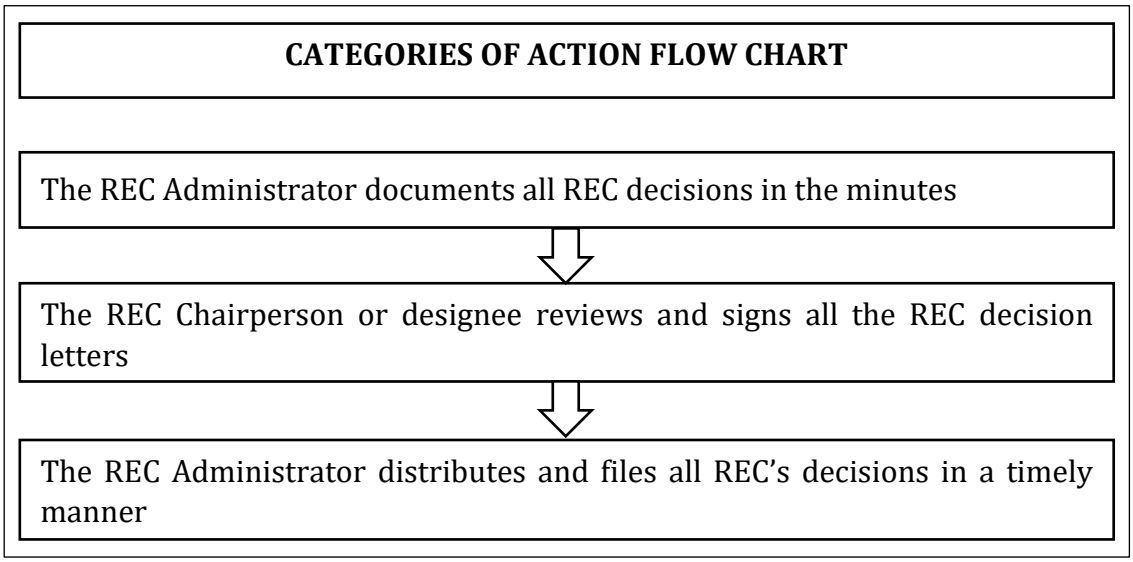
4.6.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other relevant SOPs.

4.6.6 ATTACHMENTS

None

4.6.7 SOP FLOW CHART



SOP 5: SOPS ON REVIEW REQUIRING SPECIAL CONSIDERATIONS

SOP 5.1 VULNERABLE POPULATIONS

5.1.1 BACKGROUND

The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Thus not every human being is capable of self-determination. There is need for extensive protection to some persons and sometimes excluding them from research activities that may harm them. Other persons require minimal protection beyond making sure they undertake research activities freely and with awareness of possible adverse consequence. Indeed, some types of research may, in and of themselves, create a vulnerable group – that is, the research participants lose their autonomy or are exposed to unknown risks. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically re-evaluated and may vary in different situations.

Potentially vulnerable groups may include and not limited to:

a) Children

b) Mature minors and Emancipated minors

c) Prisoners

d) The Homeless

e) The Handicapped (Mentally and Physically)

f) Mentally ill and behaviorally disordered

g) Armed forces

h) Pregnant women and fetuses

i) Terminally ill patients

SPECIFIC PROCEDURES

5.1.1.1 PRISONERS

If research participants of a given study are prisoners or are participants that may reasonably be expected to be incarcerated at some time point during the study, the following additional requirements will apply to REC review of the project:

a) National regulations and guidelines: In addition to meeting national regulations and guidelines, the project must comply with local and state requirements for inclusion of prisoners as research participants.

b) REC composition: A majority of REC members may have no association with the prison(s). Therefore, at least one member shall be a prisoner or prisoner advocate with appropriate background and experience to serve in that capacity.

c) Additional duties where prisoners are involved, the REC may review research involving prisoners only if it finds that the following conditions are met:

    i. The research under review involves solely research on the practices both innovative and accepted, which has the intent and reasonable probability of improving the health and wellbeing of prisoners as research participants.

    ii. In cases where prisoners may not benefit from the research because they are assigned to a control group in a manner consistent with the protocol approved by the REC, participants in the control group must be provided with the intervention if found beneficial.

    iii. Any possible advantages accruing to the prisoner through participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that the prisoner's ability to weigh the risks and benefits of the research in the limited- choice environment of the prison is impaired.

    iv. The risks involved in the research are commensurate with risks that would be accepted by non-prison volunteers.

    v. Selection procedures within the prison are fair to all prisoners and immune from arbitrary intervention by prison authority or prisoners. Unless the Investigator provides the REC justification in writing for

following some other procedures, control research participants must be selected randomly from the group of eligible prisoners for the research project.

vi. Any information given to research participants is presented in language that is appropriate for the participants' population.

vii. Adequate assurance exists that parole board(s) will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the clinical investigation will have no effect on his/her parole.

viii. Where there is need for follow-up examination or care of research participants after the end of their participation in the research, adequate provision has been made for such examination or care, taking into account the varying lengths of prisoner sentences, and for informing research participants of this fact.

ix. These guidelines apply whenever any participant in a research protocol becomes a prisoner at any time during the protocol, *e.g.,* after the research has commenced. This is necessary because it is unlikely that review of the research and the consent document contemplated the constraints imposed by the possible future incarceration of the research participant.

d) If a research participant becomes a prisoner after enrollment in research, all research interactions and interventions with, and obtaining identifiable private information about the participant must cease. The Principal Investigator is responsible for reporting this situation in writing to the REC immediately
e) At the earliest opportunity after receiving the Investigator's notice or otherwise becoming aware of the prisoner status of a research participant, the REC should review the protocol again with a prisoner representative as a co-opted member of the REC. The REC should take special consideration of the conditions of being a prisoner.
f) Upon this review, the REC can either (a) approve the involvement of the prisoner-participant in the research in accordance with this policy or (b) determine that this participant must be withdrawn from the research.
g) Additionally, the REC should confirm that, when appropriate, the informed consent process includes information regarding when subsequent incarceration may result in termination of participation by the Investigator without regard to the research participant's consent.
h) In special circumstances in which the principal investigator asserts that it is in the best interests of the research participant to remain in the research study while incarcerated, the REC Chairperson may determine that the participant may continue to participate in the research until the requirements of National Guidelines for Research Involving Humans as research participants are satisfied.

5.1.1.2 CHILDREN

The special vulnerability of children makes consideration of involving them as research participants particularly important in the deliberations of the REC. In order to safeguard their interests and to protect them from harm, ethical and regulatory considerations are in place for reviewing research involving children. At the same time, the REC recognizes the importance of conducting scientifically sound and ethically designed studies in this population.

a) There are two factors that make a case for clinical research in children.
    i. Children differ markedly from both animals and adults, and therefore, these models cannot substitute as alternatives to testing in children.
    ii. Lack of appropriate research in children will increase their risk of harm from exposure to practices and treatments untested in this population. In addition, new therapies could not be developed for diseases that specifically affect children.
b) Research in children requires that the REC considers probable risk, associated discomfort and possible benefits when reviewing research in a pediatric population.

i. Determination of possible benefits

In assessing the possible benefits of research intervention, the REC should consider the variability in health statuses among potential children as research participants. For example, a potential research participant might be a normal, healthy child, or a child who has been exposed to a disease or a toxin (*e.g*., meningococcal or lead) where it is known that a percentage of the children exposed will actually experience untoward consequences. A child may also be in an early state of disease, *e.g.*, an HIV- infected child, or may actually suffer from disease or other significant medical condition. Thus, the IDI REC must take into account the current health status of a child and the likelihood of progression to a worsened state without research intervention.

ii. Determination of probable risks and associated discomforts

Procedures that usually present no more than minimal risk to a healthy child include: urinalyses, obtaining small blood samples, EEGs, allergy scratch tests, minor changes in diet or daily routine, and/or the use of standard psychological or educational tests. The assessment of the probability and magnitude of the risk, however, may be different in sick children and may vary depending on the diseases or conditions the research participants may have. For example, obtaining blood samples from a hemophiliac child may present more than minimal risk to the child. On the other hand, REC may consider that children suffering from chronic illnesses who are accustomed to invasive procedures are placed at minimal risk by involvement in similar research procedures, in contrast to children who have not had such experiences. The REC must also consider the extent to which research procedures would be a burden to any child, regardless of whether the child is accustomed to the proposed procedures.

Procedures that exceed the limits of minimal risk may be difficult to define

in abstract, but should not be too difficult to identify on a case-by-case basis. Riskier procedures might include biopsy of internal organs, spinal taps, or the use of drugs whose risks to children have not yet been established. Behavioral interventions likely to cause psychological stress may also exceed minimal risk.

c) National research guidelines classify research involving children in four categories of research involving children based on degree of risk and benefit to individual participants are as follows

Research not involving greater than minimal risk.

Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual participant. Research in this category is approvable provided: (a) the risk is justified by the anticipated benefit to the research participant; and (b) the relationship of risk to benefit is at least as favorable as any available alternative approach

Research involving greater than minimal risk with no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition. Research in this category is approvable provided:

a. The risk represents a minor increase over minimal risk;
b. The intervention or procedure presents experiences to research participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings; and
c. The intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition that is of vital importance for the understanding or amelioration of the research participant's disorder or condition.
    i. Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

c) If IDI REC does not believe that a clinical investigation within the scope described in Sections 5.0 and 5.6 and involving children as research participants meets the requirements of the National guidelines for research in human participants. The clinical investigation may proceed only if:
    I. The IDI REC finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

The clinical investigation will be conducted in accordance with sound ethical principles; and

a) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in Sec. 50.55.
b) Parental_Consent: Children may be participants of research only if informed

consent is obtained from the parents or guardian. The IDI REC will determine whether the permission of both parents is necessary, and the conditions under which one parent may be considered not reasonably available. The national guidelines provide that the IDI REC may find that the permission of one parent is sufficient for research to be conducted under minimal risk research or research involving greater than minimal risk but presenting the prospect of direct benefit to individual research participant. Where research involves more than minimal risk, or is not otherwise approvable permission is to be obtained from parents, and both parents must give their permission, unless one parent is deceased, unknown, incompetent, or reasonably unavailable, or when only one parent has legal responsibility for the care and custody of the child. Where parental permission is to be obtained, the REC may find that the permission of one parent is sufficient, if consistent with national law, for clinical investigations. Where clinical investigations are covered and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child if consistent with national law. Permission by parents or guardians must be documented. Participation of children in clinical investigations who are wards of state will be accorded special consideration by REC.

a) Assent of Children: The IDI REC must determine that adequate information is provided for soliciting the assent of the children capable of providing assent based on the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in clinical investigations under a particular protocol, or for each child, as appropriate. Assent to participate in a study shall be obtained from children aged 8 years and above , and written assent shall be sought based on reasonable age ranges for comprehension i.e., 8-10, 11-15, 15 - <18 years of age.

b) A child's assent shall be obtained after parental/guardian's consent. The child's assent or dissent takes precedence over the parent's or guardian's consent. Assent for all other persons incapable of self-determination is obtained after consent from their representatives.

c) Waiver of Assent: The assent of the child is not a necessary condition for proceeding with the clinical investigation if the IDI REC determines:
    i. That the capability of some or all of the children is so limited that they cannot reasonably be consulted, or
    ii. That the intervention or procedure involved in the clinical investigation holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the clinical investigation.
    iii. Where the IDI REC determines that the research participants are capable of assenting, it may still waive the assent requirement if it finds and documents that:
    a) The clinical investigation involves no more than minimal risk to the research participants;
    b) The waiver will not adversely affect the rights and welfare of the research

participants;
c) The clinical investigation could not practicably be carried out without the waiver; and
d) Whenever appropriate, the research participants will be provided with additional pertinent information after participation.

5.1.1.3 PREGNANT WOMEN AND FETUSES

Pregnant women or fetuses prior to delivery may be involved in research if all of the following conditions are met:

a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

b) The risk to the fetus is not greater than minimal, or any risk to the fetus, which is greater than minimal, is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.

c) Any risk is the least possible for achieving the objectives of the research;

d) The woman's consent or the consent of her legally authorized representative is obtained in accordance with the informed consent provisions of unless altered or waived.

e) The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;

f) For minors who are pregnant, assent and permission are obtained in accordance with the national guidelines.

g) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

h) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy;

i) Individuals engaged in the research will have no part in determining the viability of a fetus.

After delivery, fetuses may be involved in research if all of the following conditions are met:

j) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses;

k) The individual(s) providing consent under the applicable regulations is/are fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;

l) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

m) The regulatory requirements have been met as applicable.

Fetuses of uncertain viability: After delivery, and until it has been ascertained whether or not a fetus is viable, a fetus may not be involved in research covered by national regulations and guidelines unless the following additional conditions are met:

n) The research holds out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research; or

o) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research; and

Nonviable fetuses: After delivery, a nonviable fetus may not be involved in research covered by national regulations and guidelines unless all of the following additional conditions are met:

p) Vital functions of the fetus will not be artificially maintained;
q) The research will not terminate the heartbeat or respiration of the fetus;
r) There will be no risk to the fetus resulting from the research;
s) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
t) The legally effective informed consent of both parents of the fetus is obtained according to the national guidelines. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the national regulations and guidelines.

Viable fetuses. A fetus, after delivery, that has been determined to be viable is a child and may be included in research only to the extent permitted in accordance with the national regulations and guidelines.

Research involving after delivery, the placenta, the dead fetus, or fetal material.

u) Research involving after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accordance with any applicable national regulations and guidelines regarding such activities.
v) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and all pertinent regulations and guidelines apply.

5.1.1.4 HANDICAPPED (MENTALLY AND PHYSICALLY) MENTALLY ILL AND BEHAVIORALLY DISORDERED

The IDI REC will generally follow the recommendations governing the conduct of research for this group of individuals as stipulated in the guidelines for research involving humans as research participants.

a) Selection of research participants. Research involving individuals with diminished capacity to consent should have a direct relationship to their illness or condition. Particular attention should be paid to institutionalized individuals, as issues of dependence and coercion may be factors that may compromise the voluntary nature of their participation in research. For this reason, research participants should be recruited from among non-institutionalized populations whenever possible.
b) Risk Determination: Generally, the IDI REC will follow the recommendations of the National guidelines when determining the degree of risk and its impact on the approvability of a research protocol in handicapped (mentally and physically), mentally ill and behaviorally disordered, research participants as follows:
    i. A minor increase over minimal risk may be permitted in research involving those institutionalized as handicapped (mentally and physically), mentally ill and behaviorally disordered, but only where the research is designed to evaluate an intervention of foreseeable benefit to their care.
    ii. For research that does not involve beneficial interventions and that presents more than minimal risk, the anticipated knowledge sought should be of vital importance for understanding or eventually alleviating the research participant's disorder or condition.
c) Limiting Risks. The following measures should be addressed in the protocol to limit a research participant's exposure to risk:
    i. Description of appropriate psychological or medical screening criteria to prevent or reduce the chances of adverse reactions to the therapeutic and research procedures
    ii. Specific diagnostic, symptomatic, and demographic criteria for research participant recruitment
    iii. Description of methods for assuring adequate protections for the privacy of the research participants and the confidentiality of the information gathered.
    iv. Justification of plans to hospitalize research participants or extend hospitalization for research purposes
    v. Measures to protect Individually identifiable information
    vi. Measures to ensure that proposed research procedures will not be detrimental to ongoing therapeutic regimens.
d) Informed Consent: Generally, mentally impaired adults should be presumed competent to understand the issues of being a research participant and either refuse or consent to participate in a research study. Being mentally disabled alone should not disqualify a person from consenting to participate in research; rather,

there needs to be specific evidence of incapacity to understand and to make an informed voluntary choice before they are deemed unable to consent for themselves. The REC recommends that if a mentally handicapped and/or behaviorally disordered adult research participant objects to participate in a research study, that decision should be binding, except when the individual's participation is specifically authorized by REC, on the demonstrated basis that the intervention is expected to provide a direct health benefit to the participant, and the intervention is available only in the context of the research.

5.1.1.5 OTHER VULNERABLE GROUPS

Although national regulations and guidelines list vulnerable groups, as children, mature and emancipated minors, street children, prisoners, the homeless, substance abusers, handicapped (mentally and physically) armed forces, and pregnant women. Other vulnerable groups may include, employees of the Sponsor or Investigator, terminally ill patients, and the very elderly. The IDI REC will determine special protections for these groups on a case-by-case basis, taking into account the risks and benefits and other protections afforded by institutional policies and state law.

5.1.1.6 PARTICIPANTS IN "TREATMENT INVESTIGATIONAL NEW DRUG (IND)" STUDIES

Informed consent is especially important in treatment IND studies situations because the research participants are desperately ill and particularly vulnerable. They will be receiving medications that have not been proven either safe or effective, in a clinical setting. Both the setting and their desperation may work against their ability to make an informed assessment of the risk involved. IDI REC must ensure that potential participants are fully aware of the risks involved in participation.

IDI REC discourages research studies that require research participants to meet the costs of their treatments during their participation in a given study. Researchers and sponsors are obliged to manage serious adverse events related to the study (including paying for associated) until they are fully resolved or stabilized. Researchers should provide relevant follow up procedures for research participants for an appropriate period of time after the trial.

Sponsors are encouraged, but not obliged, to provide care for concurrent illnesses not associated with the research project.

5.1.2 SCOPE

These policies and procedures apply to all research submitted to the IDI REC.

5.1.3 RESPONSIBILITY

a) IDI REC Administrator is responsible for maintaining up-to-date review tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.
b) IDI REC Chairperson (or designee) is responsible for ensuring the members are

well versed in new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

c) IDI REC Reviewer is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources.

5.1.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research Involving Humans as Research Participants Section 8.0

5.1 WHO guidelines

b) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) & GCP Guidelines

5.1.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

5.1.6 ATTACHMENTS

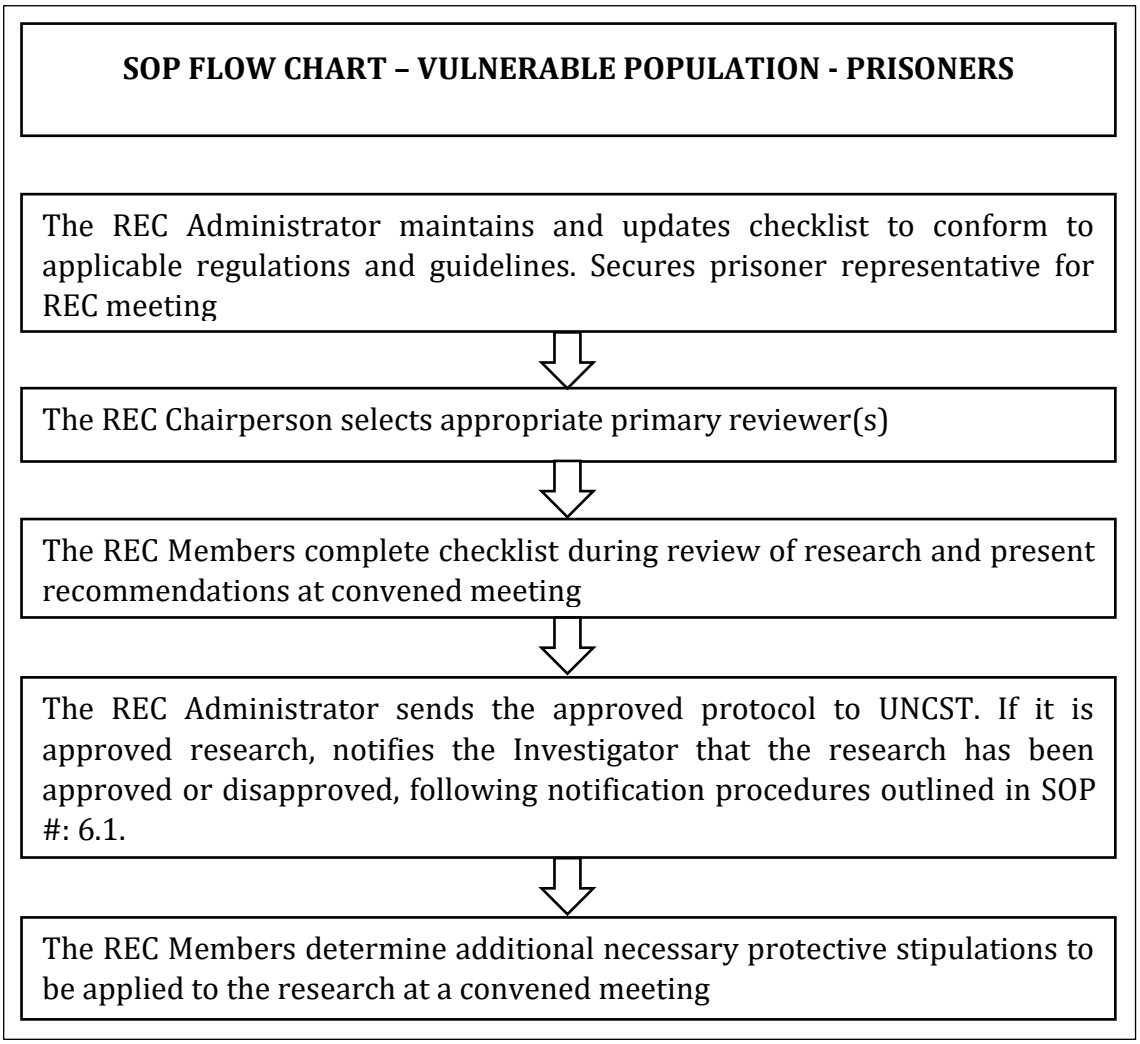
a) Form 5.1A Checklist – Requirements for Research Involving Prisoners

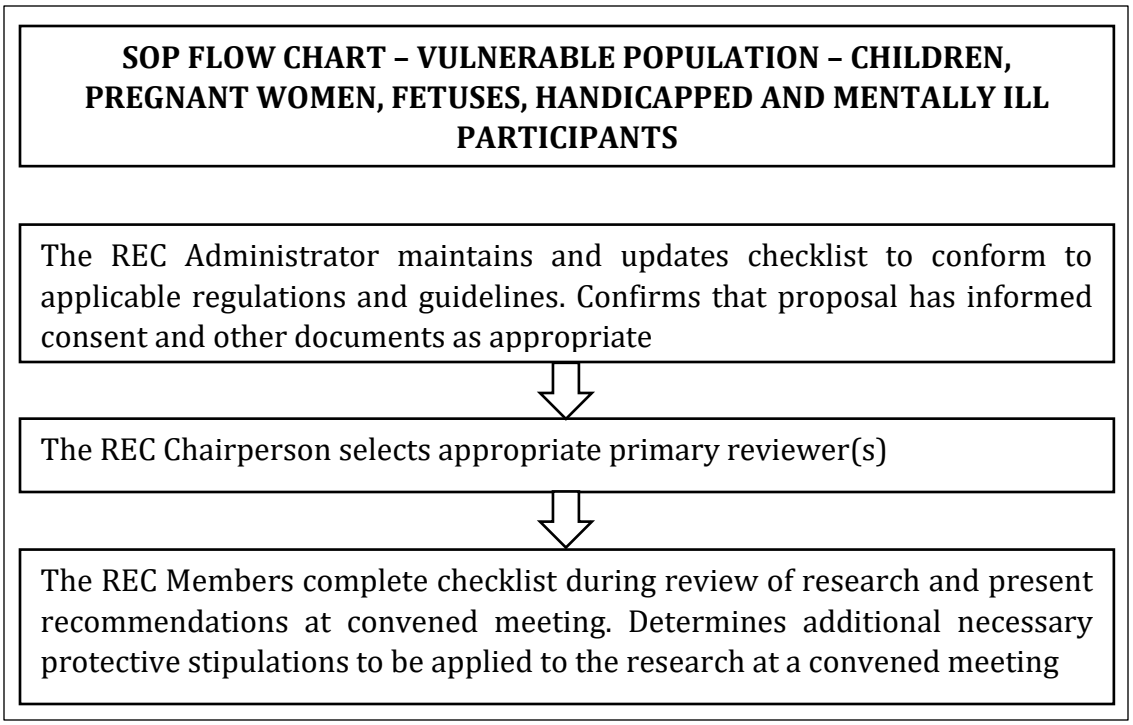
b) Form 5.1B Checklist – Requirements for Research Involving Children

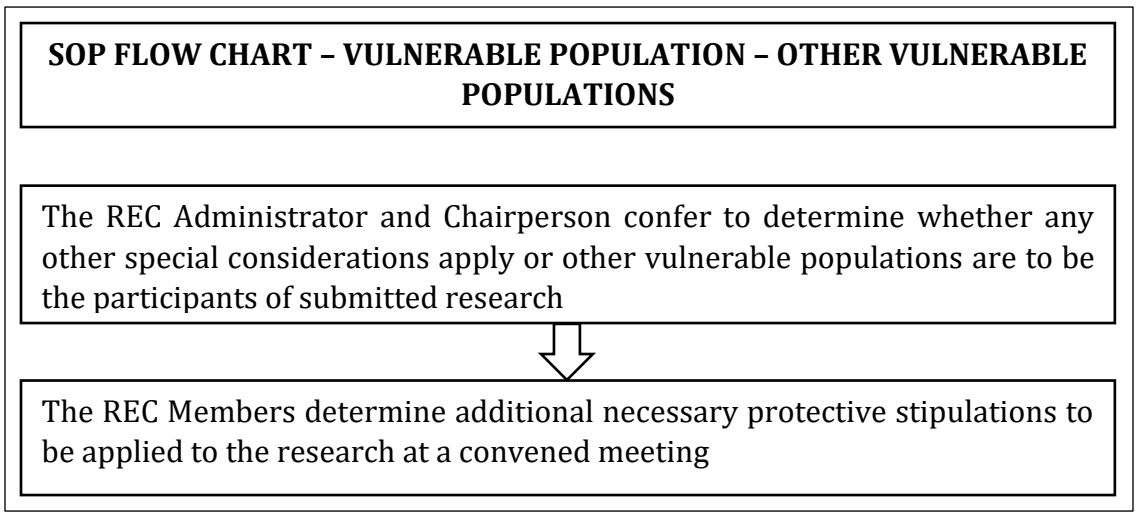
c) Form 5.1C Checklist – Requirements for Research Involving Pregnant Women & Fetuses

d) Form 5.1D Checklist – Requirements for Research Involving handicapped (mentally and physically), mentally ill and behaviorally disordered, research participants

5.1.7 SOP FLOW CHART


SOP FLOW CHART – VULNERABLE POPULATION - PRISONERS
The REC Administrator maintains and updates checklist to conform to applicable regulations and guidelines. Secures prisoner representative for REC meeting
The REC Chairperson selects appropriate primary reviewer(s)
The REC Members complete checklist during review of research and present recommendations at convened meeting
The REC Administrator sends the approved protocol to UNCST. If it is approved research, notifies the Investigator that the research has been approved or disapproved, following notification procedures outlined in SOP #: 6.1.
The REC Members determine additional necessary protective stipulations to be applied to the research at a convened meeting





SOP 5.2 CATEGORIES OF RESEARCH REQUIRING SPECIAL REVIEW

5.2.1 BACKGROUND

The categories of research defined in this guidelines involve either methodologies that might require additional considerations or nationally mandated determinations that REC is required to review and document. These categories of research include, but are not limited to:

i. Clinical research involving devices

ii. Genetic research

iii. Prospective research in emergency settings

iv. Emergency use of an investigational article

v. Medical records and chart review

vi. Residual body fluids, tissues and recognizable body parts

vii. Protocols lacking plans for human involvement

SPECIFIC PROCEDURES

5.2.1.1 CLINICAL RESEARCH INVOLVING DEVICES

In addition to the previous policy guidelines, the REC (or Chairperson if the review is expedited) will determine whether, in the context of the study or by the nature of the investigational medical device, the study presents no more than minimal risk and more than minimal risk of harm to study participants. This assessment will be based on the information provided by the Investigator and/or the Sponsor. The device risk determination must be documented in the REC meeting minutes.

If the REC determines that the device research protocol is of minimal risk, then the investigator and NDA shall be notified in writing. The investigator will then notify NDA in writing about the decision made by the REC.

No further action will be taken by the REC on the research until the Sponsor or Investigator has met the requirements for a more than minimal risk study described.

5.2.1.2 GENETIC RESEARCH

Genetic research may require special considerations. Study participants of Genetic Research. At first consideration, most genetic research may appear to meet the criteria for expedited review. These include:

a) Pedigree studies, which look for a pattern of inheritance of a gene;
b) Positional cloning studies, which are conducted to identify particular genes;
c) Diagnostic studies, which gather samples to develop techniques to determine the presence of specific DNA mutations.

However, these studies may create a vulnerable population in that participants' autonomy may be compromised. Therefore, the full REC must review these studies to answer the following questions:

a) Will the samples be made anonymous to maintain confidentiality? If not, to what extent will the results remain confidential; and who will have access to them?

b) Will the samples be used for any additional studies not made explicit at the time of donation, or will the samples be destroyed after specified, one-time use?

c) Will the donor be informed of any and all results obtained from his or her DNA?

d) Will the donor be informed of the results of the entire study?

e) Will family members be implicated in the studies without consent?

Gene therapy research (administration of recombinant vectors), which is carried out to develop treatments for genetic diseases at the DNA level presents not so obvious questions, including – considerations of delivery methods, target population, required follow-up. Such protocols require use of external co-opted members to provide independent guidance to the REC. If the project involves gene therapy to human research participants for other than clinical purposes, the study must be reviewed and approved by the National Biosafety Committee prior to REC approval. Monitoring must be adequate, and a DSMB will be required.

Because there is still minimal regulatory guidance and relatively few ethical precedents, genetic research will require close scrutiny, and the input of experts in this area.

5.2.1.3 PROSPECTIVE RESEARCH IN EMERGENCY SETTINGS (PROSPECTIVE REVIEW)

The REC, with the concurrence of a licensed physician who is either a member or a co-opted and who is not participating in the research being reviewed, may waive the requirement for informed consent in certain emergency research if it finds and documents the following:

a) The human research participants are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
b) Obtaining informed consent is not feasible because:
    i. The research participants will not be able to give their informed consent as a result of their medical condition;
    ii. The intervention under investigation must be administered before consent from the research participant's legally authorized representatives is feasible; and
    iii. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
c) Participation in the research holds out the prospect of direct benefit to the research participants because:
    i. Research participants are facing a life-threatening situation that necessitates intervention;
    ii. Appropriate animal and other pre-clinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual research participants; and
    iii. Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of research participants, the risks and benefits of standard therapy, if any, and what is

known about the risks and benefits of the proposed intervention or activity.

d) The clinical investigation could not practicably be carried out without the waiver.
e) The proposed investigational or research plan:
    i. Defines the length of the potential therapeutic window based on scientific evidence, and
    ii. The Investigator has committed to attempting to contact a legally authorized representative/guardian for each participant within that window of time and,
    iii. If feasible, to asking the legally authorized representative/guardian contacted for consent within that window rather than proceeding without consent.
    iv. The Investigator will summarize efforts made to contact legally authorized representatives/guardian and make this information available to the REC at the time of continuing review.
f) The REC has reviewed and approved informed consent procedures and an informed consent document consistent with National Guidelines for Research Involving Humans as Research Participants, Section 6. These procedures and the informed consent document are to be used with participants or their legally authorized representatives in situations where use of such procedures and documents is feasible. The REC has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a research participant's participation in the clinical investigation consistent with applicable regulations and guidelines.
g) Additional protections of the rights and welfare of the research participants will be provided, including, at least:
    i. Consultation (including, where appropriate, consultation carried out by the REC) with representatives of the communities in which the clinical investigation will be conducted and from which the participants will be drawn;

    ii. Public disclosure to the communities in which the clinical investigation will be conducted and from which the participants will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;

    iii. Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;

    iv. Establishment of an independent DSMB to exercise oversight of the clinical investigation; and

    v. If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the Investigator has committed, if feasible, attempting to contact, within the therapeutic

window, the participant's family member who is not a legally authorized representative, and asking whether he or she objects to the participant's participation in the clinical investigation. The Investigator will summarize efforts made to contact family members and make this information available to the IDI REC at the time of continuing review.

h) The study plan must ensure that, at the earliest feasible opportunity, each research participant, or if the participant remains incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member is informed of the participant's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document.
i) The study plan must ensure that there is a procedure to inform the participant, or if the participant remains incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, that he or she may discontinue the participant's participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. If a legally authorized representative or family member is told about the clinical investigation and the participant's condition improves, the participant is also to be informed as soon as feasible. If a participant is entered into a clinical investigation with waived consent and the participant dies before a legally authorized representative or family member can be contacted, all efforts should be made to inform the participant's family members.
j) If the REC determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception provided above or because of other relevant ethical concerns, the IDI REC will document its findings and provide these findings promptly in writing to the Investigator and to the Sponsor of the clinical investigation.

5.2.1.4 EMERGENCY USE OF INVESTIGATIONAL ARTICLES (RETROSPECTIVE REVIEW)

An investigational article may be used in an emergency prior to REC review, provided that the patient is in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain REC approval.

Such emergency use is reported to the REC within 5 working days, and any subsequent use of the test article is participant to prior REC review.

In such a situation, obtaining informed consent shall be considered feasible except in certain emergency situations where the Investigator has adequately documented the necessary exception under the guidelines described in Section 5.0 of the National Guidelines for Research Involving Humans as Research Participants. The Investigator must submit documentation to the REC for review within 5 working days after emergency use of the test article. In review of the documentation, the REC will ensure that the Investigator has adequately certified the following in writing prior to use of the test article:

i. The human participant was confronted by a life-threatening situation necessitating the use of the test article.
ii. Informed consent could not be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant.
iii. Time was not sufficient to obtain consent from the participant's legal representative.
iv. There was no alternative method of approved or generally recognized therapy available that provided an equal or greater likelihood of saving the life of the participant.

5.2.1.5 MEDICAL RECORDS AND CHART REVIEW

Studies involving the use of existing public records only may qualify for exempt status or expedited review. However, if the nature of the research could put participants' confidentiality at risk, the study will be reviewed by the full IDI REC. Studies that involve only chart and record review can sometimes pose significant risk to patients.

Breach of confidentiality leading to exposure of possible embarrassing information without the knowledge or consent of the patient is the commonest risk associated with this type of research. Such studies may also lead to recruitment of patients into future non-therapeutic studies in a manner, which may provoke the patient to ask how his/her record was revealed to someone not part of his/her therapeutic team. The present guidelines are to require IDI REC review of studies involving chart review or data collection and analysis.

If identifiers were to be recorded, the research would require IDI REC review to ensure that, among other things, procedures for protecting privacy and confidentiality are adequate.

Furthermore, the Investigator studying cancer risk factors may propose to go on to contact the participants (if still living) or family members (if the participant is deceased) to gather additional information, which may or may not be participant to the national guidelines.

5.2.2 SCOPE

These policies and procedures apply to all research submitted to the IDI REC.

5.2.3 RESPONSIBILITY

a) REC Administrator is responsible for maintaining up-to-date review tools for review of research pertaining to these categories based on new and evolving applicable regulations and guidelines.
b) REC Chairperson (or designee) is responsible for ensuring the IDI REC members are well versed in new and evolving regulations and guidelines pertaining to these categories, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

c) REC Reviewer is responsible for conducting appropriate review of research planned for these categories in consultation with any appropriate experts and resources.

5.2.4 APPLICABLE REGULATIONS AND GUIDELINES

1. National Guidelines for Research Involving Humans as Research Participants, 2014
2. NDA guidelines
3. National guidelines on vaccine research

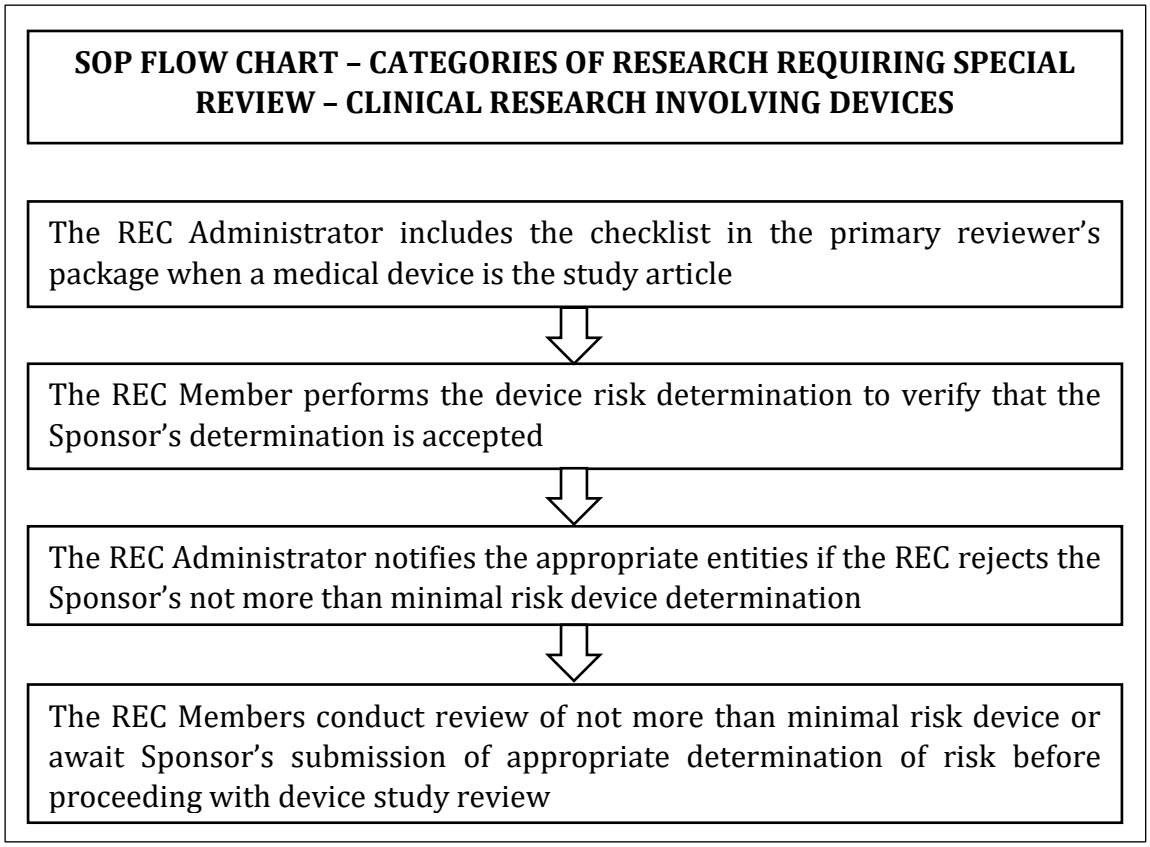
5.2.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

5.2.6 ATTACHMENTS

1. Form 5.2A Risk Determination - Devices
2. Form 5.2B Reporting Emergency Use of a Test Article
3. Form 5.2C Report of Emergency Use of a Test Article to Treat a Life-Threatening Condition
4. Form 5.2D Checklist-Emergency Research Conducted Under Exemption from Informed Consent Requirements
5. Form 5.2E Waiver of Informed Consent for Access to Medical Records for Research

5.2.7 SOP FLOWCHARTS



SOP FLOW CHART – CATEGORIES OF RESEARCH REQUIRING SPECIAL REVIEW – GENETIC RESEARCH

The REC Administrator and Chairperson identify and invite appropriate co-opted member(s) who may assist the REC in its deliberations

⇩

The REC Administrator and Chairperson ascertain deliberations of other relevant research review groups (i.e. NDA, National Biosafety Committee)

SOP FLOW CHART – CATEGORIES OF RESEARCH REQUIRING SPECIAL REVIEW – PROSPECTIVE RESEARCH IN EMERGENCY SETTINGS

The REC Administrator provides Investigators with appropriate guidelines regarding research in emergency settings

⇩

The REC Administrator includes checklist in the primary reviewer's packet when a prospective emergency research study is submitted

⇩

The REC Member completes checklist during review of research and present recommendations at convened meeting

SOP FLOW CHART – CATEGORIES OF RESEARCH REQUIRING SPECIAL REVIEW – EMERGENCY USE OF INVESTIGATIONAL ARTICLES (RETROSPECTIVE REVIEW)

The REC Chairperson (or designee) reviews submitted report(s) and present to the REC

⇩

The REC Chairperson (or designee) determine whether an emergency meeting of REC is indicated to discuss the use

SOP FLOW CHART – CATEGORIES OF RESEARCH REQUIRING SPECIAL REVIEW – MEDICAL RECORDS AND CHART REVIEW

The REC Administrator determines whether the research is exempt from REC review, eligible for expedited review, or subject to full REC review

The REC Administrator includes the Checklist in the primary reviewer's packet if subject to full or expedited REC review

SOP 6: SOPS ON COMMUNICATION AND NOTIFICATION

SOP 6.1 INVESTIGATIVE STAFF

6.1.1 BACKGROUND

It is important that staff, research participants, and other interested parties have a means of communicating information about the conduct of a research project directly to the appropriate institutional officials. It is vital that REC members, department heads at the IDI, and other officials with responsibility for oversight of research have open and ready access to the highest levels of authority within the institution. The researcher and his/her research staff interact with research participants; therefore it is vital that open and frequent communication with the investigative team be maintained.

SPECIFIC PROCEDURES

6.1.1.1 INVESTIGATOR NOTIFICATIONS

a) Initial submission: The Investigator will be notified in writing of the REC's decision as soon as possible after the meeting but not later than fourteen (14) days from the date of the meeting in which the protocol was reviewed. If the approval is pending upon receipt and review of requested materials or responses from the Investigator or Sponsor, the REC must receive the response within 60 days of the date of notification; however, this period may be extended if the Investigator/Sponsor communicates a need for an extension.
b) Renewals and revisions: Investigators will be notified in writing as soon as possible but not later than fourteen (14) days as to action taken by the REC for any continuing reviews or revisions.
c) Notification of final approval: Investigators will be notified in writing of the final approval. The REC-approved consent form will be dated with the period of approval and submitted to the Investigator with the final approval letter. Standard conditions for continued approval include, but are not necessarily limited to:
    i. Informed consent is obtained and documented as stated in SOP #s: 7.1, 7.2 and 7.3.
    ii. The REC is notified of serious adverse events within appropriate periods as described in SOP #: 4.3.
    iii. Changes to the protocol, and deviations from the protocol are reported as described in SOP #: 4.3.
    iv. Reports of unanticipated problems or any unforeseen event or events that may involve risks or affect the safety or welfare of research participants or others, or that may affect the integrity of the research must be promptly reported.
    v. Continuing review reports are submitted to the REC as described in SOP #: 4.4.
    vi. Documentation of the REC approval prior to study initiation.

6.1.1.2 DISAPPROVAL: CORRESPONDENCE WILL PROVIDE THE REASON(S) FOR DISAPPROVAL AND INSTRUCTIONS TO THE INVESTIGATOR FOR APPEAL OF THIS DECISION

a) INVESTIGATOR APPEAL OF REC ACTION

An Investigator may appeal the revisions required by the REC in the protocol and/or informed consent form. This appeal must be in writing and submitted to the REC Administrator. Investigators may also appeal against the REC decision to disapprove a study. Any such appeal may be in writing and must be reviewed by the full REC at a convened meeting. If the appeal is denied and the study disapproved, the Investigator's institution cannot override the REC's decision. However the investigator may appeal to the UNCST whose decision shall be final and binding.

b) NONCOMPLIANCE

Investigator noncompliance may often be the result of communication difficulties, therefore the REC will attempt to resolve apparent instances of noncompliance without interrupting the conduct of the study, especially if the rights and welfare of research participants may be jeopardized.

However, if it appears that an Investigator is intentionally in noncompliance, the REC, through the REC Chairperson will notify the Investigator in writing, detailing the alleged noncompliance, specifying corrective action, and stating the consequences. Copies of such correspondence shall also be sent to the Sponsor, the individual's supervisor, and Executive Secretary, UNCST.

Should noncompliance continue, appropriate action will be determined at a convened meeting? Action by the REC can include but is not limited to:

i. Halting the research until the Investigator is in compliance. If the research is halted, the following will be notified;
ii. UNCST, Sponsor, Funding agency, Investigators' institution and NDA
iii. Requiring the Investigator to complete a training program.
iv. Barring the Investigator from conducting further research.
v. Any other action deemed appropriate by the REC.

c) When unapproved research is discovered, the REC and the institution will act promptly to halt the research, ensure remedial action regarding any breach of regulatory or institutional human research participant's protection requirements, and address the question of the Investigator's fitness to conduct future research involving human participants.
d) Serious or continuing noncompliance with national policies on the protection of human research participants or the policies, procedures or determinations of the REC must be reported promptly to the Executive Secretary UNCST as well as the appropriate department or agency head for funded proposals, Sponsors if appropriate, and to NDA as appropriate.
e) The REC's responsibility is to protect the rights and welfare of research participants, which could be placed at risk if there is misconduct on the part of an Investigator or any

member of the investigative team. It is, therefore, the duty of the REC to be receptive to and act on good faith allegations of misconduct. Allegations of misconduct in science should be referred to the Executive Secretary UNCST.

6.1.1 SCOPE

This SOP applies to all research submitted to the REC.

6.1.2 RESPONSIBILITY

a) REC Administrator is responsible for overseeing all REC communications.

b) REC Administrator is responsible for generating appropriate correspondence in response to REC meetings and decisions.

c) REC Administrator is responsible for distributing REC correspondence to appropriate parties.

6.1.3 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research Involving Humans as Research Participants, 2014Section 4, Subsection 4.5.5, Subsection 4.9 part c

b) WHO guidelines for Ethical Review of Biomedical Research

c) International Conference on Harmonization of Technical Requirements for registration of pharmaceuticals for Human Use (ICH) & GCP Guidelines

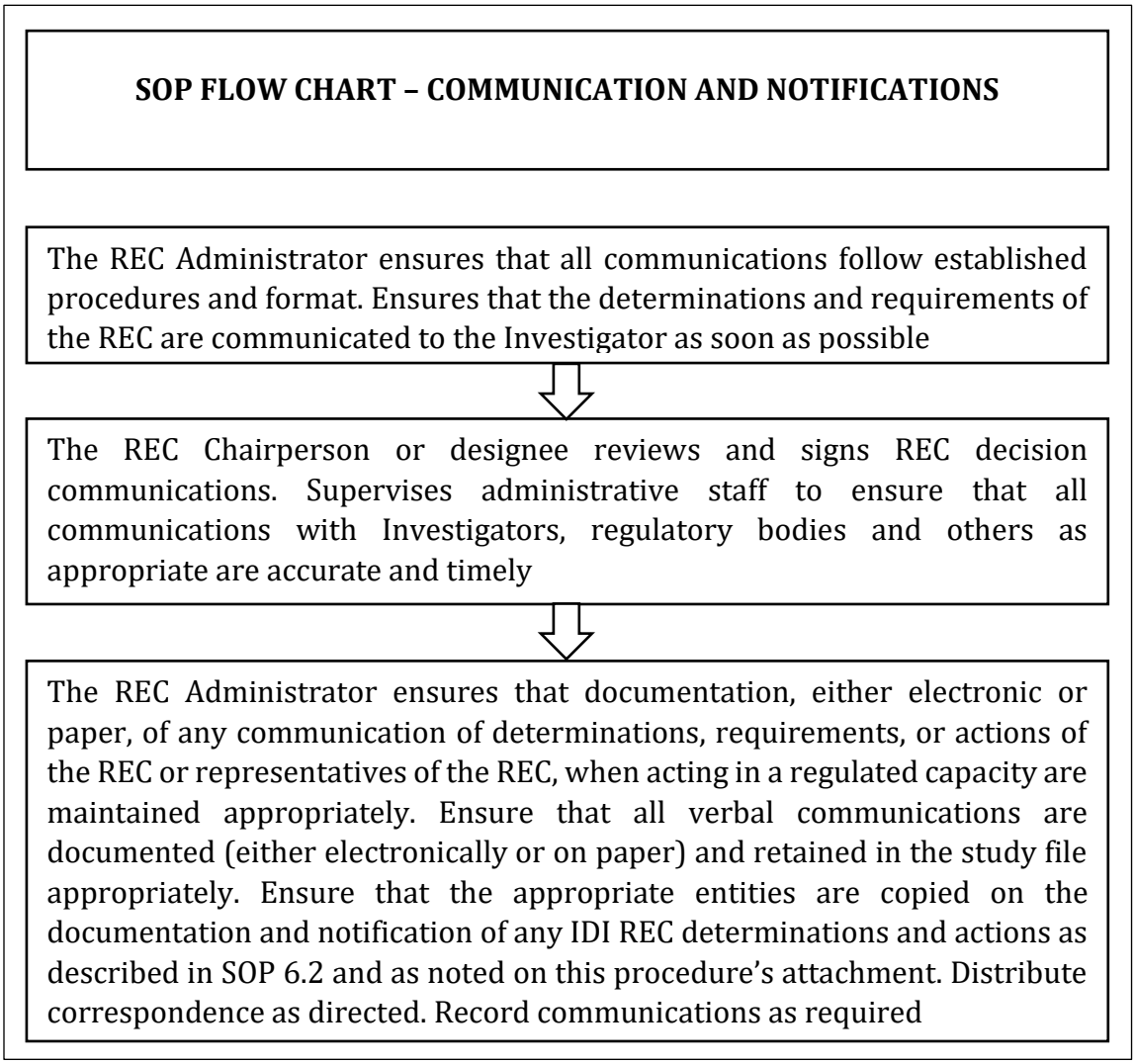
6.1.4 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6.1.5 ATTACHMENTS

a) Form 6.1A Notice of REC Approval
b) Form 6.1B Approval Withheld Pending
c) Form 6.1C Notice of Tabled Protocol
d) Form 6.1D REC Compliance Assurance
e) Form 6.1E Notice of Disapproved Study
f) Form 6.1F Notice of Renewal Approval
g) Form 6.1G Notice of Amendment Approval
h) Form 6.1H Notice of Approval - Recruitment Advertisement
i) Form 6.1I Adverse Event/IND Safety Report Acknowledgement
j) Form 6.1J Status request
k) Form 6.1K Completion Acknowledgement
l) Form 6.1L Notice of Study Suspension (Lack of Continuing Review Report)
m) Form 6.1M Notice of Study Termination (for Cause)
n) Form 6.1N Exemption Disqualification Notice
o) Form 6.1O Communication Log

6.1.6 SOP FLOW CHART



SOP 6.2 COMMUNICATION TO OTHER ENTITIES

6.2.1 BACKGROUND

The REC is required by national guidelines and institutional policy to communicate certain actions to entities that may have an interest in the status of the research being conducted.

SPECIFIC PROCEDURES

The purpose of this SOP is to ensure prompt reporting to appropriate Institutional Officials, funding sources, agency heads, regulatory agencies and any other appropriate entity of:

i. Any unanticipated problems involving risks to human research participants or others

ii. Any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the REC

iii. Any suspension or termination of REC approval.

iv. Any research that the REC cannot approve under the terms National Guidelines

6.2.2 SCOPE

This SOP applies to all research submitted to the IDI REC.

6.2.3 RESPONSIBILITY

a) REC Administrator is responsible for corresponding with other interested entities concerning the status of research under review by the REC.

b) REC Chairperson (or designee) is responsible for ensuring appropriate REC discussion and decision-making regarding unprovable emergency research, risk assessment of investigational device, adverse event assessments and Investigator non-compliance, where communication with outside entities is necessary.

6.2.4 APPLICABLE REGULATIONS AND GUIDELINES

National Guidelines for Research involving Humans as Research Participants; 2014.

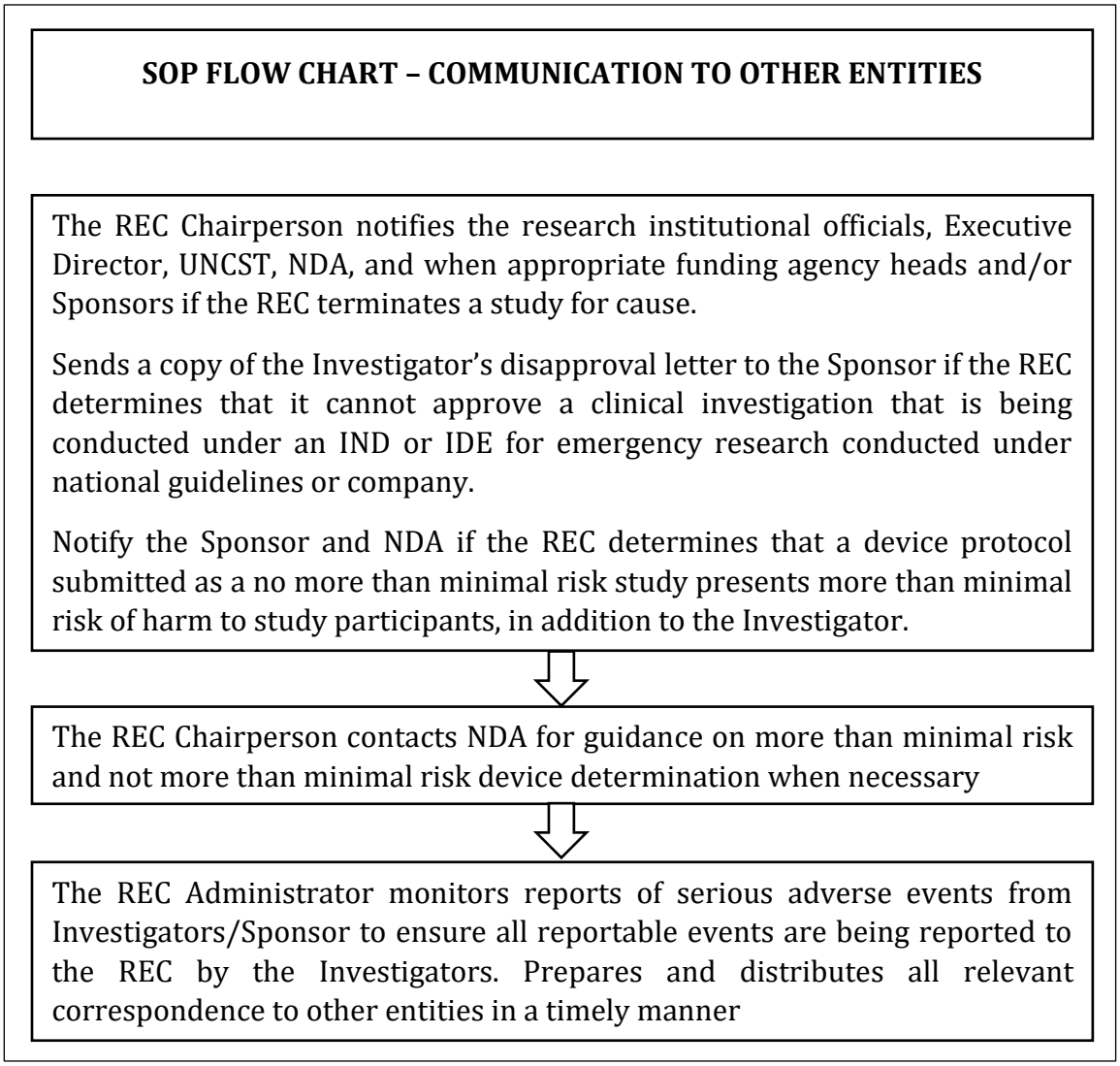
6.2.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6.2.6 ATTACHMENTS

a) Form 6.1E Notice of Disapproved Study
b) Form 6.1L Notice of Study Suspension (Lack of Continuing Review Report)
c) Form 6.1M Notice of Study Termination (for Cause)
d) Form 6.1O Communication Log

6.2.7 SOP FLOW CHART



SOP 7: SOPS ON INFORMED CONSENT

SOP 7.1 GENERAL REQUIREMENTS AND DOCUMENTATION FOR INFORMED CONSENT

7.1.1 BACKGROUND

Informed consent is an ethical and legal requirement for research involving human participants; and it should be prospectively obtained for all competent research participants. Investigators should not involve any human being as a research participant unless he/she has obtained legally effective informed consent of the research participant's or the research participant's legally authorized representative. Consent shall be sought only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that all possibilities of coercion or undue influence shall be minimized

The IDI REC requires documentation of informed consent by use of a written informed consent form approved by the IDI REC and signed and dated by the participant or the participant's legally authorized representative.

SPECIFIC PROCEDURES

7.1.1.1 THE CONSENT FORM

A written consent document should contain all the elements of informed consent described in national guidelines for research section 6.0. This form may be read to the research participant or the participant's legally authorized representative, but, in any event, the Investigator shall give either the research participant or the representative adequate opportunity to read it before it is signed. The research participant must also be offered a copy of the signed form.

7.1.1.2 REQUIRED ELEMENTS OF INFORMED CONSENT

a) A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the research participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

b) A description of any reasonably foreseeable risks or discomforts to the research participant.

c) A description of any benefits to the research participant or to others that may reasonably be expected from the research.

d) A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the research participant.

e) A statement describing the extent to which, if any, confidentiality of records identifying the research participant will be maintained and that notes the possibility that the, IDI REC, UNCST and any other authorized regulatory bodies may inspect the records.

f) For research involving greater than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

g) An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the research participant.

h) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the research participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the research participant is otherwise entitled.

7.1.1.3 ADDITIONAL ELEMENTS

When appropriate, one or more of the following elements of information shall also be provided to each research participant:

a) A statement that the particular treatment or procedure may involve risks to the research participant (or to the embryo or fetus if the participant is or may become pregnant), which are currently unforeseeable.

b) Anticipated circumstances under which the participant's participation may be terminated by the Investigator without regard to the participant's consent.

c) Any additional costs to the research participant that may result from participation in the research.

d) The consequences of a research participant's decision to withdraw from the research and procedures for orderly termination of participation by the research participant.

e) A statement that significant new findings developed during the course of the research, which may relate to the research participant's willingness to continue participation, will be provided to the research participant.

f) The approximate number of research participants involved in the study.

g) Compensation for time lost, reimbursement for transport costs and any other costs related to the research participants' participation in the research

7.1.1.4 OTHER REQUIREMENTS

a. Second person: The language of the consent document should be in the second person style so the consent form conveys a dialogue with information being provided and that there is a choice to be made by the research participant rather than presumption of the participant's consent with the use of the first person style.

b. Language should be simple: The information provided in the informed consent documents must be in a language understandable to the research participant. The informed consent document should not include complex language that would not be understandable to all research participants. Technical and scientific terms should be adequately explained using common or lay terminology.

c. Exculpatory language: Informed consent documents may not contain any exculpatory language through which the research participant is made to waive or appear to waive legal rights or releases or appears to release the Investigator, the Sponsor, or the research institution from liability for negligence.

7.1.1.5 DOCUMENTATION OF INFORMED CONSENT

Each research participant or his/her legally authorized representative must sign and date a copy of the current REC-approved consent form prior to enrollment or any participation in any phase of the study. Approval and expiration dates are indicated on each page of the consent document and each page should show page x of y. Consent documents are valid only during the dates indicated on the form; and the Investigator may use the forms only during the period for which they are valid. The research participant must also be offered a copy of

the signed document.

The REC may approve procedures for documentation of informed consent that involve (a) a written consent form signed by the research participant; (b) in limited circumstances, waiver of signed written consent form. Each of these two options is described in detail below. It is the responsibility of the REC to determine which of the procedures described below is appropriate for documenting informed consent in protocols that it reviews. Generally, only option (a) will be appropriate.

a) A written consent form signed by the research participant or legally authorized representative. In most circumstances, the REC should require that informed consent is documented by the use of a written consent form approved by the REC and signed by the research participant or the participant's legally authorized representative and the staff obtaining consent. The Investigator should provide the research participant or the legally authorized representative adequate opportunity to read the consent document before it is signed. A copy of the document must be offered to the person signing the form.
b) The written informed consent document should embody, in language understandable to the participant, all the elements necessary for legally effective informed consent (see above).
c) The research participants should be presented with an informed consent document written in a language understandable to them.
d) Illiterate participants who cannot read or write should provide verbal consent in the presence of an impartial witness. This witness should be a participant's confidant and document their name, signature and date signed.

7.1.1.6 WAIVER OF DOCUMENTATION OF CONSENT

The IDI REC may waive the requirement for the Investigator to obtain a signed consent form for some or all research participant if the REC finds either:

a) That the only record linking the research participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality

Note: When the REC waives the requirement for documentation under this condition, each research participant must be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.

b) That the research presents no greater than minimal risk of harm to research participants and involves no procedures for which written consent is normally required outside of the research context.

7.1.1.7 OBSERVATION AND MONITORING OF THE INFORMED CONSENT PROCESS

The REC foresees circumstances that may arise under which the REC may want to observe the consent process. For example, at the time of initial protocol review, the REC may determine that although the risk/benefit determination allows for consenting of potentially cognitively impaired adults, additional safeguards may be instituted to protect the rights and

welfare of research participants.

In this situation, the REC may delegate the administration or observation of the consent process to a qualified third party.

Studies involving human participants who are decisionally impaired may take place over extended periods. The REC should consider whether periodic re-consenting of individuals should be required to ensure that a participant's continued involvement is voluntary.

The REC may require that Investigators re-consent research participants after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., research participants with progressive neurological disorders). Additionally, the REC should consider whether, and when, it should require a reassessment of decision- making capacity.

7.1.2 SCOPE

These policies and procedures apply to all research submitted to the REC.

7.1.3 RESPONSIBILITY

REC Administrator is responsible for reviewing all incoming informed consent documents and for communicating with Investigators to bring documents into compliance.

7.1.4 APPLICABLE REGULATIONS AND GUIDELINES

National Guidelines for Research Involving Humans as Research Participants, 2014 Section 5.2

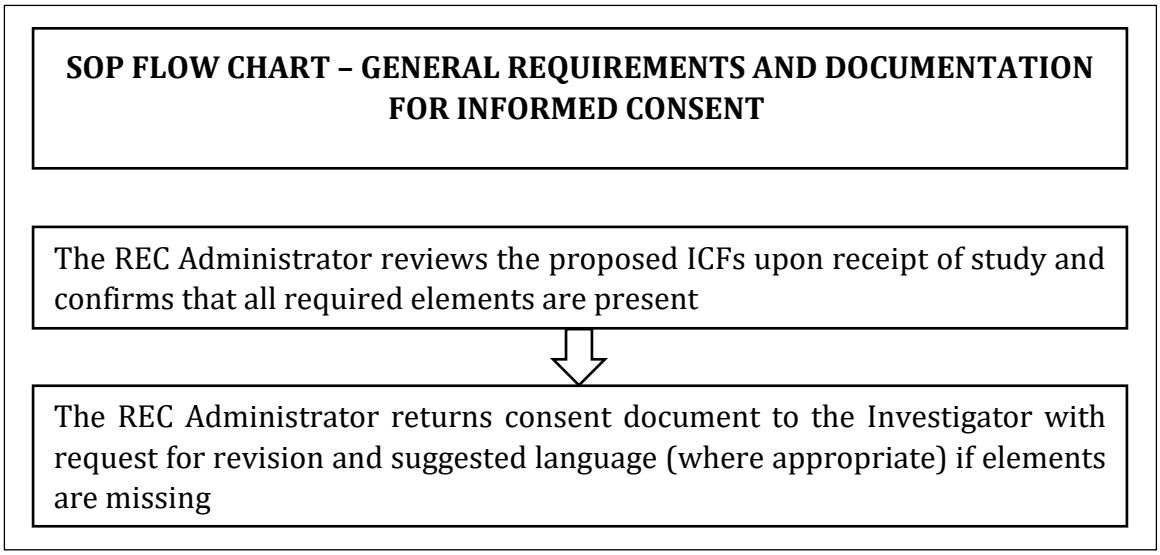
7.1.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

7.1.6 ATTACHMENTS

a) Form 7.1A Informed Consent Checklist: General
b) Form 7.1B Informed Consent Document Template: General
c) Form 7.1C Informed Consent Checklist: Tissue/Blood Storage for Future Use
d) Form 7.1D Informed consent Document Template: Tissue/Blood storage for future use
e) Form 7.1E Informed Consent checklist for genetic studies
f) Form 7.1 F Informed Consent Document Template: Genetic studies
g) Form 7.1 G Informed Consent Document template: Venipuncture
h) Form 7.1 H Statement on the risks of radiation

7.1.7 SOP FLOW CHART



SOP 7.2 EXEMPTIONS FOR INFORMED CONSENT

7.2.1 BACKGROUND

The IDI REC recognizes that there may be exemptions to requirements for informed consent and/or documentation as follows:

WAIVER OF INFORMED CONSENT

In certain circumstances, the IDI REC may waive the requirement to obtain informed consent if it finds that the research meets specific criteria that is in accordance with Section 6 of the National Guidelines for Research Involving Humans as Research Participants.

ALTERATION OF ELEMENTS OF INFORMED CONSENT

The IDI REC may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, such as written documentation (Section 6.5).

SPECIFIC PROCEDURES

7.2.1.1 WAIVER OF INFORMED CONSENT

a) The IDI REC shall require that informed consent be obtained and documented prior to initiation of study procedures except in the following emergency situations:
b) Prospective Review of Research in Emergency Settings: Obtaining informed consent shall be deemed feasible except in certain emergency situations where the Investigator has adequately documented the necessary exception under guidelines described in SOP #: 502, section 1.3.
c) Retrospective Review of Emergency Use of an Investigational Article Obtaining informed consent shall be deemed feasible except in certain emergency situations

where the Investigator has adequately documented the necessary exception under guidelines described in SOP #: 502, section 1.4.

d) In other research, the REC may waive the requirement to obtain informed consent provided the REC finds and documents that the research or demonstration project to be conducted is participant to approval of state or local government officials and is designed to study, evaluate, or examine:

    i) Public benefit or service programs;

    ii) Procedures for obtaining benefits or services under those programs;

    iii) Possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs; and

    iv) The research could not practicably be carried out without the waiver or alteration.

e) The research involves no more than minimal risk to the research participants; Waiver will not adversely affect the rights and welfare of the research participants;
f) The research could not practicably be carried out without the waive;
g) Whenever appropriate, the research participants will be provided with additional pertinent information after participation.

7.2.1.2 WAIVER OF DOCUMENTATION OF INFORMED CONSENT

The REC may waive the requirement for the Investigator to obtain a signed consent form for some or all research participant if the REC finds either:

a) That the only record linking the research participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality;

<u>Note:</u> When the REC waives the requirement for documentation under this condition, each research participant must be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.

b) That the research presents no greater than minimal risk of harm to research participants and involves no procedures for which written consent is normally required outside of the research context.
c) In cases in which the documentation requirement is waived, the REC may require the Investigator to provide research participants with a written statement regarding the research.

7.2.2 SCOPE

These procedures apply to all research submitted to the REC.

7.2.3 RESPONSIBILITY

REC Administrator (or designee) is responsible for determining whether informed consent exemptions are applicable and appropriate and for follow-up with Investigators as indicated from the exemption assessment.

7.2.4 APPLICABLE REGULATIONS AND GUIDELINES

National Guidelines for Research Involving Humans as Research Participants, 2014 Section 5.0

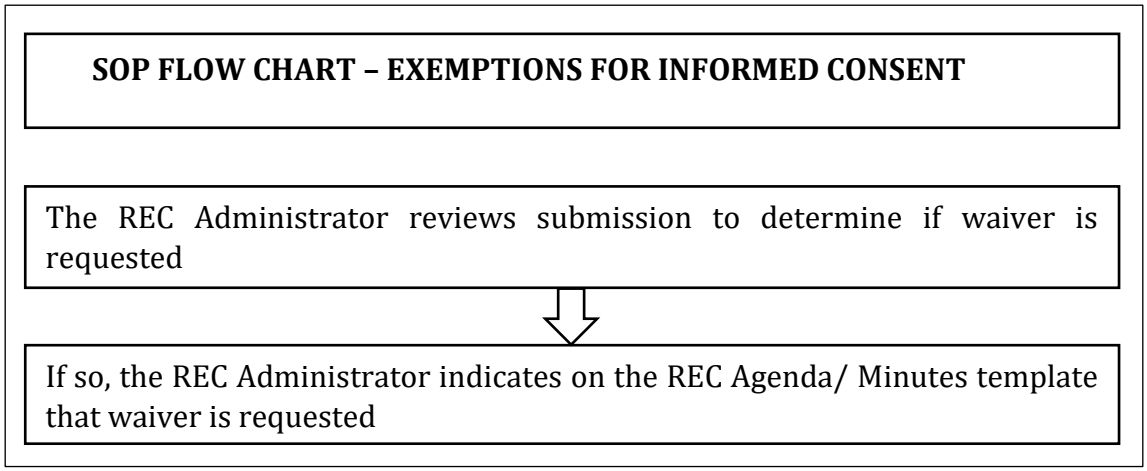
7.2.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

7.2.6 ATTACHMENTS

Form 7.2A Waiver or Alteration of Informed Consent Decision Chart

7.2.7 SOP FLOWCHART



SOP 7.3 ASSENT

7.3.1 BACKGROUND

The principle of respect for persons requires that the choice of an autonomous person be respected. Under the usual conditions of clinical research, this is accomplished by soliciting the informed consent of the prospective research participant. In the case of the cognitively impaired adult or non-autonomous child, applying the principle of respect for persons is problematic. Therefore, consent of either the parent or legally authorized representative is required. However, any individual capable of some degree of understanding (generally, a child aged 8 to 17 years, or a cognitively impaired adult) should participate in research only if they assent. When assent is required by the REC, however, the decision of the individual assenting should be binding.

SPECIFIC GUIDELINES

7.3.1.1 USE OF ASSENT

In instances where the research participant is not legally capable of giving informed consent

(*e.g.*, minors) or where the participant is cognitively impaired, the REC must find that adequate provisions are made for soliciting the assent of the participant when in the judgment of the REC, the research participant is capable of providing assent.

a) Assent means a research participant's affirmative agreement to participate in research. Mere failure to object or absence of affirmative agreement should not, be construed as assent.

b) In determining whether research participants are capable of assenting, the Investigator and the REC shall take into account the age, maturity, and psychological state of the participants involved. This judgment may be made for all research participants to be involved in research under a particular protocol as the REC may deem appropriate. If the REC determines that the capability of some or all of the research participants is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the research participants and is available only in the context of the research, the assent of the research participant is not a necessary condition for proceeding with the research.

c) Even where the REC determines that the research participants are capable of assenting, the REC may still waive the assent requirement under circumstances in which consent may be waived as stated in section 1 of SOP #: 7.2.

d) When the REC determines that assent is required; it shall also determine whether and how assent must be documented.

7.3.2 SCOPE

These procedures apply to all research submitted to the REC.

7.3.3 RESPONSIBILITY

REC Chair (or designee) is responsible for determining whether assent is required and for follow-up with Investigators, as appropriate.

7.3.4 APPLICABLE REGULATIONS AND GUIDELINES

National Guidelines for Research Involving Humans as Research Participants, 2014 Section 5.6

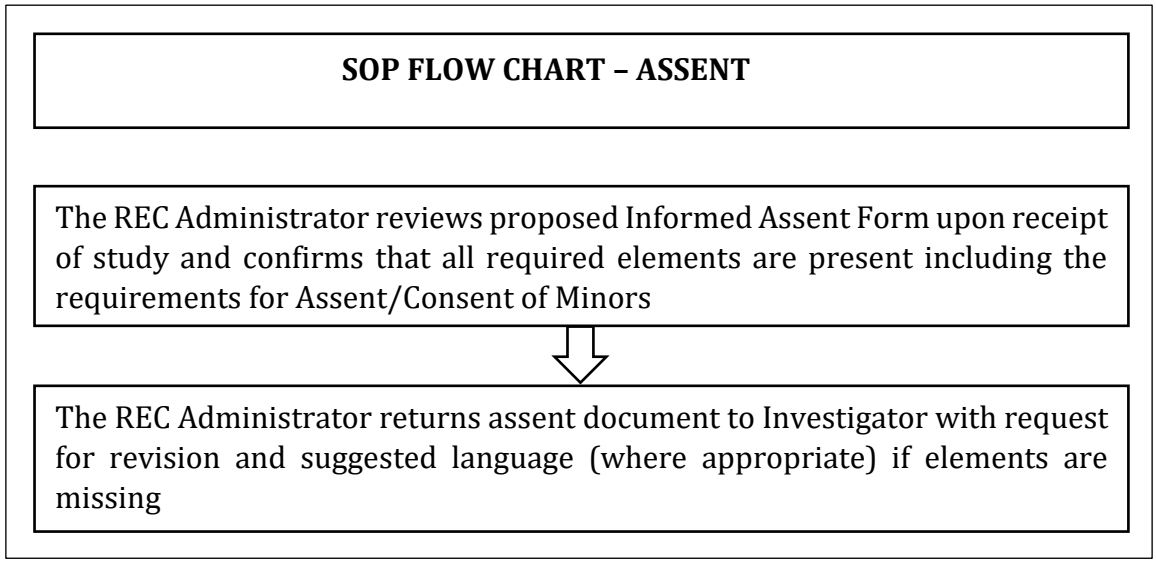
7.3.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

7.3.6 ATTACHMENTS

a) Form 7.3A Requirements Checklist for Consent/Assent of Minors
b) Form 7.3B Informed Consent Document Template: Assent
c) Form 7.3 C Informed Consent Document Template: Parental consent

7.3.7 SOP FLOW CHART



SOP 8: SOPS ON RESPONSIBILITIES OF INVESTIGATORS AND SPONSORS

SOP 8.1 REQUIRED INVESTIGATOR ACTIONS

8.1.1 BACKGROUND

Once the REC issues initial approval to the investigators, it is the Investigator's responsibility to keep the REC informed of unexpected non-serious and serious adverse events and other unexpected findings that could affect the risk/benefit ratio of the research throughout the implementation of study activities.

An Investigator is responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events. Investigators are also responsible for informing government regulatory authorities and other Sponsors of any unanticipated or serious adverse events, as appropriate.

SPECIFIC PROCEDURES

8.1.1.1 IDI REC REVIEW OF RESEARCH

Research involving humans as participants that is conducted by or under the direction of any employee, faculty, staff, student or agent of a Ugandan institution in connection with his or her institutional responsibilities may be reviewed by the REC.

8.1.1.2 RENEWAL OF IDI REC APPROVAL

a) Research ethics guidelines do not allow an REC to approve a study for more than one year. For multi-year research, the principal investigator and/or study sponsor is responsible for submitting a renewal application prior to the expiration of the current REC approval. REC notifies investigators and/or the study sponsor of the impending expiration date 8 to 4 weeks prior to the expiration of the current REC approval.

b) If the approval expires prior to submission of the renewal application, the investigator is required to suspend participant contact and data collection until the renewal is approved by REC, and no new participants may be contacted, recruited, or enrolled until the investigator obtains current REC approval.
c) The renewal application should incorporate all of the addenda and modifications submitted to and approved by the REC during the previous approval periods. Continuing review and approval is necessary as long as study procedures or follow-up procedures continue, even if recruitment of participants has ended. Continuing review approval is also mandated through data analysis.

8.1.1.3 COMPLETION/TERMINATION

Investigators should notify the REC in writing when a study is terminated or completed or after data analysis is complete

8.1.1.4 INFORMED CONSENT

The Investigator or his/her designate must obtain informed consent from research participants prior to their enrollment into the research. The Investigator must use the informed consent document approved by the REC. Approval and expiration dates are indicated on each page of the consent document and each page should show page x of y. Consent documents are valid only during the dates indicated on the form; and the Investigator may use the forms only during the period for which they are valid. Investigators must follow national guidelines for obtaining informed consent.

8.1.1.5 ADVERSE EVENT REPORTING

The REC must be informed of any serious, unexpected or alarming adverse events that occur during the approval period. REC form for reporting adverse outcomes and serious adverse events will be provided to the Investigator when the research is initially approved. All deaths, life-threatening complications, hospitalizations, or serious and/ or unexpected adverse events, *whether related to the study article or not*, must be reported to the REC as soon as possible. Investigators must also submit Sponsor-generated reports of adverse events occurring at other investigative sites.

8.1.1.6 CHANGES OR AMENDMENTS IN APPROVED RESEARCH

Changes in approved research, during the period for which approval has already been given, shall not be initiated without REC review (or expedited review, where appropriate) and approval, except where necessary to eliminate apparent immediate hazards or harm to human research participants. Investigators must submit requests for changes to the REC in writing. Upon receipt of the protocol change, the REC Chairperson will determine if the revision meets the criteria for minimal risk. If the change represents more than a minimal risk to research participants, it must be reviewed and approved by the full board of REC. Minor changes involving no more than minimal risk to the research participants will be reviewed by the expedited review process.

Changes in the risks or benefits to participants may require modifications to the consent form and re-consenting of participants. The REC may only approve modifications submitted

during a current approval year to the end of that period. For example, if the new, renewal, or continuing approval is issued on 1st January, it will have an expiration date of 31st December. If an addendum is approved during this approval time, the approval still lasts only until 31st December.

When changing investigators, the REC must receive a letter from the principal investigator indicating the change in responsibility. The new investigator should send a letter accepting responsibility for the research and his/her current CV.

8.1.1.7 UNANTICIPATED PROBLEMS

All unanticipated problems must be reported promptly to the REC. An unanticipated problem is defined as any unforeseen event or events that may involve risks or affect the safety or welfare of research participants or others, or that may affect the integrity of the research. Examples of an unanticipated problem include, but are not limited to: difficulties in recruiting participants, higher than expected adverse events, higher than expected participants' dropout rate, higher than expected protocol deviation rate, loss of multiple staff members, injury to a staff member while conducting study-related procedures, or participants' difficulties in understanding the informed consent.

8.1.1.8 PERIODIC REPORTS

The length of time approval is given to a research protocol will be no more than one year, and is dependent on the risk involved with the research. Investigators are responsible for requesting renewal in anticipation of the expiration of the approval period. Investigators or their designees and/or Sponsors are required to provide a periodic report regarding their research activities prior to the end of the approval period, or upon completion of the study In accordance with SOP #: 4.4

An REC Continuing Review Report/Renewal Request template will be available to the Investigator for this purpose. The report should be accompanied by a letter requesting for renewal signed by the principal investigator. In accordance with SOP #: 4.4. If the REC requires interim reports at a greater than annual frequency, the Investigator is required to submit such interim reports at least 14 days prior to the date specified. An REC Study Renewal Report template will be available to the Investigator for this purpose.

8.1.1.9 CONFLICT OF INTEREST

The protection of human research participants requires objectivity in communicating risks, selecting research participants, promoting informed consent, and gathering, analyzing and reporting data. Therefore, the REC should consider conflict of interest issues in its deliberations of applications.

All Investigators must reveal on their application to the REC whether they or any other person responsible for the design, conduct, or reporting of the research has an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research. In accordance with SOP #: 1.4.

REC members must also disclose known conflicts of interest. In case if any member of the REC is conflicted, he/ she must not participate in the initial or continuing review of the protocol except to provide information as may be required by the REC.

8.1.2 SCOPE

These guidelines and procedures apply to all researchers whose protocols are approved by the REC

8.1.3 RESPONSIBILITY

a) REC Administrator is responsible for tracking Investigator compliance with REC requirements stipulated during the REC's review of the Investigator's research, and for engaging appropriate Investigator sanctions when Investigators are not in compliance with REC requirements.

b) REC Chairperson (or designee) is responsible for facilitating Investigator compliance with REC requirements through his/her management of REC deliberations, and providing Investigators clear guidelines pertaining to that compliance through REC communications to the Investigator.

8.1.4 APPLICABLE REGULATIONS AND GUIDELINES

National Guidelines for Research Involving Humans as Research Participants, 2014 Section 7.0 Subsection 7.1

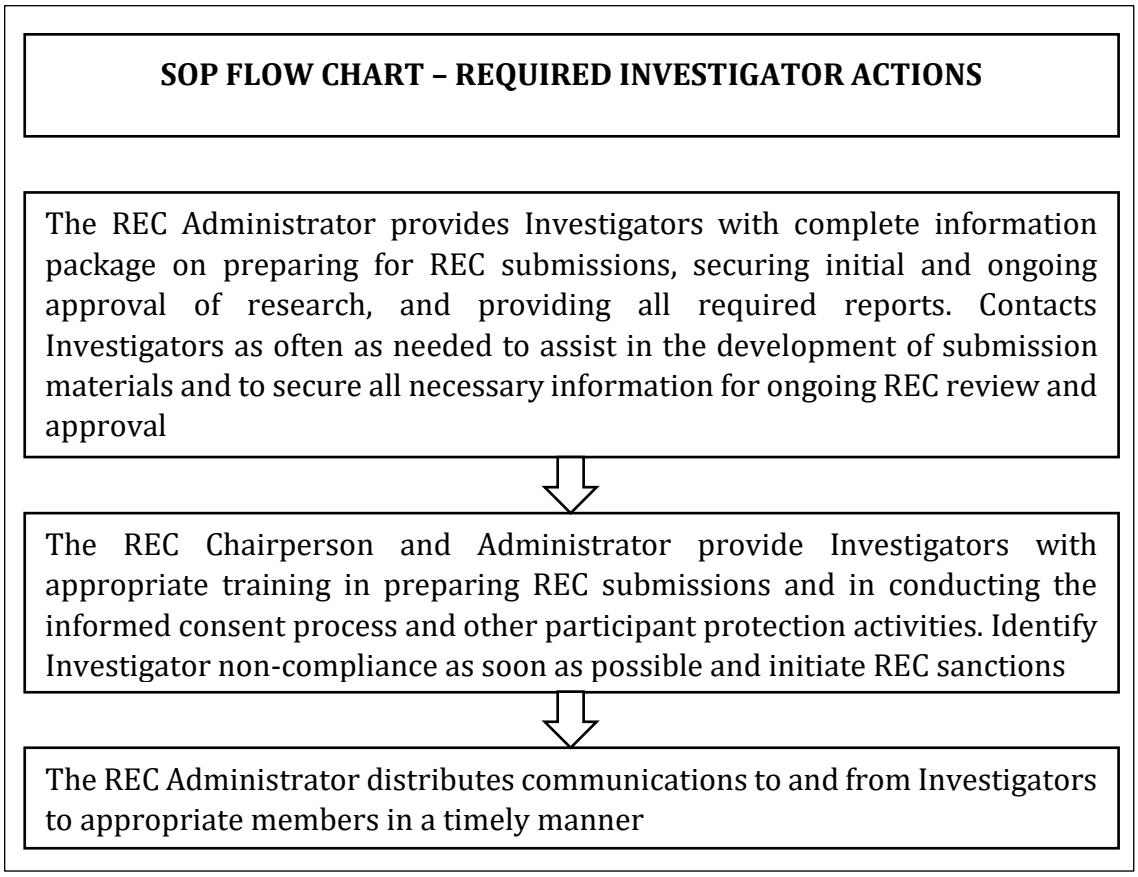
8.1.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

8.1.6 ATTACHMENTS

a) Form 8.1A Investigator Responsibilities – REC Requirements
b) Form 8.1B Essential documents

8.1.7 SOP FLOW CHART



SOP 8.2 SPONSOR RESPONSIBILITIES

8.2.1 BACKGROUND

The REC shall expect the sponsor to adhere to established ethical and regulatory mandates, and take advantage of the sponsor's ability to communicate efficiently and effectively with investigators who are participating in the sponsored research to communicate its requirements.

SPECIFIC PROCEDURES

IDI REC REVIEW OF RESEARCH

The sponsor shall require that clinical research must be reviewed by the REC before any protocol mandated procedures or activities are initiated.

8.2.1.1 INFORMED CONSENT

The sponsor shall require investigators to obtain informed consent from research participants prior to their enrollment into the research. The sponsor shall require that investigators use the informed consent document approved by the REC and use the forms

only during the period for which they are valid. The sponsor is expected to communicate serious breaches of the consent process to the IDI REC if it becomes aware of such breaches.

8.2.1.2 ADVERSE EVENT REPORTING

During the approved period, the REC must be informed as soon as possible of ***any*** serious or alarming adverse event occurring during an REC-approved drug/biologic study or any unanticipated adverse device effect caused by, or associated with, an investigational device, occurring during an REC-approved device study. All deaths, life-threatening complications, hospitalizations, or serious and/ or unexpected adverse events, *whether related to the study article or not*, must be reported to the REC as soon as possible.

Sponsors through investigators, must also submit sponsor-generated reports of adverse events occurring at other investigative sites if any.

8.2.1.3 CHANGES IN APPROVED RESEARCH

Changes in approved research, during the period for which approval has already been given, may not be initiated without REC review and approval, except when necessary to eliminate apparent immediate hazards to human research participants. If arrangements are made in advance, sponsors may submit amendments that affect the protocol directly to the REC for review. Any changes that are implemented prior to REC approval are considered protocol violations. The REC may arrange for the sponsor to distribute Approval Letters with the amendment to all sites participating in the protocol.

8.2.1.4 UNANTICIPATED PROBLEMS

The sponsor should inform investigators that all unanticipated problems must be reported to the REC. An unanticipated problem is defined as any unforeseen event or events that may affect the safety or welfare of research participants, or that may affect the integrity of the research. Examples of an unanticipated problem include, but are not limited to: higher than expected adverse events, higher than expected research participants' dropout rate, higher than expected protocol deviation rate, or participant difficulty understanding the informed consent.

8.2.1.5 PERIODIC REPORTS

The length of time approval is given to a research protocol will be no more than one year, and is dependent on the risk involved with the research. Sponsors/ Investigators or their designees are required to provide a periodic report regarding their investigation prior to the end of the approval period, or upon completion of the study.

8.2.1.6 MONITORING REPORTS

As sponsors routinely monitor investigative sites, they are in a unique position to uncover information to which the REC may not otherwise be privy. The REC requests that the sponsor provide the REC with any information that may affect the rights and welfare of participants, or their willingness to continue participation. Such information may be contained within a

monitoring report, or may be a summary of the sponsor's assessment. The REC will then work with the investigator and sponsor to rectify the situation.

In addition, the REC may conduct its own monitoring visit to investigative sites. The REC selects sites to visit, based on certain criteria, such as the conduct of a high risk study, or the enrollment of a vulnerable population. The REC may also conduct a for-cause visit, or may randomly select a site to visit. Results of concern will be shared with the sponsor.

8.2.1.7 COMPENSATION FOR PARTICIPANTS' INJURY

The sponsors are responsible for compensation or indemnity in the event of research-related injuries, disability or death in accordance with applicable Ugandan laws and regulations

8.2.1 SCOPE

These guidelines and procedures apply to all researchers and sponsors who submit human participant research for REC review.

8.2.2 RESPONSIBILITY

a) The REC Administrator is responsible for tracking sponsor compliance with REC requirements, and for notifying the Chairman of non-compliance.

b) The REC Chairperson is responsible for facilitating compliance with REC requirements through his/her management of REC deliberations, and providing sponsors with clear guidelines pertaining to that compliance through IDI REC communications to the sponsor.

8.2.3 APPLICABLE REGULATIONS AND GUIDELINES

National Guidelines for Research Involving Humans as Research Participants, 2014 Section 7 Subsection 7.2

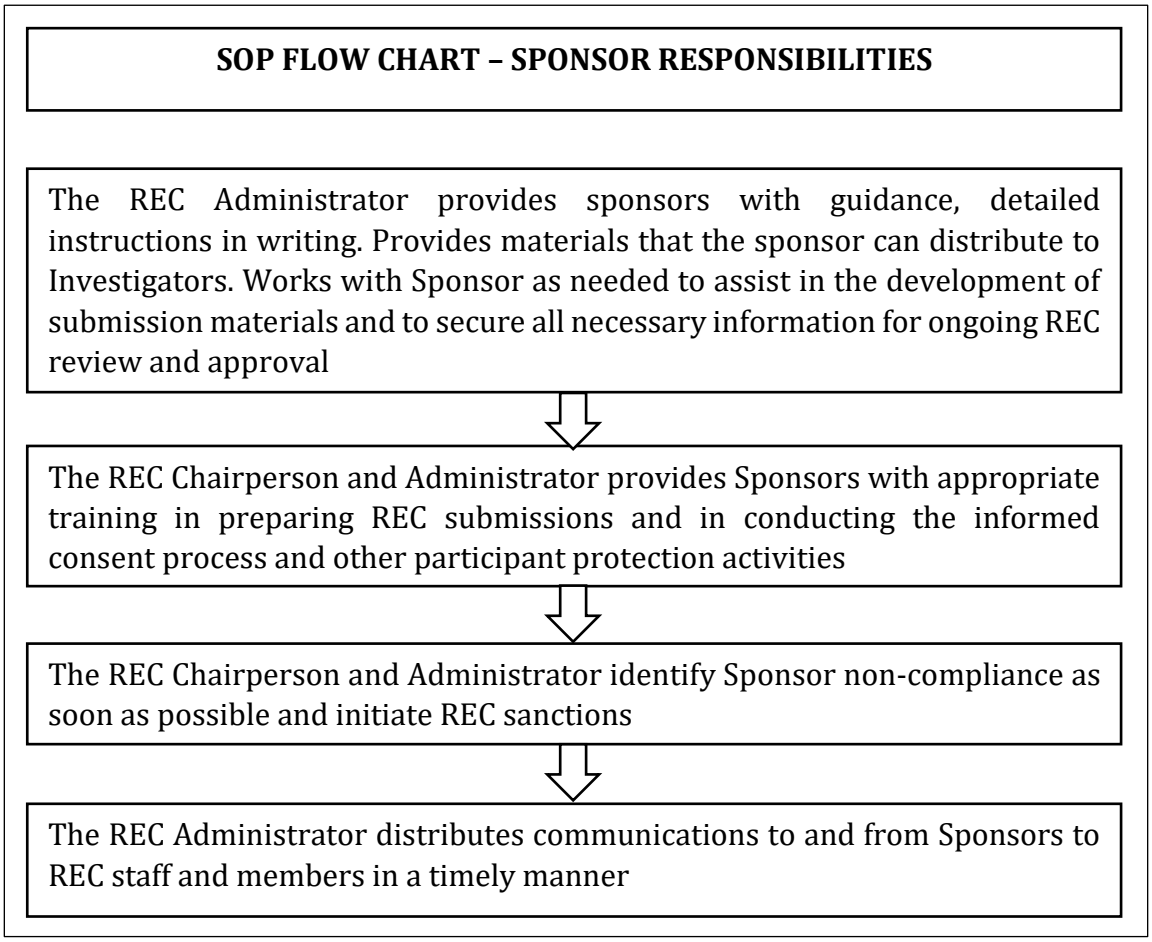
8.2.4 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

8.2.5 ATTACHMENTS

a) Form 8.2A Sponsor responsibilities
b) Form 8.2B SAE Report Form

8.2.6 SOP FLOW CHART



SOP 9: SOPS ON QUALITY ASSURANCE

SOP 9.1 QA/ QC PROGRAM

9.1.1 BACKGROUND

Quality assurance (QA) and quality control (QC) of the daily operations of the REC ensures effective support of the REC's mandate. Therefore, the QA/QC program consists of three components:

a) Regular review and assessment of standard operating procedures (SOPs)

b) Ensuring the REC administrative staff have the required education, experience and training to perform their duties appropriately

c) Ongoing assessment of REC operations and outputs

The first component is addressed in detail in SOP #: 1.1 (Maintenance SOP). The second component is addressed in detail in SOP #: 1.2 (Training and Education) and SOP #: 1.3 (Management of REC Personnel). This SOP addresses the third component.

SPECIFIC PROCEDURES

a) Ongoing assessment of REC operations and outputs is conducted through QC monitoring and QA auditing (internal and external). QC monitoring involves periodic, real time checks of specific REC operations, documents and records. The REC Administrator performs these QC steps on a routine basis.

b) Internal auditing is a retrospective assessment of REC operations through document and record review. Internal audits may be horizontal, where a particular function is assessed across several studies (e.g., minute-taking); or they may be vertical, where a particular study is audited in whole or in part (e.g., high-risk research). An independent auditor performs internal auditing on at least an annual basis.

c) Sponsors or other responsible agents (e.g., contract research organizations) periodically conduct an audit of their studies reviewed by the REC. In addition, UNCST inspections provide additional assessment of the quality of REC operations (refer to SOP #: 9.2, Audits by Regulatory Agencies). These audits are considered external audits.

d) REC discusses the results of QC, internal/external QA audits and regulatory inspections at monthly Management Review meetings. The consideration of adverse findings derived from these activities results in a determination of the root cause(s) of the adverse findings and the development and implementation of a corrective and preventive action (CAPA) plan to improve the effectiveness of the REC human research protection program. The REC chairperson chairs the Management Review meetings, and the REC Administrator monitors the implementation of CAPA plans and provides status reports at Management Review meetings.

9.1.2 SCOPE

This SOP applies to all aspects of the REC.

9.1.3 RESPONSIBILITY

a) The IDI Executive Director (or designee) is responsible for the establishment and oversight of the QA/QC program, and for authorizing the implementation of appropriate CAPA plans.
b) The REC Administrator is responsible for implementation of the QA/QC program, for reporting identified deficiencies to the REC members at Management Review meetings, and for monitoring the implementation of the CAPA plan.
c) The IDI Executive Director (or designee) and all REC members are responsible for contributing to the effectiveness of the QA/QC program.

9.1.4 APPLICABLE REGULATIONS AND GUIDELINES

National Guidelines for Research Involving Human as Research Participants of 2014 Sub-section 7.1 part i; sub-section 7.2.2 part c.

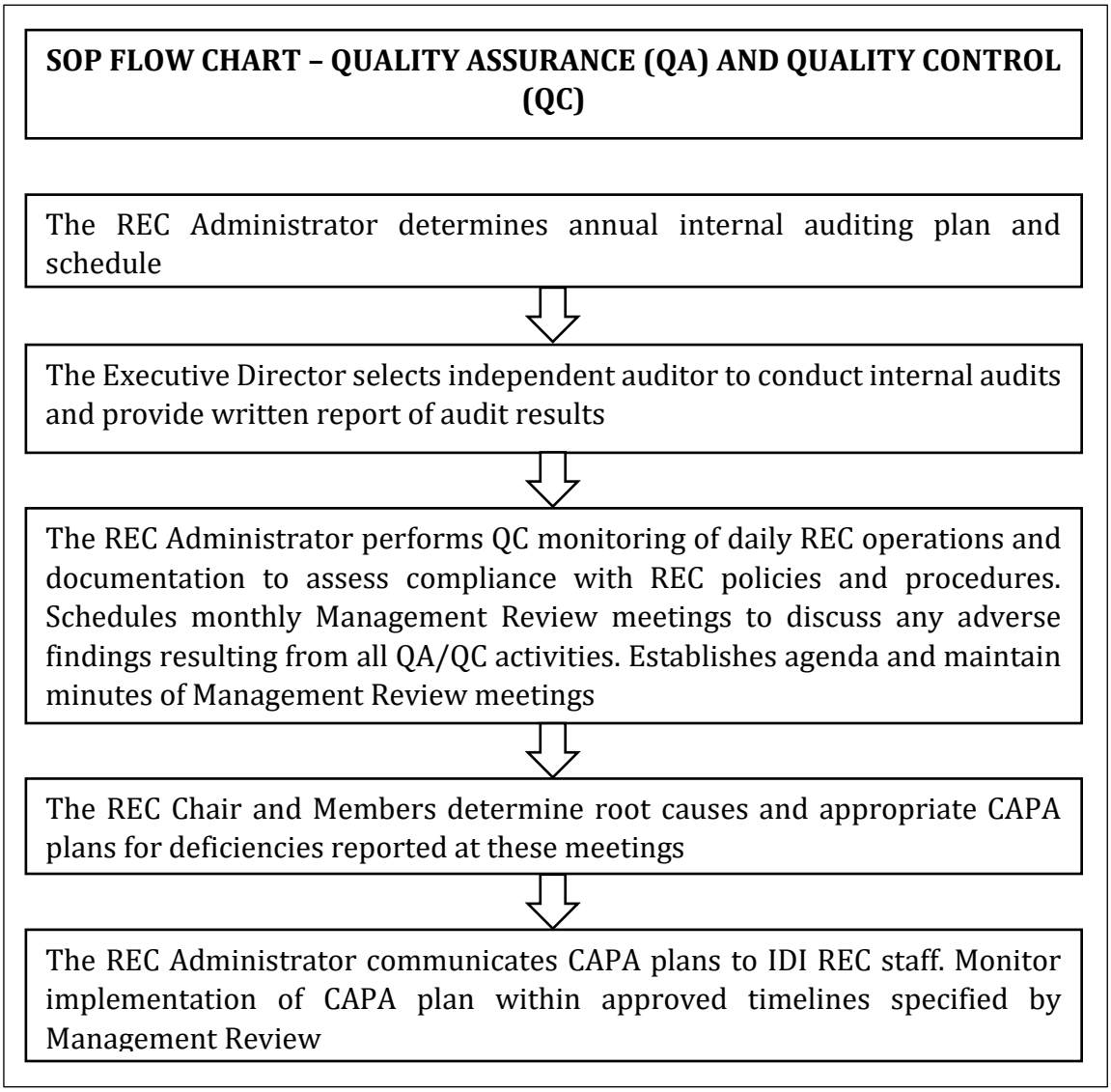
9.1.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

9.1.6 ATTACHMENTS

None

9.1.7 SOP FLOW CHART



SOP 9.2 AUDITS BY REGULATORY AGENCIES

9.2.1 BACKGROUND

IDI acknowledges that certain regulatory agencies have the authority to audit the operations of IDI REC, and supports such audits as part of its continuing effort to maintain high standards for human research protections.

Entities that may audit the IDI REC include: the UNCST, NDA, the USA's Office of Human Research Protection (OHRP), and other appropriate certified auditors including foreign

countries where data from clinical research has been submitted in an application for drug or device approval. Sponsors or funding entities of research may also be authorized to audit specific documents and procedures.

SPECIFIC PROCEDURES

9.2.1.1 PREPARING FOR AN AUDIT

For external audits the following must be notified immediately:

a) IDI Executive Director
b) REC Chairperson
c) REC administrative staff designated to participate in the audit are required to follow the steps outlined by this institution for preparing the site for an audit.

9.2.1.2 PARTICIPATING IN AN AUDIT

a) REC administrative staff are expected to know and follow the procedures outlined by the IDI REC for the conduct of a regulatory audit.
b) Prior to being granted access to REC documentation, inspectors or auditors must exhibit proof of their authority or authorization to conduct the audit and to access REC documents, and no entity other than those listed on the consent forms may have access to any document that includes research participant identifiers.
c) Auditors will be provided with adequate working area to conduct an audit and REC administrative staff and members must make every reasonable effort to be available and to accommodate and expedite the requests of such auditors.
d) Documents may be copied and taken off-site only by individuals authorized in writing by IDI's Executive Director to do so.

9.2.1.3 FOLLOW-UP AFTER AN AUDIT

Reports of the audit, either verbal or written, should be addressed by the IDI Executive Director, (with the assistance and support of REC Chair), as soon as possible after the audit.

9.2.2 SCOPE

This SOP applies to all IDI REC aspects

9.2.3 RESPONSIBILITY

a) The IDI Executive Director (or designee) is responsible for serving as the responsible official in all regulatory agency matters regarding regulatory compliance, participating as needed in regulatory agency audits, and providing support in responding to and correcting audit findings.

b) The REC Administrator is responsible for all formal regulatory agency correspondence and interactions, establishing logistical support during regulatory agency audits, serving as key institution contact during such audits, and drafting responses to regulatory agency correspondence received following such audits.

c) REC Chairperson, Members and Staff are responsible for participating in regulatory agency audits as determined by REC Administrator, and in fully cooperating with government officials during their participation in such audits.

d) REC Chairperson is responsible for assisting the REC Administrator in formal responses to regulatory agency audits and in implementing policy and procedure changes indicated by such audits.

9.2.4 APPLICABLE REGULATIONS AND GUIDELINES

a) National Guidelines for Research Involving Human as Research Participants of 2014

b) FDA Compliance Program Guidance Manual 7348.809, Institutional Review Boards

9.2.5 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

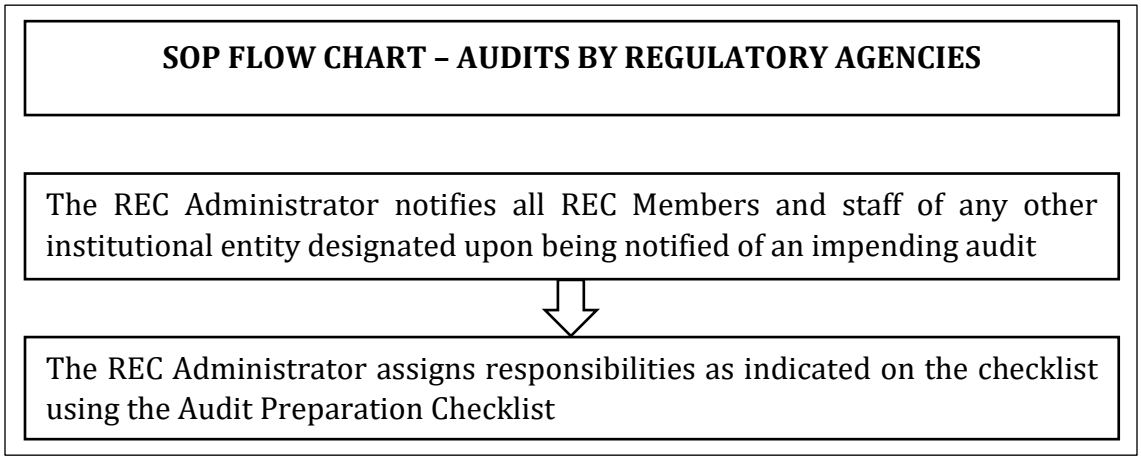
9.2.6 ATTACHMENTS

Form 9.2A A Self-Evaluation Checklist for RECs

9.2.7 PROCESS OVERVIEW

Provide guidelines concerning preparation for regulatory audits of the IDI REC and appropriate behavior toward regulators.

9.2.8 SOP FLOW CHART



APPENDICES

APPENDIX A: ATTACHMENTS TO SOPS

1. FORM 1.1A SOP REVISION WORKSHEET

Sources and Contacts for SOP Updates		
Items to be checked	**Type of Info**	**Comments**
UNCST Register and Website	UNCST Regulations and Guidance	
NDA Home Page	Clinical Research and REC Information	

Items to be discussed at next meeting to review SOPs			
SOP Affected	**Summary of New Item**	**Source and Date**	Importance (1 – 2 – 3)

Comments

_____
_____

2. FORM 1.1B SOP REVIEW MEETING TEMPLATE

AGENDA	**MINUTES**		
Date:	Date:		
To:	Attendees:		
Review Item	**Discussion Summary**	**Revise SOP**	
1. SOP #		**Yes**	**No**
		☐	☐
2. SOP #		**Yes**	**No**
		☐	☐
3. SOP #		**Yes**	No
		☐	☐
4. SOP #		**Yes**	**No**
		☐	☐
5. SOP #		**Yes**	**No**
		☐	☐

Comments			
Minutes reviewed by		Date	

3. FORM 1.1C SOP REVISION LOG

1. SOP #			**SOP Revised**	
Procedure/section change from:	**Change to:**	**Date**	On	
			By	
			Distributed	
			On	
			By	
2. SOP #			**SOP Revised**	
Procedure/section change from:	**Change to:**	**Date**	On	
			By	
			Distributed	
			On	
			By	
3. SOP #			**SOP Revised**	
Procedure/section change from:	**Change to:**	**Date**	On	
			By	
			Distributed	
			On	
			By	
4. SOP #			**SOP Revised**	
Procedure/section change from:	**Change to:**	**Date**	On	
			Distributed	

			On	
			By	
5. SOP #			**SOP Revised**	
Procedure/section change from:	**Change to:**	**Date**	On	
			Distributed	
			On	
			By	
Comments				

4. FORM 1.1D FORMS REVISION LOG FORM

Form	**Date**	**Follow-up**	
	Form replaced on:	Notify	
		☐	
	Printout	☐	
	Master	☐	
	Form replaced on:	Notify	
		☐	
	Printout	☐	

	Master	☐
	Form replaced on:	Notify
		☐
	Printout	☐
	Master	☐
	Form replaced on:	Notify
		☐
	Printout	☐
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	Printout	☐
	Master	☐
	Form replaced on:	Notify
		☐
	Printout	☐
	Master	☐
	Form replaced on:	Notify
		☐
	Printout	☐
	Master	☐

Comments

5. FORM 1.1E SOP TEMPELATE

SOP NUMBER: NAME OF SOP

1. BACKGROUND

Specific procedures

2. SCOPE

3. RESPONSIBILITY

i) REC Administrator (or equivalent)

ii) REC Chairperson (or designee)

4. APPLICABLE REGULATIONS AND GUIDELINES

5. REFERENCES TO OTHER APPLICABLE SOPS

6. ATTACHMENTS

7. SOP FLOW CHART

6. FORM 1.1F NOTIFICATION OF SOP CHANGE MEMORANDUM

To:

From:

Date:

Re: IDI REC SOP Revision

There has been a change in the following REC SOPs. The changes have been made in the master electronic document. If you have a printed copy, please replace the obsolete section.

1. SOP	Effective date
Old SOP:	New SOP:
2. SOP	Effective date
Old SOP:	New SOP:
3. SOP	Effective date
Old SOP:	New SOP:

4. SOP	Effective date
Old SOP:	New SOP:

Comments

7. FORM 1.2A BIBLIOGRAPHY AND RESOURCE LIST

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The Nuremberg Code Belmont Report

OIG Reports on IRBs

8. FORM 1.2B TRAINING CHECKLIST AND DOCUMENTATION FOR REC MEMBERS

Purpose: ☐New Member ☐Annual Requirements ☐Other (Specify)

Name: _____

	Training/Education Source	Completed	Verified by
Required			
	REC SOPs		
	Good Clinical Practice (GCP) training		
	Human Participants Protection (HSP) training		
Other requirements as determined by IDI REC members	Foundations of Human Participant Protection (example)		
	The Belmont Report		

9. FORM 1.2C TRAINING CHECKLIST AND DOCUMENTATION – REC Administrators

Purpose: ☐New Hire ☐Annual Requirements ☐Other (Specify)

Name: _____

	Training/Education Source	Completed	Verified by
Required			
	IDI REC SOPs		
	Good Clinical Practice (GCP) training		
	Human Participants Protection (HSP) training		
Other required as determined by IDI REC members			

10. FORM 1.3A IDI REC ADMINSTRATOR FUNCTIONS

Position: REC Administrator

Hours: 8:00 am – 5:00 pm

Location: IDI, Mulago

Introduction: The REC Administrator is instrumental in support of REC operations so as to meet its primary responsibility of protecting the rights and welfare of human research participants by:

a) Ensuring that submitted research is reviewed efficiently and consistent with regulations and guidelines by:

i. Having thorough knowledge of and ability to apply National regulations and guidelines and IDI REC procedures.

ii. Overseeing the accurate and timely processing, tracking, and filing of submissions to and actions by the IDI REC.

iii. Effectively communicating with Investigators, Sponsors, Chair, and IDI REC members.

iv. Obtaining and distributing information required for Chair or IDI REC review, maintaining files, preparing and distributing minutes.

v. Supervising the training of IDI REC administrative staff in requirements for IDI REC review.

vi. Assigning new protocols to IDI REC members based on known or potential conflicts as well as member expertise.

vii. Compliance with submission requirements in IDI REC SOPs.

b) Maintaining accurate records of IDI REC actions by:

i. Recording meeting minutes in sufficient detail to document IDI REC deliberations.

ii. Documenting communications with Sponsors, Investigators, regulatory entities, and any others involved in the conduct of submitted research.

iii. Maintaining an accurate and comprehensive database of reviewed and approved research.

iv. Maintaining records of expedited reviews, risk determinations, and any other activities that result in a review or action by IDI REC staff or members.

v. Maintaining, filing and archiving systems that allow access to open and closed studies.

vi. Reviewing and suggesting modifications in IDI REC agendas and minutes.

vii. Periodically reviewing IDI REC policies and procedures to ensure appropriate functioning of the IDI REC.

viii. Providing data entry to computer tracking system, generating letters, creating files and mailing notices to Investigators.

c) Ensuring that Investigators and Sponsors are informed of the actions and findings of the IDI REC by:

i. Issuing notifications of IDI REC actions to Investigators and other appropriate entities.

ii. Reviewing IDI REC SOPs on regular basis to ensure accurate information and disseminating changes to IDI REC members.

iii. Sending timely responses to written and phone messages requesting information.

iv. Sending timely decision correspondence to appropriate parties.

d) Ensuring that continuing review of research is conducted appropriately and in a timely manner by:

i. Making Investigators aware of due dates for submission of renewal and other reports.

ii. Ensuring that information submitted by Investigators is adequate for effective review.

iii. Reviewing procedures for obtaining continuing review information, adequacy of information and need for additional information from sources other than the Investigator.

e) Serving as IDI REC interface for participants, Investigators, Sponsors and regulatory agencies by:

i. Answering questions and supplying information when requested, and conveying IDI REC actions to appropriate individuals.

ii. Screening participant inquiries and resolving issues when possible, and conveying results of interactions with participants to Investigators, Sponsors, and IDI REC members as directed.

iii. Serving as the IDI REC liaison during audits by regulatory entities or Sponsors.

iv. Scheduling IDI REC meetings.

v. Conducting semiannual assessment of office function.

f) Overseeing adequacy of REC membership by:

i. Providing support to the Chairperson, Institution Official, in the recruitment,

training, and continuing education of IDI REC members.

ii. Appraising the Chairperson of IDI REC membership status and determining if additional or new regular or alternate members are required.

iii. Ensuring that a quorum is present and maintained during convened meetings.

iv. Keeping members apprised of their responsibilities regarding conflicts of interest.

v. Reviewing IDI REC minutes to ensure documentation of quorum for decisions reported.

vi. Working with IDI REC Chair and others as required, to recruit and to supervise training of new IDI REC members.

vii. Maintaining IDI REC membership logs and coordinating submissions to regulatory agencies.

viii. The Chairperson may delegate additional duties and responsibilities to the IDI REC Administrator.

11. FORM 1.4A IDI REC CONFLICT OF INTEREST POLICY STATEMENT

P.O. BOX 22418, KAMPALA

For the protection of human research participants, the IDI REC has adopted the following Conflict of Interest (COI) Policy and Statement.

1. Each protocol submitted to IDI for review must be accompanied by PI(s) COI Disclosure Statement. Protocols submitted without the appropriate COI Statements will not be accepted or reviewed until all appropriate COI documents are received.
2. COI Statements MUST be completed, signed and submitted with PI's Initial and Continuing Application for REC Review.

Note that the IDI REC Conflict of Interest Statement is *independent* of the IDI Research Conflict of Interest requirement as stipulated in the research policy.

IDI REC CONFLICT OF INTEREST POLICY

PURPOSE

Public trust in the research projects and the legitimacy of its powerful role in society require a constant amenability to public scrutiny. Consequently, it is necessary at all times to assure the continued confidence of the public in the judgment of scholars, scientists and clinicians and in the dedication of academic research institutions to the integrity of the research enterprise. The strength of this assurance is based on the assumption that scholars are honest and conduct their research with the highest standards and integrity.

This policy is intended to serve human research participants. This policy is not intended to eliminate all situations of conflict of interest, but rather to enable individuals to recognize situations that may be subject to question and resolve them to avoid conflicts of interest. Thus, an integral part of the policy is disclosure whereby individuals regularly review their professional activities.

THE POLICY

Individuals directly involved in the conduct, design or reporting of research involving human participants should not have more than a minimal personal financial interest in a company that sponsors the research or owns the technology being studied.

A conflict of interest arises when a researcher is or may be in a position to put his or her own interest before the best interests of research subjects. Conflicts involving the REC itself or conflicts involving the institution must be managed. In order to manage such conflicts, the REC must be informed of potential conflicts of interest. Researchers submitting protocols using human subjects must disclose all interests that may be perceived as a conflict with the best interest of the subject in order for the research to be considered for approval.

IMPLEMENTATION:

I) Researchers who have completed Financial Disclosure forms required by the funder to be submitted to a sponsor of the research may submit a copy of that form to the IDI REC.

II) Based on the information submitted by the researcher for review, the REC may determine that:

1. no conflict exists, or
2. a conflict exists and must be disclosed to the research participants in the informed consent statement, or
3. a conflict exists and the researcher must resolve the conflict before the research can be approved.

EXAMPLES OF REPORTABLE AND NON-REPORTABLE ACTIVITIES

Non-Reportable Activities

The following activities and relationships do not need to be reported and do not represent a conflict of interest because they have been generally accepted practices and do not violate fundamental ethical principles.

a. Receiving royalties for published scholarly works and other writings.
b. Accepting honoraria for commissioned papers and occasional lectures.
c. Receiving payment for reasonable travel and lodging expenses related to presentations of scholarly work or to a person's academic endeavour.
d. Investing in mutual funds.
e. Participating in a University approved practice corporation.
f. Payments for clinical research to an approved practice corporation or to a department fund for salary or other expenses of conducting clinical trials.

Reportable Activities

a. Conducting research in applied and/or clinical research on a technology developed by the investigator or a member of his/her immediate family (spouse, children, parent, in-laws, and siblings).
b. The financial relationship of an investigator or his/her immediate family member with the sponsor of his/her research (acting as scientific advisor or consultant, or receiving honoraria exceeding $5,000 annually, or acting as director or other executive).
c. Conducting applied and/or clinical research on a technology owned by a business in which the investigator or a member of his/her immediate family holds 5% or more of the outstanding stock or stock options.
d. Receiving royalties under institutional royalty-sharing policies from marketing the drug, device or procedures that is the subject of the research.

CONFLICT OF INTEREST STATEMENT

For the protection of human research participants, the IDI REC requires that **each** protocol submitted to the REC for review must be accompanied by a Conflict of

Interest (COI) Disclosure Statement. COI Disclosure Statements must be completed, signed and submitted with each Initial and Continuing Application for REC Review.

Protocol Principal _____

Name of Person (Investigator/Key Personnel) completing this statement:

12. FORM 1.5A DEFINITIONS RELATING TO SIGNATORY AUTHORITY

a) **Review and approval of research projects -** Any action or decision taken by the IDI REC through full or expedited review mechanisms, which grants or may appear to grant Investigators with initial or continuing approval of research, training or educational projects involving human participants.

b) **Routine internal correspondence -** Means any action, letters, memos or emails between the IDI REC and staff and members of the faculty or staff of the institution/organization that provides information concerning the review of research protocols by the IDI REC or IDI REC support staff which do not imply or appear to imply approval of this activity.

c) **Correspondence with external agencies -** Shall mean any letters, memos or emails sent to agencies of the government, funding agencies whether private or public or their agents.

d) **Decisions made by Chairperson -** Shall mean any letters, memos or email sent representing the decision or opinions of the Chairperson of the IDI REC or his/her designee as long as such correspondence does not imply review and approval of research participants.

e) **Designated staff -** Shall mean staff designated by the IDI REC Chairperson in writing.

f) **Signature stamp -** Shall mean IDI REC's mechanical stamping device bearing the reproduction of the authorized individual's signature.

13. FORM 2.1A IDI REC MEMBER DETAILS

Name	(Type in name)
Degrees	(List all relevant academic degrees)
Certification	Professional certification(s)
Title	Primary title
Company/Institution	Name of employer/affiliation
Address1	Address
Address2	Address
Phone	Primary contact phone
Fax	Primary contact fax
E-mail	Primary contact e-mail
Member status	Chair / Alternate / Regular / Co-Opted Member
Relationship to IDI	Faculty, Staff, Consultant, None
Representative Capacity	Scientific? Non-scientific? Community? Prisoner rep? Etc.
Professional Specialty	As relates to REC activities
Alternative for	Alternate: Alternate for which regular member(s)
Term	Date appointed to Date term up
Signature Authority	Y/N

14. FORM 2.2A NEW MEMBER INFORMATION PACKET CHECKLIST

	Document Name	**Document code#**
☐	WELCOME LETTER	Form 2.2B
	Documentation	
☐	Member responsibilities	Form 2.3A
☐	Reviewer duties (specific duties of REC members)	Form 2.3D
☐	REC Appointment Agreement	Form 2.2C
☐	REC Member Confidentiality Agreement	Form 2.2D
☐	REC Member Recusal Agreement	Form 1.4A
	Training and Educational Material	
☐	Belmont Report	Appendix B
☐	Foundations of Human Participant Protection and Test	
☐	IDI REC SOPs	
☐	Bibliography and Resource List	Form 1.2A
☐	Training Checklist and Documentation – REC Members	From 1.2B

15. FORM 2.2B - NEW MEMBER WELCOME LETTER

INFECTIOUS DISEASES INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418, KAMPALA

Date (today's date)

To: (IDI REC Member)

(Address)

Dear_____:

Thank you for agreeing to serve as an IDI REC member. We appreciate your willingness to assume a share of the responsibilities for human research oversight at this institution during the next *3 years*. I have enclosed documents we will need signed and returned to the IDI REC Secretariat, as well as informational and educational material. Please read and sign the following documents:

1. Form 2.2C: IDI REC Appointment Agreement
2. Form 2.2D: IDI REC Member Confidentiality Agreement
3. Form 1.4A: IDI REC Member Recusal Agreement

As was discussed with you earlier, all IDI REC members must be trained and receive continuing education in topics relevant to the protection of human research participants. I have enclosed an independent study course titled "Foundations of Human Participant Protection," (*or similar course)*. Please complete the course and submit your completed test within 3 months.

I look forward to seeing you on___. Please arrive about an hour before the meeting and we will review the duties and responsibilities of IDI REC members.

Again, thank you very much for your participation in the IDI REC. Please do not hesitate to contact me if you have any questions.

Sincerely,

Chairperson, IDI REC

Enclosures

16. FORM 2.2C- IDI REC APPOINTMENT AGREEMENT

INFECTIOUS DISEASE INSTITUTES RESEARCH ETHICS COMMITTEE

P.O. BOX 22418, KAMPALA.

Date (today's date)

To: (IDI REC Member)

(Address)

Dear_____

Capacity:_____

Term ofAppointment: _____

Introduction and Purpose

The Infectious Diseases Institute Research Ethics Committee is a regulated entity with the mandate to review biomedical and behavioral research studies that take place within Uganda. The purpose of this review is to determine if the proposed research meets certain established regulatory, policy, and ethical criteria to protect the rights and welfare of the human participants of such research. The criteria used by the IDI REC to determine the acceptability of such research is based upon principles discussed in the National Guidelines on Research Involving Humans as Research Participants, which are:

a) The sum of the benefits to the participant and the importance of the knowledge to be gained should outweigh the risks to the participants as to warrant a decision to allow the participant to accept these risks.

b) Legally effective informed consent will be obtained from each participant, unless the requirements for waiver of informed consent are met, by adequate and appropriate methods in accordance with the provisions of applicable national regulations and guidelines.

c) The conduct of the study will be reviewed at timely intervals.

Scope of Work

The IDI REC will review protocol and informed consent forms, and review or delegate the review of Investigator and site qualifications for the purpose of approving, recommending modifications to, or disapproving proposed research involving human participants as required by regulations and guidelines of the Uganda National Council for Science and Technology (UNCST) and National Drug Authority (where applicable). Criteria to be used in reviewing protocols include minimization of risk, equitability of participant selection, and adequacy of informed consent and maintenance of participant confidentiality.

As a member of the IDI REC, your presence will be used to establish a quorum; therefore, you will be expected to attend regularly scheduled meetings, which generally occur once a month. All REC members receive a packet of material pertinent to the proposed research prior to the scheduled meeting. The packet contains the meeting agenda, expedited review information, the protocol(s) and informed consent form(s) and Investigator information submitted for review. You are expected to review this information prior to the meeting and participate in the review and ensuing discussion.

You will be expected to serve as the primary reviewer for 1-3 protocols at each meeting.

The responsibilities of the primary reviewer are outlined in the description of reviewer duties (Form 2.3D and SOP #: 2.3 section 1.3.2).

Requirements

Prior to assuming responsibilities of a REC member, new appointees will be expected to observe a meeting, and complete the training course. REC members are also required to participate in continuing training and education during the term of their appointment.

Members are expected to agree to recuse themselves if they have a conflict of interest that could bias their consideration of research submitted for review, and to document this agreement at the time they accept appointment to the IDI REC.

Term

The term for REC members is for three years. This term is renewable. Members who are unable or unwilling to fulfill their duties as REC members may be removed from the IDI REC at any time by the REC Chairperson/Designee). See Member Responsibilities.

Please sign below if you agree to the terms described above.

_____ _____

IDI REC Member Date

_____ _____

IDI REC Chairperson/Designee Date

17. FORM 2.2D IDI REC MEMBER CONFIDENTIALITY AGREEMENT

INFECTIOUS DISEASES INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418, KAMPALA

Date (today's date)

To: (IDI REC Member)

(Address)

Dear _____

RE: CONFIDENTIALITY AGREEMENT

I understand and agree that information disclosed orally or in written form or discussed at IDI REC meetings may include confidential information that is proprietary to commercial entities sponsoring the proposed research and/or involves the privacy rights of individuals.

I agree that I will not disclose or divulge in any manner any confidential or private information revealed at the meeting in any form or manner to any third party for any purposes whatsoever. "Confidential or Private Information" as used in this Agreement shall not include:

1) Information or knowledge in my possession prior to disclosure at the IDI REC meeting, or from the Uganda National Council for Science and Technology;
2) Information generally available to the public or thereafter becomes generally available to the public through a source other than the IDI REC;
3) Information that was rightfully obtained by me from a third party, who, I believe, is under no obligation of confidentiality to the IDI REC with respect to such information.

Acknowledged and Agreed:

Signature_____ Date _____

Printed Name _____

18. FORM 2.2E IDI REC MEMBER DOCUMENTATION LIST

Name					
Address					
Phone		**Fax**		**Email**	

IN FILE	**Item**			
☐	**CURRENT CV / RESUME**	☐ Year 1	☐ Year 2	☐Year 3
☐	Signed IDI REC Appointment Agreement			
☐	Signed Confidentiality Agreement			
☐	Financial Disclosure			
☐	Training Checklist (102B)	☐Year 1	☐Year 2	☐Year 3
	Comments			

19. FORM 2.3A MEMBER RESPONSIBILITIES – REGULAR MEMBER

Title	IDI REC Member
Term	3 years
Responsibilities	Attend convened meetings of the IDI REC. Review submitted research. Act as primary or secondary reviewer for 1-3 studies at each meeting. Consult with Investigators as needed. Obtain continuing education germane to human participant protection.
Time Commitments	IDI REC: 10 hours per month Attend Continuing Education: 6 hours per year IDI REC members are advised to alert the REC Administrator well in advance, if possible, if they cannot attend a REC meeting, so they are not assigned protocols to review. If they cannot alert the REC Administrator or in a timely manner, and are assigned protocols to review for the next upcoming meeting, then they are expected to deliver written comments to the REC Administrator prior to the beginning of the meeting.
Other Requirements	The following financial relationships must be disclosed annually: any equity interests over $10,000 to commercial entities that sponsor or conduct research in this institution; significant payments of other types, including honoraria, co-opted fees received from commercial entities that sponsor or conduct research in this institution. A potential for a conflict of interest must be disclosed prior conducting a review of research. Conflicts of interest could include close personal or professional relationship to an Investigator; interest, financial or otherwise, in the outcome of the research.
Compensation	Faculty: None Non-faculty: Reimbursement for continuing education and training related to the IDI REC roles and responsibilities

20. FORM 2.3B MEMBER RESPONSIBILITIES – CHAIRPERSON

Title	Chairperson
Term	3 years
Responsibilities	In addition to the duties of IDI REC members, the Chairperson assumes the following duties: Chairs convened meetings of the IDI REC. Reviews all submitted Investigator reports and determine if there is reason for full IDI REC review. Perform or delegate expedited review of research applications and revisions. Review reports of serious or unexpected adverse events. Consult with Investigators as needed. Conduct training sessions with Investigators and research staff. Obtain continuing education relevant to IDI REC responsibilities. The Chairperson is empowered to suspend the conduct of a study deemed to place individuals at unacceptable risk pending IDI REC review. The Chairperson may appoint the Vice Chairperson to assist or act on behalf of the Chairperson in particular IDI REC matters and at IDI REC meetings, either as a general procedure, or on a case- by-case basis. The Chairperson also may delegate any of his/her responsibilities as appropriate to other qualified individual(s). Such documentation must be in writing.
Time Commitment	IDI REC: 32 additional hours per month Attend Continuing Education: 6 hours per year Instruction: 6 hours per year
Other Requirements	The task of making the IDI REC a respected part of the institutional review community will fall primarily on the shoulders of the Chairperson. The IDI REC must be or perceived to be, fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

Compensation	Faculty: None Non-faculty: Reimbursement for continuing education and training Reimbursement for teaching expenses

21. FORM 2.3C MEMBER RESPONSIBILITIES – REGULAR MEMBER

Title	Regular Member
Term	3 years
Responsibilities	Attend convened meetings of the IDI REC as needed. Review submitted research in place of regular member.
Time Commitments	IDI REC: 20 hours per year Attend Continuing Education: 12 hours per year
Other Requirements	The following Financial relationships must be disclosed annually: any equity interests over $10,000 to commercial entities that sponsor or conduct research in this institution; Significant payments of other types, including honoraria, co-opted fees received from commercial entities that sponsor or conduct research in this institution. A potential for a conflict of interest must be disclosed prior to conducting a review of research. Conflicts of interest could include close personal or professional relationship to an Investigator; interest, financial or otherwise, in the outcome of the research. IDI REC members are advised to alert the REC Administrator well in advance, if possible, if they cannot attend an IDI REC meeting, so they are not assigned protocols to review. If they cannot alert the REC Administrator in a timely manner, and are assigned protocols to review for the next upcoming meeting, then they are expected to deliver written comments to the REC Administrator prior to the beginning of the meeting.
Compensation	Faculty: None Non-faculty: Reimbursement for continuing education and training related to roles and responsibility of IDI REC member.

22. FORM 2.3 MEMBER RESPONSIBILITIES REVIEWERS DUTIES

NON-AFFILIATED REVIEWER	Non-IDI affiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
NON-SCIENTIFIC REVIEWER	Nonscientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Non-scientific members should advise the IDI REC if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of participants.
SCIENTIFIC REVIEWER	Scientific reviewers are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IDI REC if additional expertise in a non- scientific area is required to assess if the protocol adequately protects the rights and welfare of participants.
PRIMARY REVIEWER	In addition to the duties described in SOP #: 2.3, section 1.3.2, each regular member or alternate member will be expected to act as a primary reviewer for assigned studies at convened meetings. The primary reviewer presents his or her findings resulting from review of the application materials and provides an assessment of the soundness and safety of the protocol and recommendations specific actions to the IDI REC. He or she leads the IDI REC discussion of the study. The primary reviewers may be required to review additional material requested by the IDI REC for the purpose of study approval.

23. FORM 3.1A- IDI REC SUBMISSION FACE SHEET

PROTOCOL TITLE AND NUMBER

SITE AND RESEARCH STAFF

Principal Investigator

Title:

Phone:

Address:

Fax:

E-mail

Contact person Phone:

Address: Fax:

E-mail:

LIST CO-INVESTIGATORS Or ☐ None

NUMBER OF OPEN RESEARCH STUDIES SITE IS CURRENTLY CONDUCTING:

☐0 ☐1-5 ☐ 6-10 ☐>10

Signature of Principal Investigator or Designee _____

Date _____

24. FORM 3.1B STUDY SUMMARY FORM

Study Summary

<table>
<tr><td>1</td><td>Protocol Title:

Principal Investigator:
Name:
Phone:
Email:
Fax:

The study ☐will ☐ will not be conducted at this address

Does the PI or any sub-investigator have a financial interest (other than payment) in this study? (IDI REC will contact either the sponsor or PI for additional information.)

☐No ☐ Yes

Does the PI or any sub-investigator have an interest, other than financial, in the outcome of this study? (IDI REC may contact either the sponsor or PI for additional information.)

☐No ☐ Yes

Other interest could be close personal or professional association with the sponsor, direct participation in the research (e.g., protocol development, or any significant professional association, such as consulting work, with the sponsoring company).</td><td>Important: Please Note

Attach CV</td></tr>
<tr><td rowspan="3">2</td><td colspan="2">SPONSOR / FUNDING INFORMATION</td><td rowspan="3"></td></tr>
<tr><td>Will this protocol be supported by a government funding agency?

If yes, provide details on the funding agency</td><td>☐ No ☐ Yes</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>3</td><td colspan="2">LOCATION OF RESEARCH:</td><td></td></tr>
<tr><td></td><td colspan="2">Where will the study take place? ☐Only at the above address</td><td>Include all locations for study related activities</td></tr>
</table>

	Will the PI be conducting and/or supervising study related activity at any sites outside of Uganda? Yes ☐ No ☐ If yes, complete an *Additional Study Location Form* for each location Number of clinical research staff available to work on this project:	
4	**PARTICIPANT INFORMATION**	
A	**Will participants who do not understand English be enrolled?** ☐No ☐Yes If yes: Describe your resources to communicate with these participants: Into what language(s) will the consent form need to be translated:	Attach an additional sheet if needed.
B	**Potentially Vulnerable Populations** ☐Children ☐Nursing home residents ☐Foetuses / foetal material ☐Mentally impaired ☐Students ☐Economically disadvantaged ☐Pregnant women ☐Investigator's staff	Describe additional protections for these populations on separate page.

	☐Homeless members ☐Prisoners ☐Investigator's patients ☐Other (describe) Describe additional protections for potentially vulnerable participants: If you are recruiting children in this study, indicate the age range:		
C	**Are there community attitudes that may affect participants in this study?** If yes, describe attitudes and how they may affect participants. ☐No ☐Yes		
5	**RECRUITMENT**		
A	**How will participants be identified?**		
	☐By chart/ database review (see below) ☐From the Investigator's own patients ☐Referrals ☐Describe any other sources:	☐Course participants ☐Circumstance (i.e., homelessness) ☐Living conditions (street, nursing home) ☐Direct advertising (complete section 5E)	
B	**How will participants be recruited for participation? (Check appropriate box(es)** ☐At a scheduled visit by the Investigator ☐During class ☐By chart/ database review and investigator contact ☐By Referral If by referral, detail the procedures and submit letters to be sent to referrers.		

	☐letter ☐phone (complete section 5C) ☐Chart/database review	
C	Who gave approval for the use of the records? Describe who will make initial contact and how. If records are "private" medical or student records, provide the protocol, consent forms, letters, etc., for securing consent of the participants for the records.	Initial contact must be made by the custodian of the record, (i.e. primary care provider, therapist, school official) and written per-mission from the holder / custodian of the records must be included

D	**Direct participant advertising** Media for participant recruitment includes: (check all that apply) ☐Radio ☐Television ☐Newspaper ☐Bulletin board/flyer ☐Internet ☐Letters to patients ☐Letters to providers ☐Others Will a centrally coordinated advertisement program be used? ☐Yes ☐No				Submit all advertising (Proofs, scripts, letters, e.t.c) For approval prior to use.
6.	**PAYMENT TO PARTICIPANTS**				
	Are participants being paid for participation? If yes, indicate total ☐ No ☐Yes amount, (shilling or equivalent):				Payment includes all types of reimburse-ment, such as fares, parking fees, etc.
	Form of Payment: ☐Reimbursement only. Will participant be required to submit proof of expenses?☐No ☐Yes ☐Voucher ☐Cash ☐Check ☐Other:				
	When will participant be	☐ Each visit	☐Study completion	☐Other:	

	paid?				
7	**COSTS TO PARTICIPANTS**				
A	**Study procedures and products** Will participants or their health care providers be required to pay for any study related procedures or products? If yes, explain:☐No ☐Yes				
B	**Compensation for injury** Who is responsible for costs incurred due to injury?				
8.	**DESCRIPTION OF THE RESEARCH**				
A	Does the project involve the administration of personality tests, inventories, or questionnaires? If *yes,* provide name of the standard tests/questionnaire or 3 copies of the proposed tests.			☐No ☐Yes	
B	Does the project involve administration of ionizing radiation to participants for other than clinical purposes? If *yes* contact the (CUSTOM NAME) and Radiation Safety Office.			☐No ☐Yes	
C	Does the project involve gene therapy (administration of Recombinant vectors) to human participants for other than clinical purposes? If yes, contact the Biosafety Officer.			☐No ☐Yes	

9.	**TEST ARTICLES** Are any of the test articles regulated by NDA? If yes, complete this section ☐ No ☐Yes	
	This study involves a drug or biologic: IND #, if applicable: _____	Submit the Investigator Brochure
	This study is: ☐Phase 1 ☐Phase 2 ☐Phase 3 ☐Phase 4 ☐Treatment	
	This study involves a device: ☐Yes ☐ No This device is ☐ Investigational ☐Marketed This is a☐Significant Risk Device Study☐Non-Significant Risk Device Who is the Sponsor of the IND/IDE?	Sponsor must Include justification of Non-Significant Risk per 21 CFR 812. 66
10.	**SYNOPSIS OF THE PROTOCOL**	
A	State the objective of the research.	

B	Discuss the present knowledge and appropriate literature relevant to it.	
C	Discuss the rational for the use of the selected participant population.	
D	Discuss the statistical / quantitative methodology	
E	List the inclusion criteria.	
F	List the exclusion criteria.	
G	How will the inclusion/exclusion criteria be assessed and by whom?	
H	What are the participants' alternatives to participation in the study?	
11.	**RISKS TO PARTICIPANTS**	

A	Identify the risks (current and potential). ☐N/A	Consider all risks: physical psychological, social, legal economic
B	Describe the expected frequency, degree of severity, and reversibility. ☐N/A	
C	Describe possible late effects. ☐N/A .	
D	Risks from study article: ☐N/A	
E	Risks from research procedures (i.e., washout risks, placebo assignment, etc.) ☐N/A	
F	How will participants be assessed for the occurrence of adverse events described in section_____? ☐N/A	
G	For studies with more than minimal risk, or NDA/FDA regulated products/ studies, who will monitor the study data? ☐N/A	

H	Describe your monitoring plan ☐N/A	
12.	**BENEFITS**	
A	Is there a possibility that participants could benefit directly from taking part in this study? If yes, describe:☐ No ☐Yes	
	Describe potential benefits to the group or class from which the participants are recruited._____ _____ _____	

C	Describe potential benefits to society._____ _____	
13.	**RISK/BENEFIT ASSESSMENT**	
	Briefly assess the risk/benefit ratio of the participant's participation, include consideration of alternative therapy, benefit to the class of patients, and benefits to society.	
14.	**PROCEDURES**	
A	What will be the duration of participants' active participation?	
B	Will participants be followed after their active participation ends? If yes, describe:	☐No ☐Yes
C	Discuss the number, duration, and nature of visits/encounters (attach flowchart if available).	

D	Procedures being performed solely for the purposes of the research study (i.e. extra blood work, pregnancy testing, questionnaires, etc.)	
E	Describe all procedures that will be performed to generate data for the research.	
15.	**INFORMED CONSENT**	
A	IDI REC may approve a consent document that does not include, or alters, some or all of the elements of informed consent. Provide justifications for the following questions for requesting a waiver of written informed consent.	
B	Are you requesting Waiver or Alteration of Informed Consent? If no, skip to G?	☐No ☐Yes
C	Why will a waiver of informed consent not adversely affect the rights and welfare of participants?	
D	Why is it impracticable to carry out the research without a waiver or alteration of informed consent?	
E	How will pertinent information be provided to the participants, if appropriate, at a later date? Attach your debriefing plan.	
F	Why does the proposed research present no more than minimal risk to the participants?	
G	Who will explain the study to the potential participant?	
	Is this person an Investigator or Sub-investigator? If No, include the Delegation of Authority Form	☐No ☐Yes

H	Describe your process to obtain informed consent.		
I	Attach your informed consent document(s) for IDI REC review. If there is/are Sponsor consent documents(s) include a reference copy and prepare the informed consent document by editing the Sponsor prepared forms to include the IDI REC's standard language.		See consent document template.
16.	**CONFIDENTIALITY**		
A	Are the hospital record number, or any identifier (other than study number & initials) being sent off site? If yes, describe and explain reasons.	☐No ☐ Yes	
B	Will any external entity other than the investigative staff have access or be provided to confidential medical or health related information about the participant.	☐ No ☐ Yes	
C	Describe provisions made to maintain confidentiality of data. Include: Who will have access to raw data?		
D	Will raw data be made available to anyone other than the PI and immediate study personnel (e.g., school officials, medical personnel)? If yes, describe the procedure for sharing data. Include, with whom it will be shared, how, and why.	☐No ☐Yes	

I certify that the information contained above is accurate. I agree to provide the IDI REC with the information it requires to conduct initial and continuing review of this study including serious or unexpected adverse events on a timely basis and that if the information is not provided, the IDI REC may suspend the study.

Principal Investigator's name _____

Signature _____

Date _____

25. FORM 3.1C IDI REC SUBMISSION CHECKLIST

Principal Investigator _____

Study _____

a. Complete IDI REC "Research Project Proposal Form" completely and affix appropriate signatures. One copy of the "Research Project Proposal Form" must be attached to each packet.

b. The Investigator's Agreement Form must be submitted. One copy should be attached to each packet.

c. Submit the required numbers of packet copies.

	Required submission items
☐	Completed and signed IDI REC Research Project Proposal Form
☐	Investigator's Agreement Form complete with required attachments
☐	Research protocol
☐	Informed consent document and checklist
☐	Proposed participant instructions
☐	Other supporting material (sample of proposed advertising, patient diaries, etc.)
☐	Investigator Brochure or insert /device description (Required for NDA/ FDA regulated products)
☐	Financial disclosure statement
☐	Copy of the grant with budget
☐	Case report form
☐	Questionnaires & assessment instruments
☐	Food and Drug Administration Form 1572 (IND) or signed Investigator Agreement (IDE)
☐	Documentation that the study has been reviewed and approved by other committees charged with oversight of research.

Comments:

_____

_____

Reviewed by_____

Signature _____

Date _____

26. FORM 3.1D ACKNOWLEDGEMENT/ REQUEST FOR ADDITONAL INFORMATION

Date:

To: (Principal Investigator)

(Address)

Dear _____

Re: Request for information: (IDI REC #) (Protocol #) (Protocol) (Amendments). Date dd/mm/yyyy

Via Fax:_____ Pages via email:_____

We have received your IDI REC submission for the above captioned study.

Your study is scheduled to be reviewed on_____.

Before we can schedule your study for review, we require the following additional material, information, or clarifications:

1)_____

2)_____

3)_____

4) _____

Please do not hesitate to contact me if you have any questions.

Thank you.

_____
(Sign here)
(Name)
IDI REC Administrator

27. FORM 3.1E INVESTIGATOR DELEGATION OF RESPONSIBILITY

I, _____, located at_____I am Principal

Investigator for Protocol # titled _____

I have ensured that the individuals listed below are properly qualified and have received appropriate training. Based upon this, I have delegated the following responsibilities to the individuals named below, and assert that these duties will be performed under my direct supervision.

(If a task is not delegated, write N/A "not applicable").

RESPONSIBILITY	**PERSONNEL**	**DATE**
Administration		
Contract negotiations		
Fiscal management		
Strategic planning		
Patient database		
Performance tracking		
Quality assurance		
PROJECT MANAGEMENT		
IDI REC submissions and communications		
Patient recruitment activities		
Sponsor, CRO contact		
Regulatory files creation and maintenance		
Data management/CRF completion		
Adverse event reports		
Organizational tools		
Office staff training		

Storing, dispensing, accounting for study drug		
Overall study drug accountability		
Storing study documents		
PARTICIPANT MANAGEMENT		
Screening participants for eligibility		
Obtaining informed consent		
Participant education		
Monitoring patient compliance		
Participant enrollment and follow-up		
Clinical assessments		
Adverse event determination		
Source documentation		
Appointment scheduling		

28. FORM 3.1F STUDY SUBMISSION - ADDITIONAL STUDY LOCATION

1. **Protocol Title:**
2. **Principal Investigator**

Address of the additional study location:

Phone:

Fax:

Email:

Will the Principal Investigator will be supervising at this location:

☐No ☐Yes

Contact name:

Phone:

Fax:

3. **Does this site have a REC?**

☐No ☐Yes If yes, name of the REC*

*The study must be approved by that REC or a written waiver of jurisdiction from the site's REC must be submitted.

4. The following Sub-investigator(s) will be working out of this location

Nature of facility of additional facility:

☐Private Practice

☐Clinic

☐Hospital*

☐Research Facility

☐Other [Specify] _____

***** Include letter from appropriate hospital official indication that study may take place at the facility.

Distance of emergency facility from study site:

Emergency equipment at study site:

Who will explain the study to participants and obtain consent at the site?

5. Participants/Demographics

Approximate percent of the area's population:___percentage

Will participants who do not understand English be enrolled at this location?

☐ No ☐Yes If yes, the consent form will be translated into (state the language):

6. Comments:_____
_____
_____

29. FORM 3.2A EXEMPTION SCREENING QUESTIONS

1. For research projects involving special populations, interventions or manipulations

Does your research involve pregnant women, fetuses, prisoners including individuals on probation, or individuals with impaired decision-making capacity? ☐Yes ☐No

For studies involving children, does your research involve surveys, interviews, questionnaires or the observation of children outside a normal classroom setting, or in settings where the Investigator(s) will participate in the activities being observed? ☐Yes ☐No

2. For research using survey procedures, interview procedures, observational procedures and questionnaires:

If data are to be recorded by audiotape or videotape is there potential harm to participants if the information is revealed or disclosed? (Videotaping requires consent and may not be exempt). ☐Yes ☐No

If the participants may be identifiable in the research project records either by name, picture or through demographic data, is there potential harm to participants if the information is revealed? That is: will data collection include sensitive information (e.g. illegal activities, or sensitive themes such as sexual orientation, sexual behavior, undesirable work behavior, or other data that may be painful or very embarrassing to reveal, such as death of a family member, memories of physical abuse, or finally will such sensitive information be requested about other individuals known to or related to the participant? ☐No ☐Yes

3. For research using <u>existing</u> or <u>archived</u> data, documents, records, or specimens only:

Will any data, documents, records, information or specimens be collected from participants after the submission of this application for exemption? ☐No ☐Yes

If the data, documents, records, or specimens are originally labeled in such a manner that participants can be identified, directly or indirectly through identifying links AND not publicly available, is the Investigator recording the data for this research project in such a manner that participants can be identified, directly or indirectly through the identifying links? (i.e., will the Investigator retain sufficient demographic information that might reasonably lead to the identification of individual participants – name, phone number, address **<u>or</u>** any code number that can be used to link the Investigator's data to the source record – medical record number, social security number, student record number, club membership number or employee number e.t.c.) ☐No ☐Yes

- If you answered *YES* to <u>any</u> of the above questions STOP and submit your study to the IDI REC for review using the IDI REC Research Proposal Form and the Investigator's Agreement Form
- If you answered NO to <u>all</u> the above questions continue to complete this Claim of Exemption packet and provide 11copies to the IDI REC Administrator. A signed copy will be returned to you for your records.

30. FORM 3.2B-CLAIM OF EXEMPTION

Project or Protocol Title:

Principal Investigator:

Phone:

Contact person

Phone:

Address:

Fax:

E-mail:

SPONSOR / FUNDING INFORMATION

Will this project/protocol be supported by an external funding agency?

☐No ☐Yes

List Sub-investigator/Co-investigators: None ☐

_____

_____

Faculty Sponsor (if applicable)

_____

LOCATION OF RESEARCH:

Where will the study take place? Include all locations for Study related activities here or on separate sheet.

Will the PI be conducting and/or supervising study related activity at any sites not under the jurisdiction of this REC? If yes, please provide name and address for each location AND documentation of approval to conduct research at these sites. Note: Additional REC approval may be required from these sites if an individual at this site, not an employee/student of this institution/organization, is performing research under this application.

☐Yes ☐No

EXEMPT CATEGORY CLAIMED

Identify all that apply to your research (check applicable boxes)

1. ☐Research conducted in established or commonly accepted educational settings, involving normal educational practices. This category may include children.
2. ☐Research involving the use of educational tests (cognitive, diagnostic, aptitude,

achievement) for which participants cannot be identified, or release of the information would not be harmful to the participant. This category may include children.

3. ☐Research involving the use of survey procedures or interview procedures or observation of public behavior for which participants cannot be identified, OR release of the information would not be harmful to the participant. This category may not include children. If participants are 18 years of age or younger parental consent is required. Research may be reviewed by expedited procedures – do not use this form!
4. ☐Survey or interview of public or elected officials. Testing of public officials.
5. ☐Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available OR if the information is recorded by the Investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
6. ☐Research and demonstration projects that are conducted by or participant to the approval of Federal Department or Agency heads, and which are designed to study or evaluate public benefits or services (e.g., evaluation of public benefits programs: Medicare, Public Assistance). This category may include children.
7. ☐ Taste and food quality evaluation and consumer acceptance studies. This category may include children.
8. ☐Unidentifiable human body parts, sections or samples obtained from a morgue

If your research involves only those procedures listed in one or more of the categories above, it may be exempt. Please provide a rationale for each exempt category claimed for this research.

RATIONALE FOR EXEMPT CATEGORY CLAIMED

The information **must** include a brief specific description of the procedure(s) involving the human participants in sufficient detail to demonstrate to the IDI REC reviewer that the research protocol meets the requirements for each category of exemption claimed in this human participants research protocol. The text should be approximately 300 words or less on separate sheets in sufficient detail to allow the reviewer to judge exemption criteria.

RATIONALE FOR EXEMPT CATEGORY # (s)

SYNOPSIS OF THE PROJECT OR PROTOCOL, INCLUDE:

1. The objective of the research project and background of study.
2. The rationale for the use of the selected participant population & plans for recruitment & consent.
3. The procedures that will be performed to generate research data & risks, if any, to participants.
4. Steps to be taken to protect the privacy and/or confidentiality of participants.

5. Include copy of questionnaires, surveys or brief outline of questions to be asked.

INVESTIGATOR'S ASSURANCE

I certify that the information provided in this claim of exemption is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human participants and the ethical conduct of this research protocol. I agree to comply with all IDI REC policies and procedures, as well as with all applicable national and local laws regarding the protection of human participants in research, including, but not limited to, the following:

- The project will be performed by qualified personnel according to the research protocol,
- Maintaining a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human participants for at least three years following termination of the project,
- Necessary review by the IDI REC will be sought if changes made in the research protocol may result in the research no longer meeting the criteria for exemption.

I will complete the required educational program on ethical principles and regulatory requirements in human participants' research in a timely manner.

I have read and understand the above policy concerning IDI REC exempt protocols.

_____ _____

Principal Investigator Date

FACULTY SPONSOR'S ASSURANCE (For student and fellow projects)

By my signature as Sponsor on this research application, I certify that the student or guest Investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition,

- I agree to meet with the Principal Investigator on a regular basis to monitor study progress.
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the Principal Investigator in solving them.
- I assure that the Principal Investigator will complete the required educational program on ethical principles and regulatory requirements in human participants' research in a timely manner.
- If I will be unavailable, as when on sabbatical, leave or vacation, I will arrange for an alternate Investigator to assume responsibility during my absence, and I will advise the

IDI REC by letter of such arrangements.

_____ _____

Faculty Sponsor* (if Principal Investigator is a student or fellow) Date

*The faculty Sponsor must be a member of the Institution's faculty. The faculty Sponsor is considered the responsible party for legal and ethical performance of the project.

INSTITUTION/ DEPARTMENT HEAD SIGNATURE (If Investigator is a staff)

As department head, I acknowledge that this research is in keeping with the standards set by our institution/ department and I assure that the Principal Investigator has met all institutional/ departmental requirements for review and approval of this research.

_____ _____

Institution/ Department/Unit Head Signature Date

_____

Typed/printed Name of Institution/ Department/Unit Head

31. FORM 3.2C CLAIM OF CHECKLIST FOR ADMINISTRATOR

1 For research projects involving special populations, interventions or manipulations

Does your research involve pregnant women, fetuses, prisoners including individuals on probation, or individuals with impaired decision-making capacity?☐ No ☐Yes

For studies involving children, does your research involve surveys, interviews, questionnaires or the observation of children outside a normal classroom setting, or in settings where the Investigator(s) will participate in the activities being observed? ☐No ☐Yes

2 For research using survey procedures, interview procedures, observational procedures and questionnaires:

If data are to be recorded by audiotape or videotape is there potential harm to participants if the information is revealed or disclosed? (Videotaping requires consent and may not be exempt). ☐No ☐Yes

If the participants may be identifiable in the research project records either by name, picture or through demographic data, is there potential harm to participants if the information is revealed? That is: will data collection include sensitive information (e.g. illegal activities, or sensitive themes such as sexual orientation, sexual behavior, undesirable work behavior, or other data that may be painful or very embarrassing to reveal, such as death of a family member, memories of physical abuse, or finally will such sensitive information be requested about other individuals known to or related to the participant? ☐No ☐ Yes

3 For research using <u>existing</u> or <u>archived</u> data, documents, records, or specimens only:

Will any data, documents, records, information or specimens be collected from participants after the submission of this application for exemption? ☐No ☐Yes

If the data, documents, records, or specimens are originally labeled in such a manner that participants can be identified, directly or indirectly through identifying links AND not publicly available, is the Investigator recording the data for this research project in such a manner that participants can be identified, directly or indirectly through the identifying links? (i.e., will the Investigator retain sufficient demographic information that might reasonably lead to the identification of individual participants – name, phone number, address **<u>or</u>** any code number that can be used to link the Investigator's data to the source record – medical record number, social security number, student record number, club membership number or employee number etc.) ☐No ☐ Yes

If the answer is *YES* to <u>any</u> of the above, the study is not exempt from IDI REC review.

Does this study appear to meet criteria for exemption from IDI REC review? ☐ No ☐Yes

Does the research fall into one or more of the following categories?

a. Research conducted in established or commonly accepted educational settings, involving normal educational practices. This category may include children. ☐No ☐ Yes

b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) for which participants cannot be identified, or release of the information would not be harmful to the participant. This category may include children. ☐No ☐ Yes

c. Research involving the use of survey procedures or interview procedures or observation of public behavior for which participants cannot be identified, OR release of the information would not be harmful to the participant. This category may not include children. If participants are 18 years of age or younger parental consent is required. Research may be reviewed by expedited procedures – do not use this form! ☐No ☐Yes

d. Survey or interview of public or elected officials. Testing of public officials. ☐No ☐Yes

e. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available OR if the information is recorded by the Investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.☐ No ☐ Yes

f. Research and demonstration projects that are conducted by or participant to the approval of a government Department, and which are designed to study or evaluate public benefits or services (e.g., evaluation of public benefits programs: Medicare, Public Assistance). This category may include children.☐ No ☐Yes

g. Taste and food quality evaluation and consumer acceptance studies. This category may include children. Unidentifiable human body parts, sections or samples obtained from a morgue. ☐No ☐Yes

THIS PROJECT MEETSEXEMPTION CRITERIA ☐ No ☐ Yes

_____ _____

Authorized Signature Date

32. FORM 3.3A - IDI REC AGENDA/ MINUTES TEMPLATE

Date and Time: Place:

Call to order Attendance	Time:

I. Pre-meeting business

Continuing education/ information updates Co-I query

II. Review of Minutes from previous meeting on[Date]

☐Accept as is

☐Accept with Revisions*

☐Revise & Resubmit*

☐*See minutes for revisions

III. Serious and Unexpected adverse events

Summary of SAEs received since_____Attached

Review of Expedited Reviews and administrative actions

IV. Items for IDI REC Review

A. New protocols

Title:

Sponsor/Funder:

Investigator:

Primary Reviewers:

Discussion:

Action Items:

Decision:

Vote: # Voting: # For: # Against: # Abstained: Name(s)

B. Continuing Review

Renewal Requests #

Title:

Expiration date:

Sponsor/Funder:

Investigator:

Primary Reviewers:

Discussion:

Action Items:

Decision:

Vote: # Voting: # For: # Against: # Abstained: Name(s):

C. Lapsed with Incomplete Information / Suspended #

Title:

Expiration date:

Sponsor/Funder:

Investigator:

Primary Reviewers:

Discussion:

Action Items:

D. Other Business

E. Adjournment Time:

Next Meeting:

Respectfully submitted,

_____

IDI REC Chairperson/Designee

33. FORM 3.3B- REPORT OF IDI REC ACTIVITIES SINCE THE LAST MEETING

Period of activities from: _____/____/____ to: _____/____/____

I. EXPEDITED REVIEWS

A New protocols

Title:

Investigator:

Decision:

B Renewals

Title:

Investigator:

Decision:

C Action Items From Previous Meetings

Date of Meeting:

Action Required:

Summary of Action:

Outcome:

D Amendments

Title:

Investigator:

Decision:

E Waiver ofAuthorization

Title:

Investigator:

Decision:

_____/_____/_____

II. SERIOUS AND UNEXPECTED ADVERSE EVENTS

A IDI REC # Onset: Resolved? ☐No ☐ Yes

Study article: Summary:

Relationship to study article / study procedures ☐Related ☐ possibly related ☐not related

III. OTHER ACTIVITIES

A Site visits

Date of Visit:

_____/___/___

Action required:

Summary of action:

34. FORM 3.4A DISTRIBUTION CHECKLIST

Meeting Date: ____/___/___

Member: Attach current list

Member Address: Attach current list

☐Agenda

☐Draft Minutes

☐Report of IDI REC Activities

☐Instructional/Educational Items

☐Review Sheets

☐Primary Review

Packet for the following studies

Study number: Primary and secondary reviewers

1

2

3

4

5

Packets sent: Via:

By:

35. FORM 3.5A STUDY FOLDER CONTENT CHECKLIST

TITLE OF DOCUMENT	YES	NO	N/A
INVESTIGATOR BROCHURE	☐	☐	☐
SIGNED PROTOCOL, AMENDMENTS, IF ANY,	☐	☐	☐
INFO. GIVEN TO TRIAL PARTICIPANT			
INFORMED CONSENT FORM	☐	☐	☐
ANY OTHER WRITTEN INFORMATION	☐	☐	☐
ADVERTISEMENT FOR PARTICIPANT RECRUITMENT	☐	☐	☐
SIGNED AGREEMENT BETWEEN INVOLVED PARTIES	☐	☐	☐
DATED, DOCUMENTED APPROVAL/ FAVORABLE OPINION OF IDI REC OF THE FOLLOWING:			
Protocol and any amendments	☐	☐	☐
CRF (if applicable)	☐	☐	☐
Informed Consent Form(s)	☐	☐	☐
Any written information to be provided to the participant(s)	☐	☐	☐
Advertisement for participant recruitment (if used)	☐	☐	☐
Participant compensation (if any)	☐	☐	☐
Any other documents given approval/ favorable opinion	☐	☐	☐
INVESTIGATOR BROCHURE/PRODUCT DESCRIPTION UPDATES			
ANY REVISION TO:			

- Protocol/amendment(s) and CRF	☐	☐	☐
- Informed Consent Form	☐	☐	☐
- Any written information provided to participants	☐	☐	☐
- Advertisement for participant recruitment (if used)	☐	☐	☐
SIGNED INFORMED CONSENT FORMS	☐	☐	☐
NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, IF NEEDED, TO REGULATORY AUTHORITY(IES) AND IDI REC OF UNEXPECTED SERIOUS ADVERSE REACTIONS AND OF OTHER SAFETY INFORMATION			
NOTIFICATION BY SPONSOR TO INVESTIGATORS OF SAFETY INFORMATION	☐	☐	☐
PERIODIC REPORTS TO IDI REC	☐	☐	☐
COMPLETION REPORT BY INVESTIGATOR TO IDI REC	☐	☐	☐

36. FORM 3.5B- ARCHIVING PROCEDURE CHECKLIST

IDI REC number:

IDI REC APPROVED STUDIES IDI REC records must be retained for at least 5 years, and records relating to research, which is conducted retained for at least 5 years after completion of the research. IDI REC considers the research concluded only after all data has been analyzed.

Date Completion Report filed _____

Date IDI REC File can be closed _____

All research (whether Govt. or privately funded)

A copy of all documentation reviewed is to be maintained for at least 5 years after completion of the research at that institution

Date Completion Report filed _____

Date IDI REC File can be closed _____

File Destruction Date _____

Waiver of Authorization A copy of all documentation reviewed is to be Maintained for at least 7 years after approval of waiver.

Date Completion Report filed _____

File Destruction Date _____

37. FORM 4.1A DETERMINATION OF QUALIFICATION FOR EXPEDITED REVIEW

Before determining whether or not the study meets the Criteria for Expedited Review, the reviewer must have completed the Primary Reviewer Worksheet (Form 402A)

MINIMAL RISK DETERMINATION	Yes	No	N/A
The probability and magnitude of harm or discomfort anticipated in the proposed research greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.			
Could identification of the participants and/or their responses reasonably place them at risk of criminal or civil liability			
Or be damaging to the participants' financial standing, employability, insurability, reputation,			
Or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.			
Or Is the research classified?			

MINIMAL RISK DETERMINATION	Yes	No	N/A
DETERMINATION OF QUALIFICATION FOR EXPEDITED REVIEW			
Allowed procedures			
Clinical studies of drugs and medical devices *only* when condition a) or b) is met			
Research on drugs for which an investigational new drug application is not required. (Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)			
Research on medical devices for which			
an investigational device exemption application (21 CFR part 812) is not required; **or**			
the medical device is cleared/ approved for marketing and is being used in accordance with its cleared/approved labelling.			
Collection of blood samples by finger stick, heel stick, ear stick, or venepuncture as follows: From healthy, non-pregnant adults who weigh at least 110 pounds, the amounts drawn do not exceed 550 ml in an 8 week period and collection does not occur more frequently than 2 times per week; **or**			
From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected.			
The amount drawn does not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period **and**			
Collection does not occur more frequently than 2 times per week.			

MINIMAL RISK DETERMINATION	Yes	No	N/A
Prospective collection of biological specimens for research purposes by non-invasive means.			
Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.			
Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).			
Collection of data from voice, video, digital, or image recordings made for research purposes.			
Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.			
Continuing review of research previously approved by the convened IDI REC as follows:			
the research is permanently closed to the enrolment of new participants; **and** all participants have completed all research-related interventions; **and** the research remains active only for long-term follow-up of participants; **or**			
Where no participants have been enrolled and no additional risks have been identified; **or** Where the remaining research activities are limited to data analysis			
Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 do not apply but the IDI			

MINIMAL RISK DETERMINATION	Yes	No	N/A
REC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.			

Comments

_____

_____

Does this study meet expedited review criteria? ☐ No ☐Yes

_____ _____

IDI REC Administrator Date

_____ _____

IDI REC Reviewer Date

38. FORM 4.1B GUIDANCE - EXPEDITED REVIEW

Categories of Research That May Be Reviewed by the IDI REC through an Expedited Review Procedure1

Applicability

A. Research activities that

   i. Present no more than minimal risk to human participants, and

   ii. Involve only procedures listed in one or more of the following categories, may be reviewed by the REC through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

B. The categories in this list apply regardless of the age of participants, except as noted.

C. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human participants.

E. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the REC.

F. Categories one (1) through seven (7) pertain to both initial and continuing IDI REC review.

Research Categories

A. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   i. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   ii. Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labelling.

B. Collection of blood samples by finger stick, heel stick, ear stick, or venepuncture as follows:

   i. From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   ii. From other adults and children[2], considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

C. Prospective collection of biological specimens for research purposes by non-invasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) un cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labour; (h) supra- and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

D. Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

E. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

F. Collection of data from voice, video, digital, or image recordings made for research purposes.

G. Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

H. Continuing review of research previously approved by the convened REC as follows:

i. Where (a) the research is permanently closed to the enrolment of new participants; (b) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or

ii. Where no participants have been enrolled and no additional risks have been identified; or

iii. Where the remaining research activities are limited to data analysis.

I. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories B through H do not apply but the REC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

[1] An expedited review procedure consists of a review of research involving human participants by the IDI REC chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IDI REC.

[2] Children are defined as "persons who have not attained the legal age for consent to procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

39. FORM 4.1C EXPEDITED REVIEW – REVIEWER MATERIALS CHECKLIST

Date:

IDI REC Member:

Attach current list Member

Address:

Attach current list

☐Primary Reviewer Worksheet

☐Informed Consent Checklist

☐Form 4.1A: Determination of Qualification for Expedited Review

☐Form 4.1D: Expedited Review Determination

☐Form 5.2A: Risk Determination – Devices (if submitted as an NSR study)

☐If being reviewed off-site, copies of submission material

☐If being sent on-site, originals of submission material

_____

Signature

40. FORM 4.1D- EXPEDITED REVIEW DETERMINATION

Study:_____ IDI REC _____

☐New Protocol & Informed Consent (See Form 4.1A Determination of Qualification for Expedited Review).

Protocol is:	Approved ☐	Conditionally Approved ☐	Not Approved ☐*
Informed Consent is:	Approved ☐	Conditionally Approved ☐	Not Approved ☐

Comments

_____

_____

☐Amendment: Minor changes in approved research during approval period

☐Revised Informed Consent Document: Substantive changes require IDI REC review.

Amendment is:	Approved ☐	Conditionally Approved ☐	Not Approved ☐
Informed Consent is:	Approved ☐	Conditionally Approved ☐	Not Approved ☐ N/A ☐

Comments

_____

_____

☐Advertisement ☐other material

Recommendation	Approved ☐	Conditionally ☐	Approved	Not Approved ☐

Comments

Recommendation:	Approved ☐	Conditionally Approved ☐	Not Approved ☐

Comments

_____

Primary Reviewer (print) Date

_____

Signature

* Requires review by the full IDI REC meeting

41. FORM 4.2A PROTOCOL REVIEW WORKSHEET: PRIMARY

Study Title:

IDI REC Tracking #:

Type of Study: Drug ☐ Device ☐(requires risk determination) other ☐

Principal

Investigator: _____ **To Attend Meeting?** ☐No ☐ Yes

Criteria for Approval

1. Risks to participants are minimized

☐Research procedures are consistent with sound research design

☐Research procedures do not unnecessarily expose participants to risk

☐Researcher is qualified to conduct study

☐Routine or standard procedures to be performed on participants for the purposes of the study whenever possible

☐The research plan makes adequate provision for monitoring the data to ensure the safety of participants

Comments on Part 1:

2. Risks to participants are reasonable in relation to anticipated benefits (if any), and the importance of the knowledge that may be expected to result

☐Purpose of study is clear and acceptable

☐Results of any related studies are included

☐Number of participants and duration of participation is stated and appropriate

☐Duration of the study is clear and appropriate

☐Compensation paid to participants is appropriate

Is there a washout period?☐No ☐Yes

☐If so, is it appropriate, and are safeguards in place to assure participant will be adequately monitored?

Is there a placebo / no treatment control?☐No ☐ Yes

☐If yes, is use of placebo appropriate and does not put participants at risk?

Comments on Part 2:

3. Selection of participants is equitable

☐Justification for use of vulnerable groups provided

☐Additional safeguards have been included in the study to protect the rights and welfare of these groups

☐Presence of any special community attitudes that may affect participant participation has been addressed where applicable

☐Selection of participants reflects purposes of the research and group that will benefit from research outcome

Comments on Part 3:

_____

4. Legally effective informed consent is obtained

☐Informed Consent will be sought from each participant

☐Informed Consent procedures and documentation appear to be appropriate

Does the protocol call for waiver of informed consent? ☐No ☐Yes

If yes, is waiver appropriate? ☐No ☐Yes

5. There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data

Comments on Part 4 to 5

6. Review of Required Protocol Elements

Note: Protocols for Phase 1 studies may be less detailed than for Phase 2 and 3 studies

Required Protocol Elements Present?

Statement of objectives and purpose of the study ☐No☐ Yes

Name, address, and statement of qualification (e.g., CV) of each Investigator

and Sub-investigator☐No ☐ Yes

Name and address of each research facility to be used ☐ No ☐Yes

Name and address of each REC to be used ☐No ☐Yes

Patient selection criteria, exclusion criteria and estimated number to be studied

☐No ☐Yes

Summary of study design, including control(s) and steps to reduce bias risks ☐No ☐Yes

For drug studies, methods to determine dosing, expected maximum dosage, and

duration of exposure to drug ☐No ☐Yes

Observations and measurements to be made during the study ☐No ☐Yes

Clinical procedures, laboratory tests and other measures to be taken to monitor

the test article's effects and minimize risks to participants ☐No ☐Yes

Summary of data analysis and statistical methods to be used ☐No ☐Yes

Comments on Part 6:

7. Criteria For Review Schedule

Studies that are considered high risk will generally be reviewed at least semi-annually.

Studies may be reviewed semi-annually if the REC believes that the study population is especially vulnerable.

Studies may be reviewed more frequently if the REC believes that previous studies indicate high incidence of adverse events.

Studies may be reviewed more frequently if the REC believes close monitoring is indicated.

If the IDI REC determines that a study that had been approved for an annual review requires closer monitoring, the IDI REC may make a determination to review that study on a more frequent basis. The reasons for such a determination will be included in the minutes and communicated to the Investigator.

8. Risk Assessment:

This study is ☐Low Risk ☐Moderate Risk ☐High Risk

Do you believe the monitoring plan described is adequate for the risk? ☐No ☐Yes

Do you believe that this study needs verification from sources other than the Investigator that no material changes have occurred? ☐No ☐Yes

Do you believe that this study requires full IDI REC review more often than annually?

☐No ☐Yes

Is an interim report required? If yes, how often? ☐No ☐Yes in ☐3 months ☐in 6 months ☐other [Specify] _____

_____ _____

Primary Reviewer (print) Date

_____

Signature

42. FORM 4.2B PROTOCOL REVIEW WORKSHEET (SOCIAL): PRIMARY

Study Title:

IDI REC #:

Principal Investigator: _____

To Attend Meeting? ☐No ☐Yes

Criteria for Approval

1. Risks to participants are minimized.

☐Research procedures are consistent with sound research design

☐Research procedures do not unnecessarily expose participants to risk

☐Researcher is qualified to conduct study

☐Routine or standard procedures to be performed on participants for the purposes of the study whenever possible

☐The research plan makes adequate provision for monitoring the data to ensure the safety of participants

Comments on Part 1:

2. Risks to participants are reasonable in relation to anticipated benefits (if any), and the importance of the knowledge that may be expected to result

☐Purpose of study is clear and acceptable

☐Results of any related studies are included

☐Number of participants and duration of participation/follow-up is stated and appropriate

☐Duration of the study is clear and appropriate

☐Compensation paid to participants is appropriate

☐Is there a control group? ☐No ☐Yes

☐If yes, use of controls is appropriate and does not place any participants at risk

Comments on Part 2:

3. Selection of participants is equitable

☐Justification for use of vulnerable groups provided

☐Additional safeguards have been included in the study to protect the rights and welfare of these groups

☐Presence of community attitudes that may affect participant participation has been addressed where applicable

☐Selection of participants reflects purposes of the research and group(s) that will benefit from research outcome

Comments on Part 3:

4. Legally effective informed consent is obtained

Informed Consent will be sought from each participant ☐No ☐Yes

Informed Consent procedures and documentation appear to be appropriate ☐No ☐Yes

Does the protocol call for waiver of any elements of informed consent? ☐No ☐Yes

If yes, is waiver appropriate, that is: ☐No ☐Yes

a. The research involves no more than minimal risk to the participants.
b. The waiver or alteration will not adversely affect the rights and welfare of the participants.
c. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Is a debriefing form provided? ☐No ☐Yes

Comments on Part 4:

5. There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data described in protocol? ☐No ☐Yes

Comments/recommendations on Part 5:

6. Review of Required Protocol Elements

Required Protocol Elements Present?

Statement of objectives and purpose of the study ☐No ☐Yes

Name, address, and statement of qualification of each Investigator and Sub- investigator

☐No ☐Yes

Name and address of each facility where research will be performed by Investigator

☐No ☐ Yes

Name and address of each facility where research will be performed by other, non-Institution/Organization employees ☐ No ☐Yes

Name and address of each REC to be used (if research sites above have RECs) ☐ No ☐Yes Patient selection criteria, exclusion criteria and estimated number to be studied ☐ No ☐ Yes Summary of study design, including control(s) and steps to reduce risk of bias ☐No ☐Yes Observations and measurements to be made during the study described ☐No ☐Yes

Measures to be taken to monitor the research effects and minimize risks to participants

☐No ☐Yes

Summary of data analysis and statistical methods to be used ☐No ☐Yes

Comments on Part 6

7. Review of the Informed Consent Document (use Form 7.1A and attach)

Comments on Part 7:

8. Criteria for Review Schedule

Is the study population is especially vulnerable? ☐No ☐Yes

Is the information being obtained especially sensitive? ☐No ☐Yes

Risk Assessment:

This study is ☐Minimal Risk ☐Low Risk ☐Moderate Risk ☐High Risk

Do you believe that this study needs verification from sources other than the Investigator that no material changes have occurred? ☐No ☐Yes

Is an interim report required? If yes, how often? ☐No ☐Yes in ☐3 months ☐in 6 months☐Other [Specify]

For how long should the REC approve this study?

☐1-year ☐6 months ☐ 3 months☐ other

Reviewer (print)	Date
Signature	

43. FORM 4.2C PROTOCOL REVIEW WORKSHEET: REGULAR REVIEWER

Study Title:

IDI REC Tracking #

Principal Investigator:

Criteria for Approval

1. Risks to participants are minimized

☐Research procedures are consistent with sound research design

☐Research procedures do not unnecessarily expose participants to risk

☐Researcher is qualified to conduct study

☐Routine or standard procedures to be performed on participants for the purposes of the study whenever possible

☐The research plan makes adequate provision for monitoring the data to ensure the safety of participants

Comments on Part 1:

2. Risks to participants are reasonable in relation to anticipated benefits (if any), and the importance of the knowledge that may be expected to result

☐Purpose of study is clear and acceptable

☐Results of any related studies are included

☐Number of participants and duration of participation is stated and appropriate

☐Duration of the study is clear and appropriate

☐Compensation paid to participants is appropriate

Is there a washout period? If yes, ☐No ☐Yes

Is it appropriate ☐No ☐Yes

Are there safeguards to assure participant will be adequately monitored?

☐No ☐Yes

Is there a placebo / no treatment control? If yes, ☐No ☐Yes

Is use of placebo appropriate and does not put participants at risk? ☐No ☐Yes

Comments on Part 2:

3. Selection of participants is equitable

☐Justification for use of vulnerable groups provided.

☐Additional safeguards have been included in the study to protect the rights and welfare of these groups.

☐Presence of any special community attitudes that may affect participant participation has been addressed where applicable.

☐Selection of participants reflects purposes of the research and group that will benefit from research outcome.

Comments on Part 3:

4. Legally effective informed consent is obtained

☐Informed Consent will be sought from each participant

☐Informed Consent procedures and documentation appear to be appropriate

Does the protocol call for waiver of informed consent?☐No ☐Yes

If yes, is waiver appropriate? ☐ No ☐Yes

5. There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data

Comments on Part 4 to 5:

Reviewer (print) Date

Signature

44. FORM 4.3A SITE VISIT CONFIRMATION LETTER

INFECTIOUS DISEASES INSTITUTE RESEARCH ETHICS COMITTEE

P.O. Box 22418, KAMPALA, UGANDA

Date [Today's date]

To: (Principal Investigator)

(Address)

Dear _____

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments). Date (today's date)

This letter is to confirm our appointment for___/_____/_____at_____o'clock.

The purpose of our visit is to review the documents for the above captioned study and to tour your site in order to assure that the requirements for the conduct of the study in regard to the protection of human participants are being adequately met.

In order to conduct our review of your site, I will need the following material:

- The informed consent documents for each participant
- Source documents (if needed)
- Regulatory binder

Generally, my review takes about an hour; but I will need very little of your time, about 20 minutes is usually adequate. If I have additional questions, we can take care of them over the phone or via e- mail.

Please do not hesitate to give me a call if you have any questions regarding my visit.

Sincerely,

_____

[Name]

[Tel/Email]

45. FORM 4.3B: SITE VISIT WORKSHEET

Investigator:

Contact:

Protocol title:

1. Status:

☐Active ☐Completed ☐Terminated ☐Other

2. Patient Population:

Population from which participants are selected:

Who selects participants for the study?

How are participants identified for the study?

Males: # Females: # Enrolled:

Age Range: Race and Ethnicity:

Are there any vulnerable participants enrolled? If so, describe safeguards?☐No ☐Yes

Are participants currently being enrolled?☐No ☐Yes

3. Informed Consent:

Who explains the study to potential participants?

Is everyone who is explaining the study, qualified? If no, comment. ☐No ☐Yes

Is correct Informed Consent Form (ICF) being used? If no, comment. ☐No ☐ Yes

Informed Consent properly documented? If no, comment.☐No ☐Yes

When Is Informed Consent obtained?

Has each participant been given a copy of the consent form? If no, comment.☐No ☐Yes

Is there any advertising?☐No ☐ Yes

If yes, has it been approved by the IDI REC?☐No ☐ Yes

4. Patient Safety:

Were reportable SAE's reported appropriately? If no, comment. ☐ No ☐Yes

Has the study been recently monitored /audited? (If yes, attach available report).

☐No ☐ Yes

5. Administrative:

Have all amendments been submitted to the IDI REC?☐No ☐Yes

Are records kept confidential?☐No ☐ Yes

Who has access to research records?

Where are research records stored and in what format?

6. Reviewer Comments:

Do research staff members need additional training in any aspect of conducting clinical trials? ☐No ☐Yes

Do you feel that there is a need for additional monitoring? ☐ No ☐Yes

COMMENTS:

_____

Contact at Site

_____ _____

Reviewer Date of Visit

46. FORM 4.3C SITE VISIT REPORT

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418 KAMPALA

Date (today's date)

To: (Principal Investigator)

(Address)

Dear _____

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

Date of Visit:

Reviewer:

Thank you for your cooperation and please extend our appreciation to members of your staff for their assistance during this site visit. If you have any questions about this report, please do not hesitate to call.

Review Criteria: The following criteria are evaluated during site visits:

- Participant selection - assure that participant selection is equitable; if applicable, assure that additional safeguards to protect vulnerable participants are being met, as defined by the IDI REC in its approval letter.
- Process of obtaining informed consent - assure that informed consent is obtained and documented as required by the IDI REC Policies and national guidelines.
- Patient safety - document facilities available in the event of an emergency; assure appropriate reporting of adverse events as required in the IDI REC approval letter.
- Record keeping - assure protection of participant confidentiality; assure documentation of informed consent

Site Visit Findings:

Number of Participants Enrolled:

Number of Records Reviewed:

Correct Informed Consent in Use:

Informed consent is being taken and documented appropriately.

Adverse Events Reported to IDI REC?

Findings:

Response Required of Investigator to Address Identified Deficiencies:

Reviewer Date

47. FORM 4.3D SERIOUS ADVERSE EVENT REPORT

INVESTIGATOR

PROTOCOL NUMBER

ADDRESS

PHONE:

E-mail

PARTICIPANT: BIRTH DATE_/_____/_____

ARTICLE BEING STUDIED

INITIALS

SEX ☐ F ☐ M

ONSET DATE_/_____/ _____

ARTICLE PARTICIPANT RECEIVED (if un-blinded)

ROUTE OF ADMINISTRATION

ADMINISTERED: FROM _____/_____/_____TO_____/_____/_____

EVENT RESULTED IN:

48. FORM 4.3E ADVERSE EVENT REPORT REVIEW FORM

IDI REC TRACKING#

☐Sponsor Report ☐ Investigator Report ☐ Follow-Up Report

Test Article:

Investigator:

Participant Initials: _____

Age:_____

Sex: ☐ Male ☐ Female

Summary of Event(s):

AE Code:	Onset: Date and time	**DESCRIPTION**

Further Action Required? ☐ **No** ☐ **Yes**

IF YES:

☐Full IDI REC Review ☐ Notify Participants of Risk ☐ Amend Protocol

☐Letter ☐Addendum to ICF ☐ Other

_____ _____

Signature of Chair or Designee Date

Instructions for Acknowledgement:

☐Investigator Acknowledgement ☐ Sponsor Acknowledgement

☐Other Instructions:

☐**ACKNOWLEDGED**

49. FORM 4.3F SIGNIFICANT NEW FINDINGS REVIEW

IDI REC # **Date Received**

PROTOCOL TITLE AND NUMBER

Address:

Principal Investigator:

Contact person: Phone:

Address: Fax:

E-mail:

☐Investigator Brochure ☐ Letter from Sponsor ☐Other

Reviewer Determination: ☐ Full IDI REC Review

☐ Notify Participants of Risk

☐ Addendum to Informed Consent Form

☐ Letter

☐ Amend Protocol

☐ No Action Required

☐Other

_____ _____

Primary Reviewer Date

50. FORM 403G AMENDMENT SUBMISSION FORM

Changes to research may not be initiated prior to IDI REC approval except as necessary to eliminate apparent immediate hazard to participants; therefore, amendments must be approved by the IDI REC prior to implementation.

IDI REC # **Date Received**

PROTOCOL TITLE AND NUMBER

Address:

Principal Investigator:

Contact person Phone:

Address: Fax:

E-mail:

Brief description of modification(s): (attached ☐)

(continue on second page, if necessary)

Consent form revisions? ☐ No ☐ Yes

If yes, attach_____copies of the revised consent **with changes track-changed on original and all copies Protocol amendment?**

☐No ☐ Yes

If yes, attach_____copies of the revised protocol **with changes track-changed on original and all copies**

Investigator Brochure amended? ☐ No ☐Yes

If yes, attach revised Investigator Brochure

Should enrolled study participants be informed of these changes? ☐ No ☐Yes

Report prepared by _____ Date _____

For IDI REC Use:

☐Minor modifications acceptable for expedited review (changes are minor, administrative changes, and/or they do not make the protocol more complex or risky)

☐Major modifications that require full IDI REC review (changes potentially increase risk or make the study more complex)

51. FORM 4.4A CONTINUING REVIEW REPORT/RENEWAL REQUEST

(This report should be no more than 4 pages)

1. Protocol Title: _____

2. Protocol version and date: _____

3. Expiry date of current approval: _____

4. Period covered by this report: _____ **(provide dates)**

5. BRIEF OUTLINE OF THE RATIONALE FOR THE STUDY

Provide an outline of the rationale, methods of study, and general plan of investigation as described in the currently approved version of the proposal.

6. RESEARCH OBJECTIVES:

State the objectives of the research

7. NUMBER OF PARTICIPANTS ENROLLED:

State the number of participants that was originally approved, how many have been enrolled into the study, and how many withdrawn/terminated. If any participants

withdrew/were withdrawn, state how many and why.

Also, if modifications have been approved increasing the sample size, please state this and provide dates of approval.

Category	Total Number this Reporting Period	Cumulative Total
Number of Participants approved to enroll:		
Number Enrolled:		
Number Lost (deaths, other) and reason for each: **Deaths**		
Number Withdrawn by Investigator and reason for withdrawal(s) of each:		
Number Withdrawn (drop outs – participant withdrew him/herself) and reason for withdrawal(s) for each:		
Number of Active Participants:		
Number completed all study activities:		

8. CURRENT LITERATURE:

If there have been any publications, provide a brief summary and any relevance it may have to your research. If there has been no literature, include a statement indicating that a search of the literature revealed no new information of this participant matter.

9. SUMMARY OF ADVERSE EVENTS/ SIDE EFFECTS:

Give a brief description of all the side effects observed and their severity. Did any adverse effects occur, and were they expected or unexpected? If any unexpected side effects occurred, state what they are, whether they were reported as required, and if a protocol modification has been/will be submitted to add the side effects to the consent form for future participants.

10. SUMMARY OF RESULTS TO DATE:

In 1-2 paragraphs provide an account results that have accrued from the study. If there have been no results, indicate so. If any deviations from the protocol occurred, indicate so. A copy of the original report describing the deviation from the protocol should be attached

11. FUTURE PLANS/ ACTIVITIES:

What activities are planned for the protocol during the coming year? Continued collection of data? Analysis of data? Completion of the protocol? Submission of a modification to the current protocol to expand on results? Any proposed modifications should be mentioned, but the request to modify the protocol should be submitted separately for approval.

12. DECLARATION & SIGNTURE:

By signing this form, the Principal Investigator certifies that he/she has disclosed to the IDI REC all relevant information concerning adverse events or other issues that might affect the risk-to-benefit analysis of this study.

Signature of PI:_____ **Date:** _____

52. FORM 4.4B CONTINUING REVIEW WORKSHEET

☐Reporting study progress

☐Requesting project renewal

INVESTIGATOR: **IDI REC #:**

STUDY TITLE

Study Status:

☐Open to accrual ☐ Ongoing/Closed to accrual - Total # of Participants Enrolled ___

CRITERIA FOR CONTINUED APPROVAL

1. Risks to participants are minimized

☐ Research procedures have not unnecessarily exposed participants to risk.

☐ The study has been monitored appropriately.

Comments on Part 1:

2. Risks to participants are still reasonable in relation to anticipated benefits (if

any), and the importance of the knowledge that may be expected to result.

Have there been any unanticipated problems involving risks to participants or others?

☐No ☐ Yes ☐N/A

Have participants withdrawn from the research due to adverse experiences?

☐No ☐ Yes ☐N/A

Have there been complaints about the research from any source?

☐No ☐ Yes ☐NA

Findings obtained thus far are included.

☐No ☐ Yes ☐NA

A summary of any recent literature is included.

☐No ☐ Yes ☐NA

Findings of related studies are included (i.e., reports on multi-center trials and any other relevant information, especially information about risks associated with the research) are included.

☐No ☐ Yes ☐NA

Amendments or modifications to the research have been sent to the IDI REC for review as required.

☐No ☐ Yes ☐NA

There does not appear to have been an increase in risk since the last review

☐No ☐ Yes ☐NA

Comments on Part 2:

3. Selection of participants is equitable

Does the selection of participants still appear to be equitable?

☐ No ☐ Yes

Are additional safeguards needed to protect vulnerable groups?

☐ No ☐ Yes

Comments on Part 3:

4. Legally effective informed consent is obtained

A copy of the current informed consent document is included

☐ No ☐ Yes

Informed Consent procedures and documentation appear to be appropriate

☐ No ☐ Yes

5. There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, and there have been no breaches to the degree of confidentiality described in the consent form.

Comments:

6. Recommendations

Do you believe that this study needs verification from sources other than the Investigator that no material changes have occurred?

☐ No ☐ Yes

Do you believe that this study requires full IDI REC review more often than annually?

☐ No ☐ Yes

Is any additional information needed from the Investigator to complete review of this study?

☐ No ☐ Yes

If yes, describe

Are any actions required of the Investigator as a result of this review?

☐ No ☐ Yes

Should this study be renewed? If No, explain:

☐ No ☐ Yes

Risk Assessment: ☐ Low Risk ☐ Moderate Risk ☐ High Risk

When should the next review occur?

☐ in 3 months ☐ in 6 months ☐ Annually ☐ Other

Primary Reviewer (~~print~~) _____ Date~~_____~~

CRITERIA FOR REVIEW SCHEDULE

- Studies may be reviewed more frequently than annually if the IDI REC believes that the study population is especially vulnerable.
- Studies may be reviewed more frequently if the IDI REC believes that previous studies indicate high incidence of adverse events.
- Studies may be reviewed more frequently if the IDI REC believes close monitoring is indicated.
- If the IDI REC determines that a study that had been approved for an annual review requires closer monitoring, the IDI REC may make a determination to review that study on a more frequent basis. The reasons for such a determination will be included in the minutes and communicated to the Investigator.

53. FORM 5.1A CHECKLIST – REQUIREMENTS FOR RESEARCH INVOLVING PRISONERS

INVESTIGATOR: **IDI REC #**

STUDY TITLE

		Yes	**No**	**N/A**	**Comments**
1	Does the research have the intent, and reasonable probability, of improving the health and wellbeing of the participants themselves? OR	☐	☐	☐	If the answer to one or both of these
2	If the research does NOT have the intent, and reasonable probability, of improving the health and wellbeing of the participants themselves, is the research on conditions particularly affecting prisoners as a class (e.g., vaccine trials on hepatitis)	☐	☐	☐	Questions is yes, continue. If the answer to both questions is NO, the study cannot be approved.
2a	Has the Secretary, HHS, or designee published notice in the Federal Register of its intent to approve such research?	☐	☐	☐	
3	Is there a control group?	☐	☐	☐	If the answer to question 2 is yes, the answer to this
3a	Are control participants selected randomly from the	☐	☐	☐	

	group of eligible prisoners for the research project?				question must be YES as well.
3b	If not, has the Investigator provided justification in writing for? following some other procedures,	☐	☐	☐	If the answer to ques. 3 is yes, the answer to either ques. 3a or 3b must be YES.
4	Any possible advantages accruing to the prisoner through participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that the prisoner's ability to weigh the risks and benefits of the research in the limited-choice environment of the prison is impaired.	☐	☐	☐	
5	The probability and magnitude of **physical or psychological** harm is no more than what is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of **healthy persons**. The risks involved in the research are commensurate with risks that would be accepted by non-prison volunteers.	☐	☐	☐	
6	Selection procedures within the prison are fair to all prisoners and immune from arbitrary intervention by prison authority or prisoners.	☐	☐	☐	
7	Any information given to participants is presented in language that is appropriate for the participant population.	☐	☐	☐	
8	Adequate assurance exists that parole board(s) will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the clinical investigation will have no effect on his/her parole.	☐	☐	☐	
9	Where there is need for follow-up examination or care of participants after the end of their participation in the research, adequate provision has been made for such examination or care, taking into account the varying	☐	☐	☐	

	lengths of prisoner sentences, and for informing participants of this fact.				

The proposed research appears to be:

- ☐ (A) A study of the possible causes, effects, and processes of incarceration, and of criminal behavior that presents no more than minimal risk and no more than inconvenience to the participants,
- ☐ (B) A study of prisons as institutional structures or of prisoners as incarcerated persons, that presents no more than minimal risk and no more than inconvenience to the participants;
- ☐ (C) A study of a condition or conditions particularly affecting prisoners as a class
- ☐ (D) A study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.

COMMENTS:

Primary Reviewer _____ Date _____

54. FORM 5.1B CHECKLIST – REQUIREMENTS FOR RESEARCH INVOLVING CHILDREN

INVESTIGATOR:

IDI REC #

STUDY TITLE

CATEGORY OF RISK DETERMINATION	**BENEFIT ASSESSMENT**	**IDI REC ACTION**
I. Minimal (i)	**With or without direct benefit**	☐ **Approvable**
Document IDI REC discussion and rationale for determination of Minimal Risk category: *(Attach to Minutes and include additional sheets as needed)	Document IDI REC discussion about assessment of risk/benefit to child:	Comments:
II. Greater than Minimal Risk	**Potential benefit to child**	☐ **Approvable**
*Document IDI REC discussion and rationale for determination of Greater than Minimal Risk category:	Document IDI REC discussion about assessment of risk/benefit to child:	Comments:

CATEGORY OF RISK DETERMINATION	BENEFIT ASSESSMENT	IDI REC ACTION
III. Greater Than Minimal Risk	**No direct benefit to individual offers general knowledge about the child's condition or disorder**	**☐ Approvable (case-by-case) (ii)**
*Document IDI REC discussion and rationale for determination of Greater than Minimal Risk category:	Document IDI REC discussion about assessment of risk/benefit to child:	Comments:
IV. Greater than Minimal risk	**No direct benefit to child offers potential to, "understand prevent, or alleviate a serious problem affecting the health and welfare of participants"**	**☐ Not Approvable (iii)**
*Document IDI REC discussion and rationale for determination of Greater than Minimal Risk category:	Document IDI REC discussion about assessment of risk/benefit to child:	Comments:

i) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

ii) Risk may not be more than a minor increase over minimal risk, consent of both

parents required under normal circumstances.

	Yes	No	NA
Does the research pose greater than minimal risk to children?	☐	☐	☐
If yes: Are convincing scientific and ethical justifications given?	☐	☐	☐
If yes: Are adequate safeguards in place to minimize these risks?	☐	☐	☐
Does the study involve normal volunteers?	☐	☐	☐
If yes: Is the inclusion of normal volunteers justified?	☐	☐	☐
Have appropriate studies been conducted on animals and adults first?	☐	☐	☐
If No: Is the lack of appropriate studies conducted on animals and adults justified?	☐	☐	☐
Will older children be enrolled before younger ones?	☐	☐	☐
Is permission of both parents necessary?	☐	☐	☐
es: Are conditions under which one of the parents may be considered "not reasonably available" described?	☐	☐	☐
If yes: Are the conditions acceptable?	☐	☐	☐
l efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?	☐	☐	☐
provisions made to obtain the assent of children aged 8 year or older and, where appropriate, honoring their dissent?	☐	☐	☐
provisions made to protect participants' privacy and the confidentiality of information regarding them?	☐	☐	☐
there special problems that call for the presence of a monitor or advocate during consent procedures?	☐	☐	☐
special needs of adolescents such as counseling and confidentiality accounted for in the research design?	☐	☐	☐
there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?	☐	☐	☐
es the research involve a condition which has implications for other family	☐	☐	☐

member? (for example, genetic risk, HIV infection, Hepatitis C)			
If yes: Are adequate mechanisms in place to deal with other members of the family?	☐	☐	☐
uld parents be required to be present during the conduct of the research? (Are proposed participants to be very young? Are the procedures involved painful? Must participants stay overnight in the hospital when they otherwise would not have to?)	☐	☐	☐

Comments:

_____

_____

_____

_____ _____

Primary Reviewer Date

55. FORM 5.1C CHECKLIST – REQUIREMENTS FOR RESEARCH INVOLVING PREGNANT WOMEN AND FETUSES

INVESTIGATOR: **IDI REC #**

STUDY TITLE

SECTION 1

☐ THIS RESEARCH INVOLVES PREGNANT WOMEN OR FETUSES PRIOR TO DELIVERY

	Yes	No	N/A
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;	☐	☐	☐
The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;	☐	☐	☐
Any risk is the least possible for achieving the objectives of the research;	☐	☐	☐
The woman's consent or the consent of her legally authorized representative is obtained, unless altered or waived by the IDI REC;	☐	☐	☐
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;	☐	☐	
If the research involves children aged 17 years or younger who are pregnant, assent and permission will be obtained;	☐	☐	☐
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	☐	☐	☐
Individuals engaged in the **research** will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and	☐	☐	☐
Individuals engaged in the **research** will have no part in determining the viability of a fetus.	☐	☐	☐

If the response to any of the above is **No,** the research is not approvable by the IDI REC at this time. See Section 3

SECTION 2

☐THIS RESEARCH INVOLVES FETUSES AFTER DELIVERY

	Yes	No	N/A
Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses;	☐	☐	☐
The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the **research** on the fetus or resultant child;	☐	☐	☐
3. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	☐	☐	☐
Individuals engaged in the **research** will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy;	☐	☐	☐
Individuals engaged in the **research** will have no part in determining the viability of a fetus.	☐	☐	☐

AND

A. Fetuses of uncertain viability ☐	Yes	No	NA
Does the **research** holds out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the **research**;	☐	☐	☐
Or			
he purpose of the **research** is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the **research**;	☐	☐	☐
The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.	☐	☐	☐

And/or

B. Nonviable fetuses ☐	Yes	No	NA
1. Vital functions of the fetus will not be artificially maintained;	☐	☐	☐

2. The research will not terminate the heartbeat or respiration of the fetus;	☐	☐	☐
3. There will be no risk to the fetus resulting from the research;	☐	☐	☐
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and	☐	☐	☐
5. The legally effective informed consent of both parents of the fetus will be obtained in accord with Section 6 of the National Guidelines for Research Involving Humans as Research Participants, except when the waiver provisions of Section 6.5 do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.	☐	☐	☐

If the response to any of the above is **No,** the research is not approvable by the IDI REC at this time. See Section 3

SECTION 3

☐ **THIS RESEARCH CAN BE CONDUCTED ONLY AFTER:**

(a) The IDI REC finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses; **and**

(b) The Secretary of the UNSCT, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting, has determined either:

(1) That the research in fact satisfies the conditions of Section 9.9 of the National Guidelines for Research Involving Humans as Research Participants, as applicable, or

(2) The following:

i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses;

ii) The research will be conducted in accord with sound ethical principles; and

iii) Informed consent will be obtained in accord with the informed consent provisions of National Guidelines for Research Involving Humans as Research Participants, Section 6 and other applicable subparts, unless altered or waived in accord with Section 6.5.

Comments:

_____ _____

Primary Reviewer Date

56. FORM 5.1D CHECKLIST – REQUIREMENTS FOR RESEARCH INVOLVING HANDCAPPED PARTICIPANTS

(MENTALLY & PHYSICALLY), MENTALLY ILL AND BEHAVIORALLY DISORDERED

INVESTIGATOR: **IDI REC #**

STUDY TITLE

	Yes	No	NA
Does the IDI REC need to include a member knowledgeable about and experienced with the handicapped (mentally and/or physically), mentally ill and behaviorally disordered research participants?	☐	☐	☐
Does the research pertain to the handicapped so that it is necessary to involve persons who are handicapped, mentally ill and behaviorally disordered as participants?	☐	☐	☐
If the investigator proposes to involve institutionalized individuals, has he or she provided sufficient justification for using that population? Are non-institutionalized participants appropriate for the research and reasonably available? Does the research pertain to aspects of institutionalization?	☐	☐	☐
Are adequate procedures proposed for evaluating the mental status of prospective participants to determine whether they are capable of consenting? Are these procedures appropriate both to the participant population and the nature of the proposed research?	☐	☐	☐
Is more than minimal risk involved? If so, is the risk justified by anticipated benefits to the participating participants and the importance of the knowledge that may reasonably be expected to result?	☐	☐	☐
Is it possible to identify persons authorized to give legally valid consent on behalf of any individuals judged incapable of consenting on their own behalf? Should assent of the prospective participants also be required? If incapable of giving valid consent, can participants' objection to participation be overridden? Under what circumstances?	☐	☐	☐
Should an advocate or consent auditor be appointed to ensure that the preferences of potential participants are elicited and respected? Should someone ensure the continuing agreement of participants to participate, as the research progresses?	☐	☐	☐
Should an advocate or consent auditor be appointed to ensure that the preferences of potential participants are elicited and respected? Should			

someone ensure the continuing agreement of participants to participate, as the research progresses?	☐	☐	☐

Comments: _____

_____

_____

_____ _____

Primary Reviewer Date

57. FORM 5.2A- RISK DETERMINATION - DEVICES

INVESTIGATOR: **IDI REC #**

STUDY TITLE

	Yes	**No**
Is the device intended as an implant?	☐	☐
Does the device support or sustain human life?	☐	☐
Is the device's use of substantial importance in: diagnosing, curing, mitigating, or treating disease, or preventing impairment of health?	☐	☐
Could the investigational device cause significant harm to any participants?	☐	☐
Must participants undergo a procedure as part of the device study?	☐	☐
Could the study or any of the study procedures cause harm the participants?	☐	☐
Could be life threatening	☐	☐
Could cause permanent impairment of a body function	☐	☐
Could cause permanent damage to body structure	☐	☐
Could necessitate medical or surgical intervention to:	☐	☐
-Preclude permanent impairment of a body function	☐	☐
-Preclude permanent damage to body structure	☐	☐
Does the study device appear on the NDA, FDA list of Significant Risk (SR) devices?	☐	☐
Does this appear to be a non-significant risk (NSR) device study?	☐	☐

Comments:

Primary Reviewer Date

58. FORM 5.2B- REPORTING EMERGENCY USE OF A TEST DEVICE

SPECIFIC INFORMATION

Regulations pertaining to emergency use of a test article (investigational drug, biologic or device) are those involving greater than greater than minimal risk as may be determined by the IDI REC. Emergency use of a test article in a life-threatening condition is not considered research; nevertheless, it is under the purview of the IDI REC, because the use of an investigational test article not yet approved by the NDA is involved. The investigational drug or biologic must have received NDA approval, or the investigational device have received Investigational Device Exemption from the NDA for clinical testing, to be eligible for use in an emergency setting. Usually, IND or one that has received exemption from NDA, acquisition is conducted by the manufacturer. If approval by the NDA is not available, the Investigator must contact the NDA on an emergency basis.

For emergency use of a test article, all of the following criteria must be met:

1. The participant is facing a life-threatening condition, for which there is no conventional treatment, or conventional treatments have failed.
2. The physician has access to a test article, and believes that there is a reasonable likelihood that the article will help save the participant's life, and that there is no approved treatment that has equal or greater likelihood of helping the participant.
3. Comprehensive written informed consent is to be executed prior to initiation of the administration of the test article.

Certain emergency circumstances may not permit the execution of the standard informed consent process prior to administration of the test article. National regulations and guidelines provide an exemption from the informed consent requirement, if the participant is unable to provide effective consent, and there is insufficient time in which to obtain consent from the participant's legal representative. Under these circumstances, the opinion of another impartial physician is required on the expected benefit from the use the test article; please refer to the "Definitions and interpretations of the NDA and the National Guidelines for Research Involving Humans as Research Participants on Emergency Use of an Investigational article.

The test article is expected to be administered to a single participant as a single course (may involve multiple dosing to achieve maximal efficacy). The participant to receive the test article should not be enrolled in a research study related to the test article. If subsequent use of the test article is contemplated in the same participant or in others, a new project application to the IDI REC is required in advance of that use.

The use of a test article in an investigation designed to be conducted under emergency conditions *(e.g.* emergency room research) usually does not qualify for the emergency use exemption.

Emergency use is defined as the use of a test article on a human participant in a life-threatening situation, in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain REC approval for the use. The Investigator is

still required to obtain informed consent under these circumstances.

National Guidelines for Research Involving Humans as Research Participants exempts from REC review the emergency use of a test article so long as the emergency use is reported to the REC within five working days of its occurrence. Any subsequent use of the test article is participant to REC review. "Subsequent use" means any use of the test article that occurs after its initial emergency use. When an IDI REC receives a report by a clinical Investigator of an emergency use, the IDI REC must examine each case to assure itself and the institution that the emergency use was justified.

Although exemption from REC review is designed to permit only a single emergency use of a test article for the treatment of one patient by one physician within an institution, the regulation is not intended to limit the authority of a physician to provide emergency care in a life-threatening situation. Should a situation arise which would require the emergency use of the test article for a second patient, either by the same or a second physician, subsequent emergency use should not be withheld for the purpose of gaining IDI REC approval If it appears probable that similar emergencies will require subsequent use of the test article at the institution, every effort should be made either to sign on to the Sponsor's protocol or to develop a protocol for future emergency use of the article at the institution.

Either of these protocols would need to be prospectively reviewed and approved by the IDI REC for future use of the test article.

In emergency circumstances, it may not be feasible to obtain informed consent prior to using the test article. The regulations therefore provide an exemption from the informed consent requirement for such situations. Emergencies qualifying for this exemption are defined as:

1) life-threatening situations necessitating use of the test article;
2) where the participant is unable to provide effective consent;
3) there is insufficient time in which to obtain consent from the participant's legal representative; and
4) there is no available alternative method of approved or generally recognized therapy of equal or greater likelihood of saving the participant's life (Section 4.5.3 b) of the National Guidelines for Research Involving Humans as Research Participants).

Special procedures for documenting the unfeasibility of obtaining consent apply as follows:

1) The Investigator and another physician, who is not participating in the clinical investigation, must certify in writing the existence of all four conditions listed above before use of the test article [Section 4.5.3 b) of the National Guidelines for Research Involving Humans as Research Participants].
2) If in the Investigator's opinion,

A) immediate use of the test article is necessary to save the life of the participant; **and**

b) there is insufficient time to obtain informed consent to the test article required by Section 4.5.3 before using the test article;

c) the Investigator is to make his or her own written determinations, then obtain the written review and independent evaluation of a physician who is not participating in the clinical investigation within five working days after the use of the test article [Section 4.5.3 b)].

The documentation required by Section 4.5.3 must be submitted to the IDI REC **within five working days** after the use of the test article Section 4.5.3 b)

59. FORM 5.2C REPORT OF EMERGENCY USE OF A TEST ARTICLE TO TREAT A LIFE-THREATENING CONDITION

INVESTIGATOR: **IDI REC #**

STUDY TITLE

<table>
<tr><td colspan="3">1. Physician Phone:

Title of research project:

Emergency use of TEST ARTICLE in a single patient facing a life-threatening condition.</td><td>Important: Please Note</td></tr>
<tr><td colspan="3"></td><td></td></tr>
<tr><td colspan="2">2. SPONSOR / FUNDING INFORMATION

Is this protocol supported by an external funding agency?

If yes, provide Grant Review Form</td><td>☐ No ☐Yes</td><td></td></tr>
<tr><td colspan="4"></td></tr>
<tr><td colspan="3">3. WHERE DID THE EMERGENCY USE TAKE PLACE?</td><td>Include all locations for</td></tr>
<tr><td>☐ Hospital (Name)</td><td>☐Private Practice (Name)</td><td>☐Agency (Name)</td><td>study related activities</td></tr>
<tr><td>☐ Clinic (Name)</td><td>☐ Public area</td><td>☐Other</td><td></td></tr>
<tr><td colspan="4"></td></tr>
<tr><td colspan="2">4. PATIENT INFORMATION</td><td></td><td rowspan="4"></td></tr>
<tr><td colspan="2"></td><td>☐ Male ☐ Female</td></tr>
<tr><td colspan="2">_____

Name of Patient</td><td></td></tr>
<tr><td colspan="2">Date of birth</td><td>Medical record number</td></tr>
</table>

_____ Ethnicity/race			
Was the patient any of the following potentially vulnerable groups?			
☐ Prisoners	☐ Mentally retarded /impaired	☐ Nursing home resident	
☐ Fetuses	☐ Economically disadvantaged	☐ Students	
☐Pregnant women	☐Investigator's staff member	☐ Homeless	
☐ Investigator's patient		☐Other (describe)	

DESCRIPTION OF LIFE-THREATENING CONDITION **A** Diagnosis Why was the condition considered life-threatening? What were the symptoms and signs that made the physicians conclude that the patient? was facing a life-threatening condition? What made the physicians conclude that there was no standard acceptable treatment available, so that an investigational treatment had to be offered? On what date did the administration or application of the test article to the patient begin, and when did it or will it end?	

IS THE TEST ARTICLE REGULATED BY FDA? ☐ No ☐Yes If yes, complete this section ☐ This study involves a drug or biologic: IND #, if applicable: _____ This study is: ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☐ Treatment ☐ This study involves a device: This device is: ☐ Investigational ☐Marketed This is a: ☐ Significant Risk Device Study ☐ Non-Significant Risk Device Who is the Sponsor of the IND? **D** What was the generic name and/or code name of the test article? **E** What was the source (supplier or manufacturer) of the test article? **F** How did the physicians gain possession of the test article? What is the proposed mechanism of action of the test articles? **H** If the test article is a drug, what is the <u>drug trial phase</u> status, as assigned by the NDA? If the test article is a device, what is the <u>significant risk</u> or <u>non-significant risk</u> device status, as assigned by the NDA? **J** What was the dosage, route of administration or application, and frequency & total duration of use of the test article?	Submit the Investigator Brochure Include justification of Non-Significant Risk

COSTS **Study procedures and products** Will the patient or his/her health care provider be required to pay for any related procedures or products? If yes, explain: **Compensation for injury** Who is responsible for costs incurred due to adverse events?	☐ No	☐ Yes	
RISKS Identify the risks (current and potential). Describe the expected frequency, degree of severity, and potential reversibility. Describe possible late effects. ☐ NA Risks from study article: ☐ NA Risks from research procedures (i.e., washout risks, placebo assignment, e.t.c ☐NA How will participants be assessed for the occurrence of adverse events described above? ☐NA			Consider all risks: physical, psychological social, legal economic

H Describe your monitoring plan. ☐ NA What information is available on the response of the patient's life-threatening condition to the test article at the time of this report?			
9. FOLLOW-UP PROCEDURES What will be the duration of participants' active participation? Will the patient be followed after their active participation ends? If yes, describe:	☐ No	☐Yes	

10. INFORMED CONSENT

A) What type of informed consent process was implemented prior to administration or application of the test article to the patient?

B) Was the patient able to give informed consent? ☐ No ☐Yes

C) If the mental acuity of the patient was in doubt, the person who gave the informed consent was:

☐ Legally appointed guardian

D) Patient advocate named in a Durable Power of Attorney for Health Care

Next-of-kin ☐ Spouse ☐ Adult child ☐ Parent ☐

Adult brother/Sister ☐

E) If the patient was age <18 years, did he or she provide assent? ☐No ☐Yes

F) How will pertinent information be provided to the patients, if appropriate, at a later date?

G) Describe or attach your debriefing plan.

H) Who explained the study to the patient?

a. If circumstances prevented obtaining informed consent, explain why the patient was unable to provide effective consent; and why there was insufficient time in which to obtain consent from a legal representative of the patient.
b. Please submit the informed consent document used or to be used.
c. If already executed, please provide a copy of the document that bears signatures of the patient or his/her legal representative, the Investigator (or designee) providing information and others (as applicable) witnessing the consent.

11. CONFIDENTIALITY

See consent form template.

A Are the participant's social security number, hospital record number, or any identifier (other than study number & initials) being sent off site? If yes, describe and explain reasons.

☐No ☐Yes

B Will any external entity other than the investigative staff have access to or be provided with confidential medical or health related?

Information about the participant.

12. EXPLANATION OF REPORTING DELAY

☐No ☐ Yes If the interval between the date of initial administration of the test article and the date of submission of this application is more than five days, what was the reason for the delay in reporting?

_____ _____

Physician administering the test article Date

_____ _____

Concurring physician (if consent is not obtained) Date

60. FORM 5.2D: CHECKLIST - EMERGENCY RESEARCH CONDUCTED UNDER EXEMPTION FROM INFORMED CONSENT REQUIREMENTS

CHECKLIST-EMERGENCY RESEARCH CONDUCTED UNDER EXEMPTION FROM INFORMED CONSENT REQUIREMENTS

STUDY: IDI REC TRACKING #

	Yes	No
The protocol is under a separate investigational new drug application (IND) or investigational device exemption (IDE).	☐	☐
The protocol clearly identifies that the research may include participants who are unable to give informed consent.	☐	☐
The human participants are in a life-threatening situation that requires intervention, and	☐	☐
Available treatments are unproven or unsatisfactory, and	☐	☐
The collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions, and	☐	☐
The clinical investigation could not practicably be carried out without the waiver of informed consent:	☐	☐
The intervention under investigation must be administered before consent from the participants' legally authorized representatives is feasible; and	☐	☐
There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.	☐	☐
There is evidence that participation in the research holds out the prospect of direct benefit to the participants:	☐	☐
Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual participants; and	☐	☐

	Yes	No
Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of participants, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.	☐	☐
The protocol defines the length of the potential therapeutic window based on scientific evidence.	☐	☐
The IDI REC has reviewed and approved informed consent procedures and an informed consent document to be used with participants or their legally authorized representatives in situations where use of such procedures and documents is feasible.	☐	☐
The protocol includes documentation that the Investigator will make every reasonable effort to obtain informed consent within the therapeutic windowby:	☐	☐
Attempting to contact a legally authorized representative for each participant and obtain consent within the therapeutic window.	☐	☐
If a legally authorized representative is not reasonably available, attempting to contact, within the therapeutic window, the participant's family member who is not a legally authorized representative, and asking whether he or she objects to the participant's participation in the clinical investigation.	☐	☐
Procedures are in place to inform, at the earliest feasible opportunity, each participant, or if the participant remains incapacitated, a legally authorized representative of the participant, or if such a representative is not reasonably available, a family member, of the participant's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document.	☐	☐
That he or she may discontinue the participant's participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.	☐	☐
If a participant is entered into a clinical investigation with waived consent and the participant dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the participant's legally authorized representative or family member, if feasible.	☐	☐

	Yes	No
Procedures and information to be used when providing an opportunity for a family member to object to a participant's participation in the clinical investigation consistent with regulations and guidelines are acceptable.	☐	☐
If a legally authorized representative or family member is told about the clinical investigation and the participant's condition improves, the participant is also to be informed as soon as feasible.	☐	☐
Community disclosure and consultation will be carried out.	☐	☐
Consultation (including, where appropriate, consultation carried out by the IDI REC) with representatives of the communities in which the clinical investigation will be conducted and from which the participants will be drawn will be carried out.	☐	☐
Public disclosure to the communities in which the clinical investigation will be conducted and from which the participants will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits.	☐	☐
Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results.	☐	☐
An independent data monitoring committee to exercise oversight of the clinical investigation will be established.	☐	☐

Primary Reviewer_____ Date _____

61. FORM 5.2E- WAIVER OF INFORMED CONSENT FOR ACCESS TO MEDICAL RECORDS FOR RESEARCH

For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, the documentation must include all of the following:

☐ Identification and date of action _____

☐ Date approved _____

Does alteration or waiver, in whole or in part, of authorization satisfy the following criteria?	**Yes**	**No**
The use or disclosure of protected health information involves no more than minimal risk to the individuals;	☐	☐
The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;	☐	☐
The research could not practicably be conducted without the alteration or waiver;	☐	☐
The research could not practicably be conducted without access to and use of the protected health information;	☐	☐
The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;	☐	☐
There is an adequate plan to protect the identifiers from improper use and disclosure;	☐	☐
There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law;	☐	☐
(There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.	☐	☐
Can authorization (consent) of the individual patient be waived?	☐	☐

_____ _____

Primary Reviewer Date

62. FORM 6.1A- NOTICE OF IDI REC APPROVAL

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

This is to inform you that the Infectious Disease Institute Research Ethics Committee

(IDI REC) has approved the above research study.

The approval period is from**__/___/___to___/___/___. Your study number is___.**
Please be sure to reference either this number in any correspondence with the IDI REC.

Continued approval is conditional upon your compliance with the following requirements:

1) A copy of the **Informed Consent Document**, approved as of**__/_____/____**, is enclosed. No other consent form should be used. It must be signed by each participant prior to initiation of any protocol procedures. In addition, each participant must be given a copy of the signed consent form.
2) All protocol amendments and changes to approved research must be submitted to the IDI REC and not be implemented until approved by the IDI REC except where necessary to eliminate apparent immediate hazards to the study participants.
3) **The enclosed recruitment advertisement has been approved (only where necessary).** Advertisements, letters, internet postings and any other media for participant recruitment must be submitted to IDI REC and approved prior to use.

4) Significant changes to the study site and significant deviations from the research protocol and all unanticipated problems that may involve risks or affect the safety or welfare of participants or others, or that may affect the integrity of the research must be promptly reported to the IDI REC.

5) Enclosed is an Adverse Event Report. All deaths, life-threatening problems or serious or unexpected adverse events, *whether related to the study article or not*, must be reported to the IDI REC in a timely manner as specified in the National Guidelines for Research Involving Humans as Research Participants.

☐Please complete and submit reports to the IDI REC as follows:

a) Renewal of the study - complete and return the Continuing Review Report-Renewal Request (Form 4.4A) at least 8 weeks prior to the expiration of the approval period. The study cannot continue after_____until re-approved by the IDI REC.

b) Completion, termination, or if not renewing the project - send the report upon completion of the study.

Please call me if you have any questions about the terms of this approval.

_____

Signature

IDI REC Chairperson/ Designee

Copy: File Enclosures:

a) Approved Informed Consent Document dated _____

b) Approved Recruitment Advertisements

c) Other: _____

63. FORM 6.1B APPROVAL WITHHELD/ PENDING

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

The above referenced protocol was reviewed by the Infectious Disease Institute Research Ethics Committee

(IDI REC) on_____. The IDI REC found your proposed study to be generally satisfactory in terms of safety and protection of the rights of research participants, but the IDI REC **withheld** approval to the study pending resolution/ your response to the following questions or concerns raised by the IDI REC:

1.

2.

3.

4.

5.

If you have any questions, please do not hesitate to contact me.

_____

IDI REC Administrator

Copy: File Enclosures:

64. FORM 6.1C NOTICE OF TABLED PROTOCOL

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418 KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

This is to inform you that the Infectious Disease Institute Research Ethics Committee (IDI REC) reviewed your above referenced protocol and the informed consent. The IDI REC was unable to make a determination because it did not have enough information or had questions and concerns that could not be resolved by review of the information provided in your submission.

If you wish to have the IDI REC re-review your study, please address the following issues raised by the IDI REC:

1.

2.

3.

4.

5.

You will be required to formally re-submit this study for initial review by the IDI REC. If you have any questions regarding the determination of the IDI REC, please do not hesitate to contact me.

_____

IDI REC Administrator

Enclosures:

65. FORM 6.1D- IDI REC IRB COMPLIANCE ASSURANCE

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

Assurance #: _ _ _ _

The above referenced protocol was reviewed and approved by Infectious Disease Institute Research Ethics Committee (IDI REC) on / /.

The IDI REC operates in compliance with GCP and applicable laws and regulations. In compliance with such procedures, laws and regulations, Investigators do not participate in the review and voting process for studies in which they participate. The IDI REC consists of members of the clinical and scientific communities, non-scientists, as well as members of the community as required by the National Guidelines for Research Involving Humans as Research Participants to assure a fair and thorough review process.

Due to constantly changing membership and a minimum of clerical staff, it is not the IDI REC's policy to submit individual lists of IDI REC members. I can assure you however, that a quorum of the members was present at the meeting and duly met the requirements mandated by the National regulation.

Infectious Disease Institute Research Ethics Committee (IDI REC) is registered with the Uganda National Council for Science and Technology (UNCST), and USA's Office for Human Research Protections (OHRP).

Please refer to the UNCST (http://www.uncst.go.ug) and OHRP's (http://ohrp.osophs.dhhs.gov/irbasur.htm) websites for a list of registered RECs

……

IDI REC Chairperson/Designee

66. FORM 6.1E- NOTICE OF DISAPPROVED STUDY

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418 KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re:(IDI REC #) (Protocol #) (Protocol Title) (Amendments).

This is to inform you that the Infectious Disease Institute Research Ethics Committee (IDI REC) reviewed your above referenced protocol and the informed consent. Your study was not approved for the following reasons:

1.

2.

3.

4.

5.

National regulations and guidelines provide that Investigators have an opportunity to respond in person or in writing. If you wish to respond to this determination, please contact me at the above address or phone number.

If you have any questions regarding the determination of the IDI REC, please do not hesitate to contact me.

_____

IDI REC Chairperson/Designee

Copy: 1. _____

2. _____

67. FORM 6.1F- NOTICE OF RENEWAL APPROVAL

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

This is to inform you the Infectious Disease Institute Research Ethics Committee (IDI REC) has renewed its approval of the above research study.

The approval period is from___/___/___to_____/___/___. Your study number is___. Please be sure to reference either this number and/or the study title in any correspondence with the IDI REC.

All conditions for continued approval during the prior approval period remain in effect. These include, but are not necessarily limited to the following requirements:

1) A copy of the **Informed Consent Document**, approved as of__/_____/_____is enclosed. No other consent form should be used. It must be signed by each participant prior to initiation of any protocol procedures. In addition, each participant must be given a copy of the signed consent form.
2) All protocol amendments and changes to approved research must be submitted to the IDI REC and not be implemented until approved by the IDI REC except where

necessary to eliminate apparent immediate hazards to the study participants.

3) **The enclosed recruitment advertisement has been approved (where applicable).** Advertisements, letters, Internet postings and any other media for participant recruitment must be submitted to IDI REC and approved prior to use.

4) Significant changes to the study site and significant deviations from the research protocol must be reported.

5) Enclosed is an Adverse Event Report. All deaths, life-threatening problems or serious or unexpected adverse events, *whether related to the study article or not*, must be reported to the IDI REC.

Please complete and submit reports to the IDI REC as follows:

a) Renewal of the study - complete and return the Continuing Review Report-Renewal Request (Form 404A) at least 8 weeks prior to the expiration of the approval period. The study cannot continue after_____until re-approved by the IDI REC.

b) Completion, termination, or if not renewing the project - send the report upon completion of the study.

Please call me if you have any questions about the terms of this approval.

_____

Signature

IDI REC Chairperson/ Designee

Copy: File Enclosures:

a) Approved Informed Consent Document dated __

b) Approved Recruitment Advertisements

c) Other: _____

_____

68. FORM 6.1G- NOTICE OF AMENDMENT APPROVAL

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

This is to inform you that Infectious Disease Institute Research Ethics Committee (IDI REC) has reviewed *Amendment__, dated__/____/____*for the above captioned study. The changes to the study have been approved.

Please find revised Informed Consent document enclosed. You will note that the date of approval at the bottom right hand corner has been updated *().* No other consent form should be used. It must be signed by each participant prior to initiation of any protocol procedures. In addition, each participant must be given a copy of the signed consent form.

The approval period for the study ends on___/___/___. Any additional modifications in the research protocol, study site/ personnel, or consent form during this time period must first be reviewed and approved by the IDI REC.

Please feel free to call me if you have any questions.

_____

IDI REC Chairperson

Copy: File Enclosures:

a) Approved Informed Consent Document dated __
b) Approved Recruitment Advertisements
c) Other: _____

69. FORM 6.1H- NOTICE OF APPROVAL- RECRUITMENT ADVERSTISEMENT

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

Approval: Recruitment Advertisement

This is to acknowledge our receipt and review of your recruitment advertisement(s) for the above referenced study.

The attached ad has been approved *as revised* by the Infectious Disease Institute Research Ethics Committee (IDI REC). The IDI REC can provide guidelines for the development of future advertisements and recruitment materials.

Please contact the IDI REC Secretariat if you have any questions about the determinations of this review.

IDI REC Chairperson

70. FORM 6.1I- ADVERSE EVENT/IND SAFETY REPORT ACKNOWLEDGEMENT

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

Adverse Event/IND Safety Report Acknowledgement

AE: (list)

This is to acknowledge our receipt of the report(s) for the above referenced study. This information has been added to your study file.

_____

IDI REC Administrator

71. FORM 6.1J- STATUS REQUEST

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

The above referenced protocol was tabled to the Infectious Disease Institute Research Ethics Committee

(IDI REC) on__/__/_____. To our knowledge, the information requested in the attached letter was never received. Therefore the status of the study continues in our files as:

- ☐ approval withheld
- ☐ pending
- ☐ tabled
- ☐ pending.

Please clarify your plans with regard to this protocol and provide the information requested in the copy of the letter attached. Return your response within three weeks of the date above to: _____.Thank you.

_____
IDI REC Administrator

☐I have decided not to do this study.

☐Enclosed is the requested information. Notification of approval by the IDI REC requested.

☐Other (please specify)

Signature of the Principal Investigator	Date

72. FORM 6.1K COMPLETION ACKNOWLEDGEMENT

COMPLETION ACKNOWLEDGEMENT

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

Acknowledgement of study completion

This is to acknowledge our receipt of the Completion Report for the above referenced study. This information has been added to your study file.

_____

IDI REC Administrator

73. FORM 6.1L NOTICE OF STUDY SUSPENSION (LACK OF CONTINUING REVIEW REPORT)

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

This is to inform you we have not received your request for renewal.

The Infectious Disease Institute Research Ethics Committee (IDI REC)'s approval period for the above captioned study ended as of / / . Therefore, you must not enroll any new patients in the above captioned study, nor collect study-related data on enrolled participants.

Section 13 of the National Guidelines for Research Involving Humans as Research Participants state that a REC has authority to suspend or terminate approval of research that is not being conducted according to the REC's requirements. The IDI REC requires that Investigators submit a periodic report and request renewal of IDI REC approval 60 days prior to the end of the IDI REC approval period. Since you have not done so, the IDI REC may suspend or terminate approval. National regulations and guidelines require that such suspension or termination be reported to appropriate institutional officials, and/or the UNCST.

Please submit a completed Continuing Review Report/Renewal Request (Form 404A) to the IDI REC by / / in order to avoid further IDI REC action as described above.

Please feel free to contact me if you have any questions.

_____

IDI REC Chairperson/Designee

Copy:

File

Funding Agency Head/ Sponsor

Institutional Official(s) (Name)

74. FORM 6.1M- NOTICE OF STUDY TERMINATION (FOR CAUSE)

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418

KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #) (Protocol Title) (Amendments).

This is to inform you that the Infectious Disease Institute Research Ethics Committee

(IDI REC) has terminated your above referenced study for the following reasons:

1.

2.

3.

4.

5.

If you wish to respond to this determination, please contact the IDI REC Secretariat at the above address or phone number.

If you have any questions regarding the determination of the IDI REC for this termination, please do not hesitate to contact me.

_____

IDI REC Chairperson/Designee

Copy: File

Funding Agency Head/ Sponsor Institutional/Organization Official(s) (Name)

75. FORM 6.1N- EXEMPTION DISQUALIFICATION NOTICE

INFECTIOUS DISEASE INSTITUTE RESEARCH ETHICS COMMITTEE

P.O. BOX 22418 KAMPALA

Date (today's date)

To: (Principal Investigator) (Address)

Attention: (contact)

Re: (IDI REC #) (Protocol #(Protocol Title) (Exemption Disqualification Notice).

This is to inform you that, after review by the Infectious Disease Institute Research Ethics Committee (IDI REC), your above captioned study has been determined to require IDI REC review for the following reason(s).

1.

2.

3.

4.

5.

Please complete the enclosed submission forms (Form 301A, Form 301B & Form 301C), and be sure to include any material or information required. If this study qualifies for Expedited Review, it will be reviewed by the Chairperson or his/her designee. If it requires full IDI REC review, it will be placed on the agenda as soon as possible.

If you wish to respond to this determination, please contact me at the IDI REC Secretariat at the above address or phone number.

If you have any questions regarding your submission, please do not hesitate to contact

_____

IDI REC Chairperson/Designee

76. FORM 6.1O COMMUNICATION LOG

☐Miscellaneous Communications: Time Period - from__/__/__

Study Specific Communications: IDI REC # _____

to____/__/__

Initiator	Recipient	Date of Contact	Method Contact	Participant Type	Action Taken/ Follow-up

Key

Personnel: Initiator: Person making the contact Recipient: Person being contacted

Method: Phone: P Letter: L Fax: F E-mail: E Face-to-Face: FF Participant type: Regulatory - T Administrative: A

77. FORM 7.1A- INFORMED CONSENT CHECKLIST

Required Elements	Yes	No
A statement that the study involves research	☐	☐
An explanation of the purposes of the research	☐	☐
Safety and efficacy defined as a purpose (for clinical trial)	☐	☐
The expected duration of participation (include active & follow-up)	☐	☐
Number of visits	☐	☐
cription of the procedures, including: Procedures at each visit matches protocol Procedures clearly described (in lay language) Laboratory adequately described Experimental procedures defined	☐	☐
The following described: Reasonably foreseeable risks/discomforts of the study article Reasonably foreseeable risks & discomforts of the procedures Reasonably expected benefits to participants/others	☐	☐
Appropriate alternative treatments defined	☐	☐
Confidentiality Statement, including: Sponsor / funder and/or CRO access to records UNCST/ NDA access, IDI REC access, Other (e.g. interview service)	☐	☐
Injury statement (if more than minimal risk), including: Description of available compensation Description of available medical treatments	☐	☐
Participation statement, including; What treatment consists of, if applicable Who to contact for a research related injury	☐	☐
Participation is voluntary Refusal to participate will involve no penalty or loss of benefits Participant may stop participation at any time - without penalty / loss of benefits		
Who to contact for information about research	☐	☐

Contact for questions about research participant's rights	☐	☐
24-hour emergency contact number?	☐	☐

Comments:

Additional Elements, as Appropriate:	**Yes**	**No**	**NA**
Research may involve unforeseeable risks to the participant	☐	☐	☐
Risks to pregnant women/ embryo/ fetus or nursing baby	☐	☐	☐
Costs/additional costs to participant from participation	☐	☐	☐
Circumstances under which the participant's participation may be terminated without regard to the participant's consent	☐	☐	☐
Payment for participation described (pro-rated, reasonable)	☐	☐	☐
Procedures for orderly termination of participation	☐	☐	☐
Medical /scientific terminology defined	☐	☐	☐
A statement that significant findings during the course of research that might affect the participant's willingness to continue participation will be provided to the participant	☐	☐	☐
The approximate # of participants in the study	☐	☐	☐
Legal guardian consent, if needed	☐	☐	☐
REC volunteer statement included	☐	☐	☐
Institutional/Organization Required Elements	☐	☐	☐

See informed consent form template (Form 7.1B) for suggestions for appropriate wording

Comments:	
Primary Reviewer	Date

78. FORM 7.1B- INFORMED CONSENT DOCUMENT TEMPLATE

[Language]

[Version number]

[Version date]

[INSERT TITLE OF THE STUDY]

Dear Madam or Sir,

Introduction

You are invited to participate in a research study at the Infectious Diseases Institute (IDI). The name of the study is *"insert name of the trial".* Researchers at IDI are interested in learning more about *[provide a brief background of the study;].* This is study is being sponsored by *[Insert the name of the sponsor and other collaborating partners <<IF APPLICABLE>>*

Why is this study being done?

[provide appropriate details on the purpose of the study;].

How many people are participating in this study?

About [insert total number of participants e.g. 200] will participate in this study. You are being invited to take part in this study because you have both *HIV and TB.*

Study Procedures

You will have a total of ***7 study visits*** *[insert the appropriate number of visits]* for this study. These visits are done on days that you would be coming for your usual appointments,

<u>Visit 1 – Screening and enrolment</u>

Insert study procedures to be performed on this visit

Visit 2 and 4 (week 2 and week 4)

Insert study procedures to be performed on this visit

Visits 5 (week 6):

Insert study procedures to be performed on this visit

Visit 6 (Week 8)

Insert study procedures to be performed on this visit

Visit 7 (Week 24)

Insert study procedures to be performed on this visit

How long will the study last?

You will participate in this study for a total of 6 *months [insert appropriate time frame for which the study will last].* You should take your *HIV* medicines without missing any doses. You should not stop your *HIV* medicines but continue after completing your *TB or any other disease related to the study]* treatment and after the study is completed. After the study you will continue your usual care at IDI clinic. [Please provide appropriate guidance on how the participant will return to the standard of care after completion of their study visits, <IF APPLICABLE> e. g *If you were on dolutegravir, you will start taking it once a day 2 weeks after you have completed your TB medicines, which is recommended by our Ugandan guidelines]*

What will happen to my samples?

The sputum and blood samples you provide will be used to learn more about *[insert name of the disease e.g. TB, KS]* germs in patients with HIV. You will be asked to sign a separate consent form if you agree to allow any left-over samples to be stored for a long time. A separate consent form will also be needed for genetic testing which will be performed on your blood <<IF APPLICABLE>>. You can still participate in this study if you refuse genetic testing on your samples or if you refuse to allow the researchers to store your samples for a long time.

Home visits follow-up.

In case you miss any of your study visits, we will call you to find out how you are. A home visitor may come to see you at your home to plan the next steps.

Risks

The main risks of taking part in the study include side effects *[Insert potential side effects].* In case you develop abdominal pain, yellow eyes or vomiting, please let us know because these may be signs that your liver has been affected by the drugs.

Benefits

There may not be any direct benefit to you from being in this study. However, the results of these tests will be used to help us learn whether or not we can adjust doses of *[TB, or any other diseases in question]* drugs for the treatment of patients in the future and whether higher doses of rifampicin will affect the amount of HIV medicine in the blood.

Costs

You will not be required to pay any costs to be part of this study.

Reimbursements/Compensation

There are no costs to be paid to you for participate in this study. However, you will be required to attend to the scheduled study visits where the study team is responsible for meeting the costs of your transport during each the study visit. You will be given [insert amount of money to be reimbursed or any form of compensation e.g 30,000 or a bar of soap] UGX compensation for transport costs for each of the study visits and for any other visits that are required by the study.

Participant rights

Participation in this study is entirely voluntary. You have the right to refuse to participate in this study and this decision will not affect your treatment at IDI in any way. If you choose to participate in the study you have the right to withdraw from the study at any time. Any research results obtained prior to your withdrawal of consent may however be used and some data may have already been published.

Research-related injury

In case you feel unwell, please feel free to contact the study team by telephone or come and meet us at the *[IDI Mulago complex in room # or TB clinic]*. We might perform more tests, depending how sick you are. You will receive healthcare until complete cure and stabilization

of a research related illness. If we refer you to hospital for a research related illness, the cost of referral and management of the condition shall be paid by the study.

Sharing the Results
We plan to share the results of this research with you and the IDI after the study and the results will be published.

Reasons why you may be withdrawn from the study
You may be removed from the study without your consent for the following *reasons [Insert as many reasons as possible]:*

- If the study is stopped or canceled.

Whom to contact

This study has been approved by the *Infectious Diseases Institute Research Ethics Committee (IDI REC)*. You may contact the chairman of the Research Ethics Committee if you have any questions regarding your rights as a study participant at any time *(Insert the chair's contacts)*

Alternatives to Participation

If you choose not to participate you will continue to receive your treatment as normal at the IDI. Neither your present treatment nor your future treatment at IDI will be affected in any way by choosing not to participate in this study.

Confidentiality

All your information will be kept private and confidential. Your name or address or any other identifying information will not be shared with anyone outside the study. Codes will be used to replace your name so that no one can directly identify you. All your records from this study will be kept confidential by the investigators of this study. No information that personally identifies you will be disclosed in any publications that arise as a result of this study.

Questions about this study

The study doctor or nurse will explain this study to you. If you have any questions you may ask them now or any time during the study. You may contact also:

Insert the name of the PI

Infectious Diseases Institute,

Makerere University College of Health Sciences, *Mulago Hospital Complex, Kampala*

Mobile :

Informed consent

By signing the Informed Consent Form, you agree to participate in this study. The undersigned, hereafter known as *INSERT THE NAME OF THE STUDY e.g. SAEFRIF, NADIA,* participant agree to the following:

- The information in the patient information sheet and the written informed consent form was explained to me by the study physician and understood by me.
- All my questions were answered to my satisfaction.
- I agree to take part in the "…. study" under the conditions as described in the patient information leaflet.
- I received a copy of the patient information leaflet and a signed written informed consent form.
- I know that participation in this study is completely voluntary and that I may refuse to participate or withdraw from the study at any time.
- Refusal to participate or withdrawal after initial consent will not affect my current or future treatment.

Name of Participant (printed) Signature of participant

make a thumbprint in the box below*

Date: ____ / _____ / ____

Day Month Year

Name of Person Administering Consent (printed) Position/Title

Signature of Person Administering Consent **Date: ____ / _____ / ____**

Day Month Year

**If the patient is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to their participation in the study, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by the patient and that informed consent was freely given by the patient.*

_____ _____

Name of Person Witnessing Consent (printed) Signature of Person Witnessing Consent

Date: ____ / _____ / ___

Day Month Year

79. FORM 7.1C- CHECKLIST TO ASSESS THE ADEQUACY OF INFORMED CONSENT FORMS FOR STORAGE OF BIOLOGICAL SPECIMEN FOR FUTURE USE AT THE IDI

CHECKLIST STATEMENT	**YES**	**NO**
An explanation of the purpose for the storage of samples	☐	☐
Description of type of sample	☐	☐
Quantities of samples to be stored	☐	☐
The expected duration of sample custody	☐	☐
Place where samples will be stored	☐	☐
A description of any reasonably foreseeable risks or discomforts to the participant	☐	☐
Policies that will govern the use of samples for future research	☐	☐
A description of any benefits to the participant and to others that may reasonably be expected from the research	☐	☐

A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained	☐	☐
A statement that participation is voluntary, refusal to stored one's sample will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled	☐	☐
An explanation of whom to contact for answers to pertinent questions about the research	☐	☐
An explanation of whom to contact for answers to pertinent questions about the participants' rights	☐	☐
A section where the research participants signs to affirm his/ her participants	☐	☐
A section for research team member administering the consent	☐	☐
A section for a witness to sign in case the participant is illiterate.	☐	☐

80. FORM 7.1D- INFORMED CONSENT DOCUMENT TEMPLATE: TISSUE/BLOOD STORAGE FOR FUTURE USE

[Language]

[Version number]

[Version date]

[INSERT TITLE OF STUDY….]

INFORMED CONSENT FOR THE STORAGE OF BIOLOGICAL SPECIMENS

Introduction

Your child is being invited to take part in a research study. Before you decide whether your child can participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if

you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Please insert the purpose of the study; e.*g. ... [**The purpose of this study is to understand the effect of a higher dose of one of the TB drugs (rifampicin) on HIV medicines, in particular efavirenz and dolutegravir.*

Why store a specimen?

Start by listing the samples collected if more than one and then write the rational for storing the sample

What quantity of my child's sample will be stored?

If you agree to storage of your child's blood sample, 10 mL of *blood* will be taken every 2 weeks during the first 8 weeks of your *[HIV/AIDS /TB/ any other disease]* treatment, therefore, 60-70 mL of *blood* will be taken from your child for these purposes through-out the study period.

Handling of stored samples

Your child's blood samples and sputum will be stored at the *Infectious Diseases Institute (IDI)* in Kampala and also at the *.....laboratory of Makerere University*, *or other laboratories located outside Uganda if applicable*

How long will my child's sample be kept?

Your child's sample may be stored for a long time but not longer than 10 years

Will my child's taking part in this study be kept confidential?

Confidentiality will be maintained at all times. All samples will be coded (but it will be possible to link results to anonymized data collected from this study). Once the study has been completed, we will ensure that no one can link your child's identity to his/her clinical details.

What policies will govern the use of my child's sample in future research?

Further approval will be sought from an accredited ethics committee for any future studies other than the one you are currently enrolled in. IDI will act as the guard of all the samples obtained as part of this project for research purposes. In some cases, with permission from an ethics committee; a small amount of your child's sample will be provided to other researchers and may be sent to countries outside Uganda. [*Only if you plan to export samples to foreign countries]*

Withdrawal of Consent and Destruction of Samples

You may withdraw your parental consent to store your child's sample without affecting his/her participation in the main *clinical trial or the main study.*

To withdraw your parental consent for storage of your child's samples, you will contact the study doctor or the research office at IDI, because only he/she has access to all of your identifying information. If you withdraw your parental consent for the storage during this time, you may request that your child's blood *[include other categories of biological samples]* sample to be destroyed and no longer used in research. Any research results obtained prior to your parental withdrawal of consent will however be used.

What are risks that may be associated with storage of your child's sample?

The other potential risk is loss of confidentiality. However, several measures have been put in place to ensure that your child's information is not leaked to individuals who are not part of this research.

What are the possible benefits of taking part?

It is unlikely that the study will be of direct benefit to your child; however, it may benefit your child and other patients who on *[TB/ HIV AIDS/ or any other disease*] treatment in the future.

Who is organizing and funding the research?

This study is funded by the *[European and Developing Countries Clinical Trials Program (EDCTP). Write the appropriate organization]*

Who has reviewed the study?

This study has been reviewed by the *[Infectious Diseases Institute, Research Ethics Committee.]* You may contact the chairman of the Research Ethics Committee if you have any questions regarding your child's rights as a study participant at any time.

(Insert the contact for the chair)

Out of hour's emergency contact

For further information about this study, please contact: *[insert study Principal investigator's name and contact]*

Thank you for reading the information about our research project. If you would like to take part, please read and sign this form.

<u>Consent for storage and use in possible future research projects.</u>

I agree that the sample(s) *[outline the category of specimen e.g. blood, urine]* I give and the information gathered about me can be stored by The Infectious Diseases Institute as described in the attached information sheet. I understand that my data and sample(s) will be securely stored and be identified only by a code.

_____ _____

Name of Participant's parent (printed) Signature of participant's parent

make a thumbprint * in the box below

Date: ____ / _____ / ____

Day Month Year

_____ _____

Name of Person Administering Consent (printed) Position/Title

_____

Signature of Person Administering Consent **Date: ____ / _____ / ____**

Day Month Year

**If the patient is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to their participation in the study, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the patient and that informed consent was freely given by the patient*.

_____ _____

Name of Person Witnessing Consent (printed) Signature of Person Witnessing Consent

Date: ____ / _____ / ____

Day Month Year

81. FORM 7.1 E- CHECKLIST FOR ASSESSING THE ADEQUACY OF THE INROMED CONSENT FORM FOR GENETIC STUDIES

CHECKLIST STATEMENT	YES	NO
A statement that the study involves research	☐	☐
An explanation of the purposes of the research	☐	☐
The expected duration of the participant's participation	☐	☐
A description of the procedures to be followed	☐	☐
A description of any reasonably foreseeable risks or discomforts to the participant	☐	☐
A description of any benefits to the participant and to others that may reasonably be expected from the research	☐	☐
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant	☐	☐
A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained	☐	☐
The amount and schedule of all payments	☐	☐
The approximate number of participants involved in the study.	☐	☐
For research involving more than minimal risk an explanation as to whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained	☐	☐
Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.	☐	☐
A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise	☐	☐
A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation will be provided to the participant	☐	☐
An explanation of how to contact the research team for questions, concerns, or complaints about the research.	☐	☐

An explanation of how to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the participant's' rights; to obtain information; or to offer input.	☐	☐
An explanation of whom to contact in the event of a research-related injury to the participant.	☐	☐
A section where the research participants signs to affirm his/ her participants	☐	☐
A section for research team member administering the consent	☐	☐
A section for a witness to sign in case the participant is illiterate.	☐	☐

82. FORM 7.1 F- TEMPLATE FOR INFORMED CONSENT FORM FOR GENETIC STUDIES

INFORMED CONSENT FOR GENETIC TESTING

[LANGUAGE]

[VERSION NUMBER]

[VERSION DATE]

[INSERT THE TITTLE OF THE STUDY]

INTRODUCTION

Your child is being invited to take part in a research study. Before you decide on behalf of your child, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not to allow your child to participate in this research.

A. Purpose

The purpose of this consent form is to give you information so that you can decide whether you want your child to provide blood and health information for genetic research.

Your child's participation in this genetic research is voluntary. If you decide that he/she should not participate in the genetic research, your child may still participate in the main clinical trial. In connection with the genetic research, you will also be asked to sign this separate form on behalf of your child authorizing the use and disclosure of your unidentifiable health information for this additional study.

B. Introduction

Cells in the human body contain genes composed of deoxyribonucleic acid (DNA). The genes contain key instructions for cell function and help determine the characteristics of each individual. Genetic research uses DNA samples to help understand how different individuals respond to *[e.g. TB, e.t.c] drugs*. Some people have special genes that make some *drugs* not work as good as in other people. We want to see if this is also the case in Uganda and whether this is important in order to determine if *[TB]* treatment is successful.

C. About This Research

Your child's sample may be stored for a long time but not longer than *10 years*. If we do not use the samples, the samples will be destroyed after 10 years. Your child's health and medical information collected for the study will be retained. The DNA information obtained from your child's blood sample will be used along with the other information collected from the main clinical trial in which your child is a participant, to study the differences in response to drugs that is generally seen in people with *HIV or other diseases* that are receiving *treatment of ……*

D. Procedure

If you agree to allow your child to participate, a blood sample will be collected from him/her and used to study the interaction between your child's DNA and *HIV or other diseases* Treatment. This sample is in addition to any blood samples that will be drawn for the purpose of your child's medical care.

E. Risks

There may be non-physical risks associated with taking part in this study, such as the risks associated with a breach of privacy or confidentiality. We believe that the risk of such improper disclosure of your child's information is minimal because we have adopted strict privacy and confidentiality procedures for this research. We will make all reasonable efforts to minimize any breach of confidentiality.

F. Benefits

There will be no direct benefit to your child as a result of his/her participation in the genetic research as these tests are currently not planned during the study. It is possible that your

child's participation may contribute to the knowledge of [*insert name of Disease]*, or may help in developing new drugs or methods to detect or treat [*insert name of Disease]*,

G. Withdrawal of Consent and Destruction of Samples

You may withdraw your parental consent and discontinue his/her participation in this genetic research described above without affecting his/her participation in the *main clinical trial or observational study.*

To withdraw your parental consent, you must contact your study doctor or the research office at IDI, because only he/she has access to all of your identifying information. If you withdraw your parental consent for the genetic research during this time, you may request that your child's blood sample and DNA obtained from his/her blood sample be destroyed and no longer used in research. Any research results obtained prior to your withdrawal of consent will however be used.

H. Confidentiality The clinical study team at IDI will be the only people who will know your personal information (name, phone number, and address). The study team will replace your child's personal information with a coded identification number when his/her samples are used.

You understand that it is possible, however, that members of regulatory authorities, such as the Uganda National Council for Science and Technology and other persons required by law may have access to the research results. Although results from this research may be published; any publication will not identify your child.

I. Questions/Information

This study has been reviewed by the *Joint Clinical Research Centre, Institutional Review Board.* You may contact the chairman of the Research Ethics Committee if you have any questions regarding your child's rights as a study participant at any time.

[insert IRB chairperson contact] e.g.

Dr. David Kateete

IDI REC Chairperson

IDI REC Office,

Infectious Diseases Institute Building,

Near Mulago Hospital Complex

Telephone (Office): 0312-307000; Mobile:

If you or your child have any questions regarding this sample collection or genetic research or if your child experiences an injury caused by the sample collection procedure, you should contact

[Insert PI's name/ contact]

Infectious Diseases Institute,

Makerere University College of Health Sciences, Mulago Hospital Complex, Kampala

Email :

Telephone

The undersigned, hereafter known as *[insert name of study*] trial participant promises the following:

- The information in this genetic testing informed consent sheet and the written informed consent form was explained to me by the study physician and understood by me.
- All my questions were answered to my satisfaction.
- I agree to take part in possible future genetic studies under the conditions as described in this informed consent sheet
- I received a copy of the signed written informed consent form.
- I know that participation in this study is completely voluntary and that I may refuse to participate or withdraw from the study at any time and I still may be part of the main *[insert name of study*] trial.
- Refusal to participate or withdrawal after initial consent will not affect my current or future treatment.

_____

Name of Participant's parent (printed) Signature of participant's parent

make a thumbprint * in the box below

Date: ____ / _____ / ____

Day Month Year

_____

Name of Person Administering Consent (printed) Position/Title

_____

Signature of Person Administering Consent **Date: ____ / _____ / ___**

Day Month Year

**If the patient is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to their participation in the study, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by the patient and that informed consent was freely given by the patient.*

_____ _____

Name of Person Witnessing Consent (printed) Signature of Person Witnessing Consent

Date: ____ / _____ / ___

Day Month Year

83. FORM 7.1G: INFORMED CONSENT DOCUMENT TEMPLATE: VENIPUNCTURE

CONSENT FORM FOR VENIPUNCTURE

[Language]

[Version number]

[Version date]

[Title of Study]

PURPOSE

We are conducting a research study of_____.

PROCEDURES

For this purpose, about (tsp, tbl, cup) of your blood will be needed. The procedure involves placing a needle in a vein in your arm to take blood and will require no more than a few minutes.

RISKS

Occasionally there are minor complications, and you may experience bruising, swelling, black and blue marks, fainting and/or infection at the site.

BENEFITS

Although the results of this test may not benefit you directly, they can be made available to your physician upon request.

CONFIDENTIALITY

Data collected during this study will be confidential, except as may be required by law, and any publication resulting from the research will not personally identify you.

WITHDRAWAL

Your decision to take part in this study is a voluntary one and your medical care will not be affected if you refuse. You may terminate your participation anytime without prejudice to present or future care at the_____Name (Institution/Organization).

PARTICIPANT'S RIGHTS

Should you wish further information regarding your rights as a research participant at the (Institution/Organization), you may contact_____on telephone xxx-xxx-xxx.

INJURY/COMPLICATIONS

In the event of physical injury resulting from the research procedure, medical treatment in excess of that covered by third party payers will be provided at no cost to you, but financial compensation for injury is not available.

You will be given a copy of this consent form.

By signing below, you consent to participate in the procedure described above

Your signature _____Date _____

_____

Name (print)

(If the protocol allows the entry of participants unable to provide informed consent, the following signature line should also be placed under the area for the participant's name and signature)

_____ _____

Signature of Legal Representative Date

_____

Name of Legal Representative (print)

(If the participant is unable to read or sign their name, the following signature line should also be placed under the area for the participant's name and signature)

_____ _____

Signature of Witness to Participant Mark or Consent Date

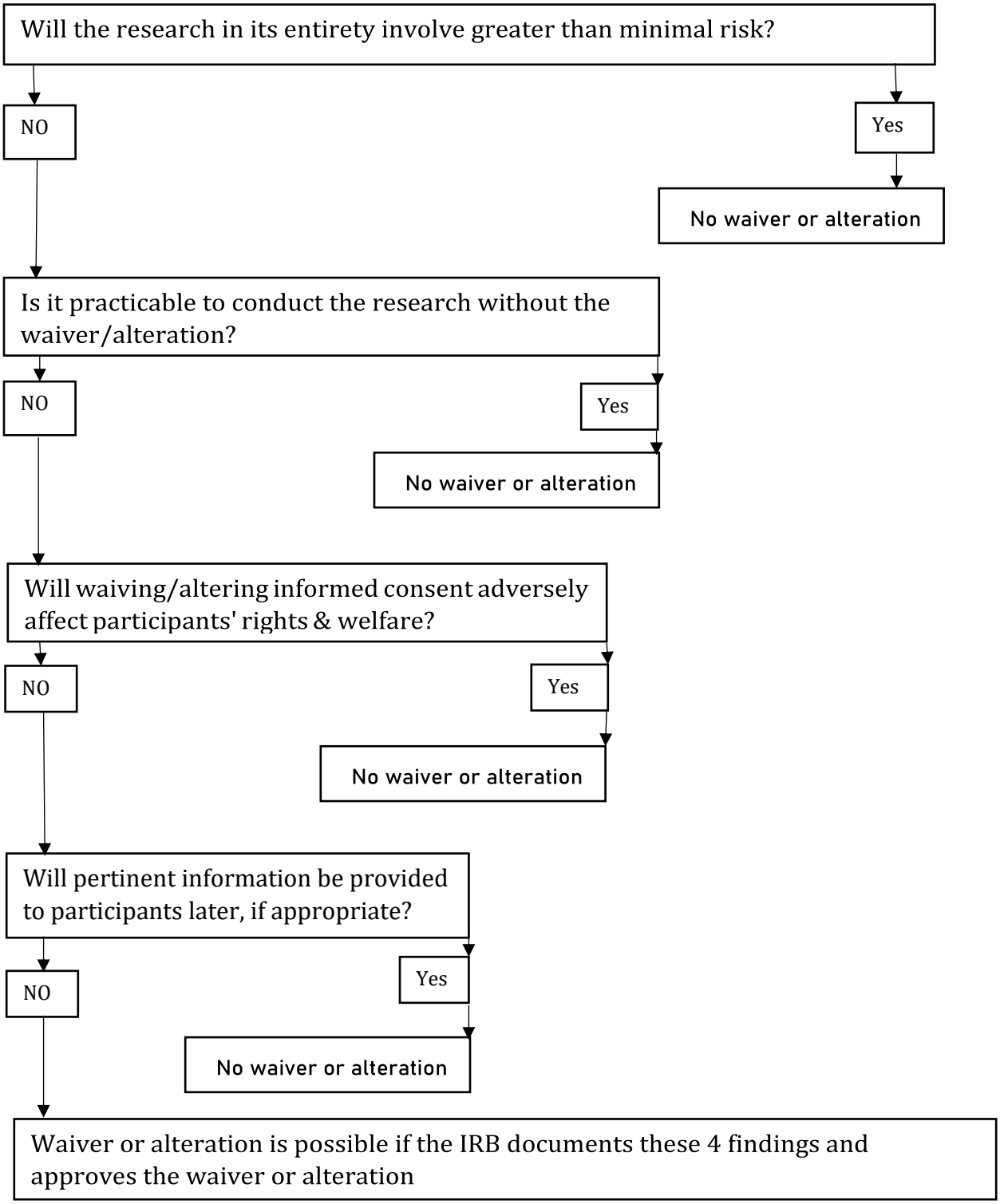
_____

Name of Witness to Participant Mark or Consent

This procedure uses radioactive materials (x-rays) and you will receive a radiation exposure. There is a risk associated with this exposure that is justified by the medical information that will be beneficial to --your/others --medical treatment. The radiation exposure received from this procedure is roughly equivalent to (number) of (typical diagnostic procedures). (Explain)

Risk/Benefit: Information allowing the IDI REC to comment on the usefulness of the procedure must be submitted. Attaching a copy of the submission to the IDI REC is sufficient. This section is particularly important whenever research organ/whole body doses exceed 3/5 Rem.

84. FORM 7.2A: WAIVER OR ALTERATION OF INFORMED CONSENT DECISION CHART



85. FORM 7.3A: REQUIREMENTS CHECKLIST FOR CONSENT/ ASSENT OF MINORS

Study_____ Date _____

Minor's name_____ Age _____

Parental Consent

- ❑ Minor is under the age of 18
- ❑ Only one parent or legal guardian must sign the consent form
- ❑ Minor is considered an emancipated minor in this state:
  - ❑ living on his/her own,
  - ❑ have borne a child,
  - ❑ married
  - ❑ is currently pregnant.
- ❑ Parental consent waived by the IDI REC

Consent/Assent of Minors

Participants aged 8 - l7 must sign the assent form. Minor participants ages 8 – 17 years of age must assent to be in the study, unless:

- ❑ The participant is incapable, mentally or emotionally, of being reasonably consulted
- ❑ The minor's assent/consent is not required because _____

_____

Comments

_____

_____

_____

_____

86. FORM 7.3B: ASSENT FORM TEMPLATE

INFORMED CONSENT DOCUMENT TEMPLATE: ASSENT

[Language]

[Version number]

[Version date]

INSERT TITLE OF STUDY

The Infectious Diseases Institute (IDI), which is part of Makerere University, is working with the [insert name of any partners e.g. Ministry of Health] to protect the health of Ugandans. IDI is conducting a study on [give a brief background of your study]. The information collected will help scientists to [insert the broad benefit of this study to a given community or Uganda as a country]

Before taking part in this research study, I would like to share with you the details of this study.

[Insert the total number of participants or number of households who will take part in this study e.g. 200] will take part in this study.

You will be required to answer a few questions that will be read to you by the study doctor or study nurse. [Quantitative research]

The nurse will also take some blood from your arm. This will probably hurt, but not for long. A black and blue mark might be left where the needle went in, and you might also feel dizzy. You will take pills/ shots …... a day/week for …... days/weeks/months. You will go to the doctor's office…. more times to have more blood tested. [In case of a clinical trial or a prospective cohort study]

You will be required to participate in a focus group discussion or in-depth interviews. The interview will take about. [give an appropriate estimate of the time frame for which the interview will last e.g. 50-60 minutes] – Qualitative research

All of the information you share with us will be kept confidential. Nothing used in a report will identify you or be linked to your name or household.

Your participation in this assessment is voluntary. You may stop at any time. You may refuse to answer questions you may not comfortable with. There is no penalty if you stop the interview or do not answer some questions.

There are no right or wrong answers. Please strive to be open and honest in your answers so that the best information possible can be collected.

There is no direct benefit to me for participating, but by answering the questions you are helping to protect your community and country.

You will receive [insert any incentive that you plan to give your participants e.g. bar of soap] for taking part in the interview.

This study was approved by the Infectious Diseases Institute Research Ethics Committee (IDI REC). You may also contact the Ethics Committee regarding any concerns, injury, or risks posed to you as a result of your participation in this study. The IDI REC Chairperson contact is

Dr. David Kateete

Chairperson, IDI Research Ethics Committee

Tel: 0312-307000

If you have any questions, please contact the Principal investigator or the study coordinator below

Insert name of the Principal investigator

Tel:

By signing this form, I confirm that I have read or have been told, and that I fully understood the above information. I agree to take part in the community-based assessment.

_____ _____

Name of Participant (printed) Signature of participant

make a thumbprint in the box below*

Date: _____ / _____ / _____

Day Month Year

_____ _____

Name of Person Administering Consent (printed) Position/Title

_____

Signature of Person Administering Consent Date: _____ / _____ / ____

Day Month Year

*If the patient is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to their participation in the study, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by the patient and that informed consent was freely given by the patient.

_____ _____

Name of Person Witnessing Consent (printed) Signature of Person Witnessing Consent

Date: _____ / _____ / ____

Day Month Year

87. FORM 7.3 C-PARENTAL CONSENT FORM

[Language]

[Version number]

[Version date]

[INSERT TITLE OF THE STUDY]

PARENTAL INFORMATION LEAFLET

Dear Madam or Sir,

Introduction

Your child is being invited to participate in a research study at the Infectious Diseases Institute (IDI). The name of the study is "insert name of the trial". Researchers at IDI are interested in learning more about [provide a brief background of the study;]. This is study is being sponsored by [Insert the name of the sponsor and other collaborating partners <<IF APPLICABLE>>

Why is this study being done?

[provide appropriate details on the purpose of the study;].

How many people are participating in this study?

About [insert total number of participants e.g. 200 children] will participate in this study. Your child is being invited to take part in this study because he/she has both HIV and TB.

Study Procedures

Your child will have a total of 7 study visits [insert the appropriate number of visits] for this study. These visits are done on days that your child will be coming for his/her usual appointments,

Visit 1 – Screening and enrolment

Insert study procedures to be performed on this visit

Visit 2 and 4 (week 2 and week 4)

Insert study procedures to be performed on this visit

Visits 5 (week 6):

Insert study procedures to be performed on this visit

Visit 6 (Week 8)

Insert study procedures to be performed on this visit

Visit 7 (Week 24)

Insert study procedures to be performed on this visit

How long will the study last?

Your child will participate in this study for a total of 6 months [insert appropriate time frame for which the study will last]. Your child will be required to take his/her HIV medicines without missing any doses. Your child should not stop his/her HIV medicines but continue after completing his/her TB or any other disease related to the study] treatment and after the study is completed.

What will happen to my samples?

The sputum and blood samples provided by your child will be used to learn more about [insert name of the disease e.g. TB, KS] germs in patients with HIV. You will be asked to sign a separate consent form on behalf of your child if you agree to allow any left-over of his/her samples to be stored for a long time. A separate consent form will also be needed for genetic testing which will be performed on your child's blood <<IF APPLICABLE>>. Your child can still participate in this study if you refuse genetic testing on his/her samples or if you refuse to allow the researchers to store his/her samples for a long time.

Home visits follow-up.

In case your child misses any of his/her study visits, we will call you to find out how your child is. A home visitor may come to see your child at your home to plan the next steps.

Risks

The main risks of taking part in the study include side effects [Insert potential side effects]. In case your child develops abdominal pain, yellow eyes or vomiting, please let us know because these may be signs that your liver has been affected by the drugs.

Benefits

There may not be any direct benefit to your child from being in this study. However, the results of these tests will be used to help us learn whether or not we can adjust doses of [TB, or any other diseases in question] drugs for the treatment of patients in the future and whether higher doses of rifampicin will affect the amount of HIV medicine in the blood.

Costs

Your child will not be required to pay any costs to be part of this study.

Reimbursements/Compensation

There are no costs to be paid to you for participate in this study. However, your child will be required to attend to the scheduled study visits where the study team is responsible for meeting the costs of transport for both you and your child during each the study visit. You

will be given [insert amount of money to be reimbursed or any form of compensation e.g. 30,000 or a bar of soap] UGX compensation for transport costs for each of the study visits and for any other visits that are required by the study.

Participant rights

Participation in this study is entirely voluntary. You have the right to refuse your child from participating in this study and this decision will not affect his/her treatment at IDI in any way. If you choose to allow your child to participate in the study, he/she has the right to withdraw from the study at any time. Any research results obtained prior to your child's withdrawal of consent may however be used and some data may have already been published.

Research-related injury

In case your child feels unwell, please feel free to contact the study team by telephone or come and meet us at the [IDI Mulago complex in room # or TB clinic]. We might perform more tests, depending how sick your child is. Your child will receive healthcare until complete cure and stabilization of a research related illness. If we refer your child to hospital for a research related illness, the cost of referral and management of the condition shall be paid by the study.

Sharing the Results

We plan to share the results of this research with you and the IDI after the study and the results will be published.

Reasons why your child may be withdrawn from the study

Your child may be removed from the study without your consent for the following reasons [Insert as many reasons as possible]:

If the study is stopped or canceled.

Whom to contact

This study has been approved by the Joint Clinic Research Centre – Research Ethics Committee (JCRC-REC). You may contact the chairman of the Research Ethics Committee if you have any questions regarding your child's rights as a study participant at any time.

Dr. David Kateete

REC Chairperson

IDI REC Office,

Infectious Diseases Institute Building,

Near Mulago Hospital Complex

Telephone (Office): 0312-307000

Alternatives to Participation

If you choose not to allow you child to participate, your child will continue to receive his/her treatment as normal at the IDI. Neither his/her treatment present treatment nor his/her future treatment at IDI will be affected in any way by choosing not to participate in this study.

Confidentiality

All your child's information will be kept private and confidential. Your child's name or address or any other identifying information will not be shared with anyone outside the study. Codes will be used to replace your child's name so that no one can directly identify him/her. All your child's records from this study will be kept confidential by the investigators of this study. No information that personally identifies your child will be disclosed in any publications that arise as a result of this study.

Questions about this study

The study doctor or nurse will explain this study to you and your child. If you have any questions you may ask them now or any time during the study. You may contact also:

Insert the name of the PI

Infectious Diseases Institute,

Makerere University College of Health Sciences, Mulago Hospital Complex, Kampala

Mobile :

Informed consent

By signing the Informed Consent Form you agree to your child's participation in this study.

The undersigned, hereafter known as INSERT THE NAME OF THE STUDY e.g SAEFRIF, NADIA, participant agree to the following:

The information in the patient information sheet and the written informed consent form was explained to me by the study physician and understood by me.

All my questions were answered to my satisfaction.

I agree to take part in the "…..study" under the conditions as described in the patient information leaflet.

I received a copy of the patient information leaflet and a signed written informed consent form.

I know that participation in this study is completely voluntary and that I may refuse to participate or withdraw from the study at any time.

Refusal to participate or withdrawal after initial consent will not affect my current or future treatment.

_____ _____

Name of Participant's Parent (printed) Signature of participant's Parent.

make a thumbprint in the box below*

Date: _____ / _____ / ____

Day Month Year

_____ _____

Name of Person Administering Consent (printed) Position/Title

_____

Signature of Person Administering Consent Date: _____ / _____ / ____

Day Month Year

*If the patient is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to their participation in the study, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by the patient and that informed consent was freely given by the patient.

_____ _____

Name of Person Witnessing Consent (printed) Signature of Person Witnessing Consent

Date: _____ / _____ / ____

Day Month Year

88. FORM 8.1A INVESTIGATOR RESPONSIBILITIES – IDI REC REQUIREMENTS

Submission Materials

		DEADLINE	
INITIAL REVIEW	**Full IDI REC** (Review by convened meeting of IDI REC members)	At least 21 days prior to the review meeting. (Complete submissions received less than 21 days to the IDI REC meeting will be reviewed at the next IDI REC meeting)	**Submission items** a) Completed and signed IDI REC Face Sheet * b) Study Summary Form complete with required attachments * c) Research protocol d) Informed consent document and checklist * e) Proposed participant instructions f) Other supporting material (sample of proposed advertising, patient diaries, etc.) g) Investigator Brochure or insert/device description (Required for NDA regulated products) h) Financial disclosure statement i) Questionnaires & assessment instruments (two copies) j) Documentation that the study has been reviewed and approved by other committees charged with oversight of research. *Required for all research participant to IDI REC review
	Exempt Review	None	Completed and signed IDI REC Face Sheet *

			Form 3.2A Exemption Screening Questions Form 3.2B Claim of Exemption

89. FORM 8.1B SERIOUS ADVERSE REPORT FORM

For the purposes of this form, a serious adverse event is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/incapacity, results in congenital anomalies/birth defects, or in the opinion of the investigators represents other significant hazards or potentially serious harm to research participants or others. A serious adverse event is considered unexpected if it is not described in the Package Insert or in the Investigator's Brochure (for investigational agents), in the protocol, or in the informed consent document.

Date: _____(dd/mm/yy)

PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR:	Institution: Phone: Email:……..
Date became aware of SAE: _____ /_____ /_____	Type of Report: ☐Initial. ☐Follow-up.
Brief description of participant:	SEX: M F AGE: (years)
Brief description of the nature of SAE, and sequence of events following onset of SAE (including diagnosis):	
Research involves a: ☐Drug☐Device ☐Procedure. Is the drug/device investigational: Yes☐ No☐	Name of Drug, Device or Procedure:
Location of SAE: ☐IDI Mulago	Severity of SAE (check only one):

☐Kiswa Health Center	☐Mild ☐Moderate ☐Severe but not fatal ☐Fatal
Is the drug/device/procedure investigational: ☐Yes ☐No	Causality: ☐Not related ☐Unlikely ☐Possibly related ☐Probably related ☐Related ☐Unknown

Outcome of SAE **(check only one):** ☐Death (due to event) ☐Death (due to other causes) ☐Hospitalization ☐Extended Hospitalization ☐Disability/incapacity ☐Requires intervention to prevent permanent impairment ☐Congenital Abnormality/ Birth defect ☐Recovered ☐Not yet recovered ☐Other (Specify) _____	***Relatedness of SAE to Research*** **(check only one):** ☐Not related (clearly not related to the research) ☐Unlikely (doubtfully related to the research) ☐Possible (may be related to the research) ☐Probable (likely related to the research) ☐Definite (clearly related to the research) Undetermined
Expectedness: ☐Expected ☐Not expected	**Recovery of Participant (check only one):** ☐Complete ☐Moderate Minimal ☐None ☐Not yet resolved ☐Unknown
Have similar SAEs occurred on this protocol: ☐Yes ☐No If "Yes", how many? _____	
What steps do you plan to take as a result of the SAE reported above (Check all that applies)?	☐No action required ☐Stop administration of study agent in the participant ☐Amend consent document ☐Amend protocol ☐Inform current participants ☐Terminate or suspend protocol ☐Other (describe): _____

If changes are required to the protocol and/or consent form(s), state how soon the amended documents will be submitted to the IRB for approval:	☐Are being submitted now ☐Within 1 – 2 months
If changes are not required, please explain as to why changes to the protocol /consent form are not necessarily based on the event:	
Report prepared by: _____ **Designation on the study:** _____	**Phone:**_____ **Email:** _____
PI'S SIGNATURE:	***DATE:***

90. FORM 8.1B ESSENTIAL DOCUMENTS

Before the Clinical Phase of the Trial Commences

During this planning stage the following documents should be generated and should be on file before the trial formally starts

Title of Document	Purpose	Located in the files of		
		Investigator	Sponsor	IDI REC
INVESTIGATOR BROCHURE	To document that relevant and current scientific information about the investigational product has been provided to the investigator	X	X	X
SIGNED PROTOCOL, AMENDMENTS, IF ANY, & SAMPLE CRF	To document Investigator and Sponsor agreement to the protocol/amendment(s) and CRF	X	X	X
INFO. GIVEN TO TRIAL PARTICIPANT		X	X	X
- INFORMED CONSENT FORM	Including all applicable translations to document the informed consent	X	X	X
- ANY OTHER WRITTEN INFORMATION	To document that participants will be given appropriate written information (content and wording) to support their ability to give fully informed consent	X	X	X
- ADVERTISEMENT FOR PARTICIPANT RECRUITMENT	(if used) To document that recruitment measures are appropriate and not coercive	X	X	X
FINANCIAL ASPECTS OF THE TRIAL	To document the financial agreement between the Investigator/institution and the Sponsor for the trial	X	X	X*
INSURANCE STATEMENT	(where required) To document that compensation to participant(s) for trial-related injury will be available	X	X	X

SIGNED AGREEMENT BETWEEN INVOLVED PARTIES	To document agreements. e.g.: Investigator/institution & Sponsor - Investigator/institution & CRO - Sponsor & CRO - Investigator/institution & authority(ies)	X	X	X*
DATED, DOCUMENTED APPROVAL/ FAVORABLE OPINION OF IDI REC/ IEC OF THE FOLLOWING:	To document that the trial has been participant to IDI REC/IEC review and given approval/favorable opinion and to identify the version number and date of the document(s)	X	X	X
- protocol and any amendments		X	X	X
- CRF (if applicable)		X	X	X
- informed consent form(s)		X	X	X
- any written information to be provided to the participant(s)		X	X	X
- advertisement for participant recruitment (if used)		X	X	X
- participant compensation (if any)		X	X	X
- any other documents given approval/ favorable opinion		X	X	X

Title of Document	Purpose	Located in the files Of		
		Investigator	Sponsor	IDI REC
IRB/INDEPENDENT ETHICS COMMITTEE COMPOSITION	To document that the IDI REC/IEC is constituted in agreement with GCP	X	X	
CV AND/OR OTHER DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S)	To document qualifications and eligibility to conduct trial and/or provide medical supervision of participants	X	X	
NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL	To document normal values and/or ranges of the tests	X	X	
MEDICAL/LABORATORY/TECHNICAL PROCEDURES /TESTS certification or accreditation or established quality control and/or external quality assessment or other validation*	To document competence of facility to perform required test(s) , and support reliability of results	X	X	
SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S)	To document compliance with applicable labeling regulations and appropriateness of instructions provided to the participants	X	X	
INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS (if not included in protocol or Investigator Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials	X	X	
SHIPPING RECORDS FOR INVESTIGATIONAL PRODUCT(S)	To document shipment dates, batch numbers and method of	X	X	

AND TRIAL-RELATED MATERIALS	shipment of investigational product(s) and trial-related materials and allows tracking of product batch, review of shipping conditions, and accountability			
CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED	To document identity, purity, and strength of investigational product(s) to be used in the trial		X	
DECODING PROCEDURES FOR BLINDED TRIALS	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining participants' treatment	X	X**	
MASTER RANDOMIZATION LIST	To document method for randomization of trial population		X**	
PRE-TRIAL MONITORING REPORT	To document that the site is suitable for the trial	X	X	
TRIAL INITIATION MONITORING REPORT	To document that trial procedures were reviewed with the Investigator and the Investigator's trial staff	X	X	

During the Clinical Conduct of the Trial In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available				
Title of Document	Purpose	Located in the files Of		
		Investigator	Sponsor	IDI REC
INVESTIGATOR BROCHURE/PRODUCT DESCRIPTION **UPDATES/**	To document that Investigator is informed in a timely manner of relevant information as it becomes available	X	X	X
ANY REVISION TO:	To document revisions of these trial related documents that take effect during trial			
- protocol/amendment(s) and CRF		X	X	X
- informed consent form		X	X	X
- any written information provided to participants		X	X	X
- advertisement for participant recruitment (if used)		X	X	X
DATED, DOCUMENTED APPROVAL/ FAVORABLE OPINION OF IDI REC/REC OF THE FOLLOWING: - protocol amendment(s) - revision(s) of: - informed consent form- any other written information to be provided to the participant - advertisement for participant recruitment- any	To document that the amendment(s) and/or revision(s) have been participant to IDI REC/IEC review and were given approval/favorable opinion and to identify the version number and date of the document(s)	X	X	

other documents given approval/favorable opinion- continuing review of trial*				
REGULATORY AUTHORITY(IES) AUTHORIZATIONS/APPROVALS/ NOTIFICATIONS WHERE REQUIRED FOR: - protocol amendment(s) and other documents	To document compliance with applicable regulatory requirements	X	X	
CVs FOR NEW INVESTIGATOR(S) AND/OR SUB-INVESTIGATOR(S)		X	X	
UPDATES TO NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/LABORATORY/ TECHNICAL PROCEDURE(S)/TEST(S) **INCLUDED IN THE PROTOCOL**	To document normal values and ranges that are revised during the trial	X	X	
UPDATES OF MEDICAL/LABORATORY/ TECHNICAL PROCEDURES/TESTS - certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required)	To document that tests remain adequate throughout the trial period	X	X	
DOCUMENTATION OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS **SHIPMENT**		X	X	

Title of Document	Purpose	Located in the files Of		
		Investigator	Sponsor	IDI REC
CERTIFICATE(S) OF ANALYSIS FOR NEW BATCHES OF INVESTIGATIONAL PRODUCTS			X	
MONITORING VISIT REPORTS	To document site visits by, and findings of, the monitor	X	X	
RELEVANT COMMUNICATIONS OTHER THAN SITE VISITS - letters - meeting notes - notes of telephone calls	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting	X	X	
SIGNED INFORMED CONSENT FORMS	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each participant in trial and to document direct access permission	X	X	X
SOURCE DOCUMENTS	To document the existence of the participant and substantiate integrity of trial data collected and to include original documents related to the trial, to medical treatment, and history of participant	X	X	
SIGNED, DATED AND COMPLETED CASE REPORT FORMS (CRF)	To document that the Investigator or authorized member of the Investigator's staff confirms the observations recorded	X copy	X orig.	
DOCUMENTATION OF CRF	To document all changes/additions or corrections made to CRF after initial	X	X	

CORRECTIONS	data were recorded	copy	orig.	
NOTIFICATION BY ORIGINATING INVESTIGATOR TO SPONSOR OF SERIOUS ADVERSE EVENTS AND RELATED REPORTS	Notification by originating Investigator to Sponsor of serious adverse events and related reports	X	X	
NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, IF NEEDED, TO REGULATORY AUTHORITY(IES) AND IDI REC OF UNEXPECTED SERIOUS ADVERSE REACTIONS AND OF **OTHER SAFETY INFORMATION**	Notification by Sponsor and/or Investigator, where applicable, to regulatory authorities and REC(s)/IEC(s) of unexpected serious adverse drug reactions	X*	X	X
NOTIFICATION BY SPONSOR TO **INVESTIGATORS OF SAFETY INFORMATION**	Notification by Sponsor to Investigators of safety information	X	X	X
PERIODIC REPORTS TO IDI REC	Interim or annual reports provided to the IDI REC	X	X*	X
PARTICIPANT SCREENING LOG	To document identification of participants who entered pre-trial screening	X	X	
PARTICIPANT IDENTIFICATION CODE LIST	To document that Investigator/institution keeps a confidential list of names of all participants allocated to trial numbers on enrolling in the trial and allows Investigator/institution to reveal identity of any participant	X	X*	

Title of Document	Purpose	Located in the files of		
		Investigator	Sponsor	IDI REC
PARTICIPANT ENROLLMENT LOG	To document chronological enrolment of participants by trial number	X		
INVESTIGATIONAL PRODUCTS ACCOUNTABILITY AT THE SITE	To document that investigational product(s) have been used according to the protocol	X	X	
SIGNATURE SHEET	To document signatures and initials of all persons authorised to make entries and/or corrections on CRFs	X	X	
RECORD OF RETAINED BODY FLUIDS/ TISSUE SAMPLES (IF ANY)	To document location and identification of retained samples if assays need to be repeated	X	X	
After Completion or Termination of the Trial After completion or termination of the trial, all of the documents identified previously should be in the file together with the following				
INVESTIGATIONAL PRODUCT(S) ACCOUNTABILITY AT SITE	To document that the investigational product(s) have been used according to the protocol and to document the final accounting of investigational product(s) received at the site, dispensed to participants, returned by the participants, and returned to Sponsor	X	X	
DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION	To document destruction of unused investigational products by Sponsor or at site	X* **	X	
COMPLETED PARTICIPANT IDENTIFICATION CODE LIST	To permit identification of all participants enrolled in the trial in case follow-up is required. (list should be	X	X	

	kept in a confidential manner and for agreed upon time)			
AUDIT CERTIFICATE	(if available) To document that audit was performed	X	X	
FINAL TRIAL CLOSE-OUT MONITORING REPORT	To document that all activities required for trial close- out are completed, and copies of essential documents are held in the appropriate files	X	X	
TREATMENT ALLOCATION AND DECODING DOCUMENTATION	Returned to Sponsor to document any decoding that may have occurred	X	X	
FINAL REPORT BY INVESTIGATOR TO THE IDI REC	To document completion of the trial	X	X	X
CLINICAL STUDY REPORT	To document results and interpretation of trial	X*	X	

*if applicable / required

** third party if applicable

*** if destroyed at the site

91. FORM 8.2A- SPONSOR RESPONSIBILITIES

Initial IDI REC Review

Investigators must receive their approval letter from the IDI REC before they initiate any procedures that are related to the protocol. The IDI REC expects sponsors to use investigators who understand and adhere to the national research ethics requirements regarding REC review and approval. The IDI REC will provide educational material if needed.

It is the responsibility of the investigator to be cognizant of national guidelines and requirements that affect the conduct of human participant research in Uganda and apply these requirements appropriately. The IDI REC may require that such knowledge and application be demonstrated before IDI REC approval is issued for studies involving certain populations and procedures.

After Initial Approval

When written approval is issued by the IDI REC, investigators can initiate the study procedures. However, continued approval is always conditional. Standard conditions for continued approval are:

Any changes in the research protocol, informed consent document, questionnaires administered to study participants or participant information during the approval period must be submitted to the IDI REC for review and must not be initiated until approved by the IDI REC.

All advertisements, letters, and any other media for participant recruitment must be submitted and approved prior to use.

Significant deviations from the research protocol must be reported as soon as possible.

A copy of the approved informed consent document must be signed and dated by each participant or the participant's legal representative prior to initiation of any study procedures. In addition, each participant must be given a copy of the signed consent form.

All deaths, life-threatening complications, hospitalizations, or serious and/ or unexpected adverse events, whether related to the study article or not, must be reported to the IDI REC as soon as possible.

The investigator must cooperate with the IDI REC in its efforts to conduct continuing review.

The IDI REC may elect to place additional, specific conditions on the conduct of a study.

Study Renewal and Study Completion Reports

Reports must be submitted by the investigator and/or study sponsor at intervals determined by the IDI REC. The expiration date and the date that an interim report is due, if required, will be stated in the study approval letter.

Serious or Unexpected Adverse Events

Part of the continuing review process is the review of unanticipated and serious adverse events. All unanticipated or serious adverse events must be reported to the IDI REC. If necessary, the sponsor and investigator will be notified as to further action required to protect research participants. Possible actions include: modification of the protocol, modification of the consent document, and/or notification of participants.

An adverse event reporting form is included with the investigator's approval letter. Investigators may use this form (Form 8.2B), MedWatch forms, standard forms supplied by the sponsor or CRO, or the form that is included in the investigator's SOPs to report serious or unexpected adverse events to the IDI REC.

Amendments

All amendments, including changes to consent forms, changes in study personnel, and deviations in the protocol must be reported to the IDI REC.

Site Visits

A representative of the IDI REC may conduct a site visit before or after a study is approved. Every attempt will be made to schedule visits at the convenience of site personnel.

MODIFICATIONS TO CURRENTLY APPROVED RESEARCH

1. Amendments and Modifications

All modifications to currently approved research are required to have IDI REC review and approval prior to implementation. The requested modifications should be outlined in a cover letter, left as track-changed in the modified documents, and the modified items such as consent forms, protocols, Investigator Brochures, study instruments, recruitment tools, etc., included with the submission. Both the track-changed copy and the clean copy (after the modification) should be submitted to the IDI REC for review

An amendment may require full IDI REC review if the modification is significant and affects the risks and benefits to participants in the research. Changes in the risks or benefits to participants may require modifications to the consent form and re-consenting of participants. The IDI REC may only approve modifications submitted during a current approval year to the end of that period. For example, if the new, renewal, or continuing approval is issued on 1st January, it will have an expiration date of 31st December. If an addendum is approved during this approval time, the approval still lasts only until 31st December. Please incorporate all modifications and addendums into the renewal application, protocol, and when applicable the informed consent forms for IDI REC consideration during the annual review.

When changing investigators, the IDI REC must receive a letter from the principal investigator indicating the change in responsibility. The new investigator should send a letter accepting responsibility for the research and his/her current CV.

RENEWAL OF IDI REC APPROVAL

National research ethics guidelines do not allow an REC to approve a study for more than one year. For multi-year research, the principal investigator and/or study sponsor is responsible for submitting a renewal application prior to the expiration of the current IDI REC approval. IDI REC notifies investigators and/or the study sponsor of the impending expiration date 8 to 4 weeks prior to the expiration of the current IDI REC approval.

If the approval expires prior to submission of the renewal application, the investigator is required to suspend participant contact and data collection until the renewal is approved by IDI REC, and no new participants may be contacted, recruited, or enrolled until the investigator obtains current IDI REC approval.

The renewal application should incorporate all of the addenda and modifications submitted to and approved by the IDI REC during the previous approval periods. Continuing review and approval is necessary as long as study procedures or follow-up procedures continue, even if recruitment of participants has ended. Continuing review approval is also mandated through data analysis.

COMPLETION/TERMINATION

Investigators should notify the IDI REC in writing when a study is terminated or completed or after data analysis is complete.

SPONSOR RELATIONSHIP WITH INVESTIGATIVE SITES

The IDI REC strongly recommends that the sponsor enter into a written contract with each investigative site. The Contract should contain language that addresses issues of research-related medical care provided to study participants, data ownership, and publication of findings.

IDI REC provides each principal investigator with guidance that outlines IDI REC expectations regarding the conduct of the study. IDI REC expects the sponsor to hold each investigator to the same standards.

CONFLICTS OF INTEREST

The IDI REC is concerned about the potential for abuse when investigators have a financial obligation or interest that may pose a conflict of interest, therefore, investigators must disclose to the IDI REC all financial conflicts of interest and explain how such conflicts will be minimized or resolved. In these situations, IDI REC may require disclosure of conflicts of interest in the consent forms.

ETHICAL CONDUCT

The IDI REC expects that all research will be conducted in accordance with Uganda's National Guidelines for Research Involving Human as Research Participants.

MONITORING OF INVESTIGATIVE SITES

As sponsors routinely monitor investigative sites, they are in a unique position to uncover information to which the IDI REC may not otherwise be privy. The IDI REC requests that the sponsor provide the IDI REC with any information that may affect the rights and welfare of participants, or their willingness to continue participation. Such information may be contained within a monitoring report, or may be summary of the sponsor's assessment. The IDI REC will then work with the sponsor to rectify the situation.

In addition, the IDI REC may conduct its own monitoring visit to investigative sites. The IDI REC selects sites to visit, based on certain criteria, such as the conduct of a high risk study, or the enrollment of a vulnerable population. The IDI REC may also conduct a for-cause visit, or may randomly select a site to visit. Results of concern will be shared with the sponsor.

92. FORM 8. 2B: SERIOUS ADVERSE EVENT REPORT FORM

SERIOUS ADVERSE EVENT REPORT FORM

For the purposes of this form, a serious adverse event is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/incapacity, results in congenital anomalies/birth defects, or in the opinion of the investigators represents other significant hazards or potentially serious harm to research participants or others. A serious adverse event is considered unexpected if it is not described in the Package Insert or in the Investigator's Brochure (for investigational agents), in the protocol, or in the informed consent document.

Date: (dd/mm/yy)

PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR:	Institution: Phone: Email:……..
Date became aware of SAE: _____ /_____ /_____	Type of Report: ☐Initial. ☐Follow-up.
Brief description of participant:	SEX: ☐M ☐F AGE: (years)
Brief description of the nature of SAE, and sequence of events following onset of SAE (including diagnosis):	
Research involves a: ☐Drug☐Device ☐Procedure. Is the drug/device investigational: Yes☐ No☐	Name of Drug, Device or Procedure:
Location of SAE: ☐IDI Mulago ☐Kiswa Health Center	Severity of SAE (check only one): ☐Mild ☐Moderate ☐Severe but not fatal ☐Fatal

Is the drug/device/procedure investigational: ☐Yes ☐No	Causality: ☐Not related ☐Unlikely ☐Possibly related ☐Probably related ☐Related ☐Unknown

PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR:	**Institution:** Phone: Email:……..
Date became aware of SAE: _____ /_____ /_____	Type of Report: ☐Initial. ☐Follow-up.
Brief description of participant:	SEX: ☐M ☐F AGE: (years)
Brief description of the nature of SAE, and sequence of events following onset of SAE (including diagnosis):	
Research involves a: ☐Drug ☐Device ☐Procedure. Is the drug/device investigational: Yes☐ No☐	**Name of Drug, Device or Procedure:** ☐Multivitamins, including a single RDA of the following: 1.4 mg B1, ☐1.4 mg B2, ☐1.9 mg B6,☐ 2.6 mcg B12, ☐18 mg niacin, ☐70 mg C, 10 mg E, and ☐0.4 mg folic acid
Location of SAE: ☐IDI Mulago ☐Kiswa Health Center	**Severity of SAE (check only one):** ☐Mild ☐Moderate ☐Severe but not fatal ☐Fatal
Is the drug/device/procedure investigational: ☐Yes ☐No	**Causality:** ☐Not related ☐Unlikely ☐Possibly related ☐Probably related ☐Related ☐Unknown

Outcome of SAE (check only one): ☐Death (due to event) ☐Death (due to other causes) ☐Hospitalization ☐Extended Hospitalization ☐Disability/incapacity ☐Requires intervention to prevent permanent impairment ☐Congenital Abnormality/ Birth defect ☐Recovered ☐Not yet recovered ☐ ☐ ☐Other (Specify)	**Relatedness of SAE to Research (check only one):** ☐Not related (clearly not related to the research) ☐Unlikely (doubtfully related to the research) ☐Possible (may be related to the research) ☐Probable (likely related to the research) ☐Definite (clearly related to the research) ☐Undetermined
Expectedness: ☐Expected ☐Not expected	**Recovery of Participant (check only one):** ☐Complete ☐Moderate ☐Minimal None ☐Not yet resolved ☐Unknown
Have similar SAEs occurred on this protocol: ☐Yes ☐No If "Yes", how many?	
What steps do you plan to take as a result of the SAE reported above (Check all that applies)?	☐No action required ☐Stop administration of study agent in the participant ☐Amend consent document ☐Amend protocol ☐Inform current participants ☐Terminate or suspend protocol ☐Other (describe):

If changes are required to the protocol and/or consent form(s), state how soon the amended documents will be submitted to the IRB for approval:	☐Are being submitted now ☐Within 1 – 2 months
If changes are not required, please explain as to why changes to the protocol /consent form are not necessarily based on the event:	
_	
_	
Report prepared by: _____ Designation on the study: _____	Phone: Email:
PI'S SIGNATURE:	DATE:

93. FORM 9.1A- A SELF-EVALUATION CHECKLIST FOR RECS

		Reg. Ref	Yes	No	NA	Comments/ Notes
	DOES THE INSTITUTION HAVE WRITTEN POLICIES OR PROCEDURES THAT DESCRIBE:					
I	**The institutional authority under which the REC is established and empowered.**					
II	**The definition of the purpose of the REC.**					
III	**The principles governing the REC to assure that the rights and welfare of human participants are protected.**					
IV	**The authority of the REC.**					
	A. The scope of authority is defined, i.e., what types of studies must be reviewed.					
	B. Authority to disapprove, modify or approve studies based upon consideration of human participant Protection aspects.	21 CFR 56.109(a)				
	C. Authority to require progress reports from the Investigators and oversee the conduct of the study.	21 CFR 56.108(a)(1) & 56.109(f)				

	D. Authority to suspend or terminate approval of a study.	21 CFR 56.108(b)(3) & 56.113				
	E. Authority to place restrictions on a study.	21 CFR 56.108(a)(1), 109(a) & 113				
V	**REC's Relationship To:**					
	A. The top administration of the institution.					
	B. The other committees and department chairpersons within the institution.					
	C. The research Investigators.					
	D. Other institutions.					
	E. Regulatory agencies.					
	DOES THE INSTITUTION HAVE WRITTEN POLICIES OR PROCEDURES THAT DESCRIBE:	Reg. Ref	Yes	No	NA	Comments/ Notes
VI	**The membership of the REC.**					
	A. Number of members.	21CFR 56.107(a)				
	B. Qualification of members.	21 CFR 56.107(a)				
	C. Diversity of members (for example, representation from the community, and minority groups), including representation by:					

	both men and women	21 CFR 56.107(b)				
	multiple professions	21 CFR 56.107(a)				
	scientific and non-scientific member(s)	21 CFR 56.107(c)				
	not otherwise affiliated member(s)	21 CFR 56.107(d)				
	D. Alternate members (if used).					
VII	**Management of the REC.**					
	A. The Chairperson:					
	selection and appointment					
	length of term/service					
	duties					
	removal					
	B. The REC members:					
	selection and appointment					
	length of term/service and description of staggered rotation or overlapping of terms, if used					
	duties					
	attendance requirements					
	removal					
	DOES THE INSTITUTION HAVE WRITTEN POLICIES OR PROCEDURES	Reg. Ref	Yes	No	NA	Comments/

	THAT DESCRIBE:					Notes
	C. Training of REC Chair and members:					
	orientation					
	continuing education					
	reference materials (REC library)					
	D. Compensation of REC members.					
	E. Liability coverage for REC members.					
	F. Use of consultants.	21CFR 56.107(f)				
	G. Secretarial/administrative staff (duties).					
	H. Resources (for example, meeting area, filing space, reproduction equipment, computers).					
	I. Conflict of interest policy:					
	no selection of REC members by Investigators					
	prohibition of participation in REC deliberations and voting by Investigators.	21 CFR 56.107(e)				
VIII.	**Functions of the REC.**					
	A. Conducting initial and continuing review.	21CFR 56.108(a)(1) and 56.109(a - f)				
	B. Reporting, in writing, findings and actions of the REC to the Investigator	21CFR				

	and the institution.	56.108(a)(1) and 56.109(e)				
	C. Determining which studies require review more often than annually.	21CFR 56.108(a)(2) and 56.109(f)				
	D. Determining which studies need verification from sources other than the Investigators that no material changes have occurred since previous IDI REC review.	21CFR 56.108(a)(2)				
	E. Ensuring prompt reporting to the IDI REC of changes in research activities.	21CFR 56.108(a)(3)				
	F. Ensuring that changes in approved research are not initiated without IDI REC review and approval except where necessary to eliminate apparent immediate hazards.	21CFR 56.108(a)(4) and 56.115(a)(1)				
	DOES THE INSTITUTION HAVE WRITTEN POLICIES OR PROCEDURES THAT **DESCRIBE:**	Reg. Ref	Yes	No	NA	Comments/ Note s
	G. Ensuring prompt reporting to the REC, appropriate institutional officials, and the NDA of:					
	* unanticipated problems involving risks to participants or others	21CFR 56.108(b)(1) and 56.115(a)(1)				

	* serious or continuing noncompliance of the requirements of the REC	21CFR 56.108(b)(2)				
	* suspension or termination of REC approval	21CFR 56.108(b)(3) and 56.113				
	H. Determining which device studies pose significant or non-significant risk.					
IX.	**Operations of the REC.**					
	A. Scheduling of meetings.	21CFR 56.108(a)(1)				
	B. Pre-meeting distribution to members, of, for example, place and time of meeting, agenda, and study material to be reviewed.					
	C. The review process:					
	description of the process ensuring that 1) all members receive complete study documentation for review; or	21CFR 56.108(a)(1)				
	2) one or more "primary reviewers"/"secondary reviewers" receives the complete study documentation for review, reports to REC and leads discussion; if other members review summary information only, these members must have access to complete study documentation					
	role of any subcommittees of the REC					
	emergency use notification and reporting procedures	21CFR				

		56.104(c), 56.108(a)(1) &108(b)(1)				
	expedited review procedure	21CFR 56.108(a)(1) & 56.110(a - c)				
	for approval of studies that are both minimal risk					
	for approval of modifications to ongoing studies involving no more than minimal risk					
	D. Criteria for REC approval contain all requirements of 21 CFR 56.111.					
	DOES THE INSTITUTION HAVE WRITTEN SOPs OR PROCEDURES THAT DESCRIBE:	Reg. Ref	Yes	No	NA	Comments/ Notes
	E. Voting requirements:	21CFR 56.108(c) & 56.107(e - f)				
	quorum required to transact business					
	diversity requirements of quorum (for example requiring at least one physician member when reviewing studies of NDA regulated articles)					
	percent needed to approve or disapprove a study					
	full voting rights of all reviewing members					

	no proxy votes (written or telephone)					
	prohibition against conflict-of-interest voting					
	F. Further review/approval of REC actions by others within the institution. (Override of disapprovals is prohibited.)	21 CFR 56.112				
	G. Communication from the REC:					
	to the Investigator for additional information	21CFR 56.108(a)(1), 56.109(a) & 56.115(a)(4)				
	to the Investigator conveying REC decision	21 CFR 56.108(a)(1) & 56.109(e)				
	to institution administration conveying REC decision	21 CFR 56.108(a)(1) & 56.109(e)				
	to Sponsor of research conveying REC decision					
	H. Appeal of REC decisions:					
	criteria for appeal					
	- to whom appeal is addressed					
	- how appeal is resolved (Override of REC disapprovals by external body/official is prohibited.)	21 CFR 56.112				

	DOES THE INSTITUTION HAVE WRITTEN POLICIES OR PROCEDURES THAT DESCRIBE:	Reg. Ref	Yes	No	NA	Comments/ Notes
X	REC Record Requirements.					
	A. REC membership roster showing qualifications.	21 CFR 56.115(a)(5)				
	B. Written procedures and guidelines.	21 CFR 56.108(a - b) & 56.115(a)(6)				
	C. Minutes of meetings:	21 CFR 56.115(a)(2)				
	- members present (any consultants/ guests/others shown separately)					
	- summary of discussion on debated issues - record of REC decisions					
	- record of voting (showing votes for, against and abstentions)					
	D. Retention of protocols reviewed and approved consent documents.	21 CFR 56.115(a)(1)				
	E. Communications to and from the REC.	21 CFR 56.115(a)(4)				
	F. 1) Adverse reactions reports, and					
	2) documentation that the REC reviews such reports.					

	H. Records of continuing review.	21 CFR 56.115(a)(3)				
	I. Record retention requirements. (at least 5 years after completion of studies).	21 CFR 56.115(b)				
	J. Budget and accounting records.					
	K. Emergency use reports.					
	L. Statements of significant new findings provided to participants.	21 CFR 56.115(a)(7)				
	DOES THE INSTITUTION HAVE WRITTEN POLICIES OR PROCEDURES THAT DESCRIBE:	**Reg. Ref**	**Yes**	**No**	**NA**	**Comments/Notes**
XI	**Information the Investigator Provides to the REC.**					
	A. Professional qualifications to do the research (including a description of necessary support services and facilities).					
	B. Study protocol which includes/addresses:					
	- title of the study					
	- purpose of the study (including the expected benefits obtained by doing the study)					
	- sponsor of the study					
	- results of previous related research					
	- participant inclusion/exclusion criteria					

	- justification for use of any special/vulnerable participant populations (for example, the decisionally impaired, children)					
	- study design (including as needed, a discussion of the appropriateness of research methods)					
	- description of procedures to be performed					
	- provisions for managing adverse reactions					
	- the circumstances surrounding consent procedure, including setting, participant autonomy concerns, language difficulties, vulnerable populations					
	- the procedures for documentation of informed consent, including any procedures for obtaining assent from minors, using witnesses, translators and document storage					
	- compensation to participants for their participation					
	- any compensation for injured research participants					
	- provisions for protection of participant's privacy					
	- extra costs to participants for their participation in the study					
	- extra costs to third party payers because of participant's participation					
	C. Investigator Brochure (when one exists).	21 CFR 56.111				

		(a)(2), 56.115(a)(1) & 21 CFR 312.55				
	DOES THE INSTITUTION HAVE WRITTEN POLICIES OR PROCEDURES THAT DESCRIBE:	Reg. Ref	Yes	No	NA	Comments/Notes
	D. The case report form (when one exists).					
	E. The proposed informed consent document:	21 CFR 56.111(a)(4 - 5) & 56.111(a)(1)				
	- containing all requirements of 21 CFR 50.25(a)					
	- containing requirements of 21 CFR 50.25(b) that are appropriate to the study					
	- meeting all requirements of 21 CFR 50.20					
	- translated consent documents, as necessary, considering likely participant population(s)					
	F. Requests for changes in study after initiation.	21 CFR 56.108(a)(4) & 56.115(a)(3 - 4)				

	G. Reports of unexpected adverse events.	21 CFR 56.108(b)(1), 115(a)(3 - 4), (b)(1) & 56.113				
	H. Progress reports.	21 CFR 56.108(a)(1) & 56.115(a)(1, 3, 4)				
	I. Final report.					
	J. Institutional forms/reports.					
XII	Exemptions From Prospective REC Review					
	A. Notify REC within 5 working days.	21 CFR 56.104(c) & 56.108(a)(3)				
	B. Emergency use.	21 CFR 56.102(d) & 56.108(a)(3)				
	C. Review protocol and consent when subsequent use is anticipated.	21 CFR 56.104(c) & 56.108(a)(3). The IDI REC may elect to use a rapid				

		means of approval is preferable				

	DOES THE INSTITUTION HAVE WRITTEN POLICIES OR PROCEDURES THAT DESCRIBE:	Reg. Ref	Yes	No	NA	Comments/Notes
XIII	Emergency Research Consent Exception	21 CFR 50.24				
	A. The REC may find that the 50.24 requirements are met.	21 CFR 56.109(c)(2)				
	B. The REC shall promptly notify in writing the Investigator and the Sponsor when it determines it cannot approve a 50.24 study.	21 CFR 56.109(e) The written statement shall include a statement of				

		the reasons for the IDI REC's determination				
	C. The REC shall provide in writing to the Sponsor a copy of the information that has been publicly disclosed under 50.24(a)(7)(ii) and (a)(7)(iii)	21 CFR 56.109(g)				
	D. In order to approve an emergency research consent waiver study, the REC must find and document:					
	(1) participants are in a life-threatening situation, available treatments unproven or unsatisfactory and collection of scientific evidence is necessary	21 CFR 50.24(a)(1)				
	(2) Obtaining informed consent is not feasible because:	21 CFR 50.24(a)(2)				
	- medical condition precludes consent	21 CFR 50.24(a)(2)(i)				
	- no time to get consent from legally authorized representative	21 CFR 50.24(a)(2)(ii)				
	- prospective identity of likely participants not reasonable	21 CFR 50.24(a)(2)(iii)				
	(3) Prospect of direct benefits to study participants because:	21 CFR 50.24(a)(3)				
	- life-threatening situation that necessitates treatment					

	- data support potential for direct benefit to individual participants					
	- risk/benefit of both standard and proposed treatments reasonable					
	(4) waiver needed to carry out study					
	(5) plan defines therapeutic window, during which Investigator will seek consent rather than starting without consent; summary of efforts will be given to REC at time of continuing review					
	(6) REC reviews and approves consent procedures and document and approves family member objection procedures					
	DOES THE INSTITUTION HAVE WRITTEN POLICIES OR PROCEDURES THAT DESCRIBE:	**Reg. Ref**	**Yes**	**No**	**NA**	**Comments/Notes**
	(7) Additional protections, including at least:					
	- consultation with community representatives					
	- public disclosure of plans, risks and expected benefits					
	- public disclosure of study results					
	- assure an independent Data Monitoring Committee established					

	- objection of family member summarized for continuing review					
	(8) Ensure procedures in place to inform at earliest feasible opportunity of participant's inclusion in the study, participation may be discontinued; procedures to inform family the participant was in the study if participant dies					
	(9) Separate IND or IDE required, even for marketed products					
	(10) REC disapproval must be documented in writing and sent to the clinical Investigator and the Sponsor of the clinical investigation; Sponsor must promptly disclose to the NDA, other Investigators and other RECs.					

APPENDIX B: GLOSSARY OF TERMS

1.	**ADVERSE EVENT**	Any untoward medical occurrence in a participant in a clinical trial who has been administered a pharmaceutical product or medical device. The event may or may not be casually related to the treatment or procedure.
2.	ASSENT	Means a child's affirmative Agreement to participant in research project failure to object does not constitute assent.
3.	AUTONOMY	Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

4.	BENEFICENCE	An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.
5.	CHILD	Person below age of 18 years.
6.	CLINICAL TRIAL	A systematic study of pharmaceutical product or medical devices in human research participants in order to discover or to verify the beneficial or adverse effects, to identify any adverse reactions in the investigational product and or to study the abortion, distribution metabolism, and excretion of the product with the objective of ascertaining its safety and efficacy. And safety.
7.	COGNITIVELY IMPAIRED	Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.
8.	COMPENSATION	Payment or medical care provided to research participants injured in research; does not refer to payment (remuneration) for participation in research. (Compare: Remuneration.)

9.	**CONFIDENTIALITY**	Pertains to privacy and non-disclosure of personal information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.
10.	**CONFLICT OF INTEREST**	A conflict of interest is defined as a close personal or professional association with the submitting Investigator(s); direct participation in the research (e.g., protocol development, Principal or Co- investigator); or any significant financial interest in the sponsoring company defined as (example, Uganda Shillings 2,000,000 or 5% ownership).
11.	**CONSENT**	See: Informed Consent.
12.	**DATA AND SAFETY MONITORING BOARD (DSMB)**	A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of research participants about new information that might affect their willingness to continue in the trial.
13.	**DEAD FETUS**	An expelled or delivered fetus that exhibits no heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord (if still attached). Generally, some organs, tissues, and cells (referred to collectively as fetal tissue) remain alive for varying periods of time after the total organism is dead.
14.	**EMANCIPATED MINOR**	Individuals below the age of majority who are pregnant married, have a child, or cater for their own livelihood.

15.	**EQUITABLE**	Fair or just; used in the context of selection of participants to indicate that the benefits and burdens of research are fairly distributed.
16.	**EXPEDITED REVIEW**	Review of proposed research by IDI REC Chairperson or a designated voting member or group of voting members rather than by the entire IDI REC. National guidelines permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.
17.	**FETUS**	The product of conception from the time of implantation until delivery. If the delivered or expelled fetus is viable, it is designated an infant. The term "fetus" generally refers to later phases of development; the term "embryo" is usually used for earlier phases of development. (See also: Embryo.)
18.	**FULL IDI REC REVIEW**	Review of proposed research at a convened meeting at which a majority of the membership of IDI REC are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of the voting members present at the meeting.
19.	**GUARDIAN**	Person having parental responsibility for a child.
20.	**HUMAN RESEARCH PARTICIPANTS**	Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the national regulations and guidelines, human research participants are defined as: living individual(s) about whom an Investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.
21.	**INFORMED CONSENT**	A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.

22.	**INSTITUTIONAL REVIEW COMMITTEE**	A specially constituted review body established or designated by an entity to protect the welfare of human research participants recruited to participate in biomedical or behavioral research.
23.	**INVESTIGATIONAL DEVICE EXEMPTIONS (IDE)**	Exemptions from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations.
24.	**INVESTIGATIONAL NEW DRUG (IND) OR DEVICE (IDE)**	A drug or device permitted by NDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.
25.	**JUSTICE**	An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.
26.	**LEGALLY AUTHORIZED REPRESENTATIVE**	A person authorized either by statute or by court appointment to make decisions on behalf of another person. In research involving humans as participants, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedure(s) involved in the research.
27.	**MATURE MINOR**	Individuals 14-17 years of age who have drug or alcohol dependency or a sexually transmitted infection
28.	**MEDICAL DEVICE**	A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

29.	**MINIMAL RISK**	Is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental or psychological examination of healthy persons
30.	**NON-AFFILIATED MEMBER**	Member of an Institutional Review Committee who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community
31.	NONSIGNIFICANT RISK DEVICE	An investigational medical device that does not present significant risk to the patient. (See also: Significant Risk Device.)

32.	NON-VIABLE FETUS	An expelled or delivered fetus which, although it is living, cannot possibly survive to the point of sustaining life independently, even with the support of available medical therapy. Although it may be presumed that an expelled or delivered fetus is nonviable at a gestational age less than 20 weeks and weight less than 500 grams, a specific determination as to viability must be made by a physician in each instance. (See also: Viable Infant.)
33.	NORMAL VOLUNTEERS	Volunteer research participants used to study normal physiology and behavior or who do not have the condition under study in a particular protocol, used as comparisons with participants who do have the condition.

34.	PHASE 1 TRIALS	Includes the initial introduction of an investigational new drug into humans. These studies are typically conducted with healthy volunteers; sometimes, where the drug is intended for use in patients with a particular disease, however, such patients may participate as research participants. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness; they are typically closely monitored. The ultimate goal of Phase 1 trials is to obtain sufficient information about the drug's pharmacokinetics and pharmacological effects to permit the design of well-controlled, sufficiently valid Phase 2 studies. Other examples of Phase 1 studies include studies of drug metabolism, structure-activity relationships, and mechanisms of actions in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of research participants involved in Phase 1 investigations is generally in the range of 20-80.
35.	**PHASE 1, 2, 3, 4 DRUG TRIALS**	Different stages of testing drugs in humans from first application in humans (Phase 1) through limited and broad clinical tests (Phases 2 and 3), to post-marketing studies (Phase 4).
36.	**PHASE 2 TRIALS**	Includes controlled clinical studies conducted to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study, and to determine the common short-term side effects and risks associated with the drug. These studies are typically well controlled, closely monitored, and conducted with a relatively small number of patients, usually involving no more than several hundred research participants.

37.	**PHASE 3 TRIALS**	Involves the administration of a new drug to a larger number of patients in different clinical settings to determine its safety, efficacy, and appropriate dosage. They are performed after preliminary evidence of effectiveness has been obtained, and are intended to gather necessary additional information about effectiveness and safety for evaluating the overall benefit-risk relationship of the drug, and to provide an adequate basis for physician labeling. In Phase 3 studies, the drug is used the way it would be administered when marketed. When these studies are completed and the sponsor believes that the drug is safe and effective under specific conditions, the sponsor applies to the FDA for approval to market the drug. Phase 3 trials usually involve several hundred to several thousand patient-participants.
38.	**PHASE 4 TRIALS**	Studies conducted after a drug has been approved by NDA, to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time.
39.	**PLACEBO**	An inert substance or sham activity used in the guise of treatment; used in controlled clinical trials as a comparator to determine if an investigational therapy is more effective than no treatment.
40.	**PRECLINICAL INVESTIGATIONS**	Laboratory and animal studies designed to test the mechanisms, safety, and efficacy of an intervention prior to its applications to humans.
41.	**PREMARKET APPROVAL**	Process of scientific and regulatory review by the FDA to ensure the safety and effectiveness of Class III devices.
42.	**PRINCIPAL**	The scientist or scholar with primary responsibility for the design and conduct of a research project. (See also: Investigator.)

	INVESTIGATOR	
43.	**PRISONER**	An individual involuntarily confined in a penal institution, including persons sentenced under a criminal or civil statue or detained pending arraignment, trial, or sentencing
44.	**PROBAND**	The person whose case serves as the stimulus for the study of other members of the family to identify the possible genetic factors involved in a given disease, condition, or characteristic.
45.	**RECOMBINANT DNA TECHNOLOGY**	DNA resulting from the insertion into the chain, by chemical or biological means, of a sequence (a whole or partial chain of DNA) not originally (biologically) present in that chain. Recombinant DNA technology is also used to develop diagnostic screens and tests, as well as drugs and biologics for treating diseases with genetic components.
46.	**RECUSE**	To disqualify (oneself) as judge in a particular case; broadly: to remove (oneself) from participation to avoid a conflict of interest.
47.	**REMUNERATION**	Payment for participation in research. (NOTE: It is wise to confine use of the term "compensation" to payment or provision of care for research-related injuries.) (Compare: Compensation.)
48.	**RISK**	The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. National regulations and guidelines define only "minimal risk." (See also: Minimal Risk.)
49.	**SERIOUS ADVERSE EVENT**	An adverse event associated with death, hospital admission, prolongation of a hospitalization persistent or significant disability or incapacity or otherwise life threatening condition in connection with a clinical trial.

50.	**SIGNIFICANT RISK DEVICE**	An investigational medical device that presents a potential for serious risk to the health, safety, or welfare of the research participant.
51.	**SITE VISIT**	A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of REC protection of human research participants or the capability of personnel to conduct the research.
52.	**TEST ARTICLE**	Any drug (including a biological product for human use), medical device for human use, or any other article participant to regulation by the NDA.
53.	**THERAPEUTIC INTENT**	The research physician's intent to provide some benefit to improving a participant's condition (e.g., prolongation of life, shrinkage of tumor, or improved quality of life, even though cure or dramatic improvement cannot necessarily be effected.) This term is sometimes associated with Phase 1 drug studies in which potentially toxic drugs are given to an individual with the hope of inducing some improvement in the patient's condition as well as assessing the safety and pharmacology of a drug.

APPENDIX C: GLOSSARY OF MEDICAL TO LAY TERMS, TO CONSIDER WHILE WRITING CONSENT DOCUMENTS

ABRASION	area where skin or other tissue is scraped away
ABSORPTION	the way a drug or other substance enters the body
ACUTE	lasting a short time but often causing a serious problem
ADHESION	being stuck together
ADRENAL GLAND	gland found over each kidney
ADVERSE EFFECT	side effect
AMNIOCENTESIS	removal of some of the water from around an unborn baby for laboratory testing
ANALGESIC	drug used to control pain
ANEMIA	decreased number of red blood cells
ANESTHESIA	loss of sensation or feeling
ANESTHETIC	drug is used to keep a person from feeling pain
ANGIOPLASTY	operation to open up a narrow blood vessel
ANOXIA	no oxygen
ANTACID	drug used to decrease acid in the stomach
ANTIBIOTIC	drug used to stop or slow down the growth of bacteria and germs
ANTIBODY	type of protein that helps protect the body against foreign matter, such as bacteria and viruses
ANTIHISTAMINE	drug used to treat allergic reactions
ANTISEPTIC	substance used to stop or slow down the growth of germs
APHASIA	not able to speak or write and not able to understand spoken or written words
ARTERY	type of blood vessel that carries blood and oxygen from the heart to the rest of the body
ARTHRITIS	swelling of one or more joints
ASPHYXIA	suffocation, unable to get enough oxygen

ASSAY	lab test
ASSENT	agreement
ATROPHY	wasting away or decrease in size
AUDIOGRAM	report of a hearing test
AUDIOLOGY	the study of hearing
AUDIOMETER	tool used to measure hearing
AUTONOMY	being able to make one's own decisions
BACTERIA	microscopic creatures that live in and around us; they sometimes cause disease
BENEFIT	a valued or desired outcome; an advantage
BENIGN	something that has no bad effects or does not spread
BETA BLOCKER	drug used to slow down the heart
BILATERAL	having to do with both sides (of the body)
BIOLOGIC	any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries
BIOPSY	removal of tissue so it can be looked at under a microscope
BOLUS	an amount given all at once
BONE MARROW	soft tissue inside bones that makes blood cells
BRONCHITIS	inflammation of the lungs
BRONCHUS	tube that carries air from the windpipe to the lungs
BULIMIA	eating disorder in which a person cannot stop eating and often vomits to make room for more food
CALCIPENIA	low in calcium
CANCER RADIOTHERAPY	treatment of cancer using X rays
CAPILLARY	tiny blood vessel

CARCINOGENIC	causing cancer
CARDIAC	having to do with the heart
CARPAL BONES	wrist bones
CATARACT	clouding of the lens of the eye
CATHETER	flexible tube
CEPHALALGIA	headache
CEREBELLUM	the part of the brain that controls the movement of the muscles and helps maintain balance
CHEMOTHERAPY	treatment of disease using drugs
CHLOASMA	tumor arising from the skin and other organs
CHRONIC	lasting a long time
CLAVICLE	collarbone
CLINICAL TRIAL	an experiment with patients
COGNITIVELY IMPAIRED	having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.
COHORT	A group of participants that have one or more characteristics in common and are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.
COMPENSATION	Payment or medical care provided to participants injured in research; does not refer to payment (remuneration) for participation in research (Compare: Remuneration).
COMPETENCE	Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate

	the consequences of acting (or not acting) on that information, and to make a choice (See also: Incompetence, Incapacity).
CONFIDENTIALITY	Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.
CONTRAINDICATED	Disadvantageous, perhaps dangerous; a treatment that should not be used in certain individuals or conditions due to risks (e.g., a drug may be contraindicated for pregnant women and persons with high blood pressure).
CONTRAINDICATIONS	medical reasons that prevent a person from using a certain drug or treatment
CONTROL (PARTICIPANTS) OR CONTROLS	Participant(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of participants is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.
CONTROLLED TRIAL	study in which the experimental procedures are compared to a standard (accepted) treatment or procedure
CONTUSION	bruise
CORNEA	clear tissue covering the front part of the eye
CROSS-OVER DESIGN	A type of clinical trial in which each participant experiences, at different times, both the experimental and control therapy. For example, half of the participants might be randomly assigned first to the control group and then to the experimental intervention, while the other half would have the sequence reversed.
CULTURE	test for infection, or organisms that could cause infection
CUMULATION	increased action of a drug when given over a period of time
CYTOID	like a cell

DATA AND SAFETY MONITORING BOARD	A committee of scientists, physicians, statisticians, and others that collect and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of participants about new information that might affect their willingness to continue in the trial.
DEOXYRIBONUCLEIC ACID (DNA)	material that makes up the genes
DEPRESSANT	drug that slows down the action of the central nervous system
DHHS	A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).
DIAGNOSTIC (PROCEDURE)	tests used to identify a disorder or disease in a living person
DOUBLE BLIND TRIAL	See Double-Masked Design
DOUBLE-MASKED DESIGN	A study design in which neither the investigators nor the participants know the treatment group assignments of individual participants. Sometimes referred to as "double-blind."
DUCT	tube that carries a body fluid
DYSPLASIA	abnormal cells
EDEMA	increased fluid
EFFICACY	effectiveness
ELECTROCARDIOGRAM (ECG)	picture of the electrical action of the heart
ELECTROENCEPHALOGRAM (EEG)	picture of brain wave activity
EMBOLUS	blood clot
EMESIS	vomiting
ENDORPHIN	substance made by the body to stop pain

EPIDERMAL	having to do with the outer layer of skin
EPIDERMIS	outer layer of skin
ESOPHAGUS	tube that goes from the throat to the stomach
EXPANDED AVAILABILITY	Policy and procedure that permits individuals who have serious or life-threatening diseases for which there are no alternative therapies to have access to investigational drugs and devices that may be beneficial to them. Examples of expanded availability mechanisms include Treatment INDs, Parallel Track, and open study protocols.
EXPERIMENTAL	Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness. (See also: Research.)
EXPERIMENTAL STUDY	A true experimental study is one in which participants are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. (See also: Quasi-Experimental Study).
EXTRAVASATE	to leak outside of a blood vessel
FDA	Food and Drug Administration; an agency of the federal government that regulates food, drugs, medical devices, cosmetics, and other products to make sure they are safe and effective to use
FETAL MATERIAL	The placenta, amniotic fluid, fetal membranes, and umbilical cord
FETUS	The product of conception from the time of implantation until delivery. If the delivered or expelled fetus is viable, it is designated an infant [45 CFR 46.203(c)]. The term "fetus" generally refers to later phases of development; the term "embryo" is usually used for earlier phases of development.
GENE THERAPY	treatment of genetic disease accomplished by altering the genetic structure of either somatic (non-reproductive) or germline (reproductive) cells

GENETIC SCREENING	tests to identify persons who have an inherited predisposition to a certain phenotype or who are at risk of producing offspring with inherited diseases or disorders
GENOTYPE	the genetic makeup of an individual.
GLUCOSE	type of sugar found in the blood
GUARDIAN	an individual who is authorized under state or local law to give permission on behalf of a child or an adult who is not able to make decisions.
GYNECOLOGIST	doctor who specializes in treating a woman's organs that are related to pregnancy and childbirth
GYNECOLOGY	the study of the reproductive system of women
HEMATOLOGIST	doctor who treats blood disorders
HEMATOMA	a bruise, a black and blue area
HEPARIN LOCK	needle placed in the arm with blood thinner to keep the blood from clotting
HUMAN PARTICIPANTS	people who take part in a research study by letting an investigator gather information about how they answer questions, respond to certain situations react to an experimental product.
HYPEROPIA	farsightedness
HYPERTENSION	high blood pressure
HYPODERMIC	under the skin
HYPOGLYCEMIA	not enough sugar in the blood
HYPOTENSION	low blood pressure
HYPOTHERMIA	low body temperature
IDIOSYNCRASY	rare side effect of a drug; unusual reaction of a person to a drug
IN VITRO	literally, "in glass" or "test tube" used to refer to processes that are done outside the living body, usually in the laboratory, as distinguished from in vivo.

IN VIVO	literally, "in the living body" processes, such as the absorption of a drug by the human body, carried out in the living body rather than in a laboratory (in vitro).
INCAPACITY	Refers to a person's mental status and an inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence (See also: Incompetence).
INCOMPETENCE	Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (See also: Incapacity.)
INFLAMMATION	swelling, redness, and pain in tissues caused by injury or damage
INFLUENZA	the flu
INFORMED CONSENT	A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, participants may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25].
INSTITUTIONAL REVIEW BOARD	A specially constituted review body established or designated by an entity to protect the welfare of human participants recruited to participate in biomedical or behavioral research
INTRAMUSCULAR (IM) INJECTION	injection of a substance into a muscle (e.g., upper arm or backside)
INTRAVENOUS (IV) INJECTION	injection of a substance into a vein
INVESTIGATOR	In clinical trials, an individual who actually conducts an investigation. Any interventions (e.g., drugs) involved in the study are administered to participants under the immediate direction of the investigator (See also: Principal Investigator).
LACTATING	making milk
LACTATION	period of time during which a woman is providing her breast milk to an infant or child

LATERAL	toward or having to do with one side (of the body)
LEGALLY AUTHORIZED REPRESENTATIVE	A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human participants research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedure(s) involved in the research
LESION	abnormal area of tissue, such as a wound, sore, rash, or boil
LIBIDO	sexual desire
LIPID	Fat
LYMPHOMA	cancerous growth made up of lymph tissue
MACRO	large or long
MAGNETIC RESONANCE IMAGING	produces multiple images of organs and structures within the body by using a large magnet to attract electrons within the body used as a diagnostic tool (See also MRI).
MASKED STUDY DESIGNS	Study designs comparing two or more interventions in which either the investigators, the participants, or some combination thereof do not know the treatment group assignments of individual participants. Sometimes called "blind" study designs (See also: Double-Masked Design; Single-Masked Design).
MASTECTOMY	surgery to remove a breast
MEDICAL DEVICE	a product, such as crutches, an x-ray machine, pacemaker, toothbrush, bandage, contact lenses, etc., that is used in treatment, prevention, or diagnosis of a medical condition and does not act on the body through chemical action.
MONITOR	check on, keep track of, watch carefully
MORBIDITY	undesired result or complication
MORTALITY	death or death rate
MRI (MAGNETIC RESONANCE IMAGING)	the use of magnetic waves to look at soft tissues of the body

MUCOID	slimy
MYOPIA	nearsightedness
NASO-GASTRIC TUBE	Tube that goes through the nose and into the stomach
NECROSIS	death of tissue or skin
NEUROLOGIST	doctor who treats disorders of the central nervous system and nerves
NEUROSIS	mental and emotional disorder
NUREMBERG CODE	A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human participants.
ONCOLOGY	the study of cancer
OPEN DESIGN	An experimental design in which both the investigator(s) and the participants know the treatment group(s) to which participants are assigned
OPHTHALMOLOGIST	doctor who treats eye disorders
ORAL ADMINISTRATION	giving a drug by mouth
ORTHODONTIST	dentist who treats teeth and jaw disorders
ORTHOPEDIST	doctor who treats bone and joint disorders
OTOLOGIST	doctor who treats disorders of the ear
OTORHINOLARYNGOLOGIST	doctor who treats disorders of the ear, nose, and throat
OTOSCOPE	tool used to look into the ear
PAP TEST	microscope test used to detect virus infection of the cervix or cancer of the vagina, cervix, or lining of the uterus (Also called Pap Smear).
PATHOGENIC	causing disease
PERCUTANEOUS	through the skin
PHALANX	finger or toe bone
PHARYNX	throat

PHASE 1 DRUG TRIAL	The first use of a new drug in humans happens in a Phase 1 study. These studies are usually conducted with healthy volunteers; but if a drug is very poisonous, or is used to treat a deadly disease, sick patients who have that disease might be participants. Usually, there are about 20 – 80 human participants in Phase 1 studies. Phase 1 trials are conducted to see how the drug acts in the body, if it is safe to use, and to find out the safe dose range. If the results of the Phase 1 studies are good, testing continues in Phase 2 studies.
PHASE 2 DRUG TRIAL	Phase 2 trials include controlled clinical studies to see if a new drug is effective to treat for a particular disease or condition, therefore, the participants who are given the drug have the condition that the drug is supposed to treat. The side effects are also studied, and more information is gathered about the best dose. Phase 2 studies are also conducted with a relatively small number of patients, usually involving no more than several hundred participants. If the evidence from the Phase 2 studies show that a drug is probably effective and relatively safe, Phase 3 studies are conducted.

PHASE 3 DRUG TRIAL	During Phase 3 trials, the new drug is given to a larger number of patients in different clinical settings to gather as much information as possible about the drug's safety and effectiveness, the best dosage, and to gather labeling information. Investigators also want to make sure that the drug has more benefits than risk. For example, a drug meant to treat a deadly disease, like some cancers, may have very bad side effects. But, if it can stop the cancer, the side effects may be considered acceptable. On the other hand, even if a drug is very effective in the treatment of a common headache, for example, but has bad side effects, that drug would be considered too toxic (poisonous) to be used to treat that condition. In Phase 3 studies, the drug is used the way it would be administered when marketed. When these studies are completed and the sponsor believes that the drug is safe and effective, the sponsor applies to the FDA for approval to market the drug. Phase 3 trials usually involve several hundred to several thousand patient-participants.

PHASE 4 DRUG TRIAL	As a condition of approval, FDA may want more studies to get additional information about the drug's risks, benefits, and optimal use. These studies, which are Phase 4 trials, could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, studying the drug in other patient populations or other stages of the disease, or studying the drug when given over a longer period of time than recommended on the label.
PLACEBO	Something that appears to be real, but is fake. In a clinical trial, one group of participants (the control group) may be given a placebo and another group (the treatment group) is given active treatment to find out if the experimental drug is any better than no treatment and to see if the effects are the result of imagination or anticipation rather than actual power of a drug. (A placebo is often referred to as a "sugar pill". A placebo probably doesn't have any sugar in it, and it doesn't even have to be a pill.)
PODIATRIST	foot doctor
POLYDIPSIA	too much thirst
POSTPARTUM	after childbirth
POTENTIATION	increase in drug action from using two drugs together instead of using each drug alone
PRINCIPAL INVESTIGATOR	The scientist or scholar with primary responsibility for the conduct of a research project (See also: Investigator).
PRN	as needed
PROCTOLOGIST	doctor who treats disorders of the rectum and anus
PROGNOSIS	forecast of the probable outcome of a disease
PROSPECTIVE STUDIES	Studies that gather information about events that occur after the identification of the group of participants to be studied. Prospective studies may involve intervention (like administration of a drug) or may be purely observational or may involve only the collection of data.
PROSTHESIS	artificial body part

PROTOCOL	The plan of study. The protocol includes a description of what the research hopes to prove, how the study will be carried out, etc.
PROXIMAL	nearest
PRURITUS	itchiness
PSYCHOLOGIST	doctor who helps people understand interested in the workings of the mind, thought, and behavior
PSYCHOSIS	severe mental disorder; craziness
PSYCHOSOMATIC	having a connection between the mind and physical symptoms
PULMONARY NEOPLASM	lung tumor
RANDOM	by chance, like the flip of a coin
RELAPSE	the return of a disease
RENAL	having to do with the kidney
RESEARCH	a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to general knowledge
RETROSPECTIVE	looking back over past experience
RISK	the probability of harm or injury (physical, psychological, social, economic) occurring as a result of participation in a research study
SCAPULA	shoulder blade
SERUM	clear liquid part of blood
SHUNT	artificial or natural channel running between two other channels
SINGLE-BLIND	Typically, a study design in which the investigator, but not the participant, knows the identity of the treatment assignment. Occasionally the participant, but not the investigator, knows the assignment.
SLEEP APNEA	breathing problems while sleeping
SOMATIC	having to do with the body

SPONSOR (OF A DRUG TRIAL)	A person or entity that initiates and pays for a clinical investigation of a drug — usually the drug manufacturer or research institution that developed the drug. The sponsor provides the protocol (study plan), makes sure the study is conducted according to the plan, and enforces compliance with applicable laws and regulations.
STERNUM	breastbone
SUBCUTANEOUS (SC)	under the skin
SUBLINGUAL	under the tongue
SYNDROME	set of signs that happen at the same time in the body
THORAX	the chest
TITRATION	slow increase or decrease in drug dosage, guided by patient's responses
TOLERANCE	decrease in response to a fixed dosage of drug; over time, higher and higher doses of a drug are needed to get the desired effect
TOPICAL APPLICATION	giving a medication by putting it directly on the skin
TOXICITY	any harmful effect of a drug or poison
TRACHEA	windpipe
TRANQUILIZER	drug used to control anxiety
TRANSDERMAL	through the skin
UROLOGIST	doctor who treats disorders of the urinary tracts of men and women
VOLUNTARY	Free of coercion, duress, or undue inducement. Used in the research context to refer to a participant's decision to participate (or to continue to participate) in a research activity.

APPENDIX D: STUDIES REQUIRING REC REVIEW

To assure the protection of human participants and to comply with federal law, the institution name requires that, prior to initiation, all research projects involving humans as participants or human material be reviewed and approved by the Institutional Review

Board. This policy applies, regardless of the source of funding and location of the study, to all biomedical and behavioral research involving human participants conducted by faculty, staff and students of the University. If the study is part of an application to a Sponsoring agency, the human protocol must be submitted for Committee review before or when the application is processed in the Office of Regulatory Affairs.

Definition of Human Participants

"Human participant" means a living individual about whom an Investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between Investigator and participant. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the Investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

Definition of Human Research

The boundary between research and innovative care is a complex and controversial issue. However, for the purposes of this Committee, human research is any activity that has the intent of securing information from humans for the purpose of advancing generalizable knowledge. Such activity may or may not differ in a significant way from customary medical or other professional practice. A research project generally is described in a protocol that sets forth explicit objectives and formal procedures designed to reach those objectives. The protocol may include therapeutic and other activities intended to benefit the participants, as well as procedures to evaluate such activities. Research objectives range from understanding normal and abnormal physiological or psychological functions or social phenomena, to evaluating diagnostic, therapeutic or preventive interventions and variations in services or practices. The activities or procedures involved in research may be invasive or non-invasive and include surgical interventions; removal of body tissues or fluids; administration or application of chemical substances or forms of energy; modification of diet, daily routine or

service delivery; alteration of environment; observation; administration of questionnaires or tests; randomization of participants; review of records, etc.

APPENDIX E: EXPEDITED REVIEW PROCEDURES FOR CERTAIN KINDS OF RESEARCH INVOLVING NO MORE THAN MINIMAL RISK, AND FOR MINOR CHANGES IN APPROVED RESEARCH

The Secretary, HHS, has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the REC through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, DHHS, Bethesda, Maryland 20892.

An REC may use the expedited review procedure to review either or both of the following:

some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the REC chairperson or by one or more experienced reviewers designated by the chairperson from among members of the REC. In reviewing the research, the reviewers may exercise all of the authorities of the REC except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

Each REC which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

The Department or Agency head may restrict, suspend, terminate, or choose not to authorize an Institution's or REC's use of the expedited review procedure.

Categories of Research That May Be Reviewed by the Research Ethics Committee (REC) through an Expedited Review Procedure1

Applicability

Research activities that (1) present no more than minimal risk to human participants, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the REC through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

The categories in this list apply regardless of the age of participants, except as noted.

The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human participants.

RECs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the REC.

Categories one (1) through seven (7) pertain to both initial and continuing REC review.

Research Categories

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

from other adults and children2, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Collection of data from voice, video, digital, or image recordings made for research purposes.

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Continuing review of research previously approved by the convened REC as follows:

where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long- term follow-up of participants; or

where no participants have been enrolled and no additional risks have been identified; or

where the remaining research activities are limited to data analysis.

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the REC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

1 An expedited review procedure consists of a review of research involving human participants by the REC chairperson or by one or more experienced reviewers designated by the chairperson from among members of the REC in accordance with the requirements set forth in 45 CFR 46.110.

2 Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998.

APPENDIX F: SIGNIFICANT RISK AND NONSIGNIFICANT RISK MEDICAL DEVICE STUDIES

The Investigational Device Exemption (IDE) regulations [21 CFR Part 812] describe two types of device studies, "significant risk" (SR) and "non-significant risk" (NSR). An SR device study is defined [21 CFR 812.3(m)] as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a participant and (1) is intended as an implant; or

(2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a participant. An NSR device investigation is one that does not meet the definition for a significant risk study. NSR device studies, however, should not be confused with the concept of "minimal risk," a term utilized in the Research Ethics Committee (REC) regulations [21 CFR part 56] to identify certain studies that may be approved through an "expedited review" procedure. For both SR and NSR device studies, IRB approval prior to conducting clinical trials and continuing review by the REC are required. In addition, informed consent must be obtained for either type of study [21 CFR part 50].

Distinguishing Between SR and NSR Device Studies

The effect of the SR/NSR decision is very important to research Sponsors and Investigators. SR device studies are governed by the IDE regulations [21 CFR part 812]. NSR device studies have fewer regulatory controls than SR studies and are governed by the abbreviated requirements [21 CFR 812.2(b)]. The major differences are in the approval process and in the record keeping and reporting requirements. The SR/NSR decision is also important to FDA because the REC serves, in a sense, as the Agency's surrogate with respect to review and approval of NSR studies. FDA is usually not apprised of the existence of approved NSR studies because Sponsors and RECs are not required to report NSR device study approvals to FDA. If an Investigator or a Sponsor proposes the initiation of a claimed NSR investigation to an REC, and if the REC agrees that the device study is NSR and approves the study, the investigation may begin at that institution immediately, without submission of an IDE application to FDA.

If an REC believes that a device study is SR, the investigation may not begin until both the REC and FDA approve the investigation. To help in the determination of the risk status of the device, RECs should review information such as reports of prior investigations conducted with the device, the proposed investigational plan, a description of participant selection criteria, and monitoring procedures. The Sponsor should provide the REC with a risk

assessment and the rationale used in making its risk determination [21 CFR 812.150(b)(10)].

SR/NSR Studies and the REC: The NSR/SR Decision

The assessment of whether or not a device study presents a NSR is initially made by the Sponsor. If the Sponsor considers that a study is NSR, the Sponsor provides the reviewing REC an explanation of its determination and any other information that may assist the REC in evaluating the risk of the study. The Sponsor should provide the REC with a description of the device, reports of prior investigations with the device, the proposed investigational plan, a description of patient selection criteria and monitoring procedures, as well as any other information that the REC deems necessary to make its decision. The Sponsor should inform the REC whether other RECs have reviewed the proposed study and what determination was made. The Sponsor must inform the REC of the Agency's assessment of the device's risk if such an assessment has been made. The REC may also consult with NDA for its opinion.

The REC may agree or disagree with the Sponsor's initial NSR assessment. If the REC agrees with the Sponsor's initial NSR assessment and approves the study, the study may begin without submission of an IDE application to FDA. If the REC disagrees, the Sponsor should notify FDA that an SR determination has been made. The study can be conducted as an SR investigation following FDA approval of an IDE application.

The risk determination should be based on the proposed use of a device in an investigation, and not on the device alone. In deciding if a study poses an SR, an REC must consider the nature of the harm that may result from use of the device. Studies where the potential harm to participants could be life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure should be considered SR. Also, if the participant must undergo a procedure as part of the investigational study, e.g., a surgical procedure, the REC must consider the potential harm that could be caused by the procedure in addition to the potential harm caused by the device. Two examples follow:

The study of a pacemaker that is a modification of a commercially--available pacemaker poses a SR because the use of any pacemaker presents a potential for serious harm to the participants. This is true even though the modified pacemaker may pose less risk, or only

slightly greater risk, in comparison to the commercially-available model. The amount of potential reduced or increased risk associated with the investigational pacemaker should only be considered (in relation to possible decreased or increased benefits) when assessing whether the study can be approved. The study of an extended wear contact lens is considered SR because wearing the lens continuously overnight while sleeping presents a potential for injuries not normally seen with daily wear lenses, which are considered NSR.

FDA has the ultimate decision in determining if a device study is SR or NSR. If the Agency does not agree with an REC's decision that a device study presents an NSR, an IDE application must be submitted to FDA. On the other hand, if a Sponsor files an IDE with FDA because it is presumed to be an SR study, but FDA classifies the device study as NSR, the Agency will return the IDE application to the Sponsor and the study would be presented to RECs as an NSR investigation.

REC and Sponsor Responsibilities Following SR/NSR Determination

If the REC decides the study is Significant Risk:

REC Responsibilities:

Notify Sponsor and Investigator of SR decision After IDE is obtained by the Sponsor; proceed to review study applying requisite criteria [21 CFR 56.111]

Sponsor Responsibilities:

Submit IDE to FDA or, if electing not to proceed with study, notify FDA (CDRH Program Operations Staff 301-594-1190) of the SR determination; Study may not begin until FDA approves IDE and REC approves the study. Sponsor and Investigator(s) must comply with IDE regulations [21 CFR part 812], as well as informed consent and REC regulations [21 CFR Parts 50 and 56]. There is no requirement for the Sponsor to notify FDA of the SR determination.

If the REC decides the study is Non-significant Risk:

REC proceeds to review study applying requisite criteria [21 CFR 56.111]

If the study is approved by the REC, the Sponsor and Investigator must comply with "abbreviated IDE requirements" [21 CFR 812.2(b)], and informed consent and REC regulations [21 CFR parts 50 and 56].

The Decision to Approve or Disapprove

Once the SR/NSR decision has been reached, the REC should consider whether the study should be approved or not. The criteria for deciding if SR and NSR studies should be approved are the same as for any other FDA regulated study [21 CFR 56.111]. The REC should assure that risks to participants are minimized and are reasonable in relation to anticipated benefits and knowledge to be gained, participant selection is equitable, informed consent materials and procedures are adequate, and provisions for monitoring the study and protecting the privacy of participants are acceptable. To assure that the risks to the participant are reasonable in relation to the anticipated benefits, the risks and benefits of the investigation should be compared to the risks and benefits of alternative devices or procedures. This differs from the judgment about whether a study poses a SR or NSR which is based solely upon the seriousness of the harm that may result from the use of the device. Minutes of REC meetings must document the rationale for SR/NSR and subsequent approval or disapproval decisions for the clinical investigation.

FDA considers studies of all significant risk devices to present more than minimal risk; thus, full REC review for all studies involving significant risk devices is necessary. Generally, REC review at a convened meeting is also required when reviewing NSR studies. Some NSR studies, however, may qualify as minimal risk [21 CFR 56.102(i)] and the REC may choose to review those studies under its expedited review procedures [21 CFR 56.110].

Examples of NSR/SR Devices

The following examples are provided to assist Sponsors and RECs in making SR/NSR determinations. The list includes many commonly used medical devices. Inclusion of a device in the NSR category should not be viewed as a conclusive determination, because the proposed use of a device in a study is the ultimate determinant of the potential risk to participants. It is unlikely that a device included in the SR category could be deemed NSR due to the inherent risks associated with most such devices.

Non-significant Risk Devices

Low Power Lasers for treatment of pain Caries Removal Solution

Daily Wear Contact Lenses and Associated Lens Care Products not intended for use directly in the eye (e.g., cleaners; disinfecting, rinsing and storage solutions)

Contact Lens Solutions intended for use directly in the eye (e.g., lubricating/rewetting solutions) using active ingredients or preservation systems with a history of prior ophthalmic/contact lens use or generally recognized as safe for ophthalmic use Conventional Gastroenterology and Urology Endoscopes and/or Accessories

Conventional General Hospital Catheters (long-term percutaneous, implanted, subcutaneous and intravascular)

Conventional Implantable Vascular Access Devices (Ports) Conventional Laparoscopes, Culdoscopes, and Hysteroscopes

Dental Filling Materials, Cushions or Pads made from traditional materials and designs Denture Repair Kits and Realigners

Digital Mammography [Note: an IDE is required when safety and effectiveness data are collected which will be submitted in support of a marketing application.] Electroencephalography (e.g., new recording and analysis methods, enhanced diagnostic capabilities)

Externally Worn Monitors for Insulin Reactions Functional Electrical Neuromuscular Stimulators

General Biliary Catheters General Urological Catheters (e.g., Foley and diagnostic catheters) Jaundice Monitors for Infants

Magnetic Resonance Imaging (MRI) Devices within FDA specified parameters Manual Image Guided Surgery

Menstrual Pads (Cotton or Rayon, only) Menstrual Tampons (Cotton or Rayon, only) Nonimplantable Electrical Incontinence Devices

Non-implantable Male Reproductive Aids with no components that enter the vagina Ob/Gyn Diagnostic Ultrasound within FDA approved parameters

Transcutaneous Electric Nerve Stimulation (TENS) Devices for treatment of pain

Wound Dressings, excluding absorbable hemostatic devices and dressings (also excluding Interactive Wound and Burn Dressings)

Significant Risk Devices

General Medical Use Catheters:

Urology - urologic with anti-infective coatings

General Hospital - except for conventional long-term percutaneous, implanted, subcutaneous and intravascular

Neurological - cerebrovascular, occlusion balloon

Cardiology - transluminal coronary angioplasty, intra-aortic balloon with control system

Collagen Implant Material for use in ear, nose and throat, orthopedics, plastic surgery, urological and dental applications

Surgical Lasers for use in various medical specialties

Tissue Adhesives for use in neurosurgery, gastroenterology, ophthalmology, general and plastic surgery, and cardiology

Anesthesiology Breathing Gas Mixers Bronchial Tubes

Electroanesthesia Apparatus Epidural and Spinal Catheters Epidural and Spinal Needles Esophageal Obturators

Gas Machines for anesthesia or analgesia

High Frequency Jet Ventilators greater than 150 BPM Rebreathing Devices

Respiratory Ventilators

Tracheal Tubes

Cardiovascular

Aortic and Mitral Valvuplasty Catheters

Arterial Embolization Devices Cardiac Assist Devices: artificial heart (permanent implant and short term use), cardiomyoplasty devices, intra-aortic balloon pumps, ventricular assist devices

Cardiac Bypass Devices: oxygenators, cardiopulmonary non-roller blood pumps, closed chest devices

Cardiac Pacemaker/Pulse Generators: antitachycardia, esophageal, external transcutaneous, implantable

Cardiopulmonary Resuscitation (CPR) Devices Cardiovascular/Intravascular Filters

Coronary Artery Retroperfusion Systems

Coronary Occluders for ductus arteriosus, atrial and septal defects Coronary and Peripheral Arthrectomy Devices

Extracorporeal Membrane Oxygenators (ECMO) Implantable Cardioverters/Defibrillators

Laser Coronary and Peripheral Angioplasty Devices Myoplasty Laser Catheters

Organ Storage/Transport Units Pacing Leads

Percutaneous Conduction Tissue Ablation Electrodes

Peripheral, Coronary, Pulmonary, Renal, Vena Caval and Peripheral Stents Replacement Heart Valves

RF Catheter Ablation and Mapping Systems Ultrasonic Angioplasty Catheters

Vascular and Arterial Graft Prostheses Vascular Hemostasis Devices

Dental

Absorbable Materials to aid in the healing of periodontal defects and other maxillofacial applications

Bone Morphogenic Proteins with and without bone, e.g., Hydroxyapatite (HA) Dental Lasers for hard tissue applications

Endosseous Implants and associated bone filling and augmentation materials used in conjunction with the implants

Subperiosteal Implants

Temporomandibular Joint (TMJ) Prostheses EAR, NOSE AND THROAT

Auditory Brainstem Implants Cochlear Implants

Laryngeal Implants

Total Ossicular Prosthesis Replacements

Gastroenterology And Urology Anastomosis Devices

Balloon Dilation Catheters for benign prostatic hyperplasia (BPH) Biliary Stents

Components of Water Treatment Systems for Hemodialysis

Dialysis Delivery Systems

Electrical Stimulation Devices for sperm collection Embolization Devices for general urological use Extracorporeal Circulation Systems

Extracorporeal Hyperthermia Systems Extracorporeal Photopheresis Systems Femoral, Jugular and Subclavian Catheters Hemodialyzers

Hemofilters

Implantable Electrical Urinary Incontinence Systems Implantable Penile Prostheses

Injectable Bulking Agents for incontinence

Lithotripters (e.g., electrohydraulic extracorporeal shock-wave, laser, powered mechanical, ultrasonic)

Mechanical/Hydraulic Urinary Incontinence Devices

Penetrating External Penile Rigidity Devices with components that enter the vagina Peritoneal Dialysis Devices

Peritoneal Shunt Plasmapheresis Systems Prostatic Hyperthermia Devices Urethral Occlusion Devices Urethral Sphincter Prostheses

Urological Stents (e.g., ureteral, prostatG)

General and Plastic Surgery Absorbable Adhesion Barrier Devices Absorbable Hemostatic Agents

Artificial Skin and Interactive Wound and Burn Dressings Injectable Collagen

Implantable Craniofacial Prostheses

Repeat Access Devices for surgical procedures Sutures

General Hospital

Implantable Vascular Access Devices (Ports) - if new routes of administration or new design Infusion Pumps (implantable and closed-loop - depending on the infused drug)

Neurological

Electroconvulsive Therapy (ECT) Devices Hydrocephalus Shunts

Implanted Intracerebral/Subcortical Stimulators Implanted Intracranial Pressure Monitors

Implanted Spinal Cord and Nerve Stimulators and Electrodes

Obstetrics and Gynecology

Antepartum Home Monitors for Non-Stress Tests Antepartum Home Uterine Activity Monitors Catheters for Chorionic Villus Sampling (CVS) Catheters Introduced into the Fallopian Tubes Cervical Dilation Devices

Contraceptive Devices:

Cervical Caps

Condoms (for men) made from new materials (e.g., polyurethane) Contraceptive In Vitro Diagnostics (IVDs)

Diaphragms Female Condoms

Intrauterine Devices (IUDs)

New Electrosurgical Instruments for Tubal Coagulation New Devices for Occlusion of the Vas Deferens Sponges

Tubal Occlusion Devices (Bands or Clips)

Devices to Prevent Post-op Pelvic Adhesions Embryoscopes and Devices intended for fetal surgery Falloposcopes and Falloposcopic Delivery Systems

Intrapartum Fetal Monitors using new physiological markers New Devices to Facilitate Assisted Vaginal Delivery Thermal Systems for Endometrial Ablation

Ophthalmics

Class III Ophthalmic Lasers

Contact Lens Solutions intended for direct instillation (e.g., lubrication/rewetting solutions) in the eye using new active agents or preservatives with no history of prior ophthalmic/contact lens use or not generally recognized as safe for ophthalmic use

Corneal Implants Corneal Storage Media

Epikeratophakia Lenticules Extended Wear Contact Lens

Eye Valve Implants (glaucoma implant) Intraocular Lenses (IOLs) [21 CFR part 813]

Keratoprostheses Retinal Reattachment Systems: fluids, gases, perfluorocarbons, perfluorpropane, silicone oil, sulfur hexafluoride, tacks

Viscosurgical Fluids

Orthopedics And Restorative Bone Growth Stimulators

Calcium Tri-Phosphate Hydroxyapatite

Ceramics Collagen and Bone Morphogenic Protein Meniscus Replacements Implantable Prostheses (ligament, tendon, hip, knee, finger)

Computer Guided Robotic Surgery

Radiology

Boron Neutron Capture Therapy Hyperthermia Systems and Applicators