**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.