



Financial Conflict of Interest Related to Research Policy


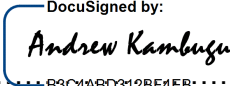
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THE INFECTIOUS DISEASES INSTITUTE LIMITED



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APPROVED BY:	APPROVED BY:
<p>DocuSigned by:  <small>6E016F3F637E487...</small></p> <p>Dr. Barbara Castelnovo HEAD OF RESEARCH DEPARTMENT THE INFECTIOUS DISEASES INSTITUTE LIMITED</p>	<p>DocuSigned by:  <small>B3C4ABD312BF4EB...</small></p> <p>Dr. Andrew Kambugu EXECUTIVE DIRECTOR THE INFECTIOUS DISEASES INSTITUTE LIMITED</p>



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Policy Statement

The Infectious Diseases Institute Limited (IDI) is committed to overseeing the conduct of research in a manner that ensures the integrity of the research process and maintains the public trust and that of research sponsors. The commitment covers the integrity and credibility of Principal Investigators, IDI staff, and the IDI research program. This policy commits IDI to ensure that there is no reasonable expectation that research results are biased by the external commitments and financial interests of persons who are responsible for the design, conduct, reporting, or direct administration of the institution research. Such individuals are, for the purposes of this policy, referred to as “research personnel.” Research, for the purpose of this policy, includes all sponsored projects, including research and non-sponsored institution research.

This policy identifies and addresses the real or apparent financial conflicts of interest presented by the intersection of research activities and personal financial interests, and defines the requirements of all research personnel to ensure that those activities are conducted objectively and without consideration of personal financial gain.

Reason for the Policy

The integrity of IDI’s research is of the utmost importance. The principles and procedures of this policy assure that institutions research personnel will report their external commitments and financial interests in a timely manner and that the real and apparent financial conflicts of interests of research personnel will be identified and responsibly managed. This policy establishes the Financial Conflicts of Interest Committee (FCOIC) as a review body for real and apparent conflicts of interest related to research.

Entities Affected by this Policy

- ✓ All Units involved in Research at the IDI.
- ✓ All IDI research personnel.
- ✓ Research Administrative managers at the IDI.
- ✓ Sub-recipients of IDI awards, where applicable, a written agreement will be established outlining which FCOI policy to be followed (i.e., IDI FCOI policy or sub-recipient’s FCOI policy if it meets sponsor requirements).



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Web address for location of this policy: <https://idi.mak.ac.ug/policy/>

References Materials

1. [42 CFR Part 50 Subpart F](#), Promoting Objectivity in Research
2. [Uganda National Council for Science and Technology \(2014\), National Guidelines for Research involving Humans as Research Participants](#)
3. SOP QA10 Conflict of Interest Resolution

Contacts

Direct any general questions about this policy to the Research Department. If you have questions about specific issues, contact the following officers.

Subject	Contact	Telephone	E-mail
Policy Clarification	Deputy Head, Research Department Stephen Okoboi	+256 312 211 242	sokoboi@idi.co.ug
Grants-related Clarification	Head, Strategy and Development Tom Kakaire	+256 312 211 422	tkakaire@idi.co.ug
Audit related Clarification	Internal Audit Suzan Acom	+256 312 211 422	sacom@idi.co.ug



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DEFINITIONS

These definitions apply to terms as they are used in this policy.

Conflict of Interest	This occurs when the IDI employee's institutional responsibilities could be compromised by his or her external activities. For instance, a conflict of interest arises when the IDI employee conducts research that is sponsored by, or involves a product of, an entity with which the IDI employee has an external relationship.
Conflict of Commitment	This occurs when an IDI employee engages in an outside activity that burdens or interferes with their fulfillment of primary commitments and obligations to IDI, even if the outside activity is valuable to IDI or contributes to their professional development and competence. The existence of a potential conflict does not indicate that the external activity is prohibited; however, most conflicts could be managed in order to protect the employee and IDI.
Conflict Management	Measures taken to address the risk of bias or the appearance of bias, protect research participants, and maintain public trust in IDI's research and its personnel when research personnel may have a real or apparent financial conflict of interest
Design, Conduct, or Reporting of Research	Oversight, decision-making, or participation in research that includes creating the structure, roles, and/or protocol of a research project; participating in the execution of the research roles and protocol; participating in the publishing, presentation, or discussion of the research results.
Direct Administration of Research	Oversight or decision-making impacting research that includes, selection of vendors, determining the allocation of funds, sponsor negotiations for the research project, protocol review and approval, or managing resulting intellectual property and licensing opportunities.
Disclose/Disclosure	To provide relevant information about research personnel's financial interests related to a research project to parties inside and outside IDI to assure full awareness of potential conflicts and institutional efforts to address them.



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External Commitment	An obligation or activity (e.g., management, employment, advisory, or consulting role) that is not related to primary commitments or obligations to IDI.
External Entity	An entity other than IDI.
Financial Interest	A monetary interest or relationship excluding stock owned through mutual funds (as long as you do not have direct control on the investment decisions) or reimbursement for reasonable travel expenses, including, but not limited to, compensation for management, advisory, or consulting roles; gifts, services, loans; payments or in-kind gifts for services; licensing, patent, royalty, and other intellectual property agreements; equity interests (e.g. stocks, stock options, bonds, property interests, dividends, convertible securities); and legal partnership interests.
Financial Conflict of Interest – Real, Apparent	<i>A Real Financial Conflict of Interest</i> arises when a financial interest, or other opportunity for personal financial gain, is likely to compromise or influence the objective design, conduct, reporting, or direct administration of research. An <i>Apparent Conflict of Interest</i> arises when there is a reasonable apprehension, which reasonably well-informed persons are likely to have, that an individual's opportunity for personal financial gain could compromise or influence the design, conduct, reporting, or direct administration of research.
Human Participant Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, involving an individual about whom an investigator (whether professional or student) conducting the research obtains (1) data through intervention or interaction with the individual, or (2) data through study of biology of persons or organs and specimens, or (3) identifiable private information.
Key Personnel	Any individuals responsible for the design, conduct, or reporting of a research study, including the following: For sponsored research: (1) Principal investigators, co-principal investigators, co-investigators, and any other individual named in a sponsored project budget, narrative, key personnel list, by Curriculum Vitae (CV) attachment, or noted anywhere else by name in a proposal or award, and (2) Anyone who during the course of a



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sponsored project assumes a role synonymous with the roles above.

For non-sponsored research: Those whose role on the research project is synonymous with the roles described above.

For Institutional Review Board protocols: Principal investigators and coinvestigators consistent with the procedures of IDI.

Management Plan	See Conflict Management above
Non-Sponsored Institution Research	The pursuit of professional interests through research that is supported by IDI funds including, but not limited to, internal allocations, gifts, endowment income, fellowships, licensing income, and cost sharing.
Report	To provide information to the Institution concerning one's external commitments and financial interests. Compare with <i>Disclose/Disclosure</i> .
Report File	Information submitted on a report, and any pertinent information gathered in relation to a report required for a complete review of external commitments and financial interests.
Research	Research, for the purpose of this policy, includes all sponsored projects and all non-sponsored IDI research.
Research Personnel	Any individual responsible for the design, conduct, or reporting of research, including key personnel, as well as those responsible for the direct administration of research.
Research-Related	An external commitment or financial interest that is likely to bias the outcome of research.
Significant Equity Interest	<p>For a publicly held business, an equity interest that when aggregated for you and your family exceeds the Public Health Service (PHS) threshold, currently: (i) \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, or (ii) representing five percent ownership in such business.</p> <p>For a privately held business, any equity interest in such business, regardless of the amount.</p>



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Significant Financial Interest (SFI)

A financial interest consisting of one or more of the following interests of the research personnel (and those of the research personnel's spouse and dependent children) that reasonably appears to be related to the research personnel's institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the research personnel (or the research personnel's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Sponsor

An external entity that funds or supports research. Sponsors include, state, local governments and private entities, both non-profit and for profit.

Sponsored Research

Research funded by a sponsor through a grant, contract, or agreement.

Unit

A department, research centre, institute, program, business service centre, office, or other operating entity of IDI.

Unit Head

A head of department, director, or administrative lead in an operating unit at IDI.



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RESPONSIBILITIES

The major responsibilities each party has in connection with this policy are as follows:

Financial Conflicts of Interest Committee (FCOIC)	<p>Ensures that all real or apparent financial conflicts of interest related to research are identified and managed.</p> <p>Review financial conflicts of interest (FCOI) reports and determine whether a real or apparent financial conflict of interest exists.</p> <p>Determine and promulgate management plans required to reduce or eliminate real or apparent financial conflicts of interest.</p> <p>Monitor compliance with management plans.</p> <p>Review management plan appeals and appeal recommendations from the Head of Research Department</p> <p>Issue binding decisions on management plan appeals.</p> <p>Participate in investigation of cases of potential non-compliance.</p> <p>Report findings in accordance with policies and regulations.</p>
Financial Conflict of Interest (FCOI) Administrators	<p>Provide regulatory, policy, and procedural expertise and administrative support to the FCOIC.</p> <p>Manage the FCOI reporting process.</p> <p>Assist in review of FCOI reports, determination of whether a real or apparent financial conflict of interest exists, and development of management plans.</p> <p>Assist and advise research personnel, units, Institution management, and others, as appropriate, on FCOI management, regulations, policy, and procedures.</p> <p>Make available to unit heads the information related to a real or potential conflict of commitment, and any non-research conflict of interest disclosed in an FCOI report.</p>
IDI Research Ethics Committee (IDI REC) for Human Participants	<p>Ensure the protection of human participants as subjects of research.</p> <p>Ensure that all required FCOI review and management requirements are met prior to approving protocols.</p> <p>May add human participant protection measures to a management plan, but may not delete plan requirements.</p>



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Key Personnel	See Research Personnel responsibilities.
Research Office	<p>Appoint a representative to serve as a non-voting member of the FCOIC and provide subject-matter expertise.</p> <p>Provide FCOI administrators to support the FCOIC and other functions necessary to the execution of this policy (see FCOI Administrators responsibilities).</p> <p>Investigate situations of potential FCOI non-compliance and report to the FCOIC, Institution Head of Research, and external agencies as necessary.</p> <p>Report to sponsors, and other regulatory bodies as necessary.</p>
Grants Office	<p>Appoint a representative to serve as a non-voting member of the FCOIC and provide subject-matter expertise.</p> <p>Ensure that all required FCOI review and management requirements are met prior to submitting proposals and executing awards and other institutional agreements.</p>
Principal Investigator	Identify all research personnel on proposals and research projects and co-investigators on Institutional Review Board protocols, inform them of related FCOI reporting requirements, and ensure that they submit FCOI reports prior to proposal or protocol submission.
Research Personnel	<p>Report external commitments and financial interests fully, accurately, timely, in accordance with the requirements set forth by this policy.</p> <p>Follow the terms of required management plans.</p> <p>May submit a written request for reconsideration of a management plan.</p> <p>Subject to sanctions for non-compliance with management plan requirements.</p>



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Head of Research	Appoint the members of the FCOIC.
Department	<p>Provide input on management plans at the request of the FCOIC.</p> <p>Review appeals of FCOIC decisions and may make recommendations to delete requirements of a management plan, but may not alter or remove requirements.</p> <p>May add requirements to a management plan.</p> <p>Implement sanctions for non-compliance with timely filing of reports or non-compliance with an approved management plan.</p>
Unit/Unit Head(s)	<p>Identify and manage all conflicts of commitment and all non-research related conflicts of interest.</p> <p>Determine if new employees or employees assuming new responsibilities are research personnel and if so, ensure that they complete an FCOI report within the required timeframe.</p> <p>If required by the FCOIC, assist in development and implementation of management plans for financial conflicts of interest related to research.</p> <p>As required by the FCOIC, implement aspects of management plans and report on plan compliance. Confer as requested with the Head of Research regarding sanctions for non-compliance.</p>
Internal Audit	Conduct an independent review and ensure that compliance to the FCOI policy is being adhered to. In situations of investigations or appeals, the internal audit will be called upon by a unit head (s).



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PRINCIPLES

Overview

The research, scholarship, and other professional activities of the IDI's staff and scholars are governed both by principles of academic freedom with responsibility and codes of academic integrity and ethical conduct. The principles outlined below protect academic freedoms, assure open publication of research results, and encourage a spirit of entrepreneurship. At the same time, IDI research personnel must exercise these ideals within the bounds of legal and ethical restraints. The conduct of research in compliance with applicable regulations and free from any reasonable expectation that the research results are biased by the financial self-interest of research personnel ensures the integrity of the research process, protects the public's investment, and engenders and maintains the public trust in the integrity of IDI's research and mission.

Principle 1: External Relationships and Research

IDI recognizes the value of engagement in external organizations and activities. Such activities and relationships enable the transfer of knowledge and skills that enhance training, research, service, and the administration of IDI programs, as well as inspire solutions to benefit the world. Entrepreneurial endeavours and productive relationships with businesses can stimulate inquiry and provide opportunities to further research. However, the financial interests that accompany such relationships may lead to real or apparent financial conflicts of interest. IDI requires that individuals participating in sponsored projects disclose any significant financial interests that may present actual or potential conflict of interest in regards to externally sponsored activities they may get involved in.

Principle 2: Legal Compliance

This policy promotes compliance with all applicable national laws and regulations regarding financial conflicts of interest, including the Uganda National Council for Science and Technology, and the National Drug Authority regulations.

It incorporates these requirements and extends them to all research conducted at IDI, whether externally sponsored or not. In addition, it provides for funding agency or contract-specific requirements where applicable and other IDI related policies.

Principle 3: Academic Freedom and Responsibility

The IDI thrives when research and scholarship activities are pursued with vigour and unencumbered by constraint and censorship. At the same time, individuals conducting these activities have a primary responsibility to the IDI and are expected to perform their duties faithfully, legally, and ethically. Real or apparent financial conflicts of interest will be appropriately



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managed to allow research personnel the latitude needed to pursue both their academic and external commitments, while ensuring that research is conducted with objectivity and integrity.

Principle 4: Open Publication of Research Results

A principal mission of the IDI is the pursuit of knowledge for the benefit and use of society. Accordingly, IDI vigorously protects the free and open publication, presentation, and discussion of research results. IDI prohibits external commitments and financial interests that restrict or unduly delay the publication and dissemination of research results, and it will not accept external agreements that preclude IDI research personnel, including graduate students and postdoctoral associates, from publishing and communicating any portion of their research, including in meetings with members of IDI community.

Principle 5: Entrepreneurship

The IDI contributes to the economic development of the nation and brings important scientific and medical discoveries to the marketplace for the benefit of the public. The IDI strongly encourages and supports the efforts of its research personnel to participate in the development and dissemination of intellectual property by entering into relationships with existing business entities or by starting their own. These relationships, however, also present situations where some degree of real or apparent financial conflict of interest is inevitable. These situations are appropriately managed, therefore, to ensure the integrity of the research process, the unbiased and effective development of IDI intellectual property, and the appropriate entrepreneurial participation and external engagement of its research personnel.

Principle 6: Human Participant Research

Research involving human participants is critical in developing knowledge and discoveries that will benefit society. Protecting the rights and welfare of human research participants is of the utmost importance and a requirement of all research personnel and IDI. Of particular concern, therefore, are external commitments and financial interests that compromise or appear to compromise the rights and well-being of human research participants. IDI scrutinizes the roles in such research of research personnel who have external commitments and financial interests with a sponsor or with an



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external entity that is related to, or can be affected by, the research. The IDI has instituted a rebuttable presumption that research personnel who are involved in the design, participant selection, informed consent process, or the clinical management of a trial cannot have a financial interest in an entity whose interest could be affected by the research. In other words, the default position is that participation in human participant research by conflicted research personnel is not allowed. However, there may be compelling circumstances in which conflicted research personnel would be permitted to participate in the research. In these cases, the management strategies for the involvement of conflicted researchers must be carefully adjusted to the level of anticipated risk. All financial interests and external relationships related to human-participant research that are not eliminated must be disclosed to all participants in the related research.

The management plan must be implemented before research personnel can participate in the design, conduct of the research, enrolment of participants, analysis of the results, reporting, or administration of the research project.

The IDI operates Research Ethics Committee for Human Participants (REC), which are charged with reviewing and monitoring human participant research conducted at IDI. The IDI-REC has established rigorous policies and procedures for the review and approval of human participant research protocols in accordance with the Uganda National Council for Science and Technology (UNCST), National Drug Authority (NDA), International Conference on Harmonization of Registration of Pharmaceuticals for Human Use Good Clinical Practices (ICH-GCP), and U.S. Code of Federal Regulations (CFR)/Food and Drug Administration (FDA), and other medicines regulation agencies. Those policies and procedures are followed in tandem with this policy.



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- Principle 7: Full and Accurate Reporting** Real and apparent financial conflicts of interest may arise from any number and type of external commitments and financial interests, and particular expertise is required to determine whether they could affect, or could be perceived to affect, research activities and results. IDI research personnel are required to disclose fully and accurately all external commitments and all research-related financial interests in accordance with the procedures, in order to provide sufficient information for the identification of real and apparent financial conflicts of interest. Research personnel must include the external commitments and financial interests of his/her spouse and dependent child(ren) in accordance with the procedures of IDI.
- Principle 8: Timely Reporting** Disclosure of external commitments and financial interests must be made at regular intervals, as required by IDI policy, to allow the IDI to identify and manage real and apparent financial conflicts of interest in a timely manner. Additional reporting events are prescribed by national regulation, funding agency- and award-specific terms, and human subject protocol submission requirements. All research personnel must disclose (1) annually, (2) when external commitments and financial interests materially change, (3) when submitting a proposal or IRB protocol, (4) when required by the specific terms of an award, (5) upon appointment, (6) when newly assigned to a research personnel role, (7) when initiating licensing activity, and (8) when otherwise required.
- Principle 9: Institutional Oversight** Three principles are accounted for in the process of Institutional review of reports of external commitments and financial interests: (1) respecting the confidentiality of reported information, (2) managing rigorously both real and apparent financial conflicts of interest, and (3) achieving consistency across IDI in the way that financial conflicts of interest are identified and managed. A central review committee will develop conflict review procedures that ensure expert, confidential, and consistent review of reports across IDI. Reviewers identify situations in which external commitments and financial interests may potentially compromise, or appear to compromise, the professional judgment of research personnel in conducting or reporting research, including the collection, analysis, and interpretation of data, the hiring



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of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods.

Principle 10: Management of Conflicts

Real or apparent financial conflicts of interest are addressed through a management plan. The plan must be designed to remove the bias, or the reasonable perception of bias, in research that the conflict raises,

while allowing that degree of personal financial and professional freedom that is consistent with research integrity, the public trust, and the protection of human participants.

Real and apparent financial conflicts of interest often can be managed, in whole or in part, by disclosing the implicated external commitments and financial interests to, as applicable, the institute, journal publishers, granting agencies, conference organizers, audiences at presentations, colleagues, collaborators, students, or human participants. Other possible management plan measures include, but are not limited to, the monitoring by independent reviewers of the related research and/or of the student participation; modification of the research plan; and disqualification of the research personnel's participation in all or a portion of the research project. Special attention is paid when research personnel have academic oversight responsibilities for graduate students, or postdoctoral associates who are working on projects that are funded by, or conducted in collaboration with, an external entity in which the research personnel have a financial interest.

Principle 11: Reporting and Management Plan Compliance

Persons subject to this policy are required to disclose fully and accurately their external commitments and financial interests and to comply with any plans developed to manage their real or apparent financial conflicts of interest. Disciplinary measures and sanctions will be imposed when they fail to report as required or when they fail to comply with management plans.



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Principle 12: Confidentiality and Sharing of Financial Information

The IDI is committed to maintaining the confidentiality of reported information as far as is practicable and consistent with legal obligations. All information and written materials provided to the Institute review committees are shared only with committee members and staff who are involved in the processing and review of the information, as well as those who create and implement management plans. Other individuals, including unit heads and IDI-REC members and staff, receive this information on a need-to-know basis. Individuals with access to confidential personal information are required to sign a confidentiality agreement.



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PROCEDURES

Administrative Structures

Financial Conflict of Interest Committee (FCOIC)

a. Authority:

The FCOIC has authority for reviewing external commitments and financial interests reported under this policy, in order to identify real or apparent financial conflicts of interest related to research, and address them in accordance with this policy and local regulations and international standards. The FCOIC has the authority to promulgate binding FCOI management plans.

b. Scope of Responsibility:

The FCOIC is responsible for ensuring that all real or apparent financial conflicts of interest are identified and managed. The FCOIC reviews reported information, requests additional material as needed, identifies real or apparent financial conflicts of interest, devises an appropriate plan to manage the conflict, communicates the plan to the research personnel, and monitors compliance with the plan.

c. Committee Membership:

The FCOIC is appointed by the Head of Research department at IDI and includes voting members no fewer than five members of the research community in Uganda. Additional members will be co-opted as and when needed. The FCOIC members will select one of the voting members to serve as chair of the FCOIC.

d. Confidentiality:

As far as is practicable and consistent with legal obligations, IDI protects the confidentiality of financial conflicts of interest information. Information and written materials provided to the FCOIC and its administrators are shared to the most limited degree possible with those committee members and staff who are involved in the processing and review of reported information and the creation and implementation of management plans and others on a need-to-know basis.



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Research Office

FCOI Administration: Research Office includes staff responsible for providing administrative support to the FCOIC (“FCOI administrators”) and other key functions necessary to the execution of this policy and procedures. FCOI administrators (1) coordinate the reporting and collection of annual and event-based reports of external commitments and financial interests, (2) provide administrative support to the FCOIC, (3) conduct preliminary reviews of reports to assess completeness, and consult with the reporters and others as required to obtain clarifications and additional information required for making an FCOI determination, (4) are exempt from review those reports that do not present a significant financial conflict of interest related to research, (5) facilitate an expedited review of reports that present a common type of conflict that can be managed through standard measures such as disclosure to a journal, (6) assist the FCOIC in developing and monitoring management plans for more complex financial conflicts of interest, and (7) assist and advise research personnel, units, and others as appropriate on FCOI management, regulations, policy, and procedures.

Reporting (Who Must File and When)

Research Personnel:

All IDI research personnel are required to report their external commitments and financial interests annually and on an event-required basis for themselves and their spouse/s and dependent children (hereinafter called “family”).

Note: For IDI REC protocols, “research personnel” includes non-student principal investigators, and co-investigators named on protocols. For current, active awards or IDI REC protocols: Research personnel who are required to report per this policy, but were not previously required to report, must report at the time of award renewal or protocol continuation.

What must be reported:

- Irrespective of dollar amount, a reporter’s external commitments or financial interests with an external entity that could constitute a conflict of commitment, such as employment, service or consulting; or intellectual property or licensing.
- Irrespective of dollar amount, a reporter’s family’s financial interest or commitments with an external entity, whose activities could be related to the reporter’s IDI duties.



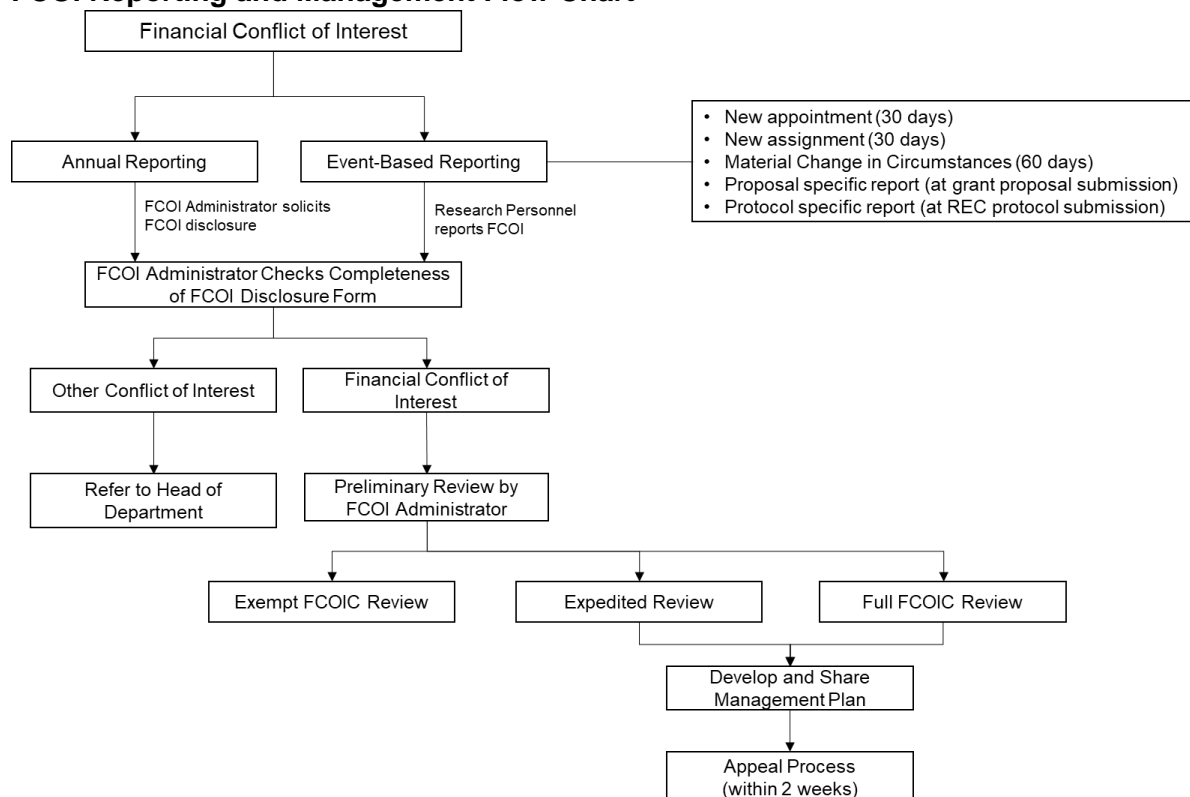
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- Significant financial interest, as defined in this policy, for a reporter or family with any external entity whose activities could be related to the reporter’s IDI duties.
- Disclose each instance of travel that is reimbursed or sponsored by an external entity when the amount of travel during the preceding 12 months reaches or exceeds \$5,000 in the aggregate for a particular entity. This aggregate value includes travel for family members. However, if the travel occurs in the course of your family member’s own activities with the entity, you do not need to report it and it does not count towards the aggregate. Disclosures must be made within 30 days of reaching the \$5,000 threshold and of every instance of sponsored or reimbursed travel occurring thereafter.
- Any financial interests or external commitments not explicitly stated in the reporting form.

For each such external relationship or financial interest, reporters must provide all of the information required in the reporting form (APPENDIX A: Financial Conflict of Interest Disclosure Form).

FCOI Reporting and Management Flow Chart





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Annual Reports

- a. **Required Reporting:** All research personnel must update their reports of external commitments and financial interests annually (“annual report”). The research office is responsible for identifying individuals responsible for the direct administration of research and any newly appointed individuals who participate in research, and ensuring that they file annual reports.
- b. **Handling of Annual Reports:** FCOI administrators coordinate the solicitation and collection of the annual reports and review reports for the purpose of identifying real and apparent conflicts of interest related to research. Information relevant to conflicts of interest and non-research-related conflict of interest is distributed to the department, which have responsibility for identifying and managing all such conflicts (e.g., HR and Finance and Administration)
- c. **Timely Reporting Requirement:** All research personnel must complete and submit their annual reports by the required deadlines.

Event-based Reports

- a. **New Appointments:** Upon the appointment of a new Staff member, or other employee, each departmental head determines whether he or she is responsible for the design, conduct, reporting, or direct administration of research and is subject to this policy. The new appointee must complete the FCOI disclosure form within one month of his or her IDI start date. The department making the appointment is responsible for ensuring that these individuals are identified and complete their FCOI disclosure form within the required timeframe.
- b. **Newly Assigned Responsibilities:** Individuals who become newly responsible for the design, conduct, reporting, or direct administration of research are required to complete FCOI disclosure form within one month of their assumption of such responsibilities.



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The department making the assignment is responsible for ensuring that these individuals are identified to the FCOI administrator in research office and complete their FCOI disclosure form within the required timeframe.

- c. **Material Change in Circumstances:** All research personnel must amend their FCOI disclosure forms within 60 days of any material changes to their responses. For PHS/NIH funded projects, disclosure should be made in 30 days of acquiring the materials change 42 CFR 60.04 (E). Material changes include but are not limited to the initiation or elimination of a reportable external commitment or financial interest for the reporter and family, a change in, or the initiation of, a sponsor, or any change that might affect a current management plan.
- d. **Proposal-Specific Report:** All research personnel, who are identified by the principal investigator, for a proposal must report proposal-specific external commitments and financial interests, including any sponsor-required information, at the time the principal investigator submits the proposal to Grants Office. Grants Office and Principal investigators ensure that research personnel submit FCOI reports prior to proposal submission. Grants Office will not submit any grant proposal for which the proposal-specific reports for all research personnel have not been submitted. Any resulting award may be distributed only after the reported proposal specific information has been reviewed and any management plan has been implemented.
- e. **Protocol-Specific Report:** Principal investigators and co-investigators for REC protocols are required to report their project-related external commitments and financial interests at the time they submit a protocol to the REC. Research Office and Principal investigators ensure that co-investigators submit FCOI reports prior to protocol submission. The protocol-specific reports must be reviewed by the REC and any required management plans implemented prior to protocol approval.

Report Review and Conflict Management Department-Level Review of Annual Reports, and Department-Level Involvement in Identification and Management of FCOI



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The department head, per the IDI Conflicts Policies (e.g. Finance Policy, Procurement Policy and Procedures Manual, Warehousing and Distribution Policy, Research Policy, under the Human Resource Manual), is responsible for addressing issues involving conflicts of commitment and non-research-related conflicts of interest.

In addition, the FCOIC and its administrators may call on department to supply additional information about reported external commitments and financial interests, and to assist in the development and implementation of management plans.

Financial Conflicts of Interest Committee (FCOIC) Review

The FCOIC and its administrators in Research Office are responsible for reviewing reports, collecting additional required information, identifying financial conflicts of interest, and determining required management plans. Under the guidance of the FCOIC, FCOI administrators review all report files to make the preliminary determination as to whether the report file shall be processed as follows:

- Exemption from Review: No real or apparent financial conflict of interest exists and hence the report does not require further consideration.
- Expedited Review: External commitments and financial interests pose real or apparent financial conflicts of interests that can be easily addressed by standard management plan measures (e.g., disclosure of the interest to journal publishers).
- Full Committee Review: External commitments and financial interests exist, that pose real or apparent financial conflicts of interests that require full FCOIC review to develop an appropriate management plan.



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- For PHS/NIH funded research, the FCOI administrators are required to review the FCOI reports within 60 days to determine whether real or apparent conflict of interest exists ([42 CFR 50.605\(a\)\(2\)](#))

Management Plan Development and Monitoring

a. **Management Plan Development:** Under the expedited and full committee review processes, FCOIC will review the FCOIC administrators' preliminary determinations of real or apparent financial conflicts of interest and oversee development of proposed management plans. The FCOIC votes on whether a real or apparent financial conflict of interest exists, and, if so, whether to approve the recommended management plans developed. Based on the FCOIC decisions, the FCOI administrator will finalize the management plan. Management measures may, as appropriate, include, but are not limited to, the following :

- Disclosure of the external commitment or financial interest to human participants, fellow researchers, students involved in the research activity, journal publishers, and/or others
- Research personnel's abstention from certain project segments or decisions
- Modification of the external commitment or financial interest
- Modification of the research plan (including the assignment of responsibilities)
- Monitoring of the potentially affected research activity by an independent individual or subcommittee
- Divestiture or severance of external commitment or financial interest
- Discontinuation of advisee's or subordinate employee's participation in External Entity

The management plan will state who is responsible for overseeing the implementation of the plan, and for reporting on compliance at stated



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intervals to the FCOIC. If the management plan prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed, who shall perform it, what records are to be kept, and what reports are made to the FCOIC.

b. **Additional Input on Management Plans:** In making review and management decisions, the FCOIC and FCOI administrators may consult with others on an as-needed basis only, including IDI administrative offices, Senior Management Team (SMT), and the Head Of Department Research, as well as the research personnel (and/or spouses or dependent children, if applicable) and department heads, particularly when the management plan will likely require department-level implementation and/or monitoring.

c. **Management Plan Notification:** The FCOIC communicates the FCOIC decision and management plan to the research personnel, department head, and those responsible for implementation of the management plan. In addition, sponsors will be notified of the existence of a managed conflict if the regulations of that agency or award so require. For NIH/PHS funded research, IDI will Send initial, annual (i.e., ongoing) and revised FCOI reports, including all required information defined in the policy to the NIH via the eRA Commons [FCOI Module](#) (a) prior to the expenditure of funds, (b) Within sixty (60) days of identification for an a research personnel who is newly participating in the project (c) Within sixty (60) days for new, or newly identified, FCOIs for existing research personnel (d) at least annually (at the same time as when IDI is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension. The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project (e) After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review ([42 CFR 50.605\(a\)\(3\)\(iii\)](#)). IDI Executive Director



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will notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and include the requirement to submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation ([42 CFR 50.605\(a\)\(3\)\(iii\)](#)). Additionally, IDI Executive Director will notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research ([42 CFR 50.606\(a\)](#)) .

d. **IDI-REC Review:** If a protocol-related external commitment or financial interest is identified in a protocol application, the REC may not approve the protocol until the FCOIC has completed a review of the report file and any necessary management plan has been approved and implemented. The IDI-REC has the authority to recommend, as a condition of protocol approval, adding human participant protection measures to an approved management plan, but does not have the authority to delete other items approved by the FCOIC.

e. **Appeals Process:** Within two weeks of notification of the FCOIC decision, research personnel must acknowledge in writing agreement to comply with any required management plan or submit a written request for reconsideration to the FCOIC, which has the authority to review and affirm the previous decision or amend the management plan. The FCOIC will notify the research personnel and the department head of the result of the appeal. Research personnel who do not agree with the FCOIC decision may submit a written request for reconsideration to the HOD Research, who may recommend to the FCOIC that they delete a requirement. The HOD Research may not alter or remove a requirement. In all cases, the HOD Research may add requirements to a management plan at his or her discretion. The FCOIC issues a final binding decision.



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Sanctions for Noncompliance

Annual Report of External Commitments and Financial Interests

Submitting the annual report by the filing deadline is a requirement of all research personnel. During the submission timeframe, research personnel will be reminded of the reporting deadline. Those who fail to submit the report will be referred to the department head and the HOD Research. At the discretion of the HOD, as the representative of the ED, the failure of an individual to comply with reporting requirements may result in one or more of the following sanctions, until the report is submitted:

- The individual will be deemed ineligible to maintain principal investigator status on sponsored projects
- The individual will be deemed ineligible to enter into technology transfer agreements
- A letter, over the signature of the HOD, will be placed in the individual's personnel file indicating that his or her good standing as a member of the IDI research community has been called into question
- Any annual salary increment will be withdrawn until the individual comes into compliance
- The individual's research activities and associated salary will be suspended until the individual comes into compliance. Any suspension of research activities and associated salary will be undertaken in accordance with IDI's policies and codes, including the Dismissal/Suspension Policy for Staff Members

In case of non compliance, remedies listed above will be applied. In addition. The research personnel will be required to (a) Disclose the FCOI in each public presentation of the results of the research, and (b) To request an addendum to previously published presentations.

Proposal-Specific Report

At a minimum, (1) research personnel who have not completed their proposal-specific report will not be able to submit the proposal or must be removed from the proposal before it is submitted, and (2) any awards for



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projects in which these research personnel are participating will not be distributed by Grants Office until any required management plans have been implemented.

Protocol-Specific Report

Research personnel submitting a protocol to the IDI-REC are required at the time of the protocol submission to report project-specific external commitments and financial interests. Protocols will not be processed until these protocol-specific reports are submitted.

Other Event-Based Reports

Research personnel are required to provide other event-based reports as required by this policy, other IDI policies, a sponsor's award or contract, or regulations. Failure to provide such reports will result in the sanctions described in Sanctions for Noncompliance above.

Management Plans

Any failure by research personnel to adhere to an approved management plan will be cause for one or more of the sanctions noted in Sanctions for Noncompliance, at the discretion of the HOD Research.

In addition, where such failure is not remedied, the non-compliance may be reported to the pertinent sponsor, if applicable, and disciplinary action may be commenced, including misconduct proceedings, and, in severe cases, termination. Any academic misconduct or termination proceedings will be conducted in accordance with the applicable institutional policies and codes, including those set forth in the IDI policy Handbook.

Audit

The IDI Research Office and/or the IDI Audit Office may conduct investigations (a retrospective review) of potential non-compliance with reporting requirements, management plans, or other policy-related issues, when necessary. Instances of non-compliance that require reporting to Legal agencies, sponsors, and/or other regulatory bodies, will be determined by Research Office, Audit, and/or the HOD Research, and acted on as required. This will be done in compliance with IDI and sponsor policies. For example,



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for NIH/PHS funded research, the retrospective review must be done within 120 days ([42 CFR 50.605\(a\)\(3\)](#)). The FCOIC, Research Office, and/or the IDI Audit Office may conduct audits and process and compliance reviews to identify needed improvements to the financial conflicts of interest process.

Record Retention

The FCOI administrators in the IDI Research Office will maintain the records regarding the financial conflicts of interest process, in accordance with IDI policy and sponsors' requirements. The records will be maintained for (a) For at least three (3) years from the date the final expenditures report is submitted to the sponsor ([42 CFR 50.604\(i\)](#))

Training

Research personnel will be informed of IDI FCOI policy, FCOI disclosure responsibilities of all foreign and domestic significant financial interests, and sponsor requirements ([42 CFR 50.604\(b\)](#)). In line with the FCOI policy ([42 CFR 50.604\(b\)](#)) A research personnel is required to complete FCOI training:

- (a) Prior to engaging in any research,
- (b) At least every four (4) years
- (c) Immediately, if;
 - i) IDI revises its FCOI policy that affects requirements of a research personnel
 - ii)a research personnel is new to an IDI
 - iii) a research personnel is not in compliance with the policy or management plan.

FCOIC members receive appropriate training and continuing education in the identification and management of financial conflicts of interest, including related Institutional policies and procedures and national regulations.

The trainings will use the blended approach consisting of the online and face to face approaches. Sponsors training materials such as those available at NIH's FCOI Training Webpage at [FCOI Training | grants.nih.gov](#) will be used



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Appendix A: FINANCIAL CONFLICT OF INTEREST DISCLOSURE FORM

Preliminary note:

This statement of Financial Conflict of Interest Disclosure Form requires you to provide information with respect to significant financial interest for you and parties that are related to you. These include:

- a. your family (spouse and dependent children).
- b. any corporation or organization of which you are a board member, an officer, a partner, participate in management or are employed by, or are, directly or indirectly, a debt holder or the beneficial owner of any class of equity securities; and
- c. Any trust or other estate in which you have a significant financial interest which you serve as a trustee or in a similar capacity.

The disclosure is required for all financial interests received from an external entity when such income meets the threshold for disclosure income in excess of \$5,000.

1. NAME OF EMPLOYEE/CONSULTANTS: (Please print)

2. CAPACITY:

_____ Principal Investigator

_____ Senior Management

_____ Officer

_____ Other (specify): _____

3. Have you or any of your family, affiliated organizations/corporations/trusts/estates provided services or products to the IDI in the past 12 months? YES NO

If yes, please provide the name of the family member, organization, corporation, trust or estate and the nature of the services or products and the value of the Significant Financial Interest (SFI).



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Provide a description and nature of the SFI (e.g. salary, royalties, consulting fees, honoraria, paid authorship, reimbursed or sponsored travel, etc).

Is the SFI from a publicly traded company or non-publicly traded company?

YES NO

If yes, please provide details.

4. Have you or any of your family, affiliated organizations/corporations/trusts/estates purchased services or products from the IDI in the past 12 months? YES NO

If yes, please describe the purchased services or products and if family, affiliated organizations/ corporations/ trusts/ estates are involved, the identity of the affiliated person and your relationship with that person:

5. Please indicate whether you or any of your family, affiliated organizations/corporations/trusts/estates had any direct or indirect interest in any business transaction(s) in the past 12 months to which IDI was or is a party?

YES NO

If yes, describe the transaction(s) and of family, affiliated organizations/corporations/trusts/estates were involved, the identity of the family, affiliated organizations/corporations/trusts/estates and your relationship:



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6. Were you or any of your family, affiliated organizations/corporations/trusts/estates indebted to pay money to the IDI at any time in the past 12 months (other than travel advances)?

YES NO

If yes, please describe the indebtedness and if family, affiliated organizations/corporations/trusts/estates were involved, the identity of the family, affiliated organizations/corporations/trusts/estates and your relationship:

7. In the past 12 months, did you or any of your family, affiliated organizations/corporations/trusts/estates receive, or become entitled to receive, directly or indirectly, any personal benefits from the IDI or as a result of your relationship with the IDI, that in the aggregate could be valued in excess of \$5,000, that were not or will not be compensation directly related to your duties to IDI? YES NO

If yes, please describe the benefit(s) and if an affiliated person is involved, the identity of the affiliated person and your relationship with that person:

8. Travel: The following information about travel is required for disclosure ONLY for travel expenses that were paid on your behalf or reimbursed directly to you by another organization but not IDI that have already or will likely reach \$5,000 or more in the past 12 months.

IDI requires you to report these expenses within 30 days of the conclusion of the trip.

a) Entity from which payment/reimbursement was received: _____

b) Departure Date: _____



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Return Date: _____

c) Purpose (e.g., Consulting, Scientific Advisory Board meeting, Sponsored research meeting, etc): _____

d) Destination (City/Country): _____

e) Reimbursed or paid expenses: (value can be “unknown” if paid on your behalf; but it is important to know the costs for disclosure purposes and itemization within category may be helpful for record-keeping.

Expense Description	Value (USD)
Lodging	
Transportation (air, taxi, etc.)	
Meals	
Other	

9. Are you or any of your family, affiliated organizations/corporations/trusts/estates a party to or have an interest in any pending legal proceedings involving IDI?

YES NO

If yes, please describe the proceeding(s) and if an affiliated person is involved, the identity of the affiliated person and your relationship with that person:

10. Do you or your family, affiliated organizations/corporations/trusts/estates have intellectual property (IP) rights and interests with a threshold of \$5,000 (e.g., patents, copyrights)?

YES NO



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If yes, please disclose these below;

11. Are you aware of any other events, transactions, arrangements or other situations that have occurred or may occur in the future that you believe should be examined by IDI's research office, or a duly constituted committee thereof in accordance with the terms and intent of IDI's conflict of interest policy? YES NO

If yes, please describe the situation(s) and if family, affiliated organizations/corporations/trusts/estates are involved, the identity of your family, affiliated organizations/corporations/trusts/estates and your relationship with that person:

I HEREBY CONFIRM that I have read and understand IDI's Financial Conflict of Interest Policy and that my responses to the above questions are complete and correct to the best of my information and belief. I agree that if I become aware of any information that might indicate that this disclosure is inaccurate or that I have not complied with this policy, I will notify Research Office or HOD Research immediately.

Signature