



INFECTIOUS DISEASES RESEARCH COLLABORATION
POLICY GUIDELINES ON THE DISCLOSURE AND MANAGEMENT OF
FINANCIAL CONFLICT OF INTEREST

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A handwritten signature in blue ink, appearing to read 'M. Bahmmmm', is written over a horizontal line.

Chairman, Board of Directors

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ACRONYMS

FCOI- Financial Conflict of Interest

IDRC – Infectious Diseases Research Collaboration

PI –Principal Investigator

SFI – Significant Financial Interest

SMT – Senior Management Team

OPERATIONAL DEFINITIONS

Financial interest: Anything of monetary value whether or not the value is readily ascertainable.

Financial conflict of interest (FCOI): Significant financial interest that could directly and significantly affect the design, conduct or reporting of a funded research.

Key person: Any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the sponsored project. This includes the Principal Investigator, Co-Investigators, Collaborators, Consultants, and any other individual who has responsibility for designing, conducting, or reporting of funded research or proposed such funding.

Pre-Award: Activity prior to official funding of a submitted proposal.

Significant financial interest (SFI): An aggregated income of the investigator, their spouse and dependent children which exceeds \$5,000 from an entity or interest that reasonably appears to be related to the Investigator's IDRC responsibilities.

Table of Contents

1.0 Purpose of the guidelines	1
2.0 Applicability.....	1
3.0 Roles and responsibilities.....	1
3.1 Senior Management Team	1
3.2 Grants department.....	1
3.3 PIs/Key Personnel	2
4.0 Disclosure of significant financial interest.....	2
4.1 Exceptions to disclosure	2
5.0 Management of financial conflicts of interest.....	3
5.1 Management of identified conflicts of interest.....	3
5.2 Management of undisclosed conflicts of interest	3
5.3 Compliance to SMT recommendations.....	4
6.0 Training.....	4
7.0 Reporting of Significant Financial Interests.....	4
7.1 Reporting disclosed financial interests	4
7.1.1. Publishing of information on publicly accessible website	4
7.1.2 Reporting to the Awarding Agency	4
7.2 Reporting undisclosed financial interests.....	4
8.0 Record keeping.....	5
9.0 Policy Amendments.....	5
Appendix A.....	6
References.....	7

1.0 Purpose of the guidelines

The purpose of these guidelines is to ensure that the Infectious Diseases Research Collaboration (IDRC) research activities promote objectivity in research. The policy requires all Principal Investigators and other key personnel involved in the design, conduct and reporting of research activities to declare any financial conflicts of interest that may bias the outcome of research project activities.

2.0 Applicability

These guidelines are applicable to all individuals at IDRC who apply for or receive domestic or foreign funds as well as those listed as key personnel in grant applications. These regulations also apply to all sub recipients of grant funds from IDRC.

3.0 Roles and responsibilities

This section details the responsibilities of all stakeholders in ensuring compliance to this policy.

3.1 Senior Management Team

- i) Ensure that where applicable, individuals listed as PIs or Key personnel; submit a disclosure of financial interest form (see appendix A) to the Grants department.
- ii) Determine whether a Principal Investigator's (PI's) significant financial interest could be affected by the research or is in an entity whose financial interest could be affected by the research.
- iii) Take action to manage identified financial conflict of interest.
- iv) Establish enforcement mechanisms to ensure Investigators' compliance.
- v) Ensure that any sub recipients of research grant funds abide by IDRC's FCOI policy or that they have a written FCOI policy

3.2 Grants department

- i) Ensure that this policy is up to date by incorporating all updates from funding agencies and Uganda government agencies
- ii) Ensure that the policy is enforced within IDRC
- iii) Ensure that all subrecipients have written and enforced FCOI policies
- iv) Ensure that this policy is available on the IDRC website
- v) Ensure that all PIs and key personnel on funded or proposed research projects are aware of the policy and their responsibilities to meet compliance requirements
- vi) Ensure that all PIs/key personnel undertake training regarding the FCOI regulations
- vii) Receive and review disclosures of significant financial interests from each Investigator/key personnel who is/are planning to participate in funded research or other funded activities.
- viii) Ensure that all SFI disclosures are up to date.
- ix) Provide initial and ongoing FCOI reports to the funding agency as required.
- x) Monitor Investigator compliance with Senior Management Committee recommendations.

3.3 PIs/Key Personnel

- i) Undertake training regarding FCOI regulations and obtain certification for the same. A copy of the certificate should be submitted to the Grants department. Training is available on funding agency websites e.g. at the link provided here:
 - a. https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html .
Alternative training will be arranged by the Grants department if deemed necessary.
- ii) Disclose theirs, their spouse's and dependent children's significant financial interests prior to engaging in a funded research grant and at least every four years. Additional disclosure may be required when;
 1. IDRC revises this policy in a way that affects the requirements of investigators and other significant implementers
 2. An investigator or other key personnel is new to IDRC
 3. An investigator or other key personnel is not in compliance with this policy

4.0 Disclosure of significant financial interest

During the pre-award period, the Grants staff will request all the designated key personnel on a given proposal to disclose any financial interests that may apply to the pending award. They will complete the disclosure of financial interest form (see appendix A). The key personnel will be expected to disclose any income or anything of monetary value received by them, their spouse and dependent children that could compromise the research in some way. These may include but may not be limited to the following;

- i) Income from a publicly traded entity that reasonably appears related to the Investigator's or key personnel's IDRC responsibilities.
- ii) Income from a non-publicly traded entity that reasonably appears related to the Investigators' or key personnel's IDRC responsibilities.
- iii) Income from intellectual property rights and interests from an entity related to the Investigator's institutional responsibilities.
- iv) Reimbursed or sponsored travel related to the Investigator's IDRC responsibilities. The information provided will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

All new key personnel assigned a role on an on-going research project will be required to disclose any financial interests as soon as they are appointed. Any disclosed interests will be reviewed and addressed within sixty working days.

4.1 Exceptions to disclosure

Key personnel are not required to declare the following;

- i) Salaries, royalties or other remuneration including shares in Intellectual property rights paid by IDRC to the Investigator or other key personnel if that individual is currently employed by or otherwise appointed by IDRC.
- ii) Income from investment vehicles such as mutual funds and retirement accounts as long as the Investigator or other key personnel does not directly control investment decisions made from these vehicles.

The disclosure forms will be received and reviewed by the Grants staff before being forwarded to the Senior Management Team. The SMT will investigate the disclosed interests with an aim of establishing whether they will significantly affect the design, conduct or reporting of the project to which the Investigator or other key personnel is attached. Investigations will include an interview with the key personnel as well as other independent verification channels.

5.0 Management of financial conflicts of interest

5.1 Management of identified conflicts of interest

In cases where financial conflicts of interest exist, the IDRC senior management team will recommend that the conflict is managed in one or more of the following ways;

- i) Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the project
- ii) Modification of the research or project plan
- iii) Severance of the relationships that cause the conflict
- iv) Ensure that the Investigator/key personnel publicly discloses the financial conflict of interest while presenting or publishing the project findings.
- v) Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the research or other project against bias resulting from the financial conflict of interest.

The recommended action and all the committee meeting discussions will be written and appropriately filed.

5.2 Management of undisclosed conflicts of interest

In the event that the SMT identifies a significant conflict of interest that was not disclosed by key personnel, it will within ninety working days review the significant financial interest and determine whether it is related to a given research project and whether a financial conflict of interest exists. If a financial conflict of interest is identified. The SMT will;

- i) Suspend the responsible key personnel from the project and appoint a suitable replacement. The change in personnel will be communicated in the shortest time possible to the funding agency.
- ii) Ensure that any bias created by the undisclosed conflict is managed appropriately.
- iii) Modify the study design where applicable.
- iv) Barr the responsible key personnel from participating in any research or other donor funded activity for two years following this incident
- v) Subject the Investigator/key personnel to disciplinary action in line with IDRC regulations.

In cases where an undisclosed conflict is not managed in a timely way and IDRC is deemed non-compliant, a retrospective review of the key personnel's activities and the project to determine whether any of the research or other activities performed during that time were biased in design, conduct or reporting will be carried out within 6 months from the date of notification. The retrospective review will be documented and the documentation will include the following;

- i) Minutes of the meetings of the SMT to held to discuss the SFI
- ii) Project number, title & the PI(s)' contact
- iii) Name of the Investigator(s)/key personnel with the FCOI
- iv) Name of the entity with which the Investigator/key personnel has a FCOI

- v) Reasons for the retrospective review
- vi) Detailed methodology used for the retrospective review
- vii) Findings of the review
- viii) Conclusions of the review

5.3 Compliance to SMT recommendations

The Grants department will receive the SMT's recommendations regarding a financial conflict of interest and ensure that the key personnel in question comply with it. Any non-compliance to the recommendations will be reported to the SMT which will take appropriate action.

6.0 Training

Investigators must complete required training/education program(s) on Financial Conflicts of Interest, the responsibilities to disclose, and the PHS regulations prior to the expenditure of PHS funds and every 4 years during the award or immediately under the designated circumstances:

- i) Institutional FCOI policies change in a manner that affects Investigator requirements
- ii) An Investigator is new to an Institution
- iii) An Institution finds an Investigator noncompliant with the Institution's FCOI policy or management plan.

Training may be organised by the Grants department or found at funding agency websites as indicated in section 3.3 above.

7.0 Reporting of Significant Financial Interests

7.1 Reporting disclosed financial interests

7.1.1. Publishing of information on publicly accessible website

The Grants department shall publish FCOI information on the IDRC website. Published information will include: the Investigator's name, title & role in the research project, the name of the entity within which the SFI is held, the approximate dollar value of the SFI or a statement that the dollar value cannot be readily determined through reference to prices or other reasonable measures of fair market value. The information provided on the website will be updated annually and within sixty days of receipt of a disclosure of an SFI.

7.1.2 Reporting to the Awarding Agency

The Senior Grants Manager will provide a FCOI report regarding any key person's significant financial interest found by the SMT to be conflicting. In cases in which an identified FCOI is eliminated prior to expenditure of grant funds, IDRC will not submit a FCOI report. For all submitted reports, the Senior Grants Manager will prepare an annual update detailing the status of the FCOI and any changes in the management plan.

7.2 Reporting undisclosed financial interests

The Grants department will submit a mitigation report to the awarding agency following a retrospective review of a non-disclosed SFI. The information provided will enable the awarding agency to understand the nature and extent of the conflict and to assess the appropriateness of the SMT's recommendation. The information provided will include the following;

- i) Minutes of the SMT meetings held in relation to the FCOI

- ii) Project number, PI contact & name of the Investigator/key personnel with a conflict
- iii) Name of the entity with which the Investigator/key personnel has a conflict
- iv) Nature of the financial interest
- v) Value of the financial interest
- vi) A description of how the FCOI relates to the funded research project
- vii) A description of the SMT recommendation

8.0 Record keeping

The Grants department will maintain files of all records relating to all key personnel disclosures of financial interests. In addition to this, all minutes of the SMT meetings related to reviewing and management of SFI will be filed and stored in the Grants department. Files will be maintained for a period of up to three years from the date on which the final expenditure report of the research project is submitted to the awarding agency.

9.0 Policy Amendments

The Senior Grants Manager will periodically review and update this policy taking into consideration changes in the research environment and awarding agency regulations.

Appendix A

Infectious Diseases Research Collaboration	
Disclosure of financial interest form	
Date	
Investigator's or key personnel's name and title	
Proposal Number	
Proposal Title	
Type of Financial Interest	
If travel, please state the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration.	
Name of entity(ies) with which the financial interest exists	
Estimated monetary value of financial interest (value stated should be an aggregate value including where applicable the income of one's spouse and dependent children)	
Additional Information	
Preliminary review by the Grants department	
Reviewed by:	
Signature:	Title:
Print Name:	Date:
Review & recommendation by the SMT (to be completed by the Chair)	
Signature:	Title:
Print Name:	Date:

References

**Federal Register Vol.76 No.165, 42CFR PART 50 and 45CFR Part 94
NIH grant policy statement**