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**Policy**  
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**Global**

***CIET policy on financial conflicts of interest  
(FCOI)***

# CIET Policy on Financial Conflicts of Interest (FCOI)

(Version of 11 August 2014)

CIET recognizes that its research fellows, research associates and support group members participate actively in community, political, religious, and cultural activities and institutions, and other personal and economic endeavors.

These many interactions inherently create the potential for conflicts of interest. If any such conflicts occur, or appear to occur, and are not appropriately disclosed and addressed, they can undermine public and professional confidence in the integrity of CIET and its research. The existence of a real or apparent conflict of interest does not necessarily mean that the outside activity at issue must be avoided or discontinued. Often, conflicts of interest can be dealt with effectively through disclosure or other steps to resolve or manage the conflict.

This document sets forth CIET policy on the disclosure, management, and resolution of financial conflicts of interest regarding CIET research and other activities. Recognizing the broad variety of both professional settings in which conflicts may occur and means of responding to them, this policy specifies only the basic principles that should guide the resolution of financial conflicts of interest. This policy extends worldwide but it especially includes the requirements necessary to conform to United States federal law regarding financial conflicts of interest in federally funded research, including the conflicts of interest regulations issued by the U.S. Department of Health and Human Services Public Health Service (PHS).

## 1. Applicability

This Policy applies to all persons who are receiving financial payment from CIET who are “researchers” involved in CIET research projects as defined in Section 2 below. Additionally, it applies to Support Group members, interns and others who are involved in the design, conduct, review or reporting of research conducted under CIET auspices.

Specific policy directives, with the exception of sections 6,7 and 8 below, apply to CIET researchers everywhere unless otherwise noted.

## 2. Definitions

- a. A “Conflict of Interest” means a significant financial interest that could directly affect institutional responsibilities, including the design, conduct, or reporting of research. .
- b. “Dependent” is defined as any person who receives more than one-half of his or her annual support from a researcher, whether or not related to that researcher.
- c. “Family Members” are defined as the researcher’s spouse or domestic partner and dependents
- e. “CIET” refers to one or more of the following: CIET International, Inc., Community Information and Epidemiological Technologies Canada, CIET Europe, CIET Trust South Africa, CIET Trust Botswana, the *Centro de Investigación de Enfermedades Tropicales (CIET)* at the *Universidad Autónoma de Guerrero, México*.
- e. “Researcher” means a person associated with CIET who has responsibility for the design, conduct, review or reporting of research conducted by CIET and under the CIET's auspices. *In the United States*

*it also applies to any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of CIET research funded by the United States Public Health Service (PHS) or other federal agencies, or proposed for such funding which may include, for example, collaborators, consultants, or sub-contractors.*

f. "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development *and, in the United States, any activity for which research funding is available from a PHS Awarding Component.*

g. "Significant Financial Interest" means one or more of the following financial interests of the researcher (and those of the researcher's family members) that reasonably appear to be related to the researcher's institutional responsibilities:

- With regard to any publicly traded entity, it is 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, the value of which exceeds \$5,000 from one enterprise or entity;
- With regard to any non-publicly traded/private entity, it is the value of remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, the value of which exceeds \$5,000, or when the researcher holds any equity interest;
- Intellectual property rights and interests, upon receipt of more than \$5,000 income related to such rights and interests;
- Salary, remuneration, or similar payments which exceed, or are expected to exceed, \$5,000 within any one-year period, when aggregated for the member and his or her family members; or
- Any reimbursed or sponsored travel, related to a researcher's CIET responsibilities. with the exception that, *in the United States, researchers need not disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C 1001(a), an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education.*

The above includes anything of monetary value, whether or not the value is readily ascertainable, including, but not limited to, salary, commissions, consulting fees, honoraria, equity interests, interests in real or personal property, dividends, royalties, rent, capital gains, and intellectual property rights. It does not include:

- compensation from CIET;
- income from seminars, lectures, or other educational activities approved by but not paid by CIET;
- income from service on advisory committees or review panels approved by but not paid by CIET;
- Income from personal investments and retirement accounts, as long as the researcher does not directly control the investment decisions.
- Travel paid for or reimbursed by CIET.

h. "Sponsored Program" means projects or activities, other than research, undertaken in association with CIET pursuant to funding from an external source.

i. "Institutional responsibilities" means a researcher's professional responsibilities on behalf of CIET such as the conduct of research, training, technical assistance, membership on institutional committees and research administration.

k. The "FCOI Officer" is a CIET officer designated by the Executive Director to administer the implementation of this policy, including to review disclosures and convene a Conflict of Interest (COI) Committee. In the case of U.S. federally-funded research, the FCOI Officer administers the duties

outlined in applicable federal regulations.

### **3. Responsibility of Researchers**

- a. Researchers who are covered by this policy share an obligation to ensure that the design, conduct or reporting of research conducted in association with CIET will be free from bias resulting from researcher financial conflicts of interest and to conduct their relationships with each other and with CIET with candor and integrity.
- b. Pursuant to that obligation, researchers have a duty to identify and, when possible, avoid financial conflicts of interest. When conflicts cannot be avoided, researchers must disclose outside financial relationships that are related to the researcher's CIET responsibilities and work with CIET officials to manage or resolve those conflicts.
- c. Accordingly, researchers must disclose any significant financial interest of themselves or their family members that are related to the researcher's CIET responsibilities, and any significant financial interest of themselves or their family members in external companies or other organizations whose financial interests could appear to affect, or be affected by, their CIET responsibilities.
- d. Disclosures under this policy shall be made as soon as possible after a significant financial interest that meets the disclosure standard arises. Disclosure shall be made according to the processes established by the Executive Director.
- e. If any application for external funding is involved, researchers shall ensure that they have disclosed all significant financial interests related to their planned CIET responsibilities prior to presenting the application to the CIET research fellow responsible for submitting the grant, and as soon as possible thereafter if a new significant financial interest meeting the disclosure standard arises. Disclosures shall also be updated as soon as possible when an existing significant financial interest ends or is materially altered. The CIET Disclosure Form and Transmittal Form for disclosure related to a grant submission are available from the FCOI Officer and are accessible to all staff.

### **4. Disclosure Policies and Procedures**

- a. Disclosure shall be made to the CIET FCOI Officer pursuant to the applicable procedures on conflicts of interest. These procedures shall be designed to facilitate the local resolution or management of any conflict, and minimize administrative burden.
- b. All such procedures shall be consistent with the following:
  - i. It is the obligation of each researcher to disclose all significant financial interests related to her/his CIET institutional responsibilities.
  - ii. Researchers shall disclose annually all significant financial interests that meet the standards of Section 3(c) above, and they shall update these disclosures within the annual period and within thirty days of (a) acquiring a new significant financial interest that reasonably would appear to affect or be affected by their CIET responsibilities, or (b) the end or material alteration of an existing significant financial interest; or (c) *prior to submission of a United States PHS-funded grant proposal*.
  - iii. Researchers shall not be subject to burdensome or random disclosure requirements; however, this shall not restrict the use of disclosure as a tool for avoiding, resolving, or managing an on-going conflict of interest or the compliance with annual monitoring by the CIET FCOI Officer or designee.
  - iv. Disclosure shall be made to the CIET FCOI Officer designated by the applicable procedures on conflicts of interest. Disclosure policies should require no more information than is necessary.
  - v. Disclosure should not be part of the collection of unrelated data (e.g., annual reports). Disclosure

documents shall be destroyed as soon as appropriate and in accordance with applicable legal requirements. *In the United States CIET shall maintain records relating to all investigator disclosures of financial interests and the institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of an FCOI) and actions under the institution's policy or retrospective review for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.*

- c. The CIET FCOI Officer will determine whether a researcher's significant financial interest is related to his or her research and, if so, whether the significant financial interest is a conflict of interest. The FCOI Officer may engage a CIET FCOI Committee for final determination.
- d. A significant financial interest is related to research or sponsored programs activities when CIET, through its Executive Director, reasonably determines that the significant financial interest:
  - i. could be affected by the research; or,
  - ii. is in an entity whose financial interest could be affected by the research.
- e. Whenever CIET identifies a significant financial interest that was not disclosed in timely fashion by an investigator or, for whatever reason, was not previously reviewed by CIET, the CIET FCOI officer will, within 60 days, review the case and confirm that a significant financial conflict of interest exists and, if so, convene the FCOI Committee to recommend appropriate action in accordance with section 6, d below..
- f. *If the researcher is involved in a United States PHS-funded grant, or a proposal for such a grant, CIET will comply with the procedures outlined in 45 CFR 50.605.*
- g. If the researcher is involved in research funded through CIET International and the FCOI Committee has determined that a conflict of interest exists, this determination must be reported to CIET International's Executive Board.

## **5. Conflict Resolution and Management**

- a. Conflicts of interest shall be avoided, resolved, or managed, as needed, pursuant to applicable policies and procedures on conflicts of interest. These policies and procedures shall be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the privacy of CIET personnel and their family members.
- b. Anyone working with CIET may request advice about a potential financial conflict of interest from the CIET FCOI Officer without being required to disclose his or her name or identifying details of the potential conflict. Any unit of CIET may request advice about a potential conflict of interest from the CIET FCOI Officer provided that no more identifying information than necessary should be disclosed unless required by law or CIET policy.
- c. In the event a FCOI is disclosed to CIET, the CIET FCOI Officer will determine if the financial conflict of interest is reportable and will insure that procedures are followed to report the FCOI.
- d. In the event the FCOI Official determines there exists an FCOI, whether reportable or not, (s)he will convene a FCOI Committee to review all required information and follow all procedures to ensure that the FCOI is reduced, eliminated and/or managed through the development and implementation of a management plan. The FCOI Officer will be Chair of the FCOI Committee. All FCOI decisions and management plans shall be reported to the CIET Executive Director and to the Executive Board of the CIET entity with jurisdiction in the matter. The researcher may not be present at or participate in the Board's deliberation on the matter, or in any other way attempt to influence improperly these deliberations or the voting.

e. If the FCOI in question involves the Executive Director or any Board member, the FCOI Officer, with the consent of the FCOI Committee, shall designate an Independent Arbitrator to approve the management plan.

f. The CIET FCOI Official shall be charged with monitoring and recommending changes, as necessary, to the CIET Policy on Financial Conflicts of Interest and monitoring recommended measures for resolving or managing specific Conflict of Interest cases.

g. Options for managing FCOI may include and are not limited to:

- public disclosure
- consent form disclosure
- modification of the research plan
- change of personnel or personnel responsibilities
- disqualification of personnel from participation in all or part of the research activities
- independent monitor

h. If the failure of an investigator to comply with CIET's conflict of interest policy has biased the design, conduct, or reporting of any PHS-funded research, CIET must promptly notify NIH of the corrective action taken or to be taken.

## **6. U.S. Federally Funded Research**

*This policy fulfills U.S. federal regulations requiring institutions receiving federal funding to have in place a written, enforced policy and process to identify and manage, reduce, or eliminate conflicts of interest of persons engaged in the design, conduct, or reporting of federally funded research.*

***In addition to satisfying applicable requirements of federal law, researchers must complete training prior to engaging in any research related to any PHS-funded grant or contract in accordance with 42 C.F.R. Part 50.601 et seq.***

## **7. Training**

a. *CIET shall provide conflict of interest training to all researchers receiving funding from the United States Public Health Service in accordance with 42 C.F.R. Part 50.601 et seq. The CIET FCOI training is available on request to the Associate Executive Director and accessible to all staff. In addition, CIET has added the FCOI Tutorial (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) as a required training module, to be completed when staff complete or update their Human Subjects training.*

b. *Each researcher must complete conflict of interest training prior to engaging in research related to any United States Public Health Service funded grant or sponsored project.*

c. *Each researcher must complete conflict of interest training at least every four years.*

## **8. Public Accessibility**

*In the United States this Policy and disclosure of Researchers' Conflicts of Interest shall be available to the public to the extent required by C.F.R. Part 50.601 et seq.*

## **9. Enforcement**

a. Enforcement of this Policy on Financial Conflicts of Interest is the ultimate responsibility of the Executive Director and the Boards of Directors, who may delegate that responsibility to other CIET

officials pursuant to this policy. Principal responsibility for implementation and enforcement of this Policy shall reside with the Executive Director.

b. Violations of this policy and implementing procedures, including the failure to file timely disclosures; filing incomplete, erroneous, or inaccurate disclosures; or failure to comply with prescribed procedures for managing or resolving conflicts of interest, will be dealt with in accordance with applicable CIET policies and procedures.

c. Appeals from administrative decisions concerning Conflicts of Interest are subject to applicable CIET policies and procedures concerning review of administrative decisions.