

Global Institute of Human Development – Shifa Tameer-e-Millat University

Financial Conflict of Interest Policy for Project Directors and Principal Investigators



Shifa Tameer-e-Millat University
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Overview

The Global Institute of Human Development is a constituent teaching department of Shifa Tameer e Millat University (www.gihd.stmu.edu.pk) with the vision to develop indigenous models of needs-based, research-led education, training and capacity building programs to inform the development of equitable, universal, sustainable health, education and social-welfare services to promote human development. It is a research-intensive educational institute which builds on decades' long legacy of improving lives through research. Its programs are informed by indigenous research, conducted to the best global standards.

The GIHD has instituted this Financial Conflict of Interest (FCOI) Policy for U.S. Public Health Service (PHS)-Supported Project Directors (PD) and Principal Investigators (PI) supported by PHS funding only.

This policy is to satisfy the requirements of the U.S. Department of Health and Human Services FCOI Regulation for PHS-funded research (42 CFR Part 50 and 45 CFR Part 94). It aims to reflect a commitment to maintaining a research culture that promotes the prevention, detection and resolution of instances of fraudulent, dishonest or other wrongful conduct, and to safeguarding the work and reputations of Institute scientists and research staff and sub-recipients.

Scope of Policy

This FCOI Policy for PHS-supported PD/PI specifies guidance for PHS principal investigators. All employees of the GIHD (including consultants, temporary employees, interns, and others working on behalf of the organization) must comply with and abide by appropriate standards of ethical conduct in carrying out their duties and responsibilities for and on behalf of the Institute.

This policy specifies the expectations for all Institute staff, with the Institute guidance being broader than that required by the federal government for PHS-supported Investigators.

The GIHD has established this FCOI policy to satisfy the requirements of the U.S. Department of Health and Human Services FCOI Regulation for PHS-funded research (42 CFR Part 50 and 45 CFR Part 94). Consistent with these regulations, this policy aims:

- To promote objectivity and integrity in the work of the GIHD and its individual staff members;
- To ensure that GIHD staff identify, disclose, and appropriately manage or eliminate situations in which their personal or familial interests might otherwise compromise or appear to compromise their objectivity as researchers or administrators.
- To establish reasonable standards of expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI).

Oversight

The Research Business Management Department has overall responsibility for this policy and serves as the Institute's Conflict of Interest Officer. It is the obligation of any PHS-supported Investigator or staff with concerns or questions about this policy to seek guidance. Questions or concerns relating to this policy should be directed to:

Mr. Mohsin Mahboob – Research Business Manager

mohsin@gihd.stmu.edu.pk

What is a Financial Conflict of Interest (FCOI)?

Financial conflict of interest (FCOI) means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research.

What is a financial interest?

In general, a financial interest is anything of monetary value, related to a Principal-Investigator's employment responsibilities, whether or not the value is readily ascertainable, in any of these categories:

- Remuneration or compensation (e.g., salary, consulting fees, honoraria, etc.) from a public or private company;
- Equity (e.g., stock, stock options or other ownership interest) in a public or private company;
- Intellectual property rights (e.g., patents, copyrights), and any royalties and licensing income from such rights;
- A position in an outside entity that gives rise to a fiduciary duty, such as director, officer, partner, trustee, employee or any position of management,
- For Investigators with PHS funding, also any reimbursed or sponsored travel.

What is a significant financial interest?

As per 42 CFR 50.603, the following definitions for a financial interest and significant financial interest are operational:

1. *“A financial interest consists of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:*
 - a. *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:*
 - i. *salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);*
 - ii. *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;*
 - b. *With regard to any non-publicly traded entity, a significant financial interest exists if:*
 - i. *the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or*
 - ii. *when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or*
 - c. ***Intellectual property*** *rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.*
2. *Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to:*
 - a. *travel that is reimbursed or sponsored by a Federal, state, or local government agency,*
 - b. *an Institution of higher education as defined at 20 U.S.C. 1001(a),*
 - c. *an academic teaching hospital, a medical center, or*
 - d. *a research institute that is affiliated with an Institution of higher education.*

The Institute's FCOI policy will specify the details of this disclosure, which will include, at a minimum:

- *the purpose of the trip,*
- *the identity of the sponsor/organizer,*
- *the destination, and*

- *the duration.*

In accordance with the Institute's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

What does not count as a financial interest?

As per 42 CFR 50.605(a)(1), a financial interest DOES NOT include:

- Salary, royalties or other remuneration paid by the GIHD to the PHS-Investigator if the Investigator is currently employed or otherwise appointed to the Institute, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- Any ownership interest in the Institute held by the Investigator, if the Institute is a commercial or for-profit organization;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles (e.g. 403b plan or target date retirement fund);
- Income from seminars, lectures, or teaching engagements 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 institute that is affiliated with an Institution of higher education; or
- Income from service on advisory committees or review panels for 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 institute that is affiliated with an Institution of higher education.

Requirements for PHS-Investigators

As per 42 CFR 50.604(b) and 42 CFR 50.604(b), all PHS-Investigators have additional FCOI requirements including:

- Will review this policy before engaging in any PHS-funded grant or contract
- Must undergo conflict of interest training before engaging in any PHS-funded grant or contract;
- Must undergo conflict of interest (COI) training every 4 years;
- Must have filed an annual disclosure form within the past 12 months;
- Must update their conflict of interest form within 30 (thirty) days of discovering or acquiring a new financial interest related to their Institute responsibilities;

- All Investigators of sponsored research to report financial interests BEFORE filing applications or proposals for funding;
- Must complete FCOI training immediately under the following circumstances:
 - o If the GIHD revises its FCOI policy resulting in a change that affects Investigator requirements;
 - o An Investigator is new to GIHD;
 - o An Investigator is found to be noncompliant with the FCOI policy or management plan;
- Investigators with financial conflicts of interest must enter into a management plan before expenditures can begin.

Who is an Investigator?

An Investigator is any person who is responsible for the design, conduct, or reporting of research funded by or proposed to the PHS, regardless of title or position, and may include, for example, collaborators, consultant, Senior Fellows, and other subrecipients. Among GIHD employees, this includes (but may not be limited to):

- Project leads/Project principals
- Project managers
- Principal Investigators
- Co-Investigators
- Key study personnel
- Essential study staff, which may include research assistants, postdocs, collaborators or consultants.

If a GIHD staff has any doubts about whether they could be classified as in “PHS- Investigator,” they should contact the Director of Research Operations. Questions or concerns regarding who is classified as an Investigator should be directed to:

Dr. Syed Usman Hamdani - usman.hamdani@stmu.edu.pk

FCOI Training

As per 42 CFR 50.604(b), Investigators who receive Public Health Service (PHS) funding:

- Will review this policy before engaging in any PHS-funded grant or contract
- Must undergo conflict of interest training before engaging in any PHS-funded grant or contract;
- Must undergo conflict of interest training every 4 years;
- Must update their COI form within 30 (thirty) days of discovering or acquiring a new financial interest related to their university responsibilities;
- Must complete FCOI training immediately under the following circumstances:
 - o If the GIHD revises its FCOI policy resulting in a change that affects Investigator requirements;
 - o An Investigator is new to GIHD;
 - o An Investigator is found to be noncompliant with the FCOI policy or management plan;
- If a financial conflict of interest exists, must enter into a management plan before expenditures can begin on a PHS-supported grant or contract.

Investigators' Disclosure Requirements

As per 42 CFR 50.603 and 42 CFR 50.604(e) (1) - (3), Investigators are required to disclose to the GIHD all of their significant financial interests (including those of the Investigator's spouse and dependent children) that reasonably appear to be related to their Institutional responsibilities that meets or exceeds the regulatory definition of a significant financial interest:

- No later than at the time of application for PHS-funded research;
- at least annually during the period of award;
- Within 30 days of discovering or acquiring a new significant financial interest (e.g., through purchase, marriage, or inheritance).

The conflicts of interest disclosure form and instructions is available to them through Human Resource department, including details on where the forms need to be submitted.

Of note, while the federal regulations for PHS-Investigators specifies only employees, their spouses or dependents, the GIHD's guidance for all employees is broader and may apply to other close relatives. Employees must review and be in compliance with both policies.

In addition, the GIHD's notification policy regarding potential conflicts of interest is more restricted, requiring notification at least 2 weeks prior to engagement in any activity to allow review, determination of a conflict, and development of a management or mitigation plan.

To ensure compliance with this policy and pursuant to 42 CFR 50.604(b) and 42 CFR 50.604(b), the GIHD requires that all PHS-Investigators:

- Must undergo conflict of interest (COI) training every 4 years;
- Must file an annual FCOI disclosure form every within the past 12 months;
- Prior to submitting any proposal to a PHS source:
 - o All Investigators of sponsored research to report financial interests BEFORE filing applications or proposals for funding;
- Prior to initiating activities on any new PHS-funded grant:
 - o Will review and acknowledge (sign) this policy before engaging in any PHS-funded grant or contract
 - o Will complete the conflict of interest training before engaging in any PHS-funded grant or contract;
- With any new FCOI GIHD staff must:
 - o Update their conflict of interest form within 30 (thirty) days of discovering or acquiring a new financial interest related to their university responsibilities;
- Must complete FCOI training immediately under the following circumstances:
 - o If the GIHD revises its FCOI policy resulting in a change that affects Investigator requirements;
 - o An Investigator is new to GIHD;
 - o An Investigator is found to be noncompliant with the FCOI policy or management plan;

Review of PHS-Investigator Disclosures

As per 42 CFR 50.604(d), PHS-Investigator disclosure forms will be reviewed by the Conflict-of-Interest Officer, who will determine whether or not it identifies an actual or potential conflict of interest of the Investigator (including those of the Investigator's spouse and dependent children) that is related to an Investigator's institutional responsibilities and, if so, what action is required to appropriately manage the situation.

The Conflict of Interest Officer may request additional information from an employee to make these determinations. When a conflict is identified, the Conflict of Interest Officer may work with the staff to put in place and to document an appropriate conflict management plan. An employee who disagrees with the decision of the Conflict-of-Interest Officer may seek review with the Director of Research Operations.

Considerations when determining whether a conflict of interest exists

The GIHD recognizes that no guidelines can anticipate all situations in which a conflict of interest may exist. Guidelines have been established to aid with making these determinations and are listed below.

When reviewing a financial conflict of interest disclosure submitted by a staff member (including, on behalf of their spouse or dependent children):

- The determination of the existence of a significant financial interest will be based on the aggregation of all Financial Interests by the staff (or the spouse or dependent children);
- The Conflict of Interest Officer may utilize several forms of review to reasonably determine whether an FCOI exists;
- The following financial interests are generally considered to represent a conflict at the GIHD:
 - i) Any activities or business endeavors, whether paid or unpaid, that could pose a conflict with a staff's responsibilities to the Institute;
 - ii) Any outside activities for which a staff earn compensation;
 - iii) PHS-Investigator or their immediate family members (spouse or dependent children) gives or accepts commissions, gifts, payments, entertainment, services, loans or promises of benefits from suppliers, government agencies or third parties that might influence the Investigator or the third party's decision-making or actions affecting the Institute. However, gifts of nominal value, e.g., cookies for a holiday that can be shared, may be acceptable.
 - iv) Occasional meals or social invitations that are in keeping with the highest standards of business ethics may be acceptable, as long as they do not obligate the PHS-Investigator in any way.
 - v) Receipt of remunerations from any publicly traded entity, received from the entity in the 12 (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:
 - a) Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
 - b) Equity interest that includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - vi) Receipt of remunerations from any non-publicly traded entity if:
 - a) The value of any remuneration received from the entity in the 12 (twelve) months preceding the disclosure, when aggregated, exceeds \$5,000, or

- b) When the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- vii) Receipt of income related to intellectual property rights and interests (e.g., patents, copyrights);
- viii) Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to an Investigator's institutional responsibilities provided, however, that this disclosure requirement does not apply to:
 - a) travel that is reimbursed or sponsored by a Federal, state, or local government agency,
 - b) an Institution of higher education as defined at 20 U.S.C. 1001(a),
 - c) an academic teaching hospital, a medical center, or
 - d) a research institute that is affiliated with an Institution of higher education.
- ix) A Fiduciary role on behalf of an Outside Organization and/or equity in a privately held Outside Organization;
- x) Equity with a value > \$50,000 or > 5% ownership in a publicly traded Outside Organization, if such entity is actively conducting or seeking to conduct business related to the research;
- xi) Payments > \$25,000 in the preceding 12 months from an Outside Organization;
- xii) Intellectual property interests (not assigned to the GIHD or other Excluded Payers) if any income has been received from such Intellectual Property interest in the preceding 12 months;

Management of Conflict of Interest

As per 42 CFR 50.604(f) and 42 CFR 50.605(a)(1), if the Institutional Official determines that a financial conflict of interest exists relating to PHS research then:

- Submission of a conflict of interest disclosure by a PHS-Investigator shall not constitute approval for the purposed of this policy, nor be deemed to constitute compliance with any applicable provisions of this policy, or GIHD Policy 111 Code of Conduct and Conflicts of Interest
- A Conflict Management Plan shall be developed and implemented by the Conflict of Interest Officer;
- No PHS -Investigator having a financial conflict of interest may participate in research without prior written approval from the Conflict of Interest Officer;
- All financial conflict of interest reviews, including any required Conflict Management Plan, must be completed before any research activity begins or research expenses are incurred under an award;

- In the event the Conflict of Interest Officer concludes that a financial conflict of interest cannot be reduced, eliminated or managed, the research project may not be allowed to proceed, unless (or until) a satisfactory Conflict Management Plan can be implemented;
- The financial conflict of interest review and Conflict Management Plan shall be completed prior to a conflicted Investigator participating in the research;
- The Conflict-of-Interest Officer shall confirm with the PHS-Investigator as part of the review process that the Disclosure on file is current as of the date of the conflict-of-interest review.

All Conflict Management Plans shall:

- Consist of measures that in the reasonable judgment of the Conflict of Interest Officer will reduce, eliminate, or manage the effects of the financial conflict of interest;
- As part of their development, the Conflict of Interest Officer may conduct factual inquiries and consult with and receive recommendations from such persons as the officer deems necessary and appropriate.
- Include terms that are consistent with all legal and regulatory requirements, the requirements of this policy
- May include one or more of the following:
 - a) Disclosure of financial conflict of interest, including to the public, human subjects, researchers and other participants, publishers, and conference organizers, either a priori or as required (e.g., by conference organizers);
 - b) Monitoring or oversight of the research by independent co-researchers, reviewers, disinterested individuals, or committees;
 - c) Maintaining copies of research data with a neutral party;
 - d) Restricting participation in any activity affecting or affected by a research project;
 - e) Requiring that the significant financial conflict of interest creating the financial conflict of interest be divested, restructured, or placed in a blind trust;
 - f) Modification or severance of relationships that create or are likely to create financial conflict of interest(s);
 - g) Modifying the terms of written agreements relating to the research;
 - h) Reduction (or cessation) of the GIHD appointment;
 - i) Requiring compliance with other relevant Institute policies, including those referenced in the section below titled "Other Relevant GIHD Policies and Procedures";

- j) Requiring that participation in the recruitment or consent of subjects in human subjects' research by a conflicted PHS-Investigator be prohibited, restricted, or otherwise limited;
- k) Requiring additional disclosures or actions with respect to matters before a human subject review committee;
- l) Requiring that the PHS-Investigator not participate in any business transactions between the GIHD and parties to agreements involving the research.

The above process for determining and managing FCOIs will apply to all of the following:

- Investigators who are new to participating in the research projects, as per 42 CFR 50.605(a)(2)
- An existing Investigator who discloses a new significant financial disclosure, as per 42 CFR 50.605(a)(2)
- A situation in which the GIHD identifies a significant financial conflict of interest that was not disclosed in a timely manner by an Investigator, or was not previously reviewed by the Institution, in which case the process as described above will occur and a Conflict Management Plan developed within 60 (sixty) days, as per 42 CFR 50.605(a)(3) and (i) – (iii)
- To complete and document a retrospective review within 120 days of the GIHD's determination of noncompliance for significant financial conflicts of interest not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation, pursuant to 42 CFR 50.605(a)(3).

Management of Conflict of Interest for subrecipients

As per 42 CFR 50.604 (g), 42 CFR 50.605(a)(4), if the GIHD conducts PHS-supported research or other activities through a subrecipient (e.g., subgrantees, contractors, or collaborators), GIHD will take reasonable steps to ensure compliance with 42 CFR 50.604(c), 42 CFR 42.50.604(c)(1)(1)-(iii), and NIH Grants Policy Statement 15.2.1, including:

- a) Confirming that the subrecipient (or their institution of employment) has its own policies in place that meet all conflict of interest requirements of the PHS sponsor;
- b) Require via a written agreement, acknowledging whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient, where applicable;
- c) Obtaining a written certification from the subrecipient that stipulates:
 - a. Its FCOI policy complies with the PHS and all applicable federal regulations;
 - b. A requirement for the subrecipient to report identified FCOIs for its PHS-Investigators to the GIHD (as the awardee Institution) in a timeframe that allows the GIHD to report identified FCOIs to the NIH, as required by the regulation; or

- c. Alternatively, if applicable, a requirement to solicit and review subrecipient Investigator disclosures that enable the GIHD (as the awardee Institution) to identify, manage and report identified FCOIs to the NIH.

Notification to External Sponsors

The GIHD will make reports to appropriate external sponsors to the extent required by and in accordance with its funding agreement with the sponsor and applicable law and regulation. As stipulated in 42 CFR 50.604(h) and 42 CFR 50.605(b), such reports will be sent:

- a) Prior to the expenditure of funds;
- b) Within 60 days of identification for a PHS-Investigator who is newly participating in a research project;
- c) At least annually (at the same time as when the Institute is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to an applicable conflict management plan(s), if applicable, until the completion of the project;
- d) Following a retrospective review to update a previously submitted report, if appropriate, pursuant to 42 CFR 50.605(a)3(iii);
- e) If bias is found, with the design, conduct or reporting of NIH-funded research and will include a Mitigation Report in accordance with the regulation, pursuant to 42 CFR 50.605(a)3(iii).
- f) If an Investigator fails to comply with this financial conflict of interest policy or if a Conflict Management Plan appears to have biased the design, conduct, or reporting of the NIH-funded research, pursuant to 42 CFR 50.606(a).

Maintenance of Records

Records relating to all PHS-Investigator disclosures of financial conflicts of interests and external activities, including the GIHD's review of and response to such disclosures, will be maintained for at least 3 (three) years from the date the final expenditures report is submitted to the PHS or for such longer periods as prescribed in the external agreement or applicable regulations, pursuant to 42 CFR 50.604(i) and 45 CFR 75.361.

Upon authorized request of a sponsoring agency, disclosure documents and related records pertaining to the specific sponsored project will be made available to appropriate officials.

Enforcement mechanisms, remedies and noncompliance

All staff are made aware upon their employment that violations of this policy, whether willful or through negligence, may result in discipline up to and including termination of employment, pursuant to 42 CFR 50.604(j).

The process for determining and managing FCOIs (described in “Management of Conflict of Interest”) will apply to complete and document a retrospective review within 120 days of the GIHD’s determination of noncompliance for significant financial conflicts of interest not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation, pursuant to 42 CFR 50.605(a)(3).

Although the GIHD does not perform clinical research to evaluate the safety or effectiveness of a drug, medical device or treatment, should it do so in the future and if during the course of that research a situation arises in which the Department of Health and Human Services determines that a PHS-funded project of such clinical research has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by the Institute as required by this Policy, the Institute will require that the Investigator disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations, pursuant to 42 CFR 50.606(c).

Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated.

Agreements with subrecipient organizations may be terminated if that organization fails to comply with its obligations under the PHS regulations.