Financial Conflict of Interest Policy
FINANCIAL CONFLICT OF INTEREST POLICY

The purpose of this policy is to prevent potential bias resulting from any Financial Conflict of Interest by individuals in the Child Health Research Foundation (CHRF).

Employees should conduct their affairs so as to avoid or minimize financial conflicts of interest and must respond appropriately when conflicts arise. To that end, this policy defines what a financial conflict of interest is, provides mechanisms for employees and the CHRF to manage those conflicts of interest that arise, and describes situations that are prohibited.

Every employee has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of financial conflict of interest arises, an employee should discuss the situation with their supervisor and/or Human Resources within 10 days of becoming aware of the situation.

Employees, and specifically principal investigators or anyone who can influence research, need to ensure that they have no financial conflict of interest present. It is not only directly financial but could include influencing the work so that a family member benefits from the research outcomes. This policy is to protect the credibility and integrity of CHRF’s work so that public trust and confidence is ensured.

Disclosure of Financial Interests

All employees are required to disclose their outside financial interests as defined below to CHRF on an annual and on an ad hoc basis, as described below.

a) Annual Disclosures: All employees who have the potential to influence research or funding outcomes, must disclose any financial interests that are related to the employee’s project responsibilities to CHRF on an annual basis at the time of the employee’s annual review. This will be accomplished by signing an annual compliance document which will be retained in their employee file in Human Resources.

b) Ad hoc Disclosures: In addition to annual disclosure, certain situations require ad hoc disclosure. If an employee begins a new project where there is a potential conflict of interest or circumstances change where an employee obtains a potential conflict of interest with an existing project, the employee must report the conflict of interest within 10 days.

CHRF is required to report the financial conflict to the appropriate funding agency as soon as discovered.

DEFINITIONS:

Family means any member of the employee’s immediate family; specifically children, spouse and parents.
Financial Interest means anything of monetary value received or held by an employee or an employee’s family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honorarium, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

a) salary, royalties, or other remuneration from CHRF;

b) income from the authorship of academic or scholarly works;

c) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the employee does not directly control the investment decisions made in these vehicles.

Financial Conflict of Interest means a financial interest that CHRF reasonably determines could directly and significantly affect the design, conduct or reporting of research.

Employees are required to adhere to the policy outlined in Annex-01 for managing funds received from the US Federal Government and other foreign donors.
Financial Conflict of Interest (FCOI) for US Govt. funding

INTRODUCTION

The purpose of this policy is to prevent potential bias resulting from any Financial Conflict of Interest (FCOI) by individuals who have direct influence in the allocation and use of US Federal Govt funding in the conduct of research wherein CHRF or CHRF subsidiaries are the recipient of public funding. The policy aligns to requirements within regulation 42 CFR Part 50 – Subpart F with the goal of promoting objectivity and transparency in research.

This FCOI policy defines the requirements and processes for investigators or individuals participating in US Federal Govt. funded research to identify and properly disclose any FCOIs. In addition, it outlines activities related to management, enforcement, and reconciliation for all appropriate studies.

DEFINITIONS

Investigator(s) include the Principal Investigator (PI)/Project Director and any other individuals, regardless of title or position who is responsible for the design, conduct, or reporting of US Federal funded (NIH, PHS, others) research, or proposed for such funding, and which may include for example, collaborators or consultants.

Foundation’s responsibilities mean an Investigator's professional responsibilities on behalf of the Foundation, and as defined by the Foundation, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards for US Federal funded research.

Financial interest means anything which has monetary value, and if the value is readily ascertainable.

Financial Conflicts of Interest (FCOI) in research involve situations in which an investigator has a significant financial interest that may compromise, or have the appearance of compromising,
professional judgment in the design, conduct, or reporting of research related to the US Federal funded activity.

**FCOI Manager**: The grant recipient’s designated official for managing the FCOI process related to a specific US Federal grant.

**Significant Financial Interest (SFI)**: A financial interest consisting 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:

(i) an SFI (Significant Financial Interest) exists if the value of any remuneration received from an entity (other than the Foundation), in the twelve months preceding the disclosure and the value of any equity interest in an 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; and,

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

*Note: SFI Disclosure Form includes the additional criteria related to the SFI definition and meets the NIH/PHS FCOI policy requirements.*

Subrecipient is a subcontractor or consortium participant who may indirectly receive grant funding via the Foundation that holds the prime contract with the US Government.

**FCOI TRAINING**

In compliance with federal regulations, all CHRF Investigators who are planning to participate in or are participating in US Federal funded research are required to review this CHRF FCOI policy and complete the NIH’s online FCOI Training module:

- Prior to engaging in research related to any US Govt-funded grant
- At least every four (4) years
- Immediately, if:
  - Foundation revises its FCOI policy that affects requirements of Investigators
  - An Investigator is new to the Foundation
  - An Investigator is not in compliance with the policy or management plan
Upon completion of the training, a certificate of completion must be sent to the Human Resource Manager. Investigators should also retain a copy for their records.

DISCLOSURE, REVIEW AND MONITORING REQUIREMENTS

Disclosure: The Principal Investigator of a Research Project will identify all Investigators required to disclose SFIs (and those of the Investigator’s spouse, partner, and dependent children) related to US Govt. funded activity, which meet the definition of SFI. The Principal Investigator and HR Manager will be responsible for ensuring disclosures of any new (e.g., marriage, purchase, or inheritance) or increased financial interests are completed:

- No later than at the time of application for US Govt-funded research,
- At least annually during the period of award, and
- Within 30 days of discovering or acquiring a new SFI.

Review and Monitoring

Prior to expenditure of funds, the HR Manager will solicit and review Investigator disclosures to determine whether a potential FCOI exists related to an investigator’s institutional responsibilities.

If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to manage, reduce, or eliminate specific SFI to prevent the potential to compromise or bias professional judgment or objectivity regarding the design, conduct or reporting of research, the HR manager will introduce an FCOI management plan. The plan may outline terms, conditions, and restrictions, if any, to ensure compliance with this policy.

Investigators must formally agree to the proposed management strategies. All management plans are required to be signed by the Investigator. Compliance of the management plan will be monitored by the HR Manager.

REPORTING REQUIREMENTS

HR Manager is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the sponsor:

- Initial report
Prior to the Foundation’s expenditure of any funds under a US Govt-funded research project, the Foundation will provide to the sponsor an FCOI report regarding any Investigator SFI, if found by the Foundation to be a financial conflict of interest, in accordance with the regulation. In cases in which the Foundation identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of NIH-awarded funds, the Foundation shall not submit an FCOI report to the NIH.

- During on-going PHS/NIH-funded research projects

Whenever, during the research project, a new Investigator discloses SFI or an existing Investigator discloses a new SFI, the Foundation will:
  - Review of disclosure of SFI
  - Determine whether it is related to research
  - Implement a management plan in interim
  - Submit a report of FCOI within 60 days after its determination that a new FCOI exists.

- Annual Report

For any FCOI previously reported to the sponsor, the Foundation shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan. Further, CHRF will notify the sponsor promptly:

  - If bias is found the Foundation will notify and submit a mitigation report to the sponsor. The mitigation report will include, at a minimum, the key elements documented in the retrospective review (discussed above) and a description of the impact of the bias on the research project and the Foundation’s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Foundation will submit FCOI reports annually.

  - If an Investigator fails to comply with the Foundation’s FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research the Foundation will take corrective action.

MAINTENANCE OF RECORDS
Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential FCOI, shall be retained by the FCOI Manager for three (3) years from the date the final expenditure report is submitted to the sponsor or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

ENFORCEMENT MECHANISMS AND REMEDIES AND NONCOMPLIANCE

Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, disciplinary proceedings may be taken against the violating individual.

Whenever the Foundation identifies a SFI that was not disclosed timely to the sponsor, Foundation will complete a retrospective review within 120 days of discovery of noncompliance to determine whether any PHS-funded research, or portion thereof, conducted during the period of the noncompliance, was biased in the design, conduct, or reporting of such research. Updated FCOI will be submitted to the sponsor. Required retrospective review elements are outlined in 42 CFR 50.605(a)(3)(iii).

Additionally, in any case in which the sponsor determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a vaccine, drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Foundation as required by this subpart, the Foundation will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the PHS funded research and to request an addendum to previously published presentations under PHS Funded research.

SUBRECIPIENT REQUIREMENTS

When carrying out the NIH/PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), Foundation shall establish a written agreement (e.g., subaward contract) which confirms that the investigators of the subrecipient institution will comply with this policy or provide certification that their organization is compliant with the Federal policy, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F).

If an SFI is identified by the sub-award recipient, they are required to notify the PI and FCOI Manager of the existence of the conflicting interest within 30 days of the identification of the
interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced, or eliminated in accordance with federal regulations.

PUBLIC ACCESSIBILITY REQUIREMENTS

CHRF will publish the foundation’s policy on its public website. CHRF will respond to all written requests for information within five (5) calendar days and then release the required information about such SFI containing the minimum elements as provided by regulation.

Records of Investigator SFI Disclosure forms will be retained for a minimum of three years from the date the final expenditure report is submitted to the sponsor.

For inquiries or concerns regarding data protection, individuals can contact CHRF's Senior Finance Manager Mr. Gautam Saha (gautam@chrfbd.org).

References
COI Regulation 42 CFR Part 50 Subpart F
NIH Guide Notices Related to Financial Conflict of Interest

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