Center for Bioethics & Research

Financial Conflicts of Interest Policy for Research

CBR Purpose

The Center for Bioethics and Research recognizes the importance of collaborations with industry, government, academia and others, and seeks to encourage such relationships. However, it is important that the financial incentives which may accompany such relationships do not create financial conflicts of interest that might undermine the validity of the research or the safety of human research subjects. Such conflicts of interest have the potential to create real or apparent bias in research and may reduce public confidence in the research enterprise.

For these reasons CBR has established the following Investigator Financial Conflicts of Interest Policy for Research. The purpose of this policy is to uphold the highest ethical standards of objectivity in research by identifying and evaluating financial conflicts of interest ("FCOI") that may affect research decisions, transactions and operations at CBR and managing them so that important collaborations can be undertaken without compromising integrity. The policy is also intended to be consistent with CBR's Financial Conflicts of Interest and Accounting Practice Policy. Additionally, this policy is intended to comply with the requirements of the United States federal regulations set forth in 42 CFR Part 50 and 45 CFR Part 94 for research funded through the Public Health Service (PHS). This policy shall be construed in accordance with such regulations and shall be deemed to include any requirements set forth in such regulations that are not expressly set forth below.

II. Covered Parties

This policy applies to all individuals, regardless of title or position, responsible for the design, conduct or reporting of PHS-Funded and Non PHS Research at or under the auspices of the Center for Bioethics and Research.

Applicability to PHS-Funded Subrecipients:

For PHS-Funded Research that involves a subrecipient (i.e., subcontractor, subgrantee or sub awardee) at other Institutions, CBR requires a written agreement from the subrecipient that establishes whether CBR's policy or the subrecipient's policy shall apply to the subrecipient's Investigators. In all cases, CBR must report to the PHS-Funding agency any subrecipient FCOI (as defined below) prior to the execution of the subcontract or within 60 days of identification of a new FCOI that arises during the term of the subcontract.

If the subrecipient's policy is used, the subrecipient must certify that its FCOI policy is compliant with 42 CFR Part 50 and 45 CFR Part 94 and that they will be responsible for ensuring that the subrecipient Institution and its Investigators comply with the United States federal regulations. Subrecipients must report to CBR, as the awardee Institution, any identified FCOI within 10 business days of the management plan agreement with the subrecipient's Investigator, but no later than 45 days after identification of the FCOI by the

subrecipient. The details of the FCOI will be reported to the funding agency as required under applicable regulations or policies.

If CBR's policy is used, the subrecipient must ensure that its Investigators disclose to CBR all Significant Financial Interests ("SFI") as defined below) that are directly related to the subrecipient's work for CBR at the time of submission of the application by CBR or at the time the subrecipient signs an institutional letter of support if during an on-going award grant or contract.

III. Center for Bioethics and Research Policy

Each Investigator responsible for the design, conduct or reporting of research at or under the auspices of CBR must disclose all of his or her SFIs, and those of the Investigator's spouse and dependent children, that reasonably appear to be related to the Investigator's Institutional Responsibilities. The Investigator is not charged with making a determination as to whether the SFI constitutes a conflict of interest or could affect the design, conduct or reporting of the Research. That determination is made by the Designated Official as further described below.

Significant Financial Interest ("SFI") Is Defined As

Any financial interests (i.e., anything of monetary value) consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children), within the previous 12 months, that reasonably appears to be related to the Investigator's Institutional Responsibilities:

1. **For all Publicly Traded Entities**
    1. Remuneration (e.g., salary, income, consulting fees, honoraria, paid authorship or any other payment) from an Entity that exceeds $5,000.
    2. Any equity interest (e.g., stock, stock option, or other ownership interest) in the Entity that exceeds $5,000; or
    3. Any remaining remuneration and equity from an Entity that, when added together, exceeds $5,000 in value.
2. **For all Non-Publicly Traded Entities**
    1. Remuneration (e.g., salary, income, consulting fees, honoraria, paid authorship or any other payment) from an Entity that exceeds $5,000.
    2. Any equity interest (e.g., stock, stock option, or other ownership interest) in the Entity regardless of value; or
    3. Any remaining remuneration and equity from an Entity that, when added together, exceeds $5,000 in value.

3. **Intellectual Property (IP) Right and Interests**
    1. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
4. **For PHS-Funded Research Investigators Only: Reimbursed or Sponsored Travel**
    1. Travel reimbursed or sponsored by an Entity other than the Investigator's current institution (i.e., paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), and related to their Institutional Responsibilities that exceeds $5,000 in value (in aggregate for a single Entity).

Exclusions: SFIs do not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by CBR to the Investigator if the Investigator is currently employed or otherwise appointed by CBR, including intellectual property rights assigned to CBR and agreements to share in royalties related to such rights.
- 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; and
- Income from seminars, lectures, teaching engagements or service on advisory committees or review panels that are sponsored by a federal, state, or local government agency within the country.

Before disbursing any funds for Research, CBR determines whether an Investigator's SFI disclosure is related to the Research, and if so, whether the SFI constitutes an FCOI. An Investigator's SFI is related when the Designated Official reasonably determines that the SFI could be affected by the Research or is in an Entity whose financial interests could be affected by the Research.

A FCOI exists when CBR reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Research. If an FCOI is identified, CBR will manage the FCOI as needed, including development and implementation of a management plan.

When SFI Disclosures Are Required to Be Filed

All Investigators applying for Research funding or conducting Research must disclose SFIs:

- Before Application for Funding: Each Investigator who is planning to Participate in Research must disclose SFIs no later than the time of application or submission of a formal proposal, if applicable.
- When executing a contract with an Entity where no application or proposal is required: Each Investigator planning to Participate in Research must disclose SFIs prior to expending any funds.

- Upon Discovery or Acquisition of a New SFI: Each Investigator must submit a disclosure within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) all new SFIs; and
- For Active Awards: Each Investigator who is participating in Research must submit an updated disclosure of SFIs at least annually during the award period. The updated disclosure will include any new information that was not initially disclosed to CBR or in any subsequent disclosure of SFIs and will include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

What SFI Disclosures Are Required

Investigators must disclose:

- The person(s) having the interest.
- The Investigator's relationship to such person(s).
- The name of the Entity with which the Investigator has the SFI; and
- The nature and approximate monetary value of the SFI.

Disclosure Obligations in Publications or Presentations

To promote transparency in scientific discourse, Investigators are expected to disclose their financial interests related to any presentation or publication of research results by the Investigator. Such interests include (i) financial interests in Entities supporting or otherwise connected to the presentation, publication or research, (ii) the Investigator's provision of legal consulting on the subject of the research, and (iii) any other interests that the Investigator reasonably believes could be material to members of an audience or readers assessing the opinions, advice, or work presented by the Investigator. This includes the disclosure of a financial interest in an Entity which owns or has a contractual relationship to the technology being reported or discussed.

When Training Is Required (PHS-Funded Research ONLY)

Investigators engaging or planning to engage in PHS-Funded Research, at or under the auspices of CBR, must complete financial conflict of interest training on Investigator responsibilities prior to engaging in PHS-Funded Research and at least once every four (4) years while they are still engaged in PHS-Funded Research. Investigators must also complete this training immediately in any of the following circumstances:

- When this policy is revised in any manner that affects the requirements applicable to PHS-Funded Investigators.
- When an Investigator is new to CBR, even if the PHS-Funded Research has already begun; or
- When CBR finds that an Investigator is not in compliance with this policy or an imposed management plan.

How SFI Disclosures Are Reviewed

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The Designated Official is responsible for appointing members to the Center's Review Committee on Research FCOIs ("Review Committee"). The Review Committee consists of no fewer than five (5) voting members from the members of CBR faculty with relevant research experience. Appointed members of the Review Committee serve three-year renewable terms. Representatives from the University of Ibadan may serve as non-voting consultants. A majority of the voting Review Committee members must be present to constitute a quorum. Members may attend meetings via phone or other electronic means (e.g., Zoom) in real time. The Review Committee may act by majority vote of the members present at a meeting with quorum, or by written or electronic consent of a majority of all members.

The Designated Official, through the Review Committee, will review all disclosures and any other relevant information (e.g., research proposal, IRB application, etc.) and determine:

- Whether the Investigator's SFI is related to the Research; and if so,
- Whether the SFI constitutes an FCOI.

If an FCOI is identified, the Review Committee will prepare and submit a report to the Designated Official detailing a recommended management plan, including any proposed conditions or restrictions to manage the FCOI. The Designated Official will make a final determination as to how to manage the FCOI and will accept, reject or modify the Review Committee's recommendation.

The Chair of the Review Committee may elect to conduct an expedited review instead of engaging the full committee for amendments or continuing reviews of SFIs which have been previously reviewed, appear to be related to SFIs covered under an active management plan or can be easily addressed by standard management plan measures. These actions and all SFIs will be reported to the Review Committee at the next scheduled meeting.

The CBR Research Compliance unit will provide copies of the final determination to the conflicted Investigator (and principal investigator, if different), the Dean at the Investigator's school or college, the Investigator's Head of Department, the Center for Bioethics and Research Institutional Review Board (if human subjects research is involved), and other relevant offices, as applicable.

The Investigator must comply with any management plan imposed by CBR and upon receipt of the determination, the Investigator must either accept or submit an appeal. Funding will be held until the Investigator agrees to comply with the final management plan.

How FCOIs Are Managed

When a FCOI has been determined to exist, the management plan will specify the actions that have been, and will be, taken to manage the FCOI. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- Public disclosure of the FCOI (e.g., when presenting or publishing the research).
- For Research involving human subjects, disclosure of the FCOI directly to the human subjects as approved by the Institutional Review Board.
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI.
- Modification of the research plan or protocol.
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research.
- Reduction or elimination of a financial interest (e.g., sale of an equity interest); and
- Severance of relationships that create the FCOI.

How to Appeal a Management Plan

The Investigator has ten (10) business days from receipt of the Designated Official's final decision to submit a written appeal to the academic director or program director, as applicable. The appeal should include the specific provisions being challenged, the reason for the appeal, and the justification for a different outcome. The Investigator may also provide an alternative management plan and any supplemental information that might be helpful in reviewing the appeal. After this secondary review, this decision will be final and not further appealable.

How Compliance with the Management Plan Is Monitored

The CBR Research Compliance unit shall take such actions that it deems reasonable to audit and monitor compliance with the management plan on an ongoing basis until the completion of the Research.

Investigators are required to comply with the final decision of the Designated Official and management plan. If an Investigator fails to comply, the Designated Official, with the aid of the Review Committee, will develop a corrective action plan. The Institution may impose sanctions for non-compliance including suspension, denial of eligibility to engage in Research, or other appropriate penalties. Such sanctions may require giving notice to professional bodies or journals, or the public.

When There Are New SFIs During Ongoing Research

In the event that a new interest is disclosed to CBR (e.g., an Investigator new to an ongoing Research project discloses an SFI or an existing Investigator discloses a new SFI during ongoing Research project) or CBR identifies a disclosed interest that was not previously reviewed in a timely manner in accordance with this policy, the Designated Official will do the following, acting directly or in conjunction with the Review Committee, within sixty (60) days:

- Determine whether a FCOI exists; and if it does,
- Implement a management plan in accordance with this policy that specifies the actions that have been, and will be, taken to manage the FCOI.

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What Happens When the FCOI Is Not Identified and Managed

In the event that a FCOI is not identified or managed in a timely manner, including:

- Failure of an Investigator to timely disclose an SFI that is subsequently determined by the Institution to constitute an FCOI.
- CBR's failure to review or manage such an FCOI; or
- Investigator's failure to comply with a FCOI management plan.

CBR will, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities on the project(s) to determine whether there was any bias in the design, conduct, or reporting of the Research during the period of noncompliance.

CBR will document the following key elements of the review:

- Project number and title.
- Principal investigators or project directors (or if multiple, the contact PI or Project Director)
- Investigator and entity resulting in the FCOI.
- Reason the retrospective review was completed.
- Detailed description of methodology used to conduct the retrospective review; and
- Findings and conclusions.

For PHS-Funded Research only, CBR will submit FCOI reports to the PHS awarding agency annually until the completion of the project, specifying the actions that will be taken to manage the financial conflict of interest going forward. If the retrospective review finds bias in the design, conduct, or reporting of PHS-funded Research, CBR will notify the PHS awarding agency promptly and submit a mitigation report, as required, which will include at minimum:

- The key elements documented in the retrospective review.
- A description of the impact of the bias on the research project; and
- CBR's plan of action or actions taken to eliminate or mitigate the effect of the bias.

For PHS-Funded Clinical Research only, in any case where the National Agency for food and Drug Administration and Control (NAFDAC) or Department of Health and Human Services determines that a PHS-funded project of Clinical Research (whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment) has been designed, conducted, or reported by an Investigator with an FCOI and was not managed or reported by the Institution as policies require, CBR will require the Investigator involved to disclose the FCOI in each public presentation of the results of the Clinical Research and to request an addendum to previously published presentations.

For NSF-Sponsored Research only, the Designated Official will provide notice to the NSF (National Science Foundation) Office of General Counsel if the Institution finds that it is unable to satisfactorily manage a FCOI.

At any time, the Designated Official may determine that interim measures are necessary regarding the Investigator's participation in the affected PHS or NSF-Funded Research.

How Records Will be Maintained

CBR will maintain records relating to all Investigator SFI disclosures, including the review of and response to the disclosures (whether or not resulting in an FCOI finding), and any other action under this policy, for at least three (3) years for Non-PHS-Funded Research and for PHS or NSF-funded Research, from the date the final expenditures report is submitted to the PHS, NSF, or, where applicable, from other dates specified in 45 CFR 74.53(b), 92.42(b), or National Science Foundation, Grant Policy Manual, Ch. 510, Conflict of Interests Policy ("NSF 510") relating to records retention.

Where to Find the Policy (Public Accessibility)

This policy and all related forms will be made publicly available on the Center for Bioethics and Research website.

For PHS-Funded Research: The CBR Research Compliance unit will make available, upon written request, SFIs disclosed to CBR that meet the following criteria: the SFI was disclosed and is still held by the Senior/Key Personnel; the Institution has determined that the SFI is related to the PHS-Funded Research; and the Institution has determined that the SFI is an FCOI. Responses will be returned within five (5) business days from when the CBR Research Compliance receives the request and shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the Research; the name of the Entity in which the SFI is held; the nature of the SFI; and the approximate dollar/Naira value of the significant financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
Information concerning the SFIs of Senior/Key Personnel will remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated. When the PHS-Funded Research is conducted by a subrecipient Investigator, and under their written agreement the subrecipient is required to comply with the subrecipient's FCOI policy, the subrecipient will have the responsibility of making such information publicly accessible.

IV. Responsible Parties

Investigators are responsible for compliance with this policy. The Designated Official is responsible for ensuring implementation and compliance with this policy. The CBR Research Compliance unit and Review Committee also support implementation and compliance of this policy.

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V. Defined Terms:

Designated Official: An institutional official designated to solicit and review disclosures of Significant Financial Interests from Investigators. The Designated Official shall be the Center for Bioethics and Research Compliance unit head and or such other individual(s) as the Institution may designate in writing.

Entity: Any business or legal entity, including a corporation (profit or non-profit), partnership, limited partnership, joint ventures, voluntary association, sole-proprietorship, or trust.

Equity Interest: Any type of ownership interest in an Entity such as owning stock or stock options (vested and unvested) but excluding interests from investments such as mutual funds and retirement accounts if the Investigator does not directly control investment decisions.

Financial Conflict of Interest ("FCOI"): A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of the Research.

Independent Monitor: An individual who is proficient in the area research, holds no SFI or role in the Research, and does not report to the conflicted investigator.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of CBR, including, but not limited to, research, teaching, professional practice, and administration (e.g. service on committees, boards and panels, etc.) if they have such responsibilities.

Investigator: The Project director or principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of the Research, taking into account the degree of independence with which the person works, which may include, but is not limited to, postgraduate students, technicians, collaborators or consultants.

Non-PHS Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioural and social-sciences research, which is not funded by a PHS awarding component or other entity or organization that has incorporated the PHS rules with regard to FCOIs. The term encompasses educational activities funded or proposed for funding by NSF.

Participate: To be responsible for the design, conduct or reporting of Research regardless of title or position.

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PHS-Funded Research: Research funded or proposed to be funded by the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH National Institutes of Health and any entity or organization that has incorporated the PHS rules with regard to FCOIs. The term includes but is not limited to research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, and research resources awards.

Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioural and social-sciences research, regardless of funding source. The term encompasses basic, sponsored, and clinical research, including applied research and product development.

Senior/Key Personnel: The project director or principal investigator and any other person identified as senior/key personnel in the grant application, contract proposal, contract, progress report, or any other report submitted to the sponsor for the PHS-Funded or Non PHS-Funded Research.

Significant Financial Interest ("SFI"): Any financial interests (i.e., anything of monetary value) consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children), within the previous 12 months, that reasonably appears to be related to the Investigator's Institutional Responsibilities:

1. **For all Publicly Traded Entities**
    1. Remuneration (e.g., salary, income, consulting fees, honoraria, paid authorship or any other payment) from an Entity that exceeds $5,000.
    2. Any equity interest (e.g., stock, stock option, or other ownership interest) in the Entity that exceeds $5,000; or
    3. Any remaining remuneration and equity from an Entity that, when added together, exceeds $5,000 in value.
2. **For all Non-Publicly Traded Entities**
    1. Remuneration (e.g., salary, income, consulting fees, honoraria, paid authorship or any other payment) from an Entity that exceeds $5,000.
    2. Any equity interest (e.g., stock, stock option, or other ownership interest) in the Entity regardless of value; or
    3. Any remaining remuneration and equity from an Entity that, when added together, exceeds $5,000 in value.
3. **Intellectual Property (IP) Right and Interests**
    1. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
4. **For PHS-Funded Research Investigators Only: Reimbursed or Sponsored Travel**

1. Travel reimbursed or sponsored by an Entity other than the Investigator's current institution (i.e., paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), and related to their Institutional Responsibilities that exceeds $5,000 in value (in aggregate for a single Entity).

Exclusions: SFIs do not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by CBR to the Investigator if the Investigator is currently employed or otherwise appointed by CBR, including intellectual property rights assigned to CBR and agreements to share in royalties related to such rights.
- 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; and
- Income from seminars, lectures, teaching engagements or service on advisory committees or review panels that are sponsored by a federal, state, or local government agency.

United States Institution of Higher Education: The term "institution of higher education" means educational institutions located in any State of the United States, the Commonwealth of Puerto Rico, the District of Columbia, Guam, American Samoa, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, and the Freely Associated States.

VI. Related Policies

1. CBR Authorship guidelines policy
2. CBR conflict of interest policy
3. CBR travel policy
4. CBR information technology use policy
5. CBR intellectual agreement research policy
6. CBR consultation policy

VII. History

Original Date Approved: July 2020.
Next Review Date: March 2023