



Financial Conflicts of Interest Policy (FCOI)

1 PURPOSE

The purpose of this policy¹ is to establish a Center-wide system for identifying, evaluating, and managing real or perceived financial conflicts of interests as they apply to members of the Center² research community who serve as investigators; or are responsible for the design, conduct, or reporting of a research project. These individuals include, but are not limited to, all investigators³, consultants, and sub-contractors who are engaged in the design, conduct and reporting of research.

2 POLICY STATEMENT

To maintain public confidence in the Center and its research, and promote objectivity in research, the Center has developed administrative processes and procedures to ensure regular oversight and compliance with all necessary FCOI regulatory requirements.

References:

42 C.F.R. §§ 50.601, et seq.,

42 C.F.R. §§50, Subpart F

45 C.F.R. §§ 94.1 et seq.

21 C.F.R. §§ 54 et seq.

76 FR 53255

The Center's policies address the following:

- Description of ethical standards of conduct; Definitions;
- Procedures:
 - Investigator training requirements;
 - Disclosure, review, and monitoring;
 - Reporting requirements; Record maintenance;
 - Public accessibility

3 DESCRIPTIONS OF ETHICAL STANDARDS OF CONDUCT

Financial Conflict of Interests (FCOI):

A FCOI exists when either an individual (or their immediate family member) or an institution has external financial interests or engages in external activities that compromise or may provide an incentive to affect the design, conduct, reporting, or review of the research. This includes cases in which the appearance of a conflict of interest is present even when no conflict actually exists. For example, outside activities that would make reasonable observers believe that the prospect of direct or indirect personal gain might

¹ This Policy Statement draws upon the Harvard University Policy on Individual Financial Conflicts of Interest, May 23, 2012, Harvard University Faculty of Medicine Policy on Conflicts of Interest and Commitment, May 2016, and the National Science Foundation Proposal & Award Policies & Procedures Guide, Chapter IX, June 2020.

² "Center" refers to Judge Baker Children's Center.

³ In this Policy, "investigator" or "investigators" will be used to refer to individuals covered by this policy.

influence an investigator's commitment to the mission of the Center and to ethical standards. Apparent conflicts can do almost as much damage as actual ones, undermining the credibility of research and calling into question the integrity of an individual or the Center or both. For this reason, it is important for an individual, in evaluating a potential conflict of interest, to consider how it might be perceived by others. Apparent conflict of interest must be avoided, and the same rigorous evaluation must be applied to situations in which there is a potential for such misunderstanding as is applied to situations in which there is the potential for actual conflict.

Compliance:

Investigators are expected to comply with all state and federal requirements applicable to conflict of Interest in research, including but not limited to licensure and professional standards of conduct, financial disclosure requirements, and laws concerning "finder's fees" for research participants, and statutes and regulations concerning conflicts of interest.

Privacy Interests and property rights: Providing the source of non-publicly available information the right of prior review, or even approval, of the final work product. Similarly, allowing sponsors a reasonable time (generally, 30 – 60 days) to review research manuscripts to ensure that the sponsors' confidential or proprietary information is not being disclosed. Please note: If there is a relationship between the investigator and the source of the information or materials, it is likely that a conflict of interest exists and must be reported. Advising of Students, Trainees, or Post-Doctoral Fellows: This relationship should principally serve the interests of students, trainees, and post-doctoral fellows in learning and self-development as well as satisfy requirements for academic advancement. Investigators should not assign students, trainees, or post-doctoral fellows to participate in research projects that could constrain their ability freely to discuss, defend, and publish their research.

When the subject matter of an investigator's instruction of and assignments to students, trainees, and post-doctoral fellows overlaps with the subject matter of the investigator's outside interest, they must exercise special care to avoid exploiting student work or subordinating the prerogatives and interests of their students to such outside activities. To this end, investigators must disclose to their students their activities with and obligations to outside entities that could benefit from the students' work or ideas and should allow the students ready access to information about sources of funds that support the students' research or scholarly work.

Supervisory Responsibility:

Investigators in key or senior positions must maintain the highest level of ethical integrity in carrying out their supervisory responsibilities. Outside interests should not influence their supervision, mentoring, evaluation, or direction of other researchers or staff.

Use of Center Resources:

Investigators may not use Center resources, including facilities, personnel, equipment, or access to confidential information – other than in a purely incidental way – for any purposes that are unrelated to their research and the mission of the Center. Use for personal profit of unpublished information emanating from Center research or other confidential Center sources, or assisting an outside organization by giving it exclusive access to such information, is prohibited.

Examples of inappropriate use of Center resources include the following:

- More than incidental use of Center staff to conduct an investigator's outside activities without prior approval by the Vice President of Administration and Operations.
- Granting outside entities access to Center resources or services for purposes unrelated to Center activities.
- Granting unauthorized access to confidential information acquired through conduct of Center business or research activity, such as personnel or security records of individuals, or proprietary knowledge about the corporate affairs or business dealings of the Center.
- Providing preferential access to an outside entity, for personal gain, to research results, materials, or products generated from Center research activities. (This does not preclude appropriate licensing arrangements, or consulting based on sponsored project results where there is significant additional work or expertise involved.)

4 DEFINITIONS

Investigator: the principal investigator, site responsible investigator, co-investigators, and any other person who is responsible for the design, conduct, or reporting of the research.

Financial Interest: A financial interest is anything of monetary value including, but not limited to, 1) salary, loans, gifts, royalties, or other payments for services, including honoraria, speaking fees, lectureship fees, study completion or enrollment bonuses or study outcomes awards made directly to research team members, payments for consulting services and services on advisory committees; 2) intellectual property rights, including patents, patent applications, copyrights, and royalties from such rights; 3) equity interests, e.g., owning or having the right or obligation to acquire stocks or stock options, partnership interests or other securities in a for-profit entity; 4) debt interests, e.g., bonds; and 5) a position as consultant, employee, director, or manager of an entity.

The term "Financial Interest" does NOT include: 1) Salary, royalties, or other remuneration paid to the individual through the Center; 2) stock owned through mutual funds; 3) reimbursement for travel expenses; or 4) intellectual property rights developed in the course of employment at a previous or current employer that remain the exclusive property of that entity or that may be widely published and for which the individual may be pursuing patent interests provided that the interest is not associated with ongoing research.

Significant Financial Interests (SFI): SFIs relate to the investigator's institutional responsibilities. An SFI consists of the following interests of the Investigator (or their immediate family): 1) Any income from any entity that exceeds \$5,000 in a rolling 12-month period; 2) Income received in a 12-month period and equity interests currently held in a publicly-traded entity that in the aggregate exceed \$5,000; 3) Any equity in a publicly traded company that exceeds \$5,000; 4) Any equity or ownership interest in a non-publicly traded company irrespective of value; 5) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; 6) 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.

An SFI **does not include**: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution,

including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution 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; 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.

The travel disclosure requirement **does not apply** to 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 institute that is affiliated with an Institution of higher education.

Non-Financial Relationship or Interest: A non-financial interest includes any relationship, position, or the promise of a position with sponsors, other external entities or persons that might influence or appear to influence the outcome of, or a decision related to, a research project. Such relationships include, but are not limited to, 1) an unpaid directorship or management position; 2) a board membership; 3) an unpaid consulting relationship; or 4) a personal relationship.

Non-financial interests also include intellectual property rights, including patents, patent applications and copyrights when there is the promise of monetary reward, but the value is presently unknown.

Technology: Any intervention, drug, device, diagnostic, medical or surgical procedure intended for use in health care or health care delivery.

Business: Any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other nongovernmental legal entity organized for profit, nonprofit, or charitable purposes.

Immediate family: The investigator's spouse or domestic partner, dependent children, and other relatives living in the same household; or any first-degree relative--specifically, a spouse, parent, sibling, or child who does not live in the same household as the researcher *if the researcher is or becomes aware* that the relative has a financial interest in the research at issue.

Associated entity: Any trust, organization, or enterprise over which the researcher, alone or together with an Immediate Family member, exercises a controlling interest.

5 PROCEDURES

5.1 Training

All investigators will receive the FCOI policy. All forms and relevant documents will be kept in a public folder accessible to all investigators. All investigators on PHS-supported research projects will be required to complete the Center's FCOI training as follows:

- Prior to engaging in research related to any PHS-funded grant
- At least every four years
- Immediately when:
 - The FCOI policy is revised affecting the requirements of the investigator
 - A new investigator joins the Center
 - An investigator is not in compliance with the policy or management plan

5.2 Disclosure, Review, and Monitoring

All investigators must report⁴ financial interests that may be relevant to the conduct for research by completing the Investigator Financial Interest form on a study-by-study basis. The reports will be submitted to the Vice President of Administration and Operations.

Investigator Financial Interest forms that report financial interests that could reasonably be related to the research study will be referred to the Conflict Review Committee (CRC) for review. The CRC will review reported financial interests that are not prohibited by the Harvard Medical School Conflicts of Interest Policy, or other applicable policies. Committee recommendations may include, but not be limited to, the following options: that the reported financial interest is: (a) not acceptable (in which case the financial interested must be divested or other action taken); (b) acceptable with some form of management (such as disclosure, restriction on the activities of the investigator, or such other form deemed appropriate); or (c) acceptable without any need for management.

All members of the Center research community will submit the Investigator Financial Interest form:

- At the start of a project
- Annually
- Immediately, and no later than 30 days, from the date of any material changes to the information submitted

Annual reports should include sufficiently detailed information for a disinterested reviewer to appraise the risk of conflicts arising from the researcher's, or her family members', outside interests. This information should include: The grant/contract number; name of the PD/PI, name of the entity in which the investigator or their family members hold a financial interest, the nature of the interest (e.g., equity, consulting fees, honoraria), any outside professional activity that was or will continue to be associated with the financial interest (e.g., service as a consultant, member of an advisory committee, or manager or fiduciary), and the size or value of the interest in a preceding 12-month period, and it may include the best approximation of the size or value of the interest for the 12 months that follow. Individuals who

⁴ Consistent with the Harvard University Policy on Conflicts of Interest, this policy distinguishes between "reporting" and "disclosing." "Reporting" means the provision by individuals of information about their financial and other interests *internally* to institutional officials. "Disclosure" means a release of information about individuals' financial and other interests to parties *external* to the institutional Conflict of Interest review and management processes.

have no reportable financial interests shall certify to that fact in writing. In addition, annual reports should include an affirmation that the researcher is aware of the Center's Conflicts of Interest Policy and complies with it.

Please note: Even if prior approval is not required, investigators, when feasible, should report expected changes or newly anticipated financial interests before they occur to enable meaningful evaluation by responsible institutional officials. If uncertain about any aspect of these obligations, investigators should seek guidance from the person designated by the Conflict Review Committee to manage the review of the reports, the Vice President of Administration and Operations.

Because related outside professional activities that involve managerial or fiduciary responsibilities may give rise to irremediable financial conflicts of interest, and because unwinding these relationships can be awkward and difficult, researchers are strongly advised to obtain prior approval of the Vice President of Administration and Operations before assuming such responsibilities

Subrecipient: A written agreement will be signed indicating whether the subrecipient will follow the Center's FCOI policy or their own. If the subrecipient follows their own FCOI policy, the Center will require:

- Certification that the subrecipient FCOI policy complies with necessary regulations
- A requirement that the written agreement include a statement that the subrecipient will report identified FCOIs for its Investigators in a time frame that allows the Center to report the identified FCOIs to the NIH as required by the regulations;
- OR, a requirement to solicit and review subrecipient Investigator disclosures that enable the Center to identify, manage, and report identified FCOIs.

Disclosure of Conflicts to Federal Sponsors: Under current PHS regulations (42 C.F.R. § 50.601, *et seq.*, and 45 C.F.R. § 94.1, *et seq.*) and NSF regulations on financial conflicts of interest, Significant Financial Interest (SFI) must be reported to and managed by the institution *and* disclosed to the sponsoring federal agency.

No sponsored research proposal should be submitted for transmission unless the Principal Investigator certifies that each investigator responsible for the design, conduct, or reporting of the research has filed an accurate and up-to-date Investigator Financial Interest form.

Prior to spending any grant funds under an award, the Center will report to federal sponsors the existence of any identified conflict and assure that it has been managed, mitigated, or eliminated in accordance with the regulations.

If the Center identifies a conflict of interest after the initial report (i. e., after funding has been expended), it must manage, reduce, or eliminate the conflict, at least on an interim basis, and report it to the federal sponsor within sixty days.

5.3 Review of Reports

The review and disposition of instances of conflict of interest will be focused on the assessment and management of risks to scholarly integrity, to the well-being of human research participants, to educational obligations to students and trainees, and to individual and institutional reputation with respect to public trust. The assessment will be fact-driven, case- specific, context-sensitive, and

informed by the principles of the Center's Financial Conflict of Interest Policy, the Harvard University Policy on Conflicts of Interest, and all applicable Federal requirements. Among the circumstances to be considered are the nature of the research, the magnitude and nature of the outside interest and the degree to which it is related to the research, the extent to which the research could be directly and substantially affected by the outside interest and vice versa, the likelihood and severity of potential harm to involved individuals and to the Center, and the consequences of prohibiting or limiting the conflicted researcher's participation in the activity.

The review will involve a two-step process. The initial review will be conducted by the Vice President of Administration and Operations and the Vice President of Finance. If this initial review suggests the possibility of a conflict of interest, the report will be submitted to the Conflict Review Committee. The Conflict Review Committee (CRC) will be comprised of the President and Chief Executive Officer (CEO) functioning as the Chair of the CRC, the Vice President of Finance, the Vice President of Administration & Operations, the Director of Manville School, and the Director of Human Resources. The CRC may ask a research staff member with specific knowledge to join the committee for specific reviews, under an agreement of full confidentiality, and may change membership as it deems necessary.

In conducting its review, the CRC will be guided by the four categories that have been identified within the policies of the Harvard Medical School. These include the following.

1. relationships that are generally *not* allowable, with certain de minimis exceptions;
2. relationships that are generally allowable only with oversight provided by the Center following disclosure, review, and approval by the Conflict Review Committee;
3. instances that will ordinarily be permissible following disclosure and, where necessary, the implementation of oversight procedures designed to ensure ethical standards, intellectual values, and institutional integrity; and
4. relationships thought to be allowable because they are (a) accepted practices and (b) generally minimal in their personal financial impact.

The investigator with reported financial interests, and other pertinent Center staff as appropriate, will be notified of the CRC determination and recommendations, if any, as part of the review notification process.

Enforcement and Noncompliance: The CRC will determine which, if any sanctions or other administrative actions are required to ensure Investigator compliance. Retrospective reviews will be conducted in accordance with relevant regulations and completed within 120 days of the determination of noncompliance whenever an FCOI or SFI is not identified or managed in a timely manner.

In circumstances in which the Department of Health and Human Services determines that a PHS-funded research project was not managed or reported by the Center as required by regulations, the Center will require the investigator to:

- Disclose the FCOI in each public presentation of the research results
- Request an addendum to previously published presentations

5.4 Record Maintenance

The Center will 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 a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

5.5 Public Accessibility

The Center will make its FCOI policy publicly accessible via their public web site.

Prior to the expenditure of funds, information regarding identified FCOIS that meet the below three criteria will be made publicly available via the Center's web site

Criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart; (B) The Institution determines that the significant financial interest is related to the PHS-funded research; and (C) The Institution determines that the significant financial interest is a financial conflict of interest.

The information available on the website shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0– \$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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 publicly.

Requested information will be made accessible within 5 calendar days of receipt of the request. All information will be updated at least annually, or within sixty days of a newly identified FCOI and will remain available for three years from the date the information was most recently updated.