

UNIVERSITY OF CAMBRIDGE CONFLICT OF INTEREST POLICY TO MEET U.S. DEPT OF HEALTH AND HUMAN SERVICES AND PUBLIC HEALTH SERVICES (OF WHICH THE NIH IS PART)

The Policy

This policy consists of a set of requirements to be followed by senior and key personnel participating in research funded by a Public Health Service (PHS) funder, most notably the National Institutes of Health (NIH).

The policy applies to any institution (foreign or U.S. domestic) that is applying for or receives research funding from a PHS funder through a grant or cooperative agreement (either directly or via another institution as a sub-awardee) and, consequently, any investigator planning to or who is already participating in such research.

Key requirements

- All Investigators must disclose any **Significant Financial Interest** (SFI) with respect to their **Institutional Responsibilities** to their Head of Department who will determine whether such interest constitutes **Financial Conflict of Interest** (FCOI).
- Where an SFI is determined to be an FCOI, a management plan will be drawn up to help manage, reduce or eliminate the FCOI.
- A disclosure of the FCOI and management plan must be submitted to the PHS-funder.
- Adherence to the management plan must be monitored.
- All PHS-funded Investigators are required to take training on conflicts of interest.
- Annual (and in some circumstances more regular) reporting of FCOIs to the PHS-funder is required.
- Before any expenditure of PHS funds, information concerning any disclosed SFI which has been determined to be an FCOI relating to PHS-funded research, must be made publicly accessible by written response within 5 working days of request.
- See also [Key Definitions](#)

This policy is drawn from the original HSS regulations:

[Title 42 – Public Health, Part 50– Policies of General Applicability, Subpart F – Promoting Objectivity in Research](#)

Who administers the policy?

Key staff required to administer the policy are:

- [All Investigators](#)
- [Each Investigator's Head of Department \(or Head of School if the Head of Department is an Investigator\)](#)
- [Each Investigator's Departmental Administrator](#)
- The Research Operation Office: The Research Support Manager in the relevant [ROO School team](#) have authorized access to submit forms through the eRA Commons Financial Conflict of Interest Module and hence will submit the Conflict of Interest disclosure report.

Investigator responsibilities

Each Investigator must disclose to his or her Head of Department any Significant Financial Interests (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities. Disclosures must be made using the [disclosure form](#) prior to applying for PHS-funded research, within 30 days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new Significant Financial Interest, and at least annually during the period of the award.

The disclosure form

The disclosure form will seek information that may need to be made publicly accessible on request, and therefore includes:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Name of the entity in which the SFI is held;
- Nature of the SFI;
- Approximate dollar value of the SFI (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.

Management Plan

Investigators must cooperate in a timely manner with the Head of Department and Departmental Administrator in developing a management plan for any SFI deemed to be an FCOI and complying with such plan.

Training

- Each Investigator, including sub-recipient Investigator(s), must complete training prior to engaging in PHS-funded research and at least every four years, and immediately under certain circumstances (see [NIH Grants and Funding FAQs](#), Section L, 1)
- NIH training is available through an [online module](#) - as well as through familiarisation with the information provided on the ROO web pages.

Head of Department and Department Administrator responsibilities

The Head of Department must review all **Significant Financial Interests** (SFI) disclosed by Investigators to determine whether any are related to research funded through a U.S. Public Health Service funder and if so, whether they constitute a Financial Conflict of Interest.

If an SFI is determined to be an FCOI, the Head of Department together with the Departmental Administrator will set out a plan to manage, reduce or eliminate the conflict.

Management plan

The management plan could include the following actions:

- Public disclosure of financial conflicts of interests (e.g. when presenting or publishing the research; to staff members working on the project, to relevant ethics committees)
- For research projects involving human subjects, disclosure of financial conflicts of interest directly to participants
- 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
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research
- Reduction or elimination of the financial interest (e.g. sale of an equity interest)
- Severance of relationships that create financial conflicts.

The management plan should also include the following details:

- The role and principal duties of the conflicted Investigator in the research project
- Conditions of the management plan
- How the management plan is designed to safeguard objectivity in the research project
- Confirmation of the Investigator's agreement to the management plan
- How the management plan will be monitored to ensure Investigator compliance;
- Other information as needed

Submission of reports

Unless the conflict is eliminable, the plan must be submitted to the PHS funder; in the case of the NIH this will be via the electronic Research Administration (eRA) Commons FCOI Module. The Head of Department and Departmental Administrator are responsible for ensuring that reports are submitted on time (via the ROO) as and when required.

Updated or annual FCOI reports must include the status of the management plan (i.e. whether the financial conflict is still being managed or an explanation of why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted.

Reports must be submitted prior to any expenditure of funds under a PHS-funded project. Note that reports need only be made if the Head of Department determines that an SFI

constitutes an FCOI. But reports must also be submitted if an Investigator does not disclose an SFI in the timeframe required or the University does not review a disclosure but later determines that an FCOI exists.

For new Investigators who join the project, for any SFI disclosed which is judged to be an FCOI, the FCOI report must be submitted within 60 days.

For a new SFI that is deemed to be an FCOI, a FCOI report must be submitted within 60 days of disclosure.

For any FCOI previously reported, the University must provide an annual FCOI report to address the status of the financial interest and any changes to the management plan. The plan must specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual reports must be submitted via eRA Commons for the duration of the project period (including extensions with or without funds) at the same time as submitting the annual progress report.

All FCOI reports must include sufficient information to enable the PHS-funder to understand the nature and extent of the FCOI and to assess the appropriateness of the management plan. The regulation provides key elements that must be included in the FCOI report to NIH. These include but are not necessarily limited to the following:

- Project number
- Programme Director (PD)/PI or Contact PD/PI if a multiple PD/PI model is used
- Name of the Investigator with the Financial Conflict of Interest
- Name of the entity with which the Investigator has a Financial Conflict of Interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
- Value of the 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
- A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research

NOTE THAT THERE IS NO REQUIREMENT TO SUBMIT A REPORT IF THE UNIVERSITY DETERMINES THAT NO DISCLOSURE OF AN SFI CONSTITUTES AN FCOI.

Retention of information

All records of all Investigator disclosures of financial interests and the University's review, or response to, such disclosure (whether or not a disclosure resulted in determination of an FCOI), and all actions under our own policies or retrospective review, must be retained for at least 3 years from the date of submission of the final expenditures report (or other dates as specified in the regulations (see [NIH Grants and Funding FAQs, Section A, 9](#)).

Failure to comply

If an Investigator fails to comply with the policy or a management plan subsequently put in place, the University must, within 120 days, undertake a retrospective review of the

research project to determine if any bias in the design, conduct or reporting of the research. If a bias is found, the PHS funder must be notified and provided with a mitigation plan and thereafter report annually as normal, unless the University decides further interim measures are necessary. The funder is entitled to suspend or terminate the award.

Frequently Asked Questions

What about sub-recipients?

If the University is passing on some of the funds to a sub-recipient, then as the awardee Institution, the University is responsible for ensuring any sub-recipient's compliance with the regulations and reporting identified financial conflicts of interests for sub-recipient investigators. The ROO will ensure that such requirement is addressed in the contract put in place with the sub-recipient.

Sub-recipients are entitled to follow the prime awardee's policy; however, where such party has its own compliant policy (as Cambridge does) they will be expected to follow their own.

What will the PHS-funder do with the reports?

The funder will evaluate the information received to determine whether the University's actions are sufficient to manage the identified FCOI and will use the information to monitor the University's compliance with the regulation, requesting further information as necessary.

What is the special requirement for clinical research?

In any case in which the HHS determines that an NIH-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 a conflicting interest that was not managed or reported by the Institution as required by the regulation, the Institution must require the Investigator(s) involved to 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.

Where can I find out more information?

See the helpful [NIH FAQ's](#)

Key definitions

Investigator is defined as the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. To ensure personnel are correctly identified for the purpose of policy compliance, consider the role of those involved rather than their title and the degree of independence with which they work.

Institutional Responsibilities are defined as an Investigator's professional responsibilities on behalf of the institution, e.g. research, research consultancy, teaching, professional practice, University committee memberships, service on panels such as ethical review boards.

A **Financial Conflict of Interest** exists when the institution, through its Designated Official (see below) reasonably determines that an Investigator's Significant Financial Interest is related to a PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the PHS-funded research.

A **Significant Financial Interest** is:

(1) 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) 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 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;

(ii) With regard to any non-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, when aggregated, exceeds \$5,000, or 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

(iii) 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 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. The Institution'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 Institution'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.

(3) The term *significant financial interest* does not include the following types of financial interests: 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

**For applicants for PHS (e.g. NIH) funding
Conflict of Interest regulations – WHAT TO DO AND WHEN**

Important: please read in conjunction with full information available [here](#)

