

Policy on Financial conflicts of interest to meet U.S. Department of Health and Human Services and Public Health Services

Subpart F of the U.S. Department of Health and Human Services Public Health Policy promotes objectivity in research by establishing standards that provide a reasonable 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 a researcher's financial conflicts of interest.

1. Policy Scope

This CRUK Scotland Institute policy consists of a set of requirements to be followed by senior and key researchers participating in research funded by a U.S. Public Health Service (PHS) funder, most notably the National Institutes of Health (NIH). It is drawn from the original U.S. regulations:

[Title 42 - Public Health, Part 50- Policies of General Applicability, Subpart F - Promoting Objectivity in Research](#)¹.

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

2. Key requirements

2.1 All researchers (investigators) participating in PHS-funded research must disclose any Significant Financial Interest (SFI)² with respect to their CRUK Scotland Institute responsibilities on the Institute's Disclosure Form to the Institute's Chief Financial Officer (CFO) for review³.

2.2 Records relating to all researcher disclosures of SFI and the CFO's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institute's determination of a financial conflict of interest – FCOI⁴) and any actions taken must be maintained for at least three years from the date the final expenditures report is submitted to the PHS funder.

2.3 Before any expenditure of PHS funds, information concerning any disclosed SFI that has been determined to be a FCOI relating to PHS-funded research must be made publicly accessible, by written response within 5 working days of request.

2.4 Researchers must submit an updated disclosure of SFI, at least annually, and within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

2.5 Where a SFI is determined by the Institute's CFO to be a FCOI, a FCOI Management Plan⁵ will be drawn up to help manage, reduce or eliminate the FCOI.

2.6 Researchers must cooperate in a timely manner with the Institute's CFO in developing a FCOI Management Plan for any SFI deemed to be a FCOI, and to comply with the plan.

2.7 A disclosure³ of the FCOI and Management Plan⁵ must be submitted to the PHS-funder.

2.8 Adherence to the FCOI Management Plan must be monitored by the CFO.

2.9 All PHS-funded researchers are required to take training⁶ on conflicts of interest.

2.10 Annual (and in some circumstances more regular) reporting⁷ of FCOIs to the PHS- funder is required.

2.11 All records of researchers (participating in PHS-funded research) disclosures of significant financial interests and the Institute'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).

3. Responsibilities

3.1 Researchers' responsibilities

All researchers participating in PHS-funded research must disclose to the CRUK Scotland Institute's CFO any SFI (and those of his/her spouse and dependent children) that reasonably appear to be related to the researcher's CRUK Scotland Institute responsibilities^{2,3}.

All researchers participating in PHS-funded research must submit an updated SFI Disclosure Form, at least annually, and within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

All researchers participating in PHS-funded research must cooperate with the CFO in developing a FCOI Management Plan⁵ for any SFI deemed to be a FCOI.

All researchers participating in PHS-funded research must comply with the FCOI Management Plan⁵.

All researchers participating in PHS-funded research must undertake the NIH training module on financial conflicts of interest, prior to engaging in the research, and at least every four years, and more frequently under other circumstances⁶.

All researchers participating in PHS-funded research must submit their training certificate to the Head of Research Integrity.

3.2 The CFO's responsibilities

The CFO must review the SFI Disclosure Forms of all researchers participating in PHS-funded research.

The CFO must determine whether the disclosed SFI is a FCOI to the PHS-funded research.

The CFO will develop a FCOI Management Plan for any SFI deemed to be a FCOI, with the researcher participating in PHS-funded research.

The CFO must retain records of SFI Disclosure Forms, review outcomes and FCOI Management Plans.

The CFO must submit a FCOI Disclosure Form and a FCOI Management Plan to the PHS-funder.

The CFO must monitor adherence to the FCOI Management Plan.

The CFO must submit a FCOI report to the PHS-funder annually.

3.3 The Head of Research Integrity's responsibilities

The Head of Research Integrity will deliver training on financial conflicts of interest to all researchers as part of the CRUK Scotland Institute's mandatory research integrity training programme.

The Head of Research Integrity will co-ordinate PHS-funded researchers to undertake the NIH training module.

The Head of Research Integrity will store training certificates.

4. Failure to comply

If a researcher participating in PHS-funded research fails to comply with the CRUK Scotland Institute's FCOI Policy or a FCOI Management Plan subsequently put in place, the Institute 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 has occurred. 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 Institute decides further interim measures are necessary. The funder is entitled to suspend or terminate the award.

5. Sub-recipients of PHS funding

If the CRUK Scotland Institute passes on some of the PHS funds to a sub-recipient, then as the awardee Institution, the Institute is responsible for ensuring any sub-recipient's compliance with the regulations and reporting of identified FCOIs for sub-recipient researchers participating in PHS-funded research. The CFO will ensure that such a requirement is addressed in the contract put in place with the sub-recipient.

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

6. Special requirement for clinical research

In any case in which the HHS 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 a researcher participating in PHS-funded research, the CRUK Scotland Institute must require the researcher(s) involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

APPENDIX

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

2. **Significant Financial Interest (SFI)** means a financial interest consisting of one or more of the following interests of the researcher participating in PHS-funded research (and those of the researcher's spouse and dependent children) that reasonably appears to be related to the researcher's CRUK Scotland Institute 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).

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

Researchers participating in PHS-funded research also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the researcher and not reimbursed to the researcher 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 centre, 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 researcher participating in PHS-funded research if the researcher 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 researcher, if the Institution is a commercial or for-profit organisation; income from investment vehicles, such as mutual funds and retirement accounts, as long as the researcher 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 centre, 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 centre, or a research institute that is affiliated with an Institution of higher education.

3. Disclosure form

Disclosures must be made using the CRUK Scotland Institute's 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 contains information that may need to be made publicly accessible on request, and therefore includes:

- Researcher's name
- Researcher's group
- Researcher'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.

The CRUK Scotland Institute SFI Disclosure form is within the **Guidance on Financial conflicts of interest to meet U.S. Department of Health and Human Services and Public Health Services** document. Complete and send the signed form to the CRUK Scotland Institute's **Chief Financial Officer**.

4. Financial Conflict of Interest (FCOI)

A FCOI exists when the CRUK Scotland Institute's **Chief Financial Officer** (Designated Official) reasonably determines that the significant financial interest of a researcher participating in PHS-funded research could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

5. FCOI Management plan

The FCOI Management Plan should include the following details:

- The role and principal duties of the conflicted researcher (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 researcher's agreement to the Management Plan
- How the Management Plan will be monitored to ensure researcher compliance
- Other information as needed (see below)

The FCOI Management Plan could also 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.

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.

6. Training on Financial interests and Conflicts of Financial Interests

Researchers participating in PHS-funded research, including sub-recipient researchers, must undertake the [NIH FCOI online training](#) module prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

- (1) The Institute revises its financial conflict of interest policies or procedures in any manner that affects the requirements of researchers
- (2) A researcher is new to the Institute
- (3) The Institute finds that a researcher is not in compliance with the Institute's Financial Conflict of Interest Policy or their FCOI Management Plan.

Certificates of training completion should be emailed to the Head of Research Integrity.

Researchers participating in PHS-funded research must also undertake the CRUK Scotland Institute's mandatory research integrity training programme, which covers, amongst other things, the requirements of this policy including researcher's responsibilities for disclosure of Significant Financial Interests.

7. Reporting FCOI

FCOI Reports must be submitted prior to any expenditure of funds under a PHS-funded project. (Reports need only be made if the Chief Financial Officer determines that disclosure of a SFI constitutes an FCOI).

FCOI retrospective reports must be submitted if a researcher participating in PHS-funded research does not disclose a SFI in the timeframe required or the Institute does not review a disclosure but later determines that a FCOI exists.

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

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

For any FCOI previously reported, the Institute must provide an annual FCOI report to address the status of the financial interest and any changes to the management plan.

Annual FCOI 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 FCO report should contain the following:

- Project number
- Programme Director (PD)/PI or Contact PD/PI if a multiple PD/PI model is used



- Name of the Investigator (researcher) with the Financial Conflict of Interest
- Name of the entity with which the Investigator (researcher) 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 PHS-funded research and why the Institute determined that the financial interest conflicts with such research
- The FCOI Management Plan (Role and principal duties of the conflicted researcher 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; and Other information as needed)
- Status of the FCOI 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

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

Glossary of terms

CFO - Chief Financial Officer

FCOI - Financial conflict of interest

FCOI report - an Institution's report of a financial conflict of interest to a PHS Awarding Component

Financial interest - anything of monetary value, whether or not the value is readily ascertainable

HSS - U.S. Department of Health and Human Services

Institutional Responsibilities - a researcher's professional responsibilities on behalf of the institution, e.g. research, research consultancy, teaching, professional practice, Institute committee memberships, service on panels such as ethical review boards.

Investigator (researcher) - principal Investigator or project director 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.

PHS – U.S. Public Health Service of the U.S. Department of Health and Human Services

PHS Awarding Component - the organisational unit of the PHS that funds the research that is subject to subpart F

SFI - Significant Financial Interest

Sub-recipient researchers – subcontractors, consortium members



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