



University of  
St Andrews

# Financial Conflicts of Interest (FCOI) for Research Funded by the Public Health Services of the United States of America Department of Health and Human Services

<b>Document type</b>	<b>Policy</b>
<b>Scope (applies to)</b>	All researchers
<b>Applicability date</b>	23/04/2020
<b>Review / Expiry date</b>	31/12/2020
<b>Approved date</b>	15/05/2020
<b>Approver</b>	Professor
<b>Document owner</b>	Head of Research Policy, Integrity & Gov
<b>School / unit</b>	Research & Innovation Services
<b>Document status</b>	Published
<b>Information classification</b>	Public
<b>Equality impact assessment</b>	None
<b>Key terms</b>	Research/Conduct and ethics
<b>Purpose</b>	To identify, declare, manage and enforce financial conflicts of interest of researchers responsible for the responsible for the design, conduct or reporting of projects applying for, or in receipt of, funding from the United States Public Health Services.

<b>Version number</b>	<b>Purpose / changes</b>	<b>Document status</b>	<b>Author of changes, role and school / unit</b>	<b>Date</b>

## Introduction

1. The University of St Andrews considers matters of research integrity to be of the utmost importance. It is essential that research staff should act, and be perceived to act, impartially and not be influenced, or be perceived to be influenced, in performing their research by any personal, business or other interests.
2. This policy considers matters relating specifically to financial conflicts of interest (FCOI) and applies to University employees who are applying for, or in receipt of, grant funding from the Public Health Services (PHS) of the United States Department of Health and Human Services (HHS). PHS component organisations including but not limited to:
  - i. National Institutes of Health (NIH);
  - ii. Centres for Disease Control and Prevention (CDC);
  - iii. Food and Drug Administration (FDA);
  - iv. Agency for Healthcare Research and Quality (AHRQ);
  - v. Substance Abuse and Mental Health Services Administration (SAMHSA);
  - vi. Agency for Toxic Substances and Disease Registry (ATSDR);
  - vii. Health Resources and Services Administration (HRSA);
  - viii. Indian Health Service (IHS).
3. The policy is applicable to any individual who is responsible for the design, conduct or reporting of a PHS funded project including University contractors, collaborators and consultants.
4. The University understands that the identification of a significant financial interest or a FCOI does not necessarily mean that there is any malpractice. However, in the interests of research integrity, the University must monitor potential FCOI, operate transparently and put mechanisms in place to ensure that potential FCOIs do not impinge upon the integrity of research conducted.

## Definitions

5. *Financial conflict of interest (FCOI)* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
6. *Investigator* means the project director, 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.
7. *Research* means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge and encompasses basic and applied research (e.g. a published article) or product development (e.g. a diagnostic test) and is funded by PHS.
8. *Significant financial interest (SFI)* means a financial interest consisting of one or more of the following interests of the investigator (or the investigator's spouse and dependent children) that reasonably appears to be related the investigator's institutional responsibilities:
  - i. If the aggregate value of any remuneration (salary or other payments for services) and equity interest (stock, stock option or other ownership interest) from any publicly traded entity in the 12 months preceding declaration exceeds \$US 5,000; or
  - ii. If the aggregate value of any remuneration (salary or other payments for services) from any non-publicly traded entity in the 12 months preceding declaration exceeds \$US 5,000

- or when the investigator (or investigator's spouse or dependent children) holds any equity interest (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; or
  - iv. Reimbursed or sponsored travel related to institutional responsibility (including that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact value may not be available).

Note that the following financial interests are **excluded** from being classed as significant financial interests:

- v. Travel that is reimbursed or sponsored by a Federal, state, or local government agency, a higher education institution (HEI), an academic teaching hospital, a medical centre, or a research institute that is affiliated with an HEI;
- vi. Salary, royalties or other remuneration paid by the institution employing the investigator;
- vii. intellectual property rights assigned to the institution and agreements to share the royalties from such rights;
- viii. Income from investment vehicles (e.g. mutual funds and retirement accounts) as long as the investigator does not directly control the investment decision made in these vehicles;
- ix. Income from service on advisory committees or review panels for a Federal, state, or local government agency, a higher education institution (HEI), an academic teaching hospital, a medical centre, or a research institute that is affiliated with an HEI;
- x. Income from seminars, lectures or teaching engagements sponsored by a Federal, state, or local government agency, a higher education institution (HEI), an academic teaching hospital, a medical centre, or a research institute that is affiliated with an HEI.

## Identification of financial conflicts of interest

9. The University will ensure that its FCOI policy is kept up-to-date and is publically accessible via its website.
10. The University will advise all research staff that the Financial Conflicts of Interest Policy is in place. In addition, during the development of relevant funding applications the appropriate contacts within the Financial Advice Services (FAS) and/or the Research Business Development & Contracts (RBDC) teams will discuss the requirement of FCOI declaration and direct applicants to Research and Innovation Services ([researchintegrity@st-andrews.ac.uk](mailto:researchintegrity@st-andrews.ac.uk)) for advice.
11. Each investigator is required to complete online training<sup>1</sup> provided by the National Institutes of Health (NIH) regarding FCOI prior to the engaging in PHS funded research. All new investigators starting during the course of the project should be directed to the training by the Principal Investigator and undertake this with 30 days of taking up position. In addition, training must be undertaken by investigators on PHS funded projects in the following circumstances:
  - i. Every four years, provided that work on the project continues;
  - ii. Immediately, should the University change its Financial Conflicts of Interest Policy;
  - iii. If an investigator is found to be non-compliant with the FCOI policy or a management plan which has been put in place.
12. An investigator who has undertaken FCOI training will submit evidence of completion of training to Research and Innovation Services ([researchintegrity@st-andrews.ac.uk](mailto:researchintegrity@st-andrews.ac.uk)).

---

<sup>1</sup> Training is available via this link <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

13. In the event that a PHS-funded project involves research through a sub-contractor (e.g. subcontractors or collaborators) the University will establish a written agreement with the sub-recipient to ensure compliance with the policy if the sub-recipient does not have an appropriate existing policy. The University will obtain written assurance from the sub-recipient that their FCOI policy complies with PHS regulations. The written agreement between the University and the sub-recipient will ensure that suitable reporting of FCOIs is carried out in relation to the sub-recipient.

### **Declaration of significant financial interest**

14. Prior to application for PHS funding, each investigator on the research project must submit a PHS Disclosure Form (Appendix, Part I & II) regardless of whether they have any significant financial interest. This must be returned to the Vice-Principal (Research & Innovation), the designated person in the University, by emailing [researchintegrity@st-andrews.ac.uk](mailto:researchintegrity@st-andrews.ac.uk). This form identifies significant financial interests only but must be submitted even where there are no potential conflicts of interest.

15. In the event that a new investigator joins the PHS-funded project, the investigator must complete the Significant Financial Conflict of Interest Disclosure Form (Part II) within 30 days of starting at the institution and return this to the Vice-Principal (Research & Innovation) who will review it and implement any further appropriate action within 30 days. This will meet the PHS requirement that any new significant financial interests which arise must be reported within 60 days.

16. Each investigator participating on the PHS-funded project must re-submit a new Significant Financial Interest Disclosure Form (Part II) annually at the start of the academic year (1 August) or within 30 days of this date.

17. Each investigator should resubmit a new Significant Financial Interest Disclosure Form (Part II) should the investigator acquire or discover a significant financial interest not previously disclosed (e.g. through marriage, purchase, inheritance) within 30 days of the change in circumstances.

18. The University will report to PHS (or the relevant component) on any significant financial interests found to be conflicting to the PHS-funded project prior to the expenditure of funds and implement a management plan. The University will report to PHS (or the relevant component) within 60 days of any subsequently identified significant financial interest.

19. For any FCOI reported by the University, the University will provide the PHS an annual FCOI report on its status and any changes to the management plan for the duration of the project.

20. The University will make available relevant details on the website so that members of the public may request information about significant financial interests related to PHS funded research. Any requests for information will be responded to within 5 working days if the following conditions are met; significant conflicts of interest have been disclosed and relate to the PHS funded project, and have been identified as FCOIs. Requests can be received and information disclosed up to three years after the end date of the project. The University will disclose the investigator's name, title, role, nature and amount of the significant financial interest.

21. The website which holds information about financial interests will be updated at least annually and within 60 days of any new information regarding significant conflicts of interest.

22. In each proposal submitted by the University to PHS for funding it will be certified that:

- i. There is a written and enforced FCOI policy at the University;

- ii. The University will report to the PHS on FCOIs prior to the expenditure of funds on the project and any management plans implemented regarding these and will submit an additional report within 60 days if any new FCOIs arise;
- iii. The University will make available information upon request regarding all FCOIs to the HHS;
- iv. The University will comply with other policies regarding FCOI set by PHS.

### **Management of significant conflicts of interest**

23. The University, specifically the Vice-Principal (Research & Innovation), will review the declarations of significant financial interest related to PHS-funded research **before expenditure of any funds** to determine whether they pose a conflict of interest. An investigator's significant financial interest is related to PHS-funded research when the institution reasonably determines that the significant financial interest could directly and significantly affect the design, conduct or reporting of the PHS- funded research.

24. Where a financial conflict of interest is identified, the University will develop and implement a management plan and if necessary a retrospective review and a mitigation report. Management of the financial conflict of interest could involve one or more of the following actions or other actions dependent upon the nature of the conflict:

- i. Public disclosure of the financial conflict of interest;
- ii. Disclosure of the financial conflict of interest to participants involved in the research;
- iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct or reporting of the research;
- iv. Modification of the research plan;
- v. Change of personnel or personnel responsibilities; or
- vi. Severance of relationships that create the financial conflict.

25. Whenever the University implements a management plan, the University will monitor compliance with the management plan on an on-going basis until the end of the project.

26. Research and Innovation Services will maintain records relating to all investigator disclosures and the institution's review of, response to and actions regarding such disclosures for at least three years from the date the final expenditures are submitted to PHS or longer according to the individual circumstances of the project.

27. The University will make available, within 30 days, information to the PHS or HHS on any funded investigator regarding their significant financial conflicts of interest and the University's response to these.

### **Enforcement action**

28. In the event that an investigator fails to comply with the Policy on Financial Conflicts of Interest, appropriate investigation and disciplinary action will take place in liaison with Human Resources and in accordance with the University's agreed Human Resources policies.

29. In the event that a financial conflict of interest is not identified or managed in a timely manner, the University will, within 120 days, of the determination of the non- compliance, complete a retrospective review of the investigator's activities and the PHS-funded research project.

30. The University will document the result of any investigation and if appropriate update the FCOI report submitted to the PHS.

31. In the event that bias relating to a FCOI is found, the University will notify the PHS promptly and submit a mitigation report to the PHS.

### **Confidentiality**

32. To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the University may be required to make such information available to the PHS and/or HHS, to a requestor of information concerning FCOI related to PHS funding or to the primary entity who made the funding available to the University if requested, or required. If the University is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the investigator will be informed of this disclosure.

<b>Version number</b>	<b>Purpose / changes</b>	<b>Document status</b>	<b>Author of changes, role and school / unit</b>	<b>Date</b>