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

Introduction

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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) for advice.
- 11. Each investigator is required to complete online training¹ 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 (<u>researchintegrity@st-andrews.ac.uk</u>).

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

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.

Version Purpose / changes number	Document status	Author of changes, role and school / unit
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