

1. Introduction:

1.1 This guidance has been issued to assist the Faculty Research Services teams in understanding what they are expected to do at both pre- and post-award stages when dealing with NIH applications and awards with regard to Financial Conflict of Interest (*refer to section 3*).

1.2 Guidance has also been made available to Investigators and Designated Departmental Officials and Departmental Champions so that they understand their responsibilities.

1.3 Due to some recent cases in other organisations, where the integrity of research was jeopardised because Investigators with a financial interest in commercial organisations had directed the National Institutes of Health-funded project towards a specific conclusion, the NIH have decided to strengthen the requirements in relation to the management of financial conflict of interest. This has resulted in the publication of the 2011 Revised Regulations.

1.4 Applications and/or research awards (new, annual renewals or revised) with a submission or issue date of the Notice of Award **after 1st August 2012** are subject to the new requirements presented in this document.

2. Definitions:

2.1 Investigator: Investigator means the principal investigator and any other person¹, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the Public Health Service of the U.S. Department of Health and Human Services², e.g. the National Institutes of Health (NIH).

2.2 Entity: Entity means any domestic or foreign, public or private organisation³ from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

2.3 National Institutes of Health (NIH): This includes the National Institutes of Health and NIH Institutes, e.g. National Cancer Institute, National Institute of Allergy and Infectious Diseases, etc.⁴

2.4 Financial Conflict of Interest (FCOI): A Financial Conflict of Interest exists when the College, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

2.5 Significant Financial Interest (SFI): A Significant Financial Interest is defined by the NIH as follows:

¹ This also includes collaborators and consultants

² http://en.wikipedia.org/wiki/United_States_Public_Health_Service

³ Excluding a Federal/government agency

⁴ <http://www.nih.gov/icd/>

- A. 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 College responsibilities⁵:
- a. For any publicly traded entity, a SFI exists if the value of any remuneration⁶ received from the entity in the 12 months **preceding** the disclosure and the value of any equity interest⁷ in the entity as of the date of disclosure, when aggregated, exceeds USD 5,000.
 - b. For any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 months **preceding** the disclosure, when aggregated, exceeds USD 5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest, i.e. the minimum declaration threshold for equity interest is USD 0,00.
 - c. Intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interest.
- B. Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their College responsibilities by commercial funders.⁸
- a. This includes travel paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available. Also refer to the College’s [Bribery Act](#)
 - b. This does not include travel which the Investigator claims through the College’s Expense Claim system and is charged to a research project
- C. SFI **does not** include the following types of financial interests:
- a. Salary, royalties or other remuneration paid⁹ by the College to the Investigator if the Investigator is currently employed/appointed by the College.
 - b. 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.
 - c. Income from seminars, lectures or teaching engagement sponsored by government, local government agency, HEI, academic teaching hospital, medical centre, research institute associated with a HEI.
 - d. Income from service on advisory committees or review panels for a government, local government agency, HEI, academic teaching hospital, medical centre, research institute associated with a HEI.

⁵ Investigator’s College responsibilities may include activities such as research, research consultation, teaching, professional practice, College committee memberships, and service on review board panels, etc.

⁶ Remuneration includes salary and any payment for services not otherwise identified as salary, e.g. consulting fees, honoraria, paid authorship

⁷ Equity interest includes any stock, stock option or other ownership interest as determined through reference to public prices

⁸ Exception: Travel sponsored or reimbursed by government, local government agency, HEI, academic teaching hospital, medical centre, research institute associated with a HEI does not need to be declared

⁹ This may include intellectual property rights assigned to the College and agreements to share royalties related to such rights

2.6 Designated Departmental Official¹⁰: As per the College’s Conflict of Interest Policy, this individual is:

- A. (where the Investigator is a member of staff or an affiliate), the Investigator’s Head of Department, via the Investigator’s line manager;
- B. (in all other cases where the Investigator is a Head of Department/Division, a Faculty Principal, or a College Official) the Investigator’s line manager

3. Research Services/JRO responsibilities:

3.1 Pre-award stage:

- 1. Research Services/JRO must email the Investigator (PI, Co-I, any named researchers, technicians) the [‘National Institutes of Health – Financial Conflict of Interest – Guidance for Investigators’](#) document and draw their attention to the three responsibilities listed.

3.2 Post-award stage (set-up stage for new, annual renewal and revised awards):

3.2.1 Where the College is the lead institution, Research Services must ensure that the following paragraph is inserted into the sub-agreement:

1 Financial Conflict of Interest

1.1 For the purposes of this Clause **XX**, Financial Conflict of Interest and Significant Financial Interest shall have the following meanings:

- (a) **Financial Conflict of Interest (FCOI)** means a conflict of interest arising where a Party’s reasonably determines that the Investigator’s Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the NIH-funded research project.

Significant Financial Interest (SFI) means a financial interest consisting any one or more of:

- i. For any publicly traded entity, a SFI exists if the value of any remuneration¹¹ received from the entity in the 12 months **preceding** the disclosure and the value of any equity interest¹² in the entity as of the date of disclosure, when aggregated, exceeds USD 5,000.
- ii. For any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 months **preceding** the disclosure, when aggregated, exceeds USD 5,000, or when the

¹⁰ Designated departmental official – point 4.1.3 of the College’s Conflict of Interest Policy: https://workspace.imperial.ac.uk/hr/Public/Procedures/con_interest/coi.pdf

¹¹ Remuneration includes salary and any payment for services not otherwise identified as salary, e.g. consulting fees, honoraria, paid authorship

¹² Equity interest includes any stock, stock option or other ownership interest as determined through reference to public prices

Investigator (or the Investigator's spouse or dependent children) holds any equity interest, i.e. the minimum declaration threshold for equity interest is USD 0,00.

- iii. Intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interest.
- iv. Investigators must also disclose the occurrence of any reimbursed or sponsored travel¹³ related to their College responsibilities.¹⁴

For the avoidance of doubt, SFI **does not** include the following types of financial interests:

- v. Salary, royalties or other remuneration paid¹⁵ by the College to the Investigator if the Investigator is currently employed/appointed by the College.
- vi. 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.

1.2 XXXX shall keep Imperial informed of any FCOI within the scope of the terms of the Prime Contract. XXXX shall report to Imperial every 6 months (*Name of Primary and Secondary Departmental Champio and their email addresses*), declaring any SFI and/or any FCOI, or in the case of none, a nil return in order to allow Imperial to comply with the terms of the Prime Contract. Any disclosure of SFI or FCOI must be capable of being reported to the NIH in accordance with the terms of the Prime Contract.

1.3 Without prejudice to any other provisions in this Agreement XXXX agrees to indemnify and keep Imperial fully indemnified against all claims made by the NIH, including the repayment of any portion of the funding paid, that results directly from XXXX's failure to disclose any SFI or FCOI.

3.2.2 Research Services/JRO must email the Investigator (PI, Co-I, any named researchers, named technicians) and draw their attention to the '[National Institutes of Health – Financial Conflict of Interest – Guidance for Investigators](#)' document and the three listed responsibilities included within the document. Research Services/JRO will inform the Principal Investigator that it is the PI's responsibility to ensure that any Investigators new to the NIH-funded project during the life of the project are informed to follow the NIH web tutorial. The training to be followed is the NIH web tutorial:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

3.2.3 Where the College is a subrecipient, Research Services/JRO will ensure that the sub-agreement received from the lead institution states that Imperial will follow its own

¹³ Paid on behalf of an investigator and not reimbursed to an investigator so that the exact monetary value may not be readily available

¹⁴ Exception: Travel sponsored or reimbursed by government, local government agency, HEI, academic teaching hospital, medical centre, research institute associated with a HEI does not need to be declared

¹⁵ This may include intellectual property rights assigned to the College and agreements to share royalties related to such rights

Financial Conflict of Interest policy including the guidance issued on the NIH Financial Conflict of Interest requirements.