

## 1. Introduction:

1.1 This guidance has been issued to assist Investigators (*definition of Investigator below*) in determining if they have a Significant Financial Interest which could have an impact on the research integrity of their NIH-funded projects. The document also explains the following Investigator responsibilities with respect to NIH funding:

- **Compulsory completion of the NIH online tutorial** prior to engaging in research related to any NIH-funded project, e.g. at pre-award stage
- **Re-visit the NIH-online tutorial** if the award runs for more than four years or if engaging in new NIH awards after a four-year period
- **Disclose any Significant Financial Interest in a timely manner** as per the deadlines set by the NIH

1.2 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.

1.3 Applications and/or research awards (new, annual renewals or revised) with a submission or issue date of the Notice of Award **after 1<sup>st</sup> 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 person<sup>1</sup>, 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 Services<sup>2</sup>, e.g. the National Institutes of Health (NIH).

**2.2 Entity:** Entity means any domestic or foreign, public or private organisation<sup>3</sup> 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.<sup>4</sup>

**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

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<sup>1</sup> This also includes collaborators and consultants

<sup>2</sup> [http://en.wikipedia.org/wiki/United\\_States\\_Public\\_Health\\_Service](http://en.wikipedia.org/wiki/United_States_Public_Health_Service)

<sup>3</sup> Excluding a Federal/government agency

<sup>4</sup> <http://www.nih.gov/icd/>

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:

- 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 responsibilities<sup>5</sup>:
  - a. For any publicly traded entity, a SFI exists if the value of any remuneration<sup>6</sup> received from the entity in the 12 months **preceding** the disclosure and the value of any equity interest<sup>7</sup> 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.<sup>8</sup>
  - 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 paid<sup>9</sup> 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.

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<sup>5</sup> 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.

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

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

<sup>8</sup> 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

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

- 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.

**2.6 Designated Departmental Official<sup>10</sup>:** 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. Investigator responsibilities:**

3.1 The College expects Investigators to follow the requirements as laid out in the 2011 Revised Financial Conflict of Interest regulation <http://grants.nih.gov/grants/policy/coi/> .

3.2 Prior to engaging in research activities related to any NIH-funded project, the Investigator must familiarise themselves with the NIH FCOI requirements as well as the College's Conflict of Interest policy<sup>11</sup>. This requirement is also applicable at application stage.

3.3 There are three main Investigator responsibilities:

- (i) Completion of training by reviewing and answering the questions in the NIH online tutorial
- (ii) Disclosure of Significant Financial Interest
- (iii) Adherence to the agreed Management Plan in case of an identified FCOI

#### **3.4 Completion of Training – NIH online tutorial:**

3.4.1 The College recommends that for training purposes, the Investigator completes the tutorial available on the NIH website: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. The tutorial includes a small number of questions which tests the Investigator's understanding of the requirements for disclosure of Significant Financial Interest linked to NIH-funded projects.

- The Investigator must go through this tutorial prior to engaging in research activities related to any NIH-funded project.
- On the last slide of the tutorial, the Investigator must type their name and print a copy for their record as this will need to be provided in case of an audit or if a copy is required by the Departmental Champion or the Faculty Research Services team.

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<sup>10</sup> 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](https://workspace.imperial.ac.uk/hr/Public/Procedures/con_interest/coi.pdf)

<sup>11</sup> [https://workspace.imperial.ac.uk/hr/Public/Procedures/con\\_interest/coi.pdf](https://workspace.imperial.ac.uk/hr/Public/Procedures/con_interest/coi.pdf)

3.4.2 If the Investigator continues to be involved in NIH-funded projects for more than 4 years, the Investigator is expected to re-familiarise themselves with the NIH tutorial and the College Conflict of Interest Policy.

3.4.3 In case of **non-compliance** with the NIH 2011 FCOI rules and/or the Management Plan, the Investigator must revisit the NIH tutorial at any given time.

3.4.4 The College will inform Investigators of any significant changes to its Conflict of Interest policy.

### **3.5 Disclosure of Significant Financial Interest (SFI)<sup>12</sup>:**

3.5.1 Investigators, who are planning to participate in, or are participating in, NIH-funded research are required to disclose to the Designated Departmental Official a listing of Significant Financial Interest that reasonably appear to be related to the Investigator's College responsibilities. The listing of Significant Financial Interest must include those linked to the Investigator's spouse and dependent children.

3.5.2 The Investigator must complete the form [‘Disclosure of Significant Financial Interest \(SFI\) linked to NIH-funded projects’](#) on an annual basis, if applicable.

3.5.3 If the value of a reported SFI changes during the year, the Investigator should disclose the change to the Designated Departmental Official in their annual disclosure.

3.5.4 The NIH clearly defines the time frame for disclosure of the SFI and what the consequences are if this process is not followed.

3.5.5 The time frames for disclosure of an SFI are:

- No later than at the time of application for the NIH-funded research
- At least annually during the period of the award
- Within 30 days of discovering or acquiring a new SFI

3.5.6 If these timeframes are not followed, one of the consequences is that College/Academic Department will have to report extensively to the NIH why the deadlines were not met.

### **3.6 Adherence to the agreed Management Plan for any identified FCOI:**

3.6.1 The Investigator signs the Management Plan.

3.6.2 By signing the Management Plan, the Investigator agrees to follow the mitigation controls put in place by the designated Departmental Official.

3.6.3 Non-compliance with the Management Plan must be reported to the NIH.

### **3.7 Special requirement for Clinical research:**

- A. If the purpose of a NIH-funded project is to evaluate the safety or effectiveness of a drug, medical device or treatment and it has been designed, conducted or reported by an

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<sup>12</sup> Refer to Annex I – High-level process map for disclosure of SFI and management of FCOI

Investigator who has a Significant Financial Interest which constitutes a financial conflict of interest, the Investigator must comply as follows:

- a. The Investigator must 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.

**Annex I - Disclosure/Management Stage (High-level process map):**

