

1. Introduction:

1.1 This guidance has been issued to assist the Designated Departmental Official and the Departmental Champion (*definition below*) in determining

- if a Significant Financial Interest should be considered a Financial Conflict of Interest
- what needs to be reported to NIH
- when reporting takes place and what the deadlines for submission are

1.2 There is also guidance available for Investigators so that they know what their responsibilities are.

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.

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/>

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 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.

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

- 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 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

2.7 Departmental Champion: This individual is a named person within each academic department whose main responsibilities are to collate documentation relating to the requirements of the 2011 Final Rule and to submit the FCOI reports via the eRA Commons FCOI module¹¹. Due to strict timelines enforced by the NIH, it is expected that each academic department receiving NIH funding will have a primary and secondary departmental champion.

3. Designated Departmental Official¹² responsibilities¹³:

3.1 Once the Investigator has disclosed their SFIs by completing the [‘Disclosure of Significant Financial Interest \(SFI\) linked to NIH-funded projects’](#) form, the Designated Departmental Official must

- (i) review all SFI disclosures made by the Investigator;
- (ii) determine if the Investigator's SFIs (and those of the Investigator's spouse and dependent children) can be affected by the NIH-funded research;
- (iii) determine if the SFI can be considered as an FCOI because the SFI can significantly affect the design, conduct, or reporting of the NIH-funded research
- (iv) develop and implement management plans to ensure that the FCOI is appropriately dealt with and controlled
 - a. complete the document [‘Management Plan for Financial Conflict of Interest \(FCOI\) on NIH-funded projects’](#)
- (v) carry out a retrospective review when the Investigator fails to disclose any existing SFI, the Investigator fails to comply with the FCOI Management Plan or the Designated Departmental Official fails to review or manage such FCOI
 - a. complete the document [‘Retrospective Review Form for Financial Conflict of Interest on NIH-funded projects’](#)
 - b. advise the Investigator to revisit the NIH web tutorial

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 Access to the eRA Commons system is granted by the College's Research Office: contact rs.compliance@imperial.ac.uk stating that access is required to the FCOI module

¹² 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

¹³ Annex I – High-level process

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

3.2 The Designated Departmental Official has only 60 days to meet the above-mentioned responsibilities. If it is acknowledged that an FCOI exists, the [departmental champion](#), who is responsible for submitting the FCOI report to the NIH, must do so within the same 60-day period (*if the College is a subrecipient, the 60 days are reduced as the lead institution needs to support our FCOI report to the NIH and they will have to do so within the 60-day period*).

3.3 The Designated Departmental Official must provide the Management Plan to the [departmental champion](#) as the information within the Management Plan forms the basis of the FCOI report.

4. Departmental Champion responsibilities¹⁴:

4.1 The Departmental Champion has the following responsibilities:

- (i) report any FCOI to the NIH via the electronic eRA Commons FCOI module (*if the College is a subrecipient, the Management Plan is sent to the lead institution as they have the responsibility to submit the FCOI report to the NIH*)
 - a. 'Reports' are defined as Initial, Annual, Revised and Mitigation reports
 - b. For any FCOI identified on an internal subproject (PS number), the Departmental Champion responsible for the PS number should report the FCOI to the Departmental Champion in the academic department where who has responsibility for the lead internal award number. The Departmental Champion for the lead award will report the FCOI to the NIH on behalf of the academic department associated with the Subproject.
- (ii) keep records of when annual FCOI reports are due which must be in line with the timing of the submission of the PI's annual progress report
- (iii) keep records of completed Disclosure of SFI and Management Plan forms as these will have to be provided within 5 days when the College receives a request from outside the College to provide such information
- (iv) keep records of completed Disclosure of SFI, Management Plan and Retrospective Review forms for up to 3 years after Research Services/JRO have submitted the final statement of expenditure of the individual NIH project
- (v) collate FCOI information from subrecipients on projects where the Imperial academic department is leading the research project and submit such information to the NIH (initial, annual, revised, and mitigation reports)
- (vi) monitor subrecipient's compliance with the FCOI regulation, Management Plan
- (vii) carry out a retrospective review when the Designated Departmental Official fails to review or manage such FCOI
 - a. complete the document ['Retrospective Review Form for Financial Conflict of Interest on NIH-funded projects'](#)

¹⁴ Annex I – High-level process

5. Reporting prior to incurring expenditure on the NIH-funded project (Initial Report)¹⁵:

5.1 If the FCOI is eliminated prior to incurring spend on the NIH-funded project, the [departmental champion](#) does not need to report to the NIH.

5.2 If the FCOI was not eliminated prior to incurring expenditure on the NIH-funded project, the [departmental champion](#) will have to submit an Initial FCOI report and thereafter an Annual FCOI report to NIH. The information submitted will be based on what is provided by the Designated Departmental Official to the [departmental champion](#).

5.3 The [departmental champion](#) will also have to report to the NIH:

- whenever an Investigator does not timely disclose an SFI
- whenever the Designated Departmental Official does not review a disclosed SFI and the Designated Departmental Official then determines that an FCOI exists

5.4 The [departmental champion](#) is required to submit the FCOI report to the NIH based on the information included within the original '[Disclosure of Significant Financial Interest \(SFI\) linked to NIH-funded projects](#)' and the '[Management Plan for Financial Conflict of Interest \(FCOI\) on NIH-funded projects](#)' forms . Therefore the Designated Departmental Official must provide an explanation for non-compliance with the reporting deadlines.

6. Submission of FCOI reports during an ongoing NIH-funded project¹⁶:

6.1 Initial FCOI Report:

6.1.1 The [departmental champion](#) must submit an FCOI report within 60 days after its determination that an FCOI exists for

- an Investigator who is newly participating in the project
- an existing Investigator who discloses a new SFI¹⁷

6.1.2 If an Investigator fails to disclose a previously existing SFI, or the Designated Departmental Official fails to review a previously existing SFI during an ongoing NIH-funded project, the Designated Departmental Official shall within 60 days:

- (i) review all SFI disclosures made by the Investigator;
- (ii) determine if the Investigator's SFIs (and those of the Investigator's spouse and dependent children) can be affected by the NIH-funded research;

¹⁵ Annex II – High-level process

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¹⁷ A new SFI is a different type or nature of SFI (e.g. royalty payment vs. consulting fees) than had previously been disclosed from the same source that meets or exceeds the threshold. In addition, a new SFI is also considered to be the same type or nature of SFI (e.g. royalty payment) from a different source (e.g. company A vs. Company B)

- (iii) determine if the SFI can be considered as an FCOI because the SFI can significantly affect the design, conduct, or reporting of the NIH-funded research
- (iv) develop and implement management plans to ensure that the FCOI is appropriately dealt with and controlled
 - a. complete the document [‘Management Plan for Financial Conflict of Interest \(FCOI\) on NIH-funded projects’](#)

6.2 The [departmental champion](#) submits an FCOI report to the NIH based on information in the Management Plan.

6.3 In addition to the FCOI, the Designated Departmental Official must within 120 days of the determination of non-compliance complete a retrospective review of the Investigator’s research activities and the NIH-funded research – refer to the [‘Retrospective Review Form for Financial Conflict of Interest on NIH-funded projects’](#) form. The purpose of this review is to determine whether the research conducted during the time period of non-compliance was biased in the design, conduct or reporting.

6.4 Based on the results of the retrospective review, if appropriate the Designated Departmental Official updates the Management Plan and the [departmental champion](#) submits a revised FCOI specifying the actions that will be taken to manage the FCOI going forward.

6.5 Mitigation report: If bias is found, the [departmental champion](#) must notify the NIH promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the department’s plan of action or actions taken to eliminate or mitigate the effects of bias. Thereafter the Designated Departmental Official must review the FCOI on an annual basis and the [departmental champion](#) submits FCOI reports annually.

6.6 Annual FCOI Report:

6.6.1 The [departmental champion](#) must provide an annual FCOI report linked to any FCOI previously reported. The Designated Departmental Official must provide the following information to the [departmental champion](#):

- Status of the financial interest
- Any changes to the Management Plan

6.6.2 Based on this information, the [departmental champion](#) reports whether the FCOI is still being managed or explain why the FCOI no longer exists.

6.6.3 Annual FCOI reports must be submitted at the same time as when the Principal Investigator is required to submit the annual progress report throughout the life of the project which includes any extension periods. The annual FCOI report is submitted separately through the eRA Commons FCOI module and is not submitted as part of the annual progress report.

6.7 Revised FCOI:

6.7.1 The [departmental champion](#) must submit a new FCOI report if any of the following elements of previously submitted FCOI report changes:

- Project Number
- Name of the Investigator with the FCOI
- Name of the entity
- Nature of the SFI

NB: 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.

7. Submission of FCOI report through eRA Commons system:

7.1 Submission through the eRA Commons system is done by the lead institution

7.1.1 Where the College is leading a project, the College reports any FCOI declared by the subrecipient through the Departmental Champion's eRA Commons FCOI account

7.1.2 Where the College is a subrecipient, the College submits the applicable SFI, FCOI forms to the lead institution. The lead institution submits through the eRA Commons system on behalf of the College.

7.2 The NIH have produced a detailed user guide of how to submit the FCOI reports through the eRA Commons system:

http://era.nih.gov/files/fcoi_user_guide.pdf

7.3 For how to **initiate/submit/edit the FCOI report**, please follow from section 7.3.2 on page 9

7.4 For how to **submit the FCOI Annual Reports**, please follow section 7.10 on page 26

8. FAQs

8.1Q Where the College is a subrecipient, will we be chased by the lead institution to submit FCOI reports?

8.1A Main award holders are required to build in a paragraph in the subcontract which indicates whether the FCOI rules of the subrecipient or those of the main award holder must be followed. It is unlikely that we will be chased for any FCOI reports because we, as an institution, would know whether we have to report or not (the lead institution is unlikely to know about this). If we do need to declare an FCOI to the lead institution, we will submit the applicable forms ([‘Disclosure of Significant Financial Interest \(SFI\) linked to NIH-funded projects’](#), [‘Management Plan for Financial Conflict of Interest \(FCOI\) on NIH-funded projects’](#), [‘Retrospective Review Form for Financial Conflict of Interest on NIH-funded projects’](#)) so that the lead institution can report to the NIH through their eRA Commons account.

8.2Q Where the College is the lead institution, will the Departmental Champions have to chase the subrecipients for any FCOI reports?

8.2A The Research Office has issued a paragraph which Research Services can use and it mentions that the subrecipient must notify our [departmental champion](#) (details provided will include name and email address) in case of a declaration of FCOI. We should not need to chase the subrecipient unless we are aware that one of their Investigators on the project has an FCOI. It is unlikely that we would know if an FCOI exists and therefore we need to assume that if they don't send through a report to us, they have no FCOI to report.

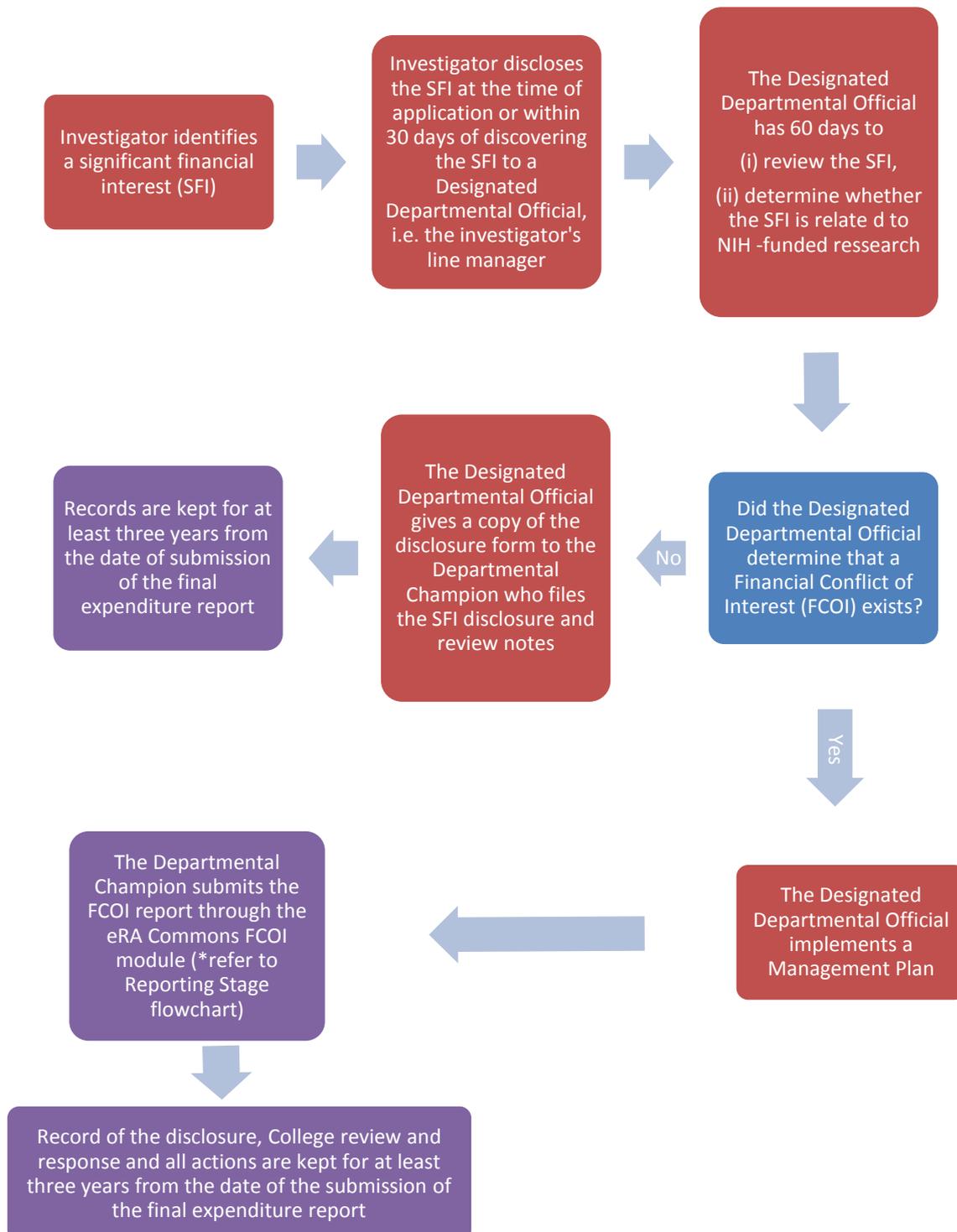
8.3Q Do the new requirements apply to all active awards?

8.3A Any Notice of Award (e.g. new awards, annual renewals, revisions) received after we have published our NIH FCOI guidance are subject to the new guidance. If an award is active at the time of publication of the requirements but this award is not renewed, then this award does not need to follow the new requirements.

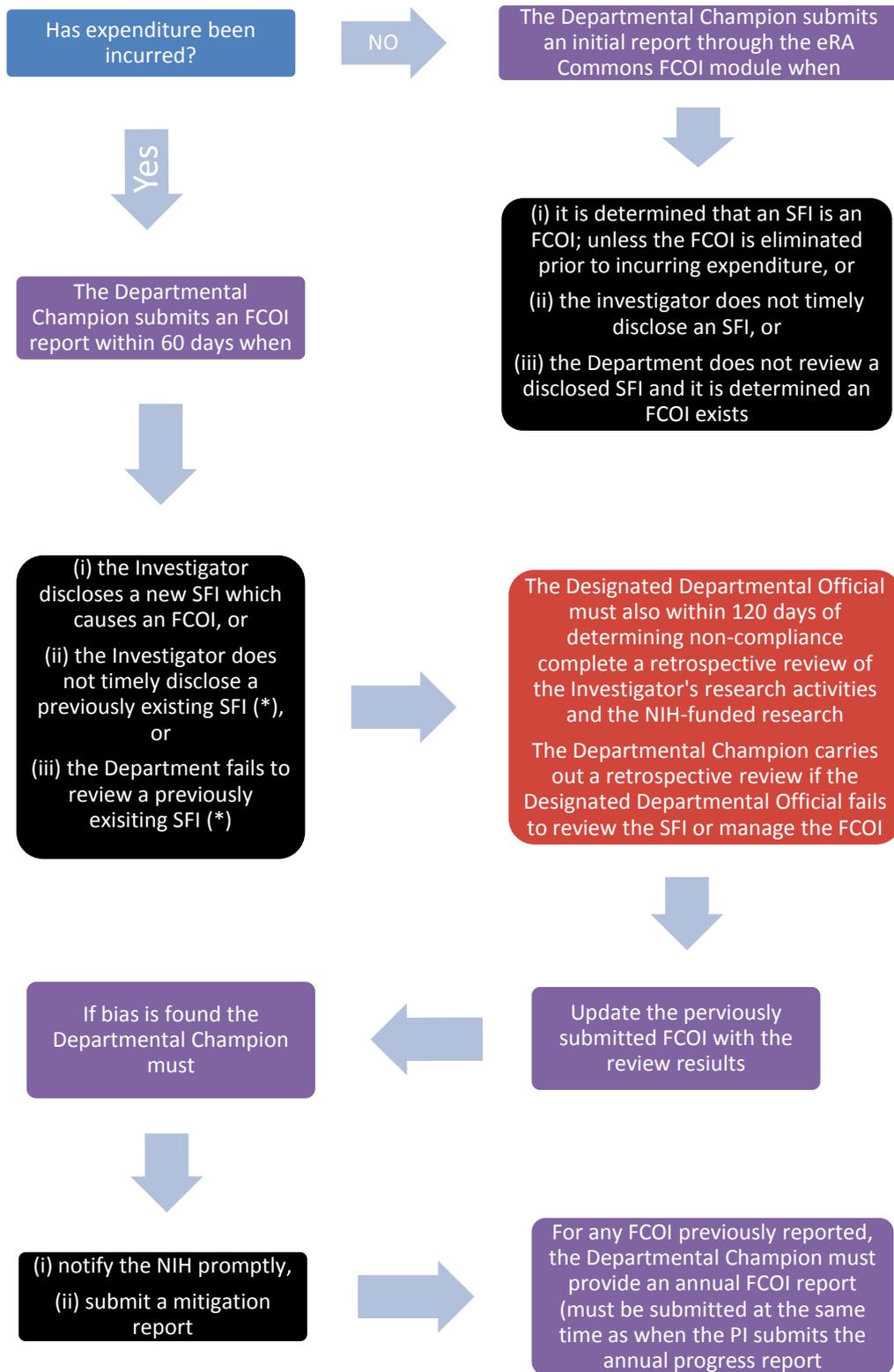
8.4Q I am a Designated Departmental Champion but don't have access to eRA Commons or the eRA Commons FCOI Module. What do I do?

8.4A Please contact the Research Office by emailing rs.compliance@imperial.ac.uk and the Research Office will create for you an eRA Commons account with access to the FCOI Module.

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



Annex II - Reporting Stage¹⁸ (assumes that an FCOI has been identified):



(*) Review the SFI; Determine if SFI is related to a NIH-funded project; Determine whether FCOI exists; Implement a Management Plan if FCOI exists

¹⁸ For Clinical research (clinical trials), the Investigator must disclose the FCOI in each public presentation of the results of the research.