

## University of Exeter Financial Conflict of Interest (FCOI) Policy

Organisations in receipt of funding from US Public Health Service (PHS) funding bodies such as the National Institutes of Health (NIH), are required to demonstrate compliance with the 2011 US Department of Health and Human Services (DHHS) regulations on disclosing and reporting financial conflicts of interest.

FCOI policy exists to ensure that research is free from bias resulting from investigator's commercial conflicts of interest. This FCOI policy aims to ensure research integrity by establishing standards to promote objectivity and provide a reasonable expectation that the design, conduct, and reporting of research funded by the NIH is not jeopardised by a FCOI.

The policy applies to everyone who applies for, designs a study for or who works on projects funded by the NIH (known as 'Investigators'), and all research funded by NIH, whether awarded directly by NIH or indirectly, for example where the University of Exeter is a sub-awardee or sub-contractor.

All University of Exeter researchers applying for or receiving NIH funding (whether awarded directly or indirectly) must be familiar with the funding conditions and be aware that NIH may undertake audits. All researchers applying for or in receipt of NIH funding must disclose any Significant Financial Interests (SFI), as described below, in order to establish whether there may be a Financial Conflict of Interest.

### Definitions:

The policy defines an '*Investigator*' as anyone involved in or responsible for the design, conduct or reporting of research funded by the NIH. This includes, but is not limited to, project directors, principal investigators, co-investigators, post-doctoral researchers, research students, honorary researchers, technicians, consultants and external collaborators.

Under the NIH policy, a *Significant Financial Interest (SFI)* consists of one or more of the following interests of the investigator, and those of an investigator's spouse and dependent children, that reasonably appear to be related to the investigator's institutional responsibilities\*:

- For any publicly traded Entity#, an SFI exists if the value of any remuneration (including salary and any payment for services not otherwise identified as salary, e.g. consulting fees, honoraria, paid authorship) received from the Entity in the 12 months preceding the disclosure and the value of any equity interest (including any stock, stock option or other ownership interest as determined through reference to public prices) in the Entity as of the date of disclosure, when aggregated, exceeds US\$ 5,000.
- For any non-publicly traded Entity#, an SFI exists if the value of any remuneration received from the Entity in the 12 months preceding the disclosure, when aggregated, exceeds US\$ 5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
- Intellectual property rights and interest (e.g. patents, copyrights) on receipt of income related to such rights and interest.
- Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to institutional responsibilities. This excludes travel reimbursed or sponsored by a US Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical centre, or a research institute affiliated with an Institution of higher education.

\**Institutional responsibilities* may include, but are not limited to, research, teaching/education, public engagement/outreach, training, professional practice

#'*Entity*' refers to any domestic or foreign, public or private organisation (excluding a US Federal/Government agency) from which an Investigator (and spouse and dependent children) receives remuneration, or in which any person has an ownership or equity interest

## **Responsibilities and Procedure for Declaring a Significant Financial Interest:**

### **All Investigators are required to:**

- Complete the online NIH FCOI tutorial prior to engaging in any research related to NIH funding and at least every four years.
- Send the certificate of training to [euresearch@exeter.ac.uk](mailto:euresearch@exeter.ac.uk)
- Investigators must also repeat the training when:
  - a) they are new to the University of Exeter,
  - b) FCOI policy changes affect the Investigator's work, or
  - c) they are found to be non-compliant with the FCOI policy.
- Be familiar with the University of Exeter's Conflict of Interest Policy
- Using the form in Appendix A, complete a Declaration of Significant Financial Interest, disclosing to the Head of Department all of the SFIs related to their institutional responsibilities at each of the following time points:
  - a) no later than the point of application for NIH funding
  - b) within 30 days of the issue date of each NIH-funded project
  - c) within 30 days of discovering or acquiring a new SFI
  - d) at least annually during the period of the award.

**The Declaration must be completed by all Investigators within the timescales above even where no SFI exists.**

**The declaration form must be submitted to the relevant Head of Department, with a copy to the responsible Research Development Manager.**

Please note that the University's annual reporting cycle runs from April to March each year. Annual reports will be requested in March.

- Should a Financial conflict of interest (FCOI) be identified, adhere to the agreed management plan for any SFIs and co-operate with any retrospective reviews.
- Principal Investigators are responsible for ensuring that all members of the research team meet their responsibilities as described above.

### **Institutions are required to:**

- Submit to the NIH; initial, ongoing and annual FCOI reports throughout the duration of the funded project via the eRA commons.
- Report information to NIH on identified SFIs and how they are being managed
- Make information accessible to the public concerning identified SFIs held by senior or key personnel according to the Policy

Institutional tasks will be undertaken by the EU/International team in Research Services, as follows:

- The relevant Research Development Manager will ensure that records are maintained, that the NIH eRA Commons record is updated as appropriate and that sub-recipient compliance is monitored.
- The relevant Research Development Manager will forward a Declaration of an SFI form to Investigators, copying in their Head of Department, at the point of application, within 30 days of the issue date of each NIH funded award and annually during the period of the grant.

### **The relevant Head of Department is responsible for:**

- Completing the online NIH FCOI tutorial prior to Investigators within the Department engaging in any research related to NIH funding and at least every four years.
- Sending the certificate of training to the EU/International team ([euresearch@exeter.ac.uk](mailto:euresearch@exeter.ac.uk))
- Reviewing the SFI to determine whether it i) relates to NIH funding and ii) constitutes a Financial Conflict of Interest within 30 days of the SFI disclosure or any deadline set by the lead applicant. An FCOI exists when an institution determines that an Investigator's SFI is related to a NIH-funded

research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

- Notifying the EU/International team as soon as a SFI is disclosed or potential FCOI has been identified
- Notifying the EU/International team that all Investigators have completed a declaration and that they have been reviewed to determine whether a potential FCOI exists
- In collaboration with the EU/International team in Research Services and the Research Ethics and Governance Manager, developing and implementing a management plan to control identified Financial Conflicts of Interest. This must be reported to the NIH within 60 days of an SFI being disclosed; reporting will be done by the EU/International team. At a minimum, the management plan must include information on the role and principal duties of the conflicted Investigator in the research project, conditions of the management plan, how the management plan is designed to safeguard objectivity in the research project, confirmation of the Investigator's agreement to the management plan and how the management plan will be monitored to ensure Investigator compliance.
- If non-compliance is found, completing a retrospective review of the investigator's activities and the NIH-funded research project within 120 days to determine whether any NIH-funded research, or portion thereof, conducted during the period of noncompliance, was biased in the design, conduct, or reporting of such research.
- If a bias is identified in the design, conduct or reporting of a project, notifying the EU/International team, completing a Mitigation Report and taking such other necessary corrective actions. Refer also to the University's Code of Good Practice in the Conduct of Research.

Where the Investigator also holds a senior management role within their College (e.g. Head of Department, Associate Dean or Pro Vice-Chancellor), the disclosure must be made to the line-managing Deputy Vice-Chancellor and the DVC will undertake the responsibilities outlined above.

The EU/International team project lead and Research Ethics & Governance Manager are available to advise Investigators and Heads of Department on the process, management plans, retrospective review and corrective actions.

#### **Relevant information:**

NIH Financial Conflict of Interest Policy <https://grants.nih.gov/grants/policy/coi/index.htm>

including Frequently Asked Questions and NIH Online Tutorial

UoE Conflict of Interest Policy

[http://www.exeter.ac.uk/media/universityofexeter/secureall/research/UoE\\_Col\\_V1.1\\_CC\\_GS\\_for\\_web\\_publication\\_04102018.pdf](http://www.exeter.ac.uk/media/universityofexeter/secureall/research/UoE_Col_V1.1_CC_GS_for_web_publication_04102018.pdf)

UoE Code of Good Practice in the Conduct of Research  
<http://www.exeter.ac.uk/cgr/researchethics/codesandpolicies/>

V3.0 26<sup>th</sup> March 2020

Appendix A – Template disclosure form

**Declaration of Significant Financial Interests<sup>1</sup> Form**

This form is to be completed by Investigators whose research is funded by the US National Institutes of Health, in accordance with the University of Exeter guidance on the US National Institutes of Health (NIH) Financial Conflict of Interest (FCOI) Policy.

This form should be submitted to the relevant Head of Department and copied to the responsible Research Development Manager.

**Section 1:**

<b>Name</b>	
<b>College/Department</b>	
<b>Title of NIH Research Project or BID/T1 Project number</b>	
<b>NIH Grant Reference</b>	
<b>Project Start Date</b>	
<b>This disclosure is:</b>	<input type="checkbox"/> My Initial Disclosure at grant application stage <input type="checkbox"/> My updated initial Disclosure at grant award stage <input type="checkbox"/> An addendum to my most recent disclosure <input type="checkbox"/> My Annual Disclosure <input type="checkbox"/> An addendum <b>for travel purposes only</b> to my recent disclosure

**Section 2:**

The purpose of this declaration is to ensure that Significant Financial Interests are disclosed and, if these are considered to present a Financial Conflict of Interest, that these are reduced, managed or eliminated.

Please provide information on any Significant Financial Interest here (add more rows if necessary) or state 'None' if no Significant Financial Interests exist:

Name of organisation in which you, your spouse or dependent children have a Significant Financial Interest	Details of Significant Financial Interest (e.g. directorship, consultancy, shareholding, reimbursed travel etc.)	Approximate value (£) of the Significant Financial Interest

--	--	--

If you would like to supply any additional details or provide clarification, please attach separate sheets.

**Declaration:**

I certify that the information I have provided indicates all Significant Financial Interests with regard to my position at the University of Exeter.

I acknowledge that I am obliged to disclose (within 30 days of discovering or acquiring) any further Significant Financial Interest that may arise after submission of this form.

I understand that the information provided on this form will be held and processed by the University for the purposes of:

- (i) maintaining a register of declarations of Significant Financial Interest;
- (ii) assessing and identifying Financial Conflicts of Interest as required by the Department of Health and Human Services (DHHS)
- (iii) managing such conflicts and reporting and responding to the DHHS accordingly;
- (iv) providing responses to any request for information regarding identified Financial Conflicts of Interest made by members of the public; and
- (v) providing information on declarations and any identified Financial Conflicts of Interest to the DHHS

I understand that the University will continue to hold this data and any related documents for six years from the date that the final expenditures report is submitted in relation to the project.

I understand that the University is obliged by DHHS regulations to make information available concerning identified Financial Conflicts of Interest by a written response to any requestor within five business days of receiving such a request. I understand that such data may be provided by the University for up to three years after the date on which the information in relation to the declaration was most recently updated. I consent to the University sharing my data with any requestor in this way.

I consent to the University sharing information with the DHHS about this disclosure.

NAME: \_\_\_\_\_

SIGNATURE: \_\_\_\_\_

DATE: \_\_\_\_\_

<sup>1</sup> Under the NIH policy, a *Significant Financial Interest (SFI)* consists of one or more of the following interests of the investigator, and those of an investigator's spouse and dependent children, that reasonably appear to be related to the investigator's institutional responsibilities\*:

- For any publicly traded Entity#, an SFI exists if the value of any remuneration (including salary and any payment for services not otherwise identified as salary, e.g. consulting fees, honoraria, paid authorship) received from the Entity\* in the 12 months preceding the disclosure and the value of any equity interest (including any stock, stock option or other ownership interest as determined through reference to public prices) in the Entity as of the date of disclosure, when aggregated, exceeds US\$ 5,000.

- For any non-publicly traded Entity#, an SFI exists if the value of any remuneration received from the Entity in the 12 months preceding the disclosure, when aggregated, exceeds US\$ 5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest.
- Intellectual property rights and interest (e.g. patents, copyrights) on receipt of income related to such rights and interest.
- Any reimbursed or sponsored (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) travel related to institutional responsibilities. This excludes travel reimbursed or sponsored by a US Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical centre, or a research institute affiliated with an Institution of higher education.

*\*Institutional responsibilities* may include, but are not limited to, research, teaching/education, public engagement/outreach, training, professional practice

*#'Entity'* refers to any domestic or foreign, public or private organisation (excluding a US Federal/Government agency) from which an Investigator (and spouse and dependent children) receives remuneration, or in which any person has an ownership or equity interest.