**US Public Health Service and National Institutes of Heath**

**Financial Conflict of Interest (FCOI) Procedures (Feb 2021)**

This procedure sets out the requirements for senior and key personnel participating in research funded by a US Public Health Service (PHS) funder, typically but not exclusively the National Institutes of Health (NIH).

The Following procedures must be followed by all applicants and awardees of NIH (and other PHS) research funding.

Training

1. Prior to applying for NIH funding applicants must appraise themselves of the Universities Financial Conflict of Interest policy contained in sections 3.4 and 10.24 of the [Financial Regulations](https://documents.manchester.ac.uk/DocuInfo.aspx?DocID=1741) and sections 10.57 and 10.64 of the [Financial Procedures](https://documents.manchester.ac.uk/DocuInfo.aspx?DocID=1742).
2. Each applicant must ensure their [Research Integrity training](https://documents.manchester.ac.uk/protected/display.aspx?DocID=41265) is up to date (this must be completed every 3 years) and for NIH funded investigators this should include completion of the additional module on Conflicts of Interest.
3. Applicants are reminded that they must complete a Register of Interest return each year in line with University policy and any significant financial interests declared through this NIH process must also be declared via the university [register of interest](https://documents.manchester.ac.uk/DocuInfo.aspx?DocID=29297) process.
4. On award all NIH / PHS funded investigators (PI/CoIs) must complete the online training course at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> Two copies of the completion certificate should be printed and retained; one for the investigator and one should be held on the on the Research Services grant record either in Pure or local project file.
5. Annually each investigator working or named on an NIH/PHS funded research project must complete an NIH FCOI declaration (shown at the end of this document) and return this to their local Research Service team supporting the award. Where no significant financial interests are declared the form should be retained on the project file or on the award record in Pure. Where a significant financial interest is declared. The RS team should notify the Head of Research Services, sending the completed declaration to [researchoperations@manchester.ac.uk](mailto:researchoperations@manchester.ac.uk) for review by the Director of Research and Business Engagement.
6. The NIH require a separate annual report on FCOI as part of general project reporting and this will show on the era Commons tool. The FCOI declarations held on the project file or in Pure should reflect what is reported within the annual return to NIH (further details can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-081.html>)

Key requirements:

* All Investigators must disclose any Significant Financial Interest (SFI) with respect to their institutional responsibilities to the Director of Research and Business Engagement using the form at the end of this procedure document. The Director of Research and Business Engagement will determine if the SFIs disclosed constitute a Financial Conflict of Interest (FCOI).
* Where an SFI is determined to be an FCOI, a management plan will be drawn up to help manage, reduce or eliminate the FCOI. Investigators must cooperate with the development of the FCOI management plan and must comply with the plan set out by the Director of Research and Business Engagement.
* A disclosure of the FCOI and management plan must be submitted to the NIH/PHS-funder.
* Adherence to the management plan must be monitored and copies of the FCOI form and any subsequent management plan must be retained on the grant record for audit purposes.
* Annual (and occasionally more regular) reporting of FCOIs to the NIH/PHS funder is required via (era) Commons. It is the investigators responsibility (with support from the local Research Services Team) to ensure FCOI reports are submitted to the NIH/PHS funder.
* For awards which are sub-contracted to us by a US university all FCOIs declared by an investigator must be reported to the US partner.
* For awards which require us to disburse funds to other partners. The University remains responsible for ensuring partners adhere to the NIH/PHS rules by following their own NIH/PHS FCOI procedure or adopting our procedure where they do not have one.
* Before any expenditure of PHS funds, information concerning any disclosed SFI which has been determined to be an FCOI relating to NIH/PHS-funded research, must be made publicly accessible by written response within 5 working days of request.

Responsibilities, Management Plan and Reporting

The Director of Research and Business Engagement must review all significant financial interests (SFI) disclosed by investigators as soon as they arise and as a minimum on an annual basis.

Investigators must disclose any SFIs that reasonably appear to be related to their institutional responsibilities prior to applying for NIH/PHS funding or within 30 days of discovering or acquiring a new SFI (e.g. through purchase, marriage of inheritance).

Where an SFI is determined to be an FCOI, the Director of Research and Business Engagement and Research Services team will agree a suitable management plan with the investigator and report the FCOI and management plan within 60 days of identifying the FCOI.

The management plan could include:

* Disclosure of the FCOI to staff members working on the project or relevant ethics committee.
* Where research involves human subjects, disclosure of the FCOI directly to participants might be necessary.
* An independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI may be appointed.
* Modification of the research plan or change of personnel or responsibilities within the project.
* Reduction or elimination of the financial interest (e.g. sale of an equity or severance of relationships that create financial conflicts).

The management plan must include:

* The role and duties of the conflicted Investigator in the research project.
* How the management plan will safeguard objectivity in the research project.
* Confirmation of the Investigator's agreement to the management plan.
* How the management plan will be monitored to ensure Investigator compliance.

For further information on the key underlying funder policy which underpins this procedure please see the following:

[Responsibility of Applicants for Promoting Objectivity in Research](https://ecfr.io/Title-42/sp42.1.50.f#se42.1.50_1604)

[Key Definitions](https://ecfr.io/Title-42/Section-50.603)

[Responsibilities of Institutions regarding Investigator financial conflicts of interest](https://ecfr.io/Title-42/Section-50.604)

Research Services Team, Directorate of Research and Business Engagement

University of Manchester

Feb 2021

**THe University of Manchester**

**NIH/PHS Funded Annual Declaration of Significant Financial Interests**

To be completed by Investigators funded by the US National Institutes of Health and other US Public Health Service funders. Full guidance on the regulations, including key definitions and FAQs can be found at <http://grants.nih.gov/grants/policy/coi/>

**PLEASE NOTE THIS FORM MUST BE COMPLETED BY ALL NIH/PHS FUNDED RESEARCHERS AND FOR ALL NIH PROJECTS ON AN ANNUAL BASIS. A SIGNED COPY MUST BE RETAINED AS PART OF THE PROJECT DOCUMENTATION.**

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| --- | --- | --- |
| Investigator/Role |  | |
| Project Title |  | |
| Email |  | |
| School |  | |
| NIH Project Title |  | |
| NIH Grant Ref. No. |  | |
| R Code |  | |
| Collaborating Organizations |  | |
| Project Start Date | Click here to enter a date. | Budget Period: |

|  |  |
| --- | --- |
|  |  |
| **Conflict of Interest Statement** | |
|  | |
| Please declare below any Significant Financial Interests (SFIs)\* that you, your spouse/partner or dependent children have which, if deemed to be a Financial Conflict of Interest under US Public Health Service regulations, must be reduced, managed or eliminated for NIH funding to be received. Where no SFIs are identified a NIL return is required.   |  |  |  | | --- | --- | --- | | Name of the entity in which the SFI is held | Nature of the SFI  (e.g. equity, consulting fee, travel reimbursement, honorarium) For sponsored travel reimbursement, the minimum information to include is:   * Purpose of the trip * Name of the sponsor/organiser * Destination * Duration | Approximate value of the SFI (US $) | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | | |
| **CERTIFICATE** | |
|  | |
| I certify that the information I have provided indicates, to the best of my knowledge, all Significant Financial Interests of mine, my spouse/partner and my dependent children with regard to my position at the University of Manchester and my NIH funded research activity.  I confirm I have completed the online NIH training in relation to Financial Conflict of Interest and retained evidence of completion <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>  I acknowledge that I am obliged to disclose promptly to the University (and within 30 days of acquiring) any Significant Financial Interest that may arise after submission of this form. Such disclosure should be made by submitting an updated version of this form to [researchoperations@manchester.ac.uk](mailto:researchoperations@manchester.ac.uk)  If I am the Principal Investigator of the Project I will ensure that all other researchers working on the Project complete and return this form on an annual basis.  I understand and consent to the information provided on this form being held and processed by the University for the purposes of:   1. Maintaining a register of declarations of SFI for the purposes of funding via an institute under the US Department of Health and Human Services (DHHS) and Public Health Services (PHS); 2. Assessing and identifying Financial Conflicts of Interest as required by the DHHS or PHS; 3. Managing such conflicts and reporting and responding to the DHHS or PHS accordingly; 4. Providing responses (within 5 days) to any request for information regarding identified Financial Conflicts of Interest made by members of the public; and 5. Providing information on declarations and any identified Financial Conflicts of Interest to the DHHS or PHS subject to the provisions of the Data Protection Act 1998.   I understand that the University will continue to hold this disclosure form and any related documents for a minimum of three years from the date that the final expenditure 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 from the date that the final expenditure report is submitted in relation to the project. I consent to the University disclosing my data to any requestor in this way. I consent to the University sharing information with the DHHS about this disclosure.   |  |  |  |  | | --- | --- | --- | --- | | Signed |  | Date | Click here to enter a date. | | |
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Please complete and return the form to your Research Services (RSS) Team and where an SFI has been disclosed to [researchoperations@manchester.ac.uk](mailto:researchoperations@manchester.ac.uk).

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If you have any queries relating to this form please contact [researchoperations@manchester.ac.uk](mailto:researchoperations@manchester.ac.uk) in the first instance.

\*the definition of an SFI can be found here <http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3181>. You are advised to read this to ensure that you do not have a SFI. Examples of SFI include the following:

• Income or receipt of payments of any kind exceeding $5,000;

• Ownership interests in a single outside entity of greater than 1% or of an amount exceeding $5,000;

• Serving as a trustee for a trust or estate, or having a beneficial interest in a trust or estate whose value exceeds $5,000;

• Indebtedness to or from a business or company in an amount exceeding $5,000;

• Intellectual property rights with an established fair market value exceeding $5,000 or which generate income of any value;

• Unvalued stock options or other options for ownership in a privately held company of any value;

• Service on a governing or advisory board, or in a fiduciary or managerial role, for, or as a general partner of, an entity with or without pay;

• Other opportunity for tangible, personal benefit; and

• Reimbursed or sponsored travel.