

National Institutes of Health (NIH) Financial Conflict of Interest (FCOI) Policy Guidance for UCL Academic Departments, Divisions and Institutes

Overview

This guidance serves to summarise NIH's FCOI requirements for UCL's Academic Departments / Divisions / Institutes applying for, or in receipt of, NIH Funding. The full policy and associated detailed guidance (including FAQs) is available on the NIH website:

- [NIH Financial Conflict of Interest Policy](#)
- [NIH FCOI FAQs](#)

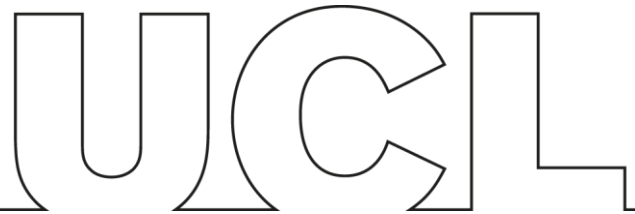
All organisations in receipt of NIH funding required to demonstrate compliance with the NIH Financial Conflict of Interest Policy. The policy applies to funding awarded directly by the NIH itself or its Institutes or indirectly e.g. where UCL is (or receives funding from) a sub-awardee or sub-contractor. The policy applies to any staff involved in or responsible for the design, conduct, or reporting of research funded by the NIH which including (but not limited to): Principal Investigators (PIs), Co-Investigators (Co-Is), Honorary Staff, Post-Doctoral Researchers; Students, Technicians, External collaborators or consultants. For the purpose of this guidance and the NIH policy, all such individuals are referred to as '**Investigators**'.

At the highest level, the NIH FCOI policy requires UCL to disclose Financial Conflicts of Interests (FCOI) where we reasonably determine that an Investigator has a '**Significant Financial Interest**', related to an NIH-funded research project, that could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

Furthermore the policy requires UCL to comply with the strict NIH FCOI reporting requirements via the NIH FCOI module within ERA Commons, within strict guidelines. Additionally the NIH stipulate regular and compulsory NIH FCOI training for all Investigators and additional requirements regarding the subsequent management and disclosure of identified FCOIs.

It must be noted that the NIH FCOI Policy is supplementary to, and should be followed in conjunction with, the College's own policies, procedures and guidelines on related matters, included but not limited to:

- [UCL Declaration of Interest Policy](#), noting principle 24: '*Where a conflict of interest relates to an externally funded research project (i.e. where the interest influences, potentially influences, or could be perceived to influence, the design, conduct or reporting of such project), any steps agreed on how to declare and manage the conflict must be compatible with the terms and conditions of the award and the associated Funder's Conflict of Interests policy.*'
- [UCL Gifts and Hospitality Policy](#)
- [UCL Anti-corruption and Bribery Policy](#)
- [UCL Code of Conduct for Research](#)
- [UCL General code of ethical principles](#)
- [UCL Statement on Research Integrity](#)



Definition of a Financial Conflict of Interest

In terms of the NIH policy, a financial conflict of interest exists when, after investigation, the College reasonably determines that an Investigator has a **Significant Financial Interest** ('SFI') that is related to an NIH-funded research project and that could directly and significantly affect the design, conduct or reporting of the NIH-funded research. SFIs that do not directly and significantly affect the design, conduct or reporting of the NIH-funded research are not FCOIs.

A **Significant Financial Interest** is a financial interest consisting of one or more of the following interests of an Investigator (and those of an Investigator's spouse and dependent children), that reasonably appears to be related to the Investigator's College responsibilities (these may include activities such as research, research consultation, teaching, professional practice, College committee memberships, and service on review board panels, etc.):-

- 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.

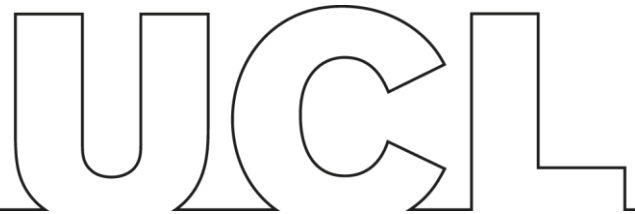
*In the policy, 'Entity' refers to any domestic or foreign, public or private organisation (excluding a US Federal/government agency) from which an Investigator (and spouse and dependent children), receives remuneration or in which any person has an ownership or equity interest.

Responsibilities of UCL Academic Departments, Divisions and Institutes:

Guidance for 'Investigators' (as defined above)

Under the NIH Conflict of Interest Policy, Investigators are responsible for:

1. **Compulsory completion of the [NIH online tutorial](#).** Investigators must complete the online NIH FCOI tutorial prior to engaging in research related to any NIH grant and at least every four (4) years. In addition, Investigators must repeat training when:
 - FCOI policy changes affect the requirements of the Investigator
 - The Investigator is new to UCL
 - When the UCL Academic Department finds an Investigator non-compliant with UCL's FCOI policy on NIH-funded projects or management plan
2. **Disclosure of any Significant Financial Interest (SFI),** see above definition. The time frames for disclosure of SFIs 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 SFIFailure to disclose as per the timelines above will result in additional reporting obligations to the NIH
3. Adherence to the agreed Management Plan (in the case of an identified FCOI)
 - Non-compliance with the Management Plan must be reported to the NIH.
4. **Disclosure of any FCOIs** in each public presentation of the results of a project (and as an addendum to previously published presentations) for any FCOI not properly managed or reported by the Investigator for a



RESEARCH SERVICES GUIDANCE NOTE

project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment.

5. **Disclosure of commercially reimbursed or sponsored travel:** a requirement for any such travel (where the monetary value may not be readily available) related to the Investigator's UCL responsibilities to be disclosed.
6. **Receive disclosures of Significant Financial Interest of Investigators at other institutions,** where UCL has or will subcontract institutions whose staff are to perform part of the project, and forward this to their Departmental / Divisional / Institute Manager (if not directly sent).

Guidance for Heads of Departments / Divisions / Institutes (via the Investigator's line manager)

Under the NIH Conflict of Interest Policy, UCL HoDs / Institute Directors are responsible for:

1. **Review of the Significant Financial Interest (SFI)** to determine whether it constitutes a Financial Conflict of Interest (FCOI) due to potential for impact:
 - of the SFI on the outcome of the NIH-funded project, or
 - of the NIH-funded project outcome on the value of the SFI
2. **Ensuring that the above review has been completed** well before the 60-day deadline, or any deadline set by the lead applicant (where UCL is in receipt of a sub-agreement)
3. **Development and implementation of management plans** to control identified FCOIs
4. **Undertaking retrospective reviews** (in the event an Investigator fails to comply with the NIH FCOI policy and management plan).
5. **In the event that a bias is identified in the design, conduct or reporting of a project,** the Head of Department / Division / Institute will promptly notify the NIH (copying in UCL's Director of Research Services), complete a Mitigation Report and take such other necessary corrective actions.

Where the Investigator is the UCL Head of Department / Division / Institute, the Designated Departmental Official (DDO) will be the relevant UCL Dean of Faculty or their nominee; where the Investigator is the UCL Dean of Faculty, the DDO shall be the relevant Vice Provost.

Guidance for Departmental / Divisional / Institute Managers

In support of the above, the Investigator's Departmental / Divisional / Institute Manager is responsible for:

1. **Reporting identified Financial Conflict of Interest (FCOI) via the NIH eRA Commons FCOI module** ([guide](#) available), within the 60-day deadline or, where UCL is a sub-recipient, to the lead applicant within the deadline set by that lead applicant.
2. **Reporting any FCOI** identified on behalf of a sub-recipient via the eRA Commons FCOI module.
3. **Maintaining records of FCOI** report due dates
4. **Maintaining records of the Significant Financial Interest, FCOI forms,** etc.
5. **Monitoring sub-recipient compliance** with the FCOI policy requirements and any Management Plans
6. **Undertaking retrospective reviews** (in the event the Designated Departmental Official does not review a disclosed SFI within the defined review timeframe)
7. **Report disclosures of Significant Financial Interest of Investigators at other institutions,** where UCL has or will subcontract institutions whose staff are to perform part of the project.

UCL Research Services will register these Departmental / Divisional and Institute Managers in eRA Commons so that they have access to the FCOI module. Any Departmental Champions who need to be added to the list and to the eRA Commons FCOI module should email researchservices@ucl.ac.uk

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