US Financial Conflicts of Interest Policy

for use with U.S. federal funding and in particular U.S. Department of Health & Human Services (HHS) and U.S. Public Health Services (PHS) Funding Applications

This policy is to be adhered to and read by any individual who is involved in US federally funded research either directly or via a collaborator. Under US federal regulations, compliance with this policy, and enforcement of it by the University, is a legally binding contractual obligation. As such you are required to read and comply with this policy and sign the accompanying declaration confirming that you have done so. If an individual is found not to be compliant with this policy or to have made a false declaration then the University may decide to take disciplinary action against that individual.

1. Summary

The purpose of this policy is the promotion of objectivity by the establishment of standards to ensure there is no reasonable expectation that the design, conduct or reporting of research will be biased by any conflicting financial interest of an individual. Employees have a responsibility to promote and respect the financial and reputational interests of the University. Yet the damage to the reputations of individuals and the University caused by Conflicts of Interests could be considerable. The University’s Protocol on Conflict of Interest, approved by the University Council, requires that all Staff (including Honorary and Emeritus) and Registered Students are required to recognise and disclose activities that might give rise to conflicts of interest or the perception of conflicts and to ensure that such conflicts are seen to be properly managed or avoided.

Conflicts of interest (CoI) may be financial, non-financial or both and the current protocol can be found at

https://bham.sharepoint.com/sites/workinghere/SitePages/conflictsofinterest.aspx

In an environment of increased global funding it is however often necessary to adhere to additional policies to satisfy international regulations. All those to whom the current University Protocol applies also need to be aware of, and comply with, the requirements of external/ third party requirements affecting their activities.

This Policy governs Financial Conflict of Interest applying specifically to U.S. federal funding sources and is based on the expectation that all Investigators (as defined below) should conduct their affairs so as to avoid or minimise Financial Conflict of Interest and must respond appropriately when a Financial Conflict of Interest does arise. Violation of any part of this policy may constitute cause for disciplinary action by the University.

If you are unsure what to do in any situation then guidance can be sought in the first instance from your line manager or the University Official as defined below. If in doubt staff should always disclose activity so that the University can make a decision on whether a Financial Conflict of Interest is present.

There are additional procedures in place to cover procedural processes for the implementation of the policy and adherence to the funder requirements through the relevant support team in RSSD.
2. Definitions

Financial Conflict of Interest means a Significant Financial Interest that would be determined could directly and significantly affect the design, conduct or reporting of the research.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by a US federal organisation or proposed for such funding. For purposes of the requirements of this policy, "Investigator" includes the Investigator's spouse and dependent children.

PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

Significant Financial Interest (SFI) means 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 institutional responsibilities:

- Publicly traded entity: Value of any remuneration (e.g., salary, consulting fees, honoraria, paid authorship) received from the entity in the twelve months preceding the disclosure and value of any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure that when aggregated exceeds $5,000;
- Non-publicly traded entity: Value of any remuneration received in the twelve months preceding the disclosure that when aggregated exceeds $5,000, or any equity interest;
- Intellectual property (IP) rights and interests (e.g., patents, copyrights) in excess of $5,000 upon receipt of income. IP rights assigned to the University and agreements to share in royalties related to such rights are excluded from the SFI definition; and
- Reimbursed or Sponsored Travel in excess of $5,000 related to the Investigator’s institutional responsibilities, excluding travel that is reimbursed or sponsored by the following:
  - A federal, state, or local government agency located in the United States
  - A United States Institution of higher education as defined at 20 U.S.C. 1001(a)
  - An academic teaching hospital
  - A medical center, or
  - A research institute that is affiliated with a United States Institution of higher education

Such disclosures must disclose as a minimum the purpose of the trip, the identity of the sponsor/ funder, the destination, the duration and if known the monetary value.

- The following types of financial interests are excluded from being a SFI:
  - Payments the Investigator receives from or through the University if the Investigator is currently employed or otherwise appointed are excluded, specifically including:
- salary, royalties, or other remuneration, including travel reimbursement;
- IP rights assigned to the University and agreements to share in royalties related to such rights;
  - income from investments, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions;
  - income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government agency located in the United States, a United States Institution of higher education as defined in 20 U.S.C. 1001(a) [a U.S. institution of higher education], an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education;

**University Official** means the person appointed by the University who is responsible for the collection of, and coordination of the review of, disclosures of Significant Financial Interests of the Investigator related to the Investigator’s University Responsibilities. For the purposes of this policy the University Official will be a designated individual located in Research Strategy & Services Division and as detailed in the associated Declaration of Significant Financial Interests Form.

**University Responsibilities** means the Investigator’s professional responsibilities associated with his or her University position such as members of Staff, students etc. engaged in research, teaching, outreach, clinical service, administrative activities, training and appointment on internal and external committees or boards.

### 3. Disclosure of Significant Financial Interests Process

Every Investigator, as defined above, has an obligation to become familiar with and abide by the provisions of this policy. All Investigators are required to disclose their Significant Financial Interests, as defined above, to the University on an annual or ad hoc basis in line with this policy. The University Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms specifically under this policy. This is in addition to those disclosures made for non-federal funders under the general University Conflict of Interest Policy and the Code of Practice for Research.

**a) Annual disclosures**

All Investigators must disclose their Significant Financial Interests that are related to their employment activity at the University through the University Official on an annual basis. All forms should be submitted to the University Official indicated on the disclosure form by 31st January for the previous calendar year.

**b) Ad hoc disclosures**

In the event that an Investigator’s employment begins in the middle of the calendar year above then a disclosure must be made within 30 days of their employment start date.

If the circumstances of an Investigator’s Significant Financial interests changes at any time then a disclosure should be made in addition to any previous disclosures made. This additional disclosure should be made within 30 days of discovering or acquiring the new or amended Significant Financial Interest.

In addition to the above if an Investigator is applying for a NIH PHS-sponsored project either directly or as a collaborator they must, in addition to any disclosures previously made, affirm...
the currency and value of the annual disclosure or submit an ad hoc disclosure with the previously disclosed outside entity.

4. Review of Disclosures

Review Process

If a disclosure is made by the Investigator it will be reviewed by the University Official and a referral will be made to a senior nominated officer. The senior nominated officer will be the Head of College in the case of most Staff or Registered Students, the PVC for Research and Knowledge Transfer in the case of Head of College or the Provost for any other Staff (see appendix 1). The outcome of the decision by the senior nominated officer will either be to manage the conflict including the reduction or removal of the conflict as appropriate or if the conflict cannot be managed this will be communicated to the funder who will make a decision as to whether the research can be undertaken.

A Financial Conflict of Interest exists when it is related to the NIH-supported research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research) and when the senior nominated officer determines that the SFI could directly and significantly affect the design, conduct or reporting of the Research. The senior nominated officer may involve the Investigator in the determination of whether a SFI is related to the PHS/NIH-funded research.

If, in the view of the senior nominated officer, the SFI could present a Financial Conflict of Interest, the decision will be submitted to the University Official by the nominated senior officer together with a plan for how the Financial Conflict of Interest can be reduced, eliminated or managed. The University Official will submit the plan to the funder via their preferred system. The Investigator and senior nominated official are required to produce annual updates on how the Financial Conflict of Interest is being managed.

If it is determined that a Financial Conflict of Interest can be managed then a written management plan must be put in place. The Investigator with the Financial Conflict of Interest will be required to agree and sign the written management plan before any related research commences.

Managing a conflict

When a Significant Conflict of Interest is disclosed that may directly and significantly affect the design, conduct or reporting of the research then there are a number of actions that may be taken to manage, reduce or eliminate a Financial Conflict of Interest. Examples of conditions or restrictions that might be imposed to manage Financial Conflict of Interest include but are not limited to:

- Public disclosure of Significant Financial Interests (e.g., when presenting or publishing the research; to staff members working on the project; to the University's Ethical Review Committee(s), Animal Welfare and ethical Review Body, etc.;
- Monitoring of research by independent reviewers
- Modification of the research plan
- Disqualification from participation in all or a portion of the research funded by the US
- Divestiture of Significant Financial Interests
- Severance of relationships that create actual or potential Financial Conflict of
Interest
- If the funded project is for clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment that has been designed, conducted, or reported by an Investigator with a conflicting interest that was not managed or reported by the University as required by the regulation, the University must require the Investigator(s) involved to 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.

5. Reporting to the Funder

The University Official is required to report to the funder any Financial Conflict of Interest or non-compliance in accordance with the funder’s regulations. Where the University is the Prime contractor the report will be sent directly to the funder prior to any funds being expended, or within 60 days of any subsequently identified Financial Conflict of Interest during the course of the project.

Where the University is a sub-recipient the report will be sent to the prime contractor in accordance with the timelines set out by the prime contractor in order to allow them to report to the funder within the 60 day period.

If a management plan is put in place to manage any Financial Conflict of Interest then a report will be required to the funder on an annual basis. Reports will be submitted via the eRA commons Financial Conflict of Interest module by the University official and will include sufficient information to enable the funder to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the University’s management plan.

6. Non-Compliance

In the event of an Investigator’s failure to comply with this policy, the University through the senior nominated officer and/or in accordance with its written procedures may suspend all relevant activities or take other appropriate disciplinary action until the matter is resolved or action deemed appropriate by the University is implemented. The University’s decision on the action to be taken will be provided in writing to the Investigator and, where applicable, to the US funder.

Retrospective Review Process

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:
- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the University to constitute a Financial Conflict of Interest;
- Failure by the University to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

the University shall, within 120 days of the University’s determination of noncompliance, complete a “retrospective review” of the Investigator’s activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during
the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

A retrospective review will be carried out by the senior nominated officer who will document the reason for the retrospective review, the methodology undertaken to form the review, the findings and conclusions. Any previously submitted report to the funder will be updated specifying the actions to be taken to manage the Financial Conflict of Interest going forward. If bias is found resulting from the Financial Conflict of Interest that affects the design, conduct or reporting of the research, the senior nominated officer via the University Official will submit a mitigation report to the funder identifying the elements in the review, a description of the impact of the bias on the project and the plan of action to eliminate or mitigate the risk.

The University shall document the retrospective review which must include at least the following key elements:

a) Project number;
b) Project title;
c) PD/PI or contact PD/PI if a multiple PD/PI model is used;
d) Name of the Investigator with the FCOI;
e) Name of the entity with which the Investigator has a Financial Conflict of Interest
f) Reason(s) for the retrospective review;
g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
h) Findings of the review; and
i) Conclusions of the review.

7. Training

Each Investigator must complete training on the principles of this policy in order to fully understand the regulations and types of disclosures/ Significant Financial Interests that will need to be considered and made. The training needs to be completed before an application is submitted to any US funder and at least every four years thereafter. The training must also be completed in the event that this policy is substantially revised in a manner that affects the Investigator’s responsibility, or if the Investigator is new to the University and applies for US funding, or if there is a change in the Significant Financial Interests of the Investigator, or if it is determined that an Investigator has not complied previously with the policy or with any management plans put in place.

The following tutorial training should be completed for all US federal funding and irrespective of the tutorial being hosted by the NIH:


A copy of the certificate of completion issued upon successful completion of the above should be submitted to the University Official.

8. Record Retention

The University Official will retain all disclosure forms, the University’s review and response to any disclosure, conflict management plans and any related documents for a minimum of 3 years after the date of submission of the final expenditure report to the funder or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or
annual financial report, respectively, as reported to the HHS awarding agency or pass-through entity in the case of a subrecipient unless any litigation, claim or audit is initiated during the three-year period, in which case the records will be maintained until all actions have been resolved and final action taken.

9. Confidentiality and Public Disclosure

To the extent permitted by law, all disclosures, management plans and related documents and information will kept confidential, however the University may be required to make such information available to the funder or to a requestor of information regarding financial conflicts relating to key/senior personnel.

In the event the University is requested to disclose information regarding a Significant Financial Interest that meets all the criteria below then it will respond to the requestor within 5 working days of the request.

- A Significant Financial Interest was disclosed and is still held by the key senior personnel
- A determination has been made that the Significant Financial Interest is related to the funded research
- A determination had been made that the Significant Financial Interest is a Financial Conflict of Interest

The information disclosed will be consistent with the requirements of the specific funder in each case but as a minimum will include:

- Investigator’s name;
- Investigator’s title and role with respect to the research project;
- Name of the entity in which the Significant Financial Interest is held;
- Nature of the Significant Financial Interest; and
- Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

10. Clinical Research Requirements

If the funded project is for clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment that has been designed, conducted, or reported by an Investigator with a conflicting interest that was not managed or reported by the University as required by the regulation, the University must require the Investigator(s) involved to 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.
Appendix 1: Procedure for disclosing and managing Financial Conflicts of Interest relating to US federal funded research (RSSD represents University Official based in Research Strategy & Services Division)

1. PI notifies RSSD regarding
2. RSSD requests PI complete disclosure form and training and provides
3. Significant Financial Interest declared by PI annually
   - If Null Declaration made: Free to submit disclosure form submission requested annually
   - If Declaration made:
     - RSSD forwards declaration to appropriate senior nominated officer (HoC)
     - Senior nominated officer decides if conflict exists
     - If No conflict: Application either not submitted or funding withdrawn
     - If Yes but conflict can be managed, reduced or eliminated:
       - Management plan submitted to RSSD who submit to US funder
       - Funder accepts plan and project continues. Annual report submitted by PI to funder via RSSD on management plan progress