

PHS Financial Conflict of Interest Policy

OFFICE OF INSTITUTIONAL EFFECTIVENESS (OIE)
GRANTS AND SPONSORED PROGRAMS
FINANCIAL CONFLICT OF INTEREST POLICY

Overview

All members of the Manchester University (the University) community (trustees, senior administrative officers, deans, faculty and staff) serve the educational purposes to which the University is dedicated. Accordingly, all such members of the University community have a clear obligation to conduct the affairs of the University in a manner consistent with those purposes and to make all decisions solely on the basis of a desire to promote the best interests of the institution. The University maintains and enforces a general Conflict of Interest Policy that permit members of the faculty, staff, administration and trustees. to identify, evaluate and correct or remove real, apparent and potential conflicts of interest. In addition, it is the University's intent to comply with Public Health Service (PHS), its components including the National Institutes of Health (NIH), the National Science Foundation (NSF), and other federal agency disclosure regulations in order to maintain eligibility to submit applications for grant, cooperative agreement or contract funding to those agencies.

The policies and processes detailed here are designed to promote objectivity in research and to ensure that the design, conduct and reporting of research conducted at the University and sponsored with federal funds are not biased by any perceived or real financial conflict of interest (FCOI) of an Investigator. This policy is intended to comply with the current federal regulations governing FCOIs entitled "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" ([42 C.F.R. Part 50, Subpart F](#)).

This policy applies to all members of the University community who apply for, or receive, PHS research funding by means of a grant or cooperative agreement. It does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an Institution, is applying for, or receives, PHS research funding, PHS Awarding Components will make case-by-case determinations on the steps to be taken, consistent with this subpart, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from an FCOI of the individual.

Acronyms, Terms, and Definitions

Approval: a conflict has been identified for which a management plan can be developed and implemented.

Approval with Conditions or Restrictions: a conflict has been identified, and a management plan can be developed only for parts of the conflict with conditions or restrictions.

Disclosure of significant financial interests: an Investigator's disclosure of significant financial interests to an Institution.

Financial Conflict of Interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report: an Institution's report of an FCOI to a PHS Awarding Component.

Financial interest: anything of monetary value, whether or not the value is readily ascertainable.

Institutional responsibilities: an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on FCOIs, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator: the Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage: taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI: a Project Director or Principal Investigator of a PHS-funded research project.

PHS: the Public Health Service of the U.S. Department of Health and Human Services, and any Awarding Component of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Prohibition: a conflict has been identified for which a management plan cannot be developed.

Research: a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used here, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel: the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.

Significant financial interest (SFI):

1. 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:
 - I. With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - II. With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - III. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2. Investigators also must disclose the occurrence of 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 their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an 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 an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

3. The term "*significant financial*" interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an 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 an Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an 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 an Institution of higher education.

Training

The University's Office of Institutional Effectiveness (OIE) shall be responsible for ensuring that each Investigator is informed about this FCOI policy and will ensure that each Investigator has completed training prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract and at least every (4) years thereafter, and immediately when any of the following applies:

1. this FCOI Policy, the SFI Disclosure Form, or the University's procedures are materially revised in any manner that affects the requirements of the Investigators;
2. an Investigator is newly appointed to the University; or
3. the University finds that an Investigator is not in compliance with this policy or their FCOI management plan.

"Immediately" shall mean the training is provided or made available and the Investigators participate in the training expeditiously following the event that triggers the training requirement. The OIE will be responsible for retaining records of FCOI training completed on behalf of the University.

Disclosure

The University will designate an Oversight Committee to determine if an SFI constitutes an FCOI and be responsible for management plans and review of FCOIs. Manchester University, via the OIE, will provide initial and ongoing FCOI reports to the PHS as required pursuant to [42 C.F.R. Part 50.605\(b\)](#).

The OIE will be responsible for collecting the initial disclosure of SFIs via the customary internal routing and approval process. The following procedures will be followed with respect to SFI disclosure:

1. The initial disclosure shall be provided prior to the submission of all proposals to any PHS component agency, including NIH. This initial disclosure will apply to the Investigator and any other personnel who would be responsible for the design, conduct, or reporting of research to be funded by the project, which may include, for example, consultants and unpaid collaborators. The PD/PI on the proposed project will be responsible for completing an SFI Disclosure form for themselves and then obtaining an SFI Disclosure Form from all participating Investigators.

2. The SFI Disclosure Form shall ask the Investigator to list all of the Investigator's SFIs (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appear to be related to the Investigators Institutional responsibilities (as defined above).
3. The SFI Disclosure Form must conform to the requirements of the FCOI Regulations ([42 C.F.R. Part 50.604](#)). The form must include, at a minimum, the name of the entity, the nature of the financial interest (e.g., equity, consulting fee), the monetary value of the financial interest or its approximate value if the interest is one whose value cannot readily be determined, and any supporting documentation determined by the OIE as needed to make a determination of whether an FCOI exists (such as a copy of the applicable consulting agreement or stock purchase agreement). For travel reimbursements, the disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the approximate monetary value. In addition, the Investigator must cooperate with all requests for additional information as needed. All such internal disclosures shall be treated as confidential personnel information with all necessary precautions to protect any sensitive proprietary company or sponsor information.
4. The Investigator shall review and update as appropriate the SFI Disclosure Form during the period of the award at least annually. Should an SFI be determined to also be an FCOI, the reporting and requisite FCOI management plan shall be required to be completed prior to the expenditure of any funds under a PHS grant, cooperative agreement, or contract. In addition, an updated SFI Disclosure Form must be submitted within 30 days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI. An Investigator who is new to participating in PHS or NSF-funded research projects, shall submit an SFI Disclosure Form at the time the Investigator is identified as a possible participant in the PHS-funded project, such that training can be completed and timely reporting of an FCOI (if any) can be made to the respective funding agency. The SFI Disclosure Form shall notify the Investigator of this requirement to provide updated disclosures.
5. When an Investigator who is new to a PHS-funded research project discloses an SFI or an existing Investigator discloses a new SFI, Manchester will within 60 days: review the disclosure; assess whether the SFI constitutes an FCOI with PHS-funded research; and if

so, implement, at least, on an interim basis, the actions that have been, and will be, taken to manage such FCOI.

6. Whenever the University identifies an SFI that was not disclosed timely by an Investigator, the University shall review within 60 days as described above. In addition, the University has 120 days following a determination of noncompliance (failure by the Institution to review or manage an untimely FCOI or failure by the Investigator to comply with an FCOI management plan) to complete a retrospective review of the Investigator's activities and PHS-funded research project. If bias is found during the course of this review, a mitigation report will also be required to be submitted. These reviews and reports will be made in accordance with the requirements of the FCOI Regulations ([42 C.F.R. Part 50, Subpart F](#)).

Management of FCOIs

The University shall confidentially review SFI Disclosure Forms from each Investigator to determine if the research is funded by PHS or a component agency such as NIH. The University will determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. An Investigator's SFI is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the SFI: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether an SFI is related to the PHS-funded research. An FCOI exists when the Institution, through its designated official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. In making the determination, The University can take into account financial interests in that same entity related to PHS, NSF or other federal funded research disclosed in an earlier disclosure by the Investigator. The OIE (the University's designated liaison to federal funding agencies with regard to research projects) may consult with appropriate governmental officials in making such deliberations.

Following initial review, all cases involving the disclosure of an SFI having a value greater than \$5,000 (measured by aggregating the various categories of interests reported) shall be consideration for expedited review or full review (depending upon the level of financial interests involved) in accordance with the Disclosure section of this policy. One of the following dispositions of the case will result: *Approval, Approval with Conditions or Restrictions,*

or *Prohibition*. All conflicts which are approved shall include a management plan which shall be implemented by an oversight committee designated by the University. The University will monitor compliance with management plans on an ongoing basis until the completion of the PHS-funded research project.

For all management plans, examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to: (1) public disclosure of SFIs; (2) for research projects involving human subjects, disclosure of FCOIs directly to participants; (3) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI; (4) modification of the research plan; (5) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all, or a portion of the research; (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (6) severance of relationships that create financial conflicts.

For all management plans, the University is required to monitor Investigator compliance with the management plan on an on-going basis until the completion of the PHS-funded research project.

Reporting

Prior to the expenditure of any funds under a PHS-funded research project, The University Oversight Committee shall: review all Investigator disclosures of SFIs; determine whether any SFIs relate to PHS-funded research; determine whether an FCOI exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOIs. If the University identifies an FCOI and eliminates it prior to the expenditure of any awarded funds, the University is not required to submit an FCOI report to the respective agency.

For any FCOI reported to the respective agency relating to an on-going PHS-funded research project, an annual report that conforms to the requirements of the applicable FCOI Regulations shall be made to the applicable funding agency by the PI for the duration of the research project in the time and manner specified by the applicable funding agency.

Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, Manchester University shall ensure public accessibility of information about the FCOI, via a written response to any requestor within 5 business days of a request, of information concerning an SFI which was disclosed and is still held by the senior/key personnel on the project, which is

determined to be related to the PHS-funded research, and which is determined to be an FCOI. The information shall consist of the information required to be provided under the FCOI Regulations ([42 C.F.R. Part 50, Subpart F](#)).

Subrecipient Requirements

If carrying out PHS-funded research through a subrecipient, Manchester University will incorporate as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of Manchester (the awardee Institution) or that of the subrecipient will apply to the subrecipient's Investigators.

If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with [42 C.F.R. Part 50, Subpart F](#). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the awardee Institution for disclosing SFIs that are directly related to the subrecipient's work for the awardee Institution;

Manchester will comply with all the provisions of [42 C.F.R. Part 50.604](#) regarding subrecipients including, providing FCOI reports to the appropriate PHS awarding agency regarding all FCOIs of all subrecipient Investigators, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

Remedies

If an Investigator fails to comply with this policy or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS-funded research, Manchester University shall promptly notify the agency of the corrective action taken or to be taken. Manchester University shall ensure compliance with the requirements for retrospective review and prepare a mitigation report, if needed, for submission to the applicable funding agency as required under the FCOI Regulations ([42 C.F.R. Part 50, Subpart F](#)). The agency may take its own action as it deems appropriate, which may include suspension of funding, or require the University to take further action to maintain the objectivity of the research.

Enforcement and Sanctions

All PHS-funded Manchester University Investigators and those applying for PHS funding are subject to this policy (except those applying to or funded by the Phase I Small Business Innovative Research or the Small Business Technology Transfer program) are expected to comply with it fully and promptly. Whenever an Investigator has violated either policy, for example by a failure to disclose an SFI, the University will take appropriate action.

Records

The University, through the OIE, will maintain all SFI Disclosure Forms and all related records of actions taken by the University with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS as governed by [42 C.F.R. Part 50 Subpart F](#). The OIE will maintain records of the initial disclosure of SFIs via the routing and approval form for submission of proposals. The OIE will also maintain records related to FCOI training. The OIE will retain records related to annual SFI disclosures and records related to SFIs determined to be FCOIs, subsequent management plans, and any other related materials connected to oversight of the management plan for at least three years from the date of submission of the final expenditures report or final payment.

Adapted from Bucknell University with appreciation.