

University of Manitoba Directive: Financial Conflicts of Interest (FCOI) in Public Health Service (PHS) Funded Research

PURPOSE

The University recognizes that the advancement and dissemination of knowledge that occurs through conducting research must remain free from bias that may result from Financial Conflicts of Interest.

This Directive sets out the requirements that PHS funded Investigators must follow when a Financial Conflict of Interest may be present. It sets out the University's processes for ensuring that research conducted at, or under the auspices of the University of Manitoba with funding from any US Public Health Service or US Department of Health and Human Services Awarding Component is free from bias related to Financial Conflicts of Interests.

BACKGROUND

The United States Public Health Services (PHS) requires that all awardee Institutions (including the University of Manitoba) and its researchers comply with the requirements of the US Federal PHS regulations on Financial Conflicts of Interest (FCOIs) as a condition of the award.

These regulations are available here ([PHS Code of Federal Regulations – Promoting Objectivity in Research](#)) ([42 CFR Part 50, Subpart F](#)) and ([45 C.F.R. Part 94](#)) (PHS Regulations).

The regulations explicitly require that the Institutions that receive an award have a written and enforced policy on FCOI for PHS funded research that complies with the PHS Regulations.

DIRECTIVE APPLICABILITY

This Directive will ONLY apply to those Investigators who apply for or choose to participate in research funded by US PHS sponsoring agencies or other agencies adopting the Regulations and only to their research activities that are funded by these agencies, including research through a grant or subaward agreement between the University and a PHS Awarding Component or with a PHS Awarded Institution.

This Directive is in addition to all other University Policies and requirements regarding conflicts of interest and the responsible conduct of research.

UNIVERSITY OF MANITOBA'S COMPLIANCE WITH THE PHS REGULATION

The Directive:

- 1) Describes the disclosure requirements regarding reporting of Significant Financial Interests (SFI) by PHS Investigators in compliance with the requirements of the US Federal Regulations,
- 2) Sets out the process by which a Designated Official confirms whether an SFI is connected to a PHS Investigator's Institutional Responsibilities and assesses whether it is a Financial Conflict of Interest (FCOI) for a PHS Awarding Component-funded project, and
- 3) Describes the University's responsibility for managing and reporting FCOIs to the PHS Awarding Component, for informing Investigators of the FCOI Directive, and for ensuring compliance with the PHS Regulations.

1. Definitions

- a) “Designated Institutional Official” or “DIO” means the person(s) designated by the University, through the Office of the Vice President (Research and International), to oversee the solicitation and review of significant financial interest disclosure statements as related to PHS pending applications and funded research.
- b) “Disclosure” means a PHS Investigator’s disclosure of SFI status to the University.
- c) “Financial Conflict of Interest” or “FCOI” means an SFI that could directly and significantly affect the design, conduct, or reporting of PHS funded research.
- d) “Financial Interest” means anything of monetary value, whether or not the value is readily ascertainable.
- e) “Institutional Responsibilities” means a PHS Investigator’s professional responsibilities on behalf of the University, the responsibilities of the PHS Investigator pursuant to the policies, procedures, and rules of the University, and (as applicable) any other responsibilities outlined in the PHS Investigator’s job description, employment agreement or appointment letter with the University. This may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as the Research Ethics Boards, Grant Application Review committees as well as presentations, conference panels and speaker engagements.
- f) “Manage” means to take action to address a 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.
- g) “PHS” means the Public Health Service of the U.S. Department of Health and Human Services, and any component of the PHS to which the authority involved may be delegated, including the National Institutes of Health.
- h) “PHS Awarding Component” means the organizational unit of the PHS that funds research that is subject to the PHS Regulations.
- i) “PHS Investigator” means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, reporting, review or oversight of PHS funded research, or proposed for such funding, which may also include, for example, collaborators and consultants. PHS Investigator also includes Senior/Key Personnel identified as essential to work performance of the study in the contract proposal and contract or deemed as such by the University in the grant application, progress report, or any other report submitted to the PHS by the University. For the purposes of this Directive, PHS Investigator includes the spouse and dependent children of the PHS Investigator.
- j) “PHS Regulations” means the US Regulations 42 C.F.R. Part 50 and 45 C.F.R. Part 94, as they may be amended from time to time.
- k) “Significant Financial Interest” or “SFI” means:
 - (i) A Financial Interest consisting of one or more of the following interests of the PHS Investigator (and those of the PHS Investigator’s spouse and dependent children) that reasonably appears to be related to the PHS Investigator’s Institutional Responsibilities:
 - With regard to any publicly traded entity, a Significant Financial Interest 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 USD \$5,000. 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.

- With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the Disclosure, when aggregated, exceeds USD \$5,000, or when the PHS Investigator (or the PHS Investigator's spouse or dependent children) holds an equity interest of any value (e.g., in stock, stock option, or other ownership interest).
- Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
- PHS Investigators must also disclose the occurrence of any reimbursed or sponsored travel. (i.e., that which is paid on behalf of the PHS Investigator and not reimbursed to the PHS Investigator so that the exact monetary value may not be readily available), that is related to the PHS Investigator's Institutional Responsibilities: provided, however, that this Disclosure requirement does not apply to travel that is reimbursed or sponsored by a US Federal, State or local government agency, a US institution of higher education, a US academic teaching hospital, a US medical center, or a US research institute that is affiliated with an US institution of higher education.
 - This Disclosure will include, at a minimum the purpose of the trip, the identity of the sponsor/organizer, destination the duration and the estimated or exact monetary value. The Designated Official(s) will determine if further information is needed, in order to determine whether the travel constitutes a FCOI with the PHS funded research.

(ii) "Significant Financial Interest" does not include the following types of Financial Interests:

- Salary, royalties, or other remuneration paid by the University to the PHS Investigator if the PHS Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights.
- 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 US Federal, State or local government agency, a US institution of higher education, a US academic teaching hospital, a US medical center, or a US research institute that is affiliated with a US institution of higher education.
- Income from service on advisory committees or review panels for a US Federal, State or local government agency, a US institution of higher education, a US academic teaching hospital, a US medical center, or a US research institute that is affiliated with a US institution of higher education.

- l) "PHS Funded Subrecipient" means a third-party organization (subcontractor or sub awardee) that receives funding from UM (as the prime awardee) to participate in any research funded by the Public Health Service. Monies and responsibilities are passed down to a PHS Funded Subrecipient through a subaward or subcontract that outlines the scope of work, budget and laws and regulations that the PHS Funded Subrecipient must adhere to.
- m) "PHS Funded Subrecipient Investigator" means an Investigator who is planning to participate in, or who is participating in any research funded by the Public Health Service through a subaward or subcontract between the University and a PHS Funded Subrecipient.

2. Significant Financial Interest Reporting by PHS Investigators

- a) All PHS Investigators must disclose in writing the Significant Financial Interest status of themselves, their spouse, and dependent children.
- b) PHS Investigators who are new to the University and are transferring PHS funding to the University must disclose their Significant Financial Interest status before funds can be dispersed.
- c) Initial disclosure must be made before each PHS funding application is submitted.
- d) The Disclosure must include all SFIs received in the 12 months preceding the application submission or declare that none have been received.
- e) A new Disclosure must be submitted within 30 days of discovering or acquiring a new SFI.
- f) A renewal SFI Disclosure must be submitted 12 months from the date of the last SFI Disclosure as long as any awarded or pending PHS applications are on file and must include updated information on any previously disclosed SFIs.
- g) All Disclosures must be submitted using the forms provided by the University.

3. Assessment and Record-Keeping by the Designated Institutional Official

- a) The DIO must review all SFI Disclosures to determine if any Disclosed SFIs relate to PHS funding and if any SFIs represent a FCOI.
- b) The Designated Official's determination that a Significant Financial Interest is a Financial Conflict of Interest is final.
- c) The review and determination will be conducted by the DIO prior to the University's expenditure of any funds under a PHS funded research project, and:
 - (i) Within 60 days of a new PHS Investigator disclosing an SFI.
 - (ii) Within 60 days of a PHS Investigator disclosing a new SFI previously undisclosed.
 - (iii) Within 60 days of the University identifying a SFI that was not disclosed in a timely manner by a PHS Investigator or that was not previously reviewed by the University during an ongoing PHS funded research project.
- d) The DIO, on behalf of the University, must maintain records relating to all PHS Investigator Disclosures of SFIs and the University's review of, and response to, such Disclosures (whether or not a disclosure results in the determination of a FCOI) and all actions under this Directive for at least three (3) years from the date the final expenditures report is submitted to the PHS awarding component, the date of final payment or, where applicable, for other time periods specified.

4. Management and Reporting of FCOI

- a) If the Designated Official determines through his or her review that there is a FCOI, they must prepare a FCOI management plan. The Plan must include elements, conditions, or restrictions to ensure that the FCOI is properly Managed.
- b) Key elements of the management plan include:
 - (i) Role and principal duties of the conflicted PHS Investigator in the research project.
 - (ii) Conditions of the management plan.
 - (iii) How the management plan is designed to safeguard objectivity in the research project.
 - (iv) Confirmation of the PHS Investigator's agreement to the management plan.
 - (v) How the management plan will be monitored to ensure PHS Investigator compliance. The Designated Institutional Official may include additional elements in any management plan that ensure the FCOI is properly Managed.

- c) Conditions or restrictions imposed to Manage a FCOI may include:
- (i) Public disclosure of the FCOI (e.g., when presenting or publishing research).
 - (ii) For research projects involving humans, disclosure of the FCOI directly to the participants.
 - (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from a FCOI.
 - (iv) Modification of the research plan.
 - (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
 - (vi) Reduction or elimination of the Financial Interest (e.g., sale of an equity interest).
 - (vii) Severance of relationships that create Financial Conflicts of Interest.
- d) The PHS Investigator is required to comply with the management plan prescribed by the DIO.
- e) On behalf of the University, the DIO must monitor compliance with the management plan on an ongoing basis until the completion of the project.
- f) Reporting requirements to the PHS Awarding Component
- (i) The University, through the DIO, must provide initial and ongoing FCOI reports to PHS after the award is granted but prior to the University's expenditure of any funds under a PHS funded research project and at least annually, thereafter, in accordance with the PHS Regulations.
 - (ii) All reports must be submitted in the time and manner specified by PHS for the duration of the project period (including extensions with or without funds). In the case of the National Institute of Health, such annual reports must be submitted at the same time as when the grantee is required to submit the National Institute of Health annual progress report, or multi-year progress report or at the time of extension.
 - (iii) For any FCOI previously reported by the University, the report must address the status of the FCOI and any changes to the management plan for the duration of the PHS funded research project. The annual FCOI report must specify whether the financial conflict is still being Managed or explain why the FCOI no longer exists.
 - (iv) PHS Subrecipients: The University must provide FCOI reports to the PHS awarding component regarding all FCOIs of all PHS Subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
 - (v) FCOI reports by the University must include sufficient information to enable PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of the University's management plan. Each FCOI report must contain:
 - Grant number.
 - Name of the UM PHS Investigator who has the FCOI.
 - Name of the Prime Awardee Institution and PI (if other than the above).
 - Name of the UM Principal PHS Investigator (if other than the above).
 - Name of the entity with which the PHS Investigator has a FCOI.
 - Nature of the FCOI (e.g. equity, consulting fees, travel reimbursement, honoraria).
 - Value (or estimated value) of the Financial Interest/s per year recorded as:
 - \$0 - \$4,999
 - \$5,000 - \$9,999
 - \$10,000 - \$19,999
 - Amounts between \$20,000 - \$100,000 in increments of \$20,000.
 - Amounts above \$100,000 in increments of \$50,000; or a statement that a value cannot be readily determined.

- A description of how the Financial Interest relates to the PHS funded research and the basis for the University's determination that the Financial Interest conflicts with such research.
- Key elements of the FCOI management plan.

5. Other University and PHS Investigator Responsibilities: Training, Subcontracting and Public Accessibility of Information

5.1 Education

- a) The University is required to provide training that covers its Institutional requirements for SFI disclosure and the requirements of the Directive and to track and monitor completion of the University training module and the NIH Tutorial.
- b) NIH training and Tutorial modules are available to PHS Investigators via the FCOI webpage at: <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>.
- c) Each PHS Investigator must complete both training modules as follows:
 - (i) When a PHS Investigator joins the University.
 - (ii) Prior to engaging in PHS-funded research whether or not they are remunerated by the grant.
 - (iii) At least every four years, and
 - Immediately after this Directive is substantively amended or replaced; or
 - If the University finds that a PHS Investigator is not in compliance with this Directive or their management plan.

5.2 Subcontracting

If the University proposes to carry out the PHS funded research through a PHS Subrecipient, the University through the Office of the Vice President (Research & International) must take reasonable steps to ensure that:

- (i) The written agreement with the PHS Subrecipient establishes whether this Directive or the Subrecipient's FCOI policy will apply to the Subrecipient Investigators.
- (ii) If the PHS Subrecipient Investigators must comply with the PHS Subrecipient's FCOI policy, the University shall obtain from the Subrecipient a certification that its policy complies with the PHS Regulations. If the PHS Subrecipient Investigators must comply with the PHS Subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the PHS Subrecipient to report all identified financial conflicts of interest to the University. Such time periods shall be prior to the expenditure of funds under the sub-award agreement and not greater than 45 days after a subsequently identified conflict of interest has been disclosed to the PHS Subrecipient Institution.
- (iii) If the PHS Subrecipient Investigators must comply with this Directive, the University, through the Office of the Vice President (Research & International) must obtain a written agreement specifying that the PHS Subrecipient Investigators must comply with this Directive, and the time periods for each PHS Subrecipient to submit all PHS Subrecipient Investigator Disclosures of Significant Financial Interests to the University. Such time periods shall be sufficient to enable the University, through the DIO to complete in a timely fashion its review, management and reporting obligations under this Directive. Such time periods shall be at the time of application for funding, prior to the expenditure of funds, not greater than 30 days after a subsequently identified conflict of interest has arisen and at least annually in accordance with the requirements of the PHS awarding component.

5.3 Public Accessibility of Information

The University, through Office of the Vice President (Research & International), shall maintain an up-to-date version of this Directive on its publicly accessible website.

- (i) At all times after an award has been granted, the University, through the Office of the Vice President (Research & International) shall make available, by written response within 5 business days of receipt of a request, the information listed below concerning any SFI that meets the following criteria:
 - SFI was disclosed and is still held by the PHS Investigator for the PHS funded research project.
 - The University through the DIO determines that the SFI is related to PHS funded research.
 - The University, through the DIO determines that the SFI is a FCOI.
- (ii) The University's written response to a request must include the following minimum information:
 - The PHS Investigator's name.
 - The PHS Investigator's position with respect to the research project.
 - Value (or estimated value) of the Financial Interest/s per year recorded as:
 - \$0-\$4,999
 - \$5,000-\$9,999
 - \$10,000-\$19,999
 - Amounts between \$20,000-\$100,000 in increments of \$20,000.
 - Amounts above \$100,000 in increments of \$50,000; or
 - A statement that a value cannot be readily determined.
 - The entity with which the PHS Investigator has a FCOI.
- (iii) The written response from the DIO shall note that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.
- (iv) The above-noted information, as updated, shall remain available for responses to written requests via Office of the Vice President (Research & International) for at least three (3) years from the date that the information was most recently updated.

6. Non-Compliance

- a) If by failing to comply with this Directive or with a Management Plan, a PHS Investigator appears to have biased the design, conduct or reporting of any PHS funded research, the University, through the DIO, shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.
- b) In the event of non-compliance with this Directive, the University may initiate actions under applicable collective and other agreements or University policy.
- c) Retrospective Review and Mitigation: Whenever the University identifies a SFI that was not disclosed in a timely fashion by a PHS Investigator or, for whatever reason, was not previously reviewed during an ongoing PHS funded project (including but not limited to when the SFI was not reviewed in a timely fashion or reported by a PHS Subrecipient):

Step 1: The DIO shall, within 60 days, determine whether the Disclosures relate to PHS funding and whether the SFI is a FCOI.

- (i) The Disclosures relate to the PHS funding when the DIO reasonably determines that the SFI could be affected by the PHS funded research or when the SFI is an entity whose financial interest could be affected by the research.
- (ii) The DIO may involve the PHS Investigator in the determination of whether a SFI is related to the PHS funded research.
- (iii) The DIO's determination that a Significant Financial Interest is a Financial Conflict of Interest is final.

Step 2: If the DIO determines that a FCOI exists, they must implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to Manage the FCOI going forward.

Step 3: Within 120 days of the University's determination of noncompliance, the University shall complete a retrospective review of the PHS Investigator's activities and the PHS funded project to determine whether any PHS funded research, or portions thereof, conducted during the period of noncompliance, was biased in the design, conduct, or reporting of such research.

Step 4: The University will document the retrospective review; including at minimum:

- Project number.
- Project title.
- PHS Principal Investigator.
- Name of the PHS Investigator with the FCOI.
- Name of the entity with which the PHS Investigator has a FCOI.
- Reason(s) for the retrospective review.
- Detailed methodology used for the retrospective review (e.g., process used, composition of the review panel, documents reviewed).
- Findings of the review.
- Conclusions of the review.

Step 5: Based on the results of the retrospective review, if appropriate, the DIO will:

- Update the previously submitted FCOI report, specifying the actions that will be taken to Manage the FCOI going forward.
- If bias is found, notify the PHS awarding component promptly and submit a mitigation report to PHS.
- The mitigation report must include the elements cited in Step 4; must describe the impact of the bias on the project; and the University's plan to eliminate or mitigate the effect of the bias.
- The University's plan will include, at minimum: impact on the project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; and analysis of whether the project is salvageable.

The University will, thereafter, submit FCOI reports annually as specified in Section 5 of this Directive.

- d) In any case in which the PHS determines that a PHS funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a PHS Investigator with a FCOI that was not Managed or reported by the University as required by the PHS Regulations, the PHS Investigator is not only required to disclose the FCOI in each public presentation of the results of the research, but to publish an addendum to any previously published presentations.
- e) Pursuant to the US Regulations, on the basis of its review of records or other information that may be available, the PHS may decide that a particular FCOI will bias the objectivity of the PHS-funded project to such an extent that further corrective action is needed or that the University has not Managed the FCOI in accordance with this Directive, and may determine that issuance of a Stop Work Order by the contracting officer or other enforcement action is necessary until the matter is resolved. Upon receipt of a Stop Work Order, the recipient of such order must notify the Office of the Vice President (Research & International) and the DIO, who will forward such order to the PHS Investigator and, if applicable the PHS Subrecipient(s). The University, the PHS Investigator and the PHS Subrecipient must comply with the terms of the Stop Work Order.