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Parent Policy: [Conflict Policy – Conflict of Interest and Commitment and Institutional Conflict](#)

Financial Conflict of Interest for National Institutes of Health (NIH) and Other Applicable Research Funding Sources Reporting and Assessment Procedure

Office of Administrative Responsibility:	Quality Management in Clinical Research, Disclosure, Assurance and Institutional Research
Approver:	Provost and Vice-President (Academic), Vice-President (Research) and Vice-President (Finance and Administration)
Scope:	Compliance with this University of Alberta procedure extends to all members of the University of Alberta community who are applying for, receiving funding from, or participating in a research project funded by the NIH .

Overview

In addition to compliance with the University of Alberta's [Conflict Policy – Conflict of Interest and Commitment and Institutional Conflict](#) and the other accompanying procedures, all University of Alberta staff, acting as **Investigators**, who are applying for and/or receiving NIH funding or who are participating in a NIH funded research project, either as an **awardee** or **sub-recipient**, must comply with this procedure.

Purpose

- To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator **financial conflict of interest (FCOI)** in order to comply with **NIH Regulation**.
- To clarify reporting requirements regarding training and reporting of **significant financial interests (SFI)** by University of Alberta personnel;
- To outline the process by which the **designated official** confirms whether any disclosed financial interest reasonably appears associated with an Investigator's **institutional responsibilities**, is therefore an SFI, and if so, determines whether it is related to the NIH funded research and assesses whether it is a FCOI for the NIH funded project; and
- To outline the responsibilities of the designated official and the University of Alberta in managing and reporting FCOIs to NIH and/or via an awardee institution.

PROCEDURE

Summary

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1. TRAINING OF AND REPORTING BY INVESTIGATORS

1.1. Who must undergo training:

- a. All Investigators must be trained by the University of Alberta and must demonstrate competency in the training material pertaining to the NIH Regulation and this Procedure at the following times:
 - i. at the time of first application for NIH funding or first participation in NIH funded research where the University of Alberta is the awardee or sub-recipient;
 - ii. at least every four years;
 - iii. immediately when any of the following circumstances apply:
 - this procedure is revised in a manner that affects the requirements of Investigators
 - an Investigator is new to the University of Alberta and is receiving NIH funds, unless the Investigator has demonstrated valid training from a previous institution
 - where the University of Alberta finds that an Investigator is not in compliance with this procedure or a specific **management plan**

1.2. Who must **disclose**:

All Investigators, trained pursuant to 1.1, must complete and submit a **Disclosure and Consent Report** for each NIH funded project at the following times:

- a. Initial disclosure must:
 - i. be made at the time of application for NIH funding or participation in NIH funded research;
 - ii. include all SFIs in the 12 months preceding the disclosure; and
- b. Subsequent disclosure must occur:
 - i. within 30 days of discovering or acquiring (including but not limited to a purchase, marriage/partnership agreement, inheritance, etc.) a new SFI, and
 - ii. on an annual basis during the term of the NIH funded research, disclosing:
 - all SFIs received in the 12 months preceding the disclosure that were not previously reported; and
 - updated information regarding any previously disclosed SFI.
- c. New arrivals to the University of Alberta:

All Investigators who are new to the University of Alberta and are receiving NIH funding or who are participating in a NIH funded research project where the University of Alberta is the awardee or sub-recipient, must demonstrate valid training and make the initial disclosure and ongoing disclosures as noted in 1.2.a and 1.2.b above.

1.3. Steps to Disclose to the University of Alberta

Trained Investigators must:

- a. complete Disclosure and Consent Reports for themselves, and on behalf of their spouse/adult interdependent partner and their dependent children;
- b. complete Disclosure and Consent Reports for each NIH application or NIH funded project; and
- c. provide information regarding third party entity(ies) or individual(s) named in any disclosed SFI(s), if required by the designated official. Third parties may be informed that their information may be disclosed to the NIH, or in case of FCOI, to the public. Obtaining consent from applicable third party will be done via the Informed Consent from Third Party form, held by the designated official.

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2. ASSESSMENT BY DESIGNATED OFFICIAL

- a. The designated official must review all Disclosure and Consent Reports from Investigators (regardless of the presence or number of SFIs) and determine whether:
 - i. Any disclosed SFI is related to the NIH project;
 - The Investigator's SFI is related to NIH research when the designated official reasonably determines that the SFI could be affected by the NIH funded research; or is an entity whose financial interest

could be affected by the research. The designated official may involve the Investigator in the designated official's determination of whether a SFI is related to the NIH funded project.

- ii. Any SFI is a FCOI.
 - a FCOI exists when the University of Alberta, through its designated official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NIH funded research.
- b. The review and determination noted in 2a must be conducted by the designated official at the following times:
 - i. prior to the University of Alberta's release of any funds under a NIH funded research project;
 - ii. within 60 days whenever, in the course of an ongoing NIH funded project, an Investigator who is new to participating in the project discloses a SFI or an existing Investigator discloses a new SFI to the University of Alberta; and
 - iii. within 60 days whenever the University of Alberta identifies a SFI that:
 - was not disclosed in a timely manner by an Investigator; or
 - for whatever reason, was not previously reviewed by the University of Alberta during an ongoing NIH funded research project.
- c. The designated official, on behalf of the University of Alberta, will maintain records relating to all Investigator disclosures of SFIs and the University of Alberta's review of, and response to, such disclosures (whether or not a disclosure resulted in the University of Alberta's determination of a FCOI) and all actions under the University of Alberta's policy or retrospective review related to the SFI and/or FCOI, according to the *Research Records Stewardship Guidance Procedure* as well as the NIH Regulation.
- d. The University of Alberta is required to submit to NIH, or permit NIH on site to review, all records pertinent to compliance with this procedure.
- e. The review and determination noted in 2a may be guided by the **NIH Conflict Review Committee**.
- f. Investigators have the ability to challenge the decisions made by the designated official. To review rulings, the **NIH FCOI Appeal Review Committee** will convene on a case-by-case basis.

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3. MANAGEMENT AND REPORTING OF FCOI

- a. If it is determined that there is a FCOI, the designated official must prepare a management plan.
- b. The Investigator is required to comply with the management plan prescribed by the designated official.
- c. On behalf of the University of Alberta, the designated official will monitor compliance with the management plan until the completion of the project or the FCOI no longer exists.
- d. The University of Alberta, through its designated official, must provide initial and ongoing FCOI reports to NIH. As outlined in the NIH Regulation, FCOI reports must include sufficient information to enable NIH to understand the nature and extent of the financial conflict and to assess the appropriateness of the University of Alberta's management plan.

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4. SUBCONTRACT AND PUBLIC ACCESSIBILITY OF INFORMATION

- a. Sub-recipient (another institution is awardee/prime institution):

If an Investigator at the University of Alberta carries out NIH-funded research as a sub-recipient, the University of Alberta must take reasonable steps to ensure that any sub-recipient Investigator complies with this Procedure.

- i. The sub-recipient must complete training, comply with this Procedure and submit disclosures to the University of Alberta's designated official.
- ii. The University of Alberta will certify that its policy complies with the 2011 NIH FCOI Regulations, specifically 42 CFR Part 50 Subpart F or 45 CFR Part 94, upon the sub-recipient Investigator achieving compliance with this Procedure. Depending on the awardee institution, sub-recipients may have to complete other training and/or additional disclosure forms pertinent to the awardee institution's policies.

b. External subcontractors (University of Alberta is awardee/prime institution)

If the prime Investigator at the University of Alberta carries out the NIH-funded research via an external subcontractor at another institution, the University of Alberta must take reasonable steps to ensure that any external subcontracted investigators comply with this Procedure:

- i. The University of Alberta will incorporate, as part of a written agreement with the external subcontracted investigator, terms that establish whether this Procedure or the external subcontracted institution's policy will apply to the external subcontracted investigators.
- ii. If the external subcontracted Investigator must comply with their institutional financial conflicts of interest policy, the University of Alberta shall obtain from the sub-recipient, as part of the written agreement referenced above, certification that the external subcontractor's institutional policy complies with the NIH regulations, specifically 42 CFR Part 50 Subpart F or 45 CFR Part 94. The agreement shall also specify FCOI reporting time periods for the external subcontractor. Such time periods shall be sufficient to enable the University of Alberta to provide timely FCOI reports to NIH.
- iii. If the external subcontracted Investigators must comply with this Procedure, the University of Alberta must obtain a written agreement specifying time periods for the external subcontractor to submit all Investigator disclosures of SFIs to the University of Alberta. Such time periods shall be sufficient to enable the University of Alberta to comply in a timely fashion with its review, management and reporting obligations under this Procedure.

c. Public Accessibility of Information

- i. The University of Alberta shall maintain an up-to-date, written and enforced policy (and associated procedures) on FCOIs, that complies with the NIH regulations and make such policy available via a publicly accessible website.
- ii. After an award has been granted, the University of Alberta shall record information concerning any SFI that meets all of the following criteria:
 - a disclosed SFI, which is held by an Investigator, identified by the University of Alberta as senior/key personnel for the NIH funded research project in the grant application, contract proposal, contract, progress report, or other required report submitted to the NIH;
 - any SFI related to the NIH funded research determined by the designated official; and
 - any FCOI determined by the designated official.
- iii. This recorded information shall be comprised of the relevant project, Investigator and SFI details and shall remain available to written requests for at least 3 years from the date that the information was most recently updated. Information will only be supplied for those Investigators who meet all criteria listed above in 4cii.

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5. NON-COMPLIANCE CONSTITUTES MISCONDUCT

- a. In the event of non-compliance, the University of Alberta may initiate actions under applicable collective, other agreements or University of Alberta policies. The designated official retains the ability to advise the Research Services Office of non-compliance.
- b. When the University of Alberta identifies any SFI that was not disclosed in a timely fashion by an Investigator or, for whatever reason, was not previously reviewed by the institution during an ongoing NIH funded project (including but not limited to when the SFI was not reviewed in a timely fashion or reported by an external subcontractor), the designated official will determine within 60 days if any SFI meets the criteria for a FCOI and if so, follow the dictated procedure herein for FCOI management. Within 120 days, the designated official must create a retrospective review of the Investigator's activities with respect to the NIH funded research and submit a mitigation report to NIH.
- c. In any case in which NIH determines that a clinical research NIH funded project, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by the University of Alberta as required by the regulations, the University of Alberta requires the Investigator involved to disclose the FCOI in each public presentation which involves the results of the NIH funded research, and also to request an addendum to previously published presentations including details of the FCOI.
- d. On the basis of its review of records or other information that may be available, NIH may decide that a particular FCOI will bias the objectivity of the NIH funded project to such an extent that further corrective action is needed or that the University of Alberta has not managed the FCOI in accordance with this Procedure, the designated official may request the Investigator cease spending the NIH funds until the matter is resolved.

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DEFINITIONS

Any definitions listed in the following table apply to this document only with no implied or intended institution-wide use. [▲ Top](#)

NIH	<p>National Institutes of Health (NIH) and other US Public Health Service (PHS) funding sources, within the Department of Health and Human Services (HHS), and any other research funding source which has adopted the HHS Final Rule at 42 CFR Part 50 Subpart F and 45 CFR Part 94, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors," respectively. Other funding sources which have adopted the aforementioned HHS Final Rule include those listed by the US Federal Demonstration Partnership. Reporting requirements under the Final Rule are administered by the NIH.</p>
Investigator	<p>The project director, principal investigator and/or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by NIH or proposed for such funding, which may include, for example, collaborators or consultants. Investigator also includes senior/key personnel identified as such by the University of Alberta in the grant application, progress report, or any other report submitted to NIH by the University of Alberta under this Procedure. Where the University of Alberta is the awardee, an Investigator may also include personnel from a sub-recipient institution which is relying on this Procedure.</p>
Awardee	<p>An institution that receives funding directly from a NIH funding source.</p>
Sub-recipient	<p>An Investigator from the University of Alberta, who is the recipient of NIH funding via a subgrant from an awardee institution.</p>
Financial Conflict of Interest (FCOI)	<p>A Significant Financial Interest (SFI), defined below, that could directly and significantly affect the design, conduct, or reporting of NIH funded research.</p>
NIH Regulation	<p>The US Federal Department of Health and Human Safety Final Rule found at 42 CFR Part 50, Subpart F and 45 CFR Part 94, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors.</p>
Significant Financial Interest (SFI)	<p>(1) A financial interest (anything of monetary value, whether or not the value is readily ascertainable) consisting of one or more of the following interests of the Investigator (and those of the Investigator's partner and dependents) that reasonably appears to be related to the Investigator's institutional responsibilities:</p> <ul style="list-style-type: none"> i. With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 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 CAD. 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, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000 CAD, or when the investigator (or the Investigator's partner or dependents) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- iii. Intellectual property rights and interests (e.g., patents regardless of filing status, copyrights), upon receipt of income regarding those rights and interests in excess of \$5,000 CAD per year per entity (payor).

(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 when the annual aggregated amount paid to the specific Investigator, exceeds \$5,000 CAD per entity. This disclosure also applies to partner and dependents. This disclosure will include, at a minimum:

- i. the purpose of the trip,
- ii. the identity of the sponsor/organizer,
- iii. the destination, and
- iv. the duration.

The designated official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI related to the NIH funded research.

(3) If an Investigator receives more than \$5,000 CAD per year from one entity in total payments for multiple SFIs (as defined in (1) and (2) above), then the details of each such SFI must be disclosed.

(4) Exclusions: The term SFI does not include the following types of financial interests:

- i. salary, royalties, or other remuneration paid by the University of Alberta to the Investigator if the 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;
- ii. income from investment vehicles, such as mutual funds and retirement accounts, as long as an Investigator does not directly control the investment decisions made in these vehicles;
- iii. income from seminars, lectures, or teaching engagements sponsored by an US federal, state, or local government agency, an US institution of higher education, an US academic teaching hospital, an US medical center, or an US research institute that is affiliated with an US institution of higher education; similar income from non-US equivalents of these entities where the annual aggregated amount paid to an Investigator does not exceed \$5,000 CAD per entity; or
- iv. income from service on advisory committees or review panels for an US federal, state, or local government agency, an US institution of higher education, an US academic teaching hospital, an US medical center, or an US research institute that is affiliated with an US institution of higher education; similar income from non-US

	<p>equivalents of these entities where the annual aggregated amount paid to an Investigator does not exceed \$5,000 CAD per entity.</p> <p>(5) In the event that an Investigator has no SFIs to disclose, the disclosure must still be completed, following the timelines above.</p>
Designated Official	The individual appointed to this position by the University of Alberta. (nih@ualberta.ca)
Institutional Responsibilities	<p>An Investigator's institutional responsibilities includes:</p> <ul style="list-style-type: none"> i. participation in teaching programs, including classroom teaching, supervision of graduate students and personal interactions with and advising students; ii. participation in research (defined as including the preparation or performance of creative works and reflective inquiry) and the dissemination of the results of research by means appropriate to the discipline; iii. provision of service to the discipline of the staff member; participation in the governance of the University of Alberta, the Faculty and the Department; and dissemination of knowledge to the general public by making available the staff member's expertise and knowledge of the discipline all of which shall be carried out according to the standards of professional conduct expected of a staff member; iv. clinical service, if identified in the staff member's job description; and v. any other responsibility outlined in the staff member's job description, employment agreement or appointment letter with the University of Alberta, or as identified in the University of Alberta's Calendar as a responsibility of a student to the University of Alberta (as applicable).
Management Plan	A written plan to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias, when a FCOI is determined. The designated official in consultation with the Investigator creates the management plan. The Investigator is required to comply with the management plan prescribed by the designated official, and the designated official will monitor compliance with the plan until the completion of the project as well as provide initial and ongoing FCOI reports to the NIH.
Disclose	An Investigator's submission of a completed Disclosure and Consent Report, defined herein, to the University of Alberta.
Disclosure and Consent Report	A tool for Investigators to disclose the absence or presence of SFIs and to consent to the release of their information according to this Procedure, provincial laws and the NIH Regulation. This reporting tool can be accessed on the University of Alberta website using the Investigator's CCID.
NIH Conflict Review Committee	This committee is assembled on a case-by-case basis for complex and unique SFI and FCOI decisions, identified by the designated official. It will be a five-member committee chaired by the designated official.
NIH FCOI Appeal Review Committee	This committee is assembled on a case-by-case basis when an Investigator challenges decisions made by the designated official. The Associate Vice-President (AVP) of Disclosure, Assurance and Information Research (DAIR; or equivalent position) will convene the committee with independent assessors. The chair of the committee will be named by the AVP of DAIR or equivalent position. In order to call this committee to assembly, contact the University of Alberta's Disclosure Services (osdhr@ualberta.ca)

FORMS

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[Online Disclosure and Consent Reporting tool](#)

RELATED LINKS

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[Department of Health and Human Services: 42 CFR Part 50 and 45 CFR Part 94](#) (United States Government)

[United States Federal Demonstration Partnership](#) (United States Government)

[Research and Scholarship Integrity Policy](#) (UAPPOL)

[Research and Scholarship Integrity Enforcement Procedure](#) (UAPPOL)

[Research Records Stewardship Guidance Procedure](#) (UAPPOL)