

Financial Conflicts of Interest

Conflicts of interest in research may occur when outside financial interests compromise, or have the appearance of compromising, the professional judgment of a researcher when designing, conducting, or reporting research.

Western University of Health Sciences' (WesternU) Sponsored Project Financial Conflict of Interest Disclosure policy seeks to maintain the appropriate balance among all competing interests that have the potential to produce bias in the design, conduct or reporting of research or distort technology transfer transactions.

In 2011, the Public Health Service (PHS) released revised financial conflict of interest (FCOI) regulations (42 CFR 50) that apply to any institution receiving funds from a PHS entity. Such institutions must revise their institutional FCOI policy to be in full compliance with all of the regulations. WesternU's FCOI policy complies with this new regulation.

The purpose of this FCOI website is to provide:

1. an effective, one-stop-shop for WesternU researchers to get up-to-date and adequate information on the new requirements.
2. a high-visibility location to display WesternU's FCOI policy in compliance with regulatory requirements.
3. links to the mandatory training, full policy documentation and essential details on processes that investigators must follow to meet these new requirements.

Policy Change

WesternU's revised FCOI policy and its implementation plan will reflect the following federally required changes:

Lower monetary threshold: The minimum threshold for reporting a significant financial interest (SFI) will be lowered from \$10,000 to \$5,000, with a \$0 threshold for disclosure of equity in a non-publicly traded company.

MANDATORY TRAINING REQUIREMENTS: All externally-funded investigators must complete FCOI training on the regulation, the Institution's policy and the Investigator's responsibilities to disclose significant financial interests (SFIs) "prior to engaging in research related to any NIH-funded grant or cooperative agreement". This applies to any newly-funded projects, including noncompeting continuation awards. As defined by 42 CFR 50, "Investigator means the Project Director or Principal Investigator (PD/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 collaborators or consultants". To meet this requirement:

ALL INVESTIGATORS MUST SUCCESSFULLY COMPLETE WESTERN U'S ON-LINE FCOI TRAINING COURSE LOCATED IN THE FACULTY AND STAFF TRAINING CENTER ON BLACKBOARD (<https://bb.westernu.edu/webapps/login/>). ONCE IN BLACKBOARD, YOU WILL NEED A USER NAME AND PASSWORD TO ENTER THE SITE. AFTER YOU ARE IN, CLICK ON FACULTY AND STAFF TRAINING CENTER FROM THE LIST OF COURSES ON THE RIGHT HAND SIDE OF THE SCREEN. AFTER

ACCESSING THE TRAINING CENTER, CLICK ON CONFLICTS OF INTEREST ON THE LEFT OF THE SCREEN. IF YOU NEED ASSISTANCE, CONTACT TECH SUPPORT AT 469-5432.

Training completions will be recorded automatically and the records will be made available to the Office for Sponsored Research and Contract Management for verification of investigator compliance with the mandatory training requirement.

Disclosure of all externally-funded travel reimbursements: Externally-funded investigators must disclose *all* travel reimbursements that are either sponsored by (paid directly to the investigator) or reimbursed directly to the investigator from an outside entity, with some exceptions. Exceptions include: travel reimbursements from an institution of higher education, a federal/state/local government, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education. This disclosure requirement does *not* apply to funding provided to the investigator by the Institution, for example as part of sponsored research projects paid from departmental discretionary or gift funds.

FCOI information made accessible to the public: The new regulations require that the Institution's FCOI policy and information concerning identified FCOIs held by PD/PIs or Senior/Key Personnel, and their FCOI management plans, be made publicly available via a publicly accessible Web site or make the written policy and information available to any requestor within five business days of a request prior to the expenditure of funds. WesternU has opted to publicly post the required information on this website.

Resources

- [2011 Public Health Service \(PHS\) Regulations](#)
- [National Institute of Health Financial Conflict of Interest FAQ](#)

Resources currently in development

- The Office of Research and Biotechnology is developing an **electronic disclosure process** that will replace the current paper-based procedure, and will reduce the administrative burden for faculty disclosing FCOIs related to research projects.
- FCOI FAQs

WESTERN UNIVERSITY OF HEALTH SCIENCES POLICIES AND PROCEDURES ON FINANCIAL CONFLICTS OF INTEREST

It is the intent of WesternU to be in full compliance with all Public Health Service regulations (42 CFR 50) pertaining to financial conflicts of interest (FCOI).

All WESTERNU INVESTIGATORS must complete the [Conflict of Interest Disclosure Form](#) (click to go to form) on a regular basis as required. This form may be obtained by contacting Ms. Susan Dominguez (sdominguez@westernu.edu) in the Office of Research and Biotechnology, 909-469-5619.

Disclosure

The evaluation of potential conflicts that are related to sponsored projects shall be conducted as part of the normal proposal transmittal process for external funding requests. Any WesternU employee submitting a proposal for external funding and naming the University as the fiduciary agent is required and expected to promptly report, with sufficient and appropriate detail, all required significant financial interests (SFIs) at the time the proposal is submitted to the Office for Sponsored Research and Contract Management. Any SFI must be disclosed and resolved by the Institution PRIOR to submission of the proposal to the Office for Sponsored Research and Contract Management or to the sponsoring agency. Thus, the Investigator must anticipate that additional time may be required to resolve any actual or potential SFIs prior to submission to any such submission.

During the period of an award, the principal investigator (PI) must update all SFIs annually or within 30 days of the acquisition or discovery of new SFIs. *Note that SFIs of the Investigator, the Investigator's spouse and dependent children that reasonably appear to be related to the Investigator's institutional responsibilities must be reported. Moreover, under 42 CFR 50, "Investigator" also refers to sub grantees, contractors, consortium participants, collaborators or consultants. Actual or potential SFIs are to be reported by the Investigator on the [Conflict of Interest Disclosure Form](#) (click to go to form).

Review

An actual or potential SFI exists when the **Initial Review Authority**, in consultation with the PI, reasonably determines that such an SFI could affect the design, conduct or reporting of the research or educational activities or distort technology transfer transactions funded or proposed for funding by the sponsoring agency. The **Initial Review Authority** shall be the Assistant Vice President of the Office for Sponsored Research and Contract Management or such other person as WesternU policy requires.

In instances wherein an actual or potential SFI is found, another review shall be performed by an **SFI Review Committee** consisting, at a minimum, of the following persons:

1. Assistant Vice President of the Office for Sponsored Research and Contract Management
2. Manager, Office of Research Regulatory Affairs
3. Manager, Technology Transfer and Intellectual Property Services
4. Faculty member appointed by the Faculty Senate
5. Faculty member appointed by the Vice President for Research and Biotechnology

Consultants or other persons from either within or outside the University whose input is deemed important to the review process may be invited by the Vice President for Research and Biotechnology to participate in the review process. The SFI Review Committee has the duty and responsibility to evaluate with care all potential and actual SFIs reported or known to them prior to taking any action.

Resolution

The SFI Review Committee, in consultation with the Investigator, must develop and execute an SFI **management plan**. In managing or resolving an actual or potential SFI, the SFI

Review Committee may choose to prohibit involvement in the proposed project or attach conditions that will provide management of the potential conflict or oversight of the project.

Examples of conditions or restrictions that may be imposed to manage, reduce or eliminate actual or potential SFIs include, but are not limited to:

- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification from participation in the portion of agency-funded research that would be affected by the SFI;
- divestiture of SFIs;
- severance of relationships that create actual or potential conflicts.

If the SFI Review Committee determines that imposing conditions or restrictions would be either ineffective or inequitable and that the potential negative impacts that may arise from an SFI are outweighed by interests of scientific progress, technology transfer or the public health and welfare, then the research may be allowed to proceed without imposing such conditions or restrictions.

If restrictions or conditions are imposed on a sponsored grant or contract and if there is an inability to satisfactorily manage an actual or potential SFI, then WesternU shall so inform the sponsoring agency. Appeal of any actions taken by the Initial Review Authority or the SFI Review Committee may be pursued through the regular grievance procedure contained in the current Faculty Handbook.

Resolutions for actual or potential SFIs must be put into a memorandum-of-understanding that is executed between the Investigator and WesternU.

Sanctions

Violations of this policy shall be considered a violation of WesternU policy and regulations and shall be subject to disciplinary procedures, including sanctions up to and including suspension and dismissal as provided for in other WesternU policies and procedures.

Compliance with this policy may be enforced by exercise of administrative oversight of funded research and management of WesternU facilities and other WesternU property.

Other Considerations

Records of all financial disclosures and of all actions taken to resolve actual or potential SFIs will be maintained until at least three (3) years after the letter of the termination or completion of the award to which they relate or the resolution of any action involving those records.

This policy covers all employees of WesternU who are submitting proposals for external funding.

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The disclosure and supporting documents filed in compliance with this policy will be maintained as confidential to the extent possible under applicable local, state and federal requirements.