



Policy No	200.2.POL.009
Effective Date	November 23, 2020
Issued By	President's Office
Superseded version	May 28, 2019

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## Financial Conflicts of Interest in Research Policy

### 1. Background, Purpose, and Scope:

Effective August 24, 2012, the Department of Health and Human Services has amended existing Public Health Service (“PHS”) regulations for promoting objectivity in research (42 CFR part 50 subpart F). These regulations are designed to encourage research integrity by requiring disclosure and management of any financial conflicts of interest (FCOI) of investigators who receive research funding from the National Institutes of Health (“NIH”). To comply with the amended regulations, and companion rules published by the National Science Foundation (“NSF”) in October 1995, the Institute revised its written policy on financial conflicts of interest in research. This policy:

- a) informs all investigators of the federal conflict of interest rules and their responsibilities under those rules;
- b) mandates conflict of interest training for investigators before they engage in research under a federally funded grant and at prescribed intervals thereafter;
- c) requires investigators applying for, or receiving, federal research funding to disclose any significant financial interests;
- d) designates institutional officials who will review disclosure statements, identify any financial interests that could directly and significantly affect the design, conduct or reporting of the funded research, and determine appropriate measures to manage or eliminate the conflicts of interest;
- e) establishes mechanisms for ensuring compliance with the policy and any stipulated remedial measures, and imposes sanctions, as appropriate, for an investigator's failure to comply; and
- f) requires institutional reporting to the funding agency of any conflict of interest, if mandated, and maintenance of related records for three years from the date of submission of final grant expense reports.

This policy is intended to supplement, not replace, the general policy on conflicts of interest disclosure (50.POL.001 Disclosure of Potential Conflicts of Interest Policies and Procedures) of The Wistar Institute (“Institute”). Members of the scientific staff, as well as other



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employees, are also subject to policy 50.POL.001, which at a minimum requires annual disclosure of personal financial interests and external commitments, irrespective of the receipt of grant funding from federal sources.

As noted, this policy affects only research funded by agencies of the PHS, and the NSF. Because the rules issued by the U.S. Department of Health and Human Services (for PHS-sponsored research) and the NSF are not identical, the Institute has chosen to conform the policy to the PHS rules, and to apply the PHS rules to NSF-funded research unless the NSF rules clearly require otherwise.

The Institute considers compliance with these rules fundamental to maintaining continued public trust in the integrity of research conducted at the Institute. Members of the scientific staff are encouraged to direct any questions concerning the rules to the Institute's Vice President, General Counsel, Secretary, & Government Relations.

2. Persons or Departments Affected: The following have responsibilities under this policy:

- A. All Investigators (as defined below);
- B. Departments responsible for administration of federal grants and reporting to federal sponsors, i.e. PHS and NSF, including Research and Administrative services (RAS) and Research Financial Administration (RFA);
- C. Departments involved in managing non-federal funding sources including the Institute's commercial partners, i.e. Business Development (BD) and Institutional Advancement (IA);
- D. Departments responsible for the COI disclosure processes (RAS and Legal); and
- E. COI Committee (as defined below), is responsible for assessing and managing FCOI.

3. Definitions

A. "Family" means an Investigator's spouse (including same-sex partners/spouses), domestic partner, or dependent children.



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B. "Equity Interest(s)" means stock, stock options, warrants, and other existing or contingent ownership interests in a commercial entity.

C. "Financial Conflict of Interest" or "FCOI" means a Significant Financial Interest (as defined in Section I.H below) that could directly and significantly affect the design, conduct, or reporting of PHS or NSF-funded research.

D. "Institutional Responsibilities" means an Investigator's professional responsibilities on behalf of the Institute, and as defined by the Institute in policy 50.POL.001 Disclosure of Potential Conflicts of Interest Policies and Procedures, including but not limited to, activities such as research, research consultation, teaching, administration, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

E. "Investigator" means a project director or a principal investigator and any other person, including collaborators and consultants, who are responsible for the design, conduct or reporting of research, including key personnel, for which PHS or NSF funding is sought or obtained.

F. "Ethics Administrator" has responsibilities defined in this policy and is the individual appointed by the President & CEO as Research Integrity Officer under PHS policy.

G. "Research" means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development.

H. "Significant Financial Interest" or "SFI" means any of the following items of monetary value received by an Investigator, alone or in combination with his or her Family (and not excluded in subsection 5 below) that appear reasonably related to the Investigator's Institutional Responsibilities:

1. payments or anything of monetary value in or from a *publicly traded entity* where:
  - a) the aggregate value of the payments received during the 12-month period preceding the disclosure, or expected over the next 12



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months, exceeds \$5,000; or

- b) the aggregate value as of the date of disclosure of any Equity Interest in the entity exceeds \$5,000, as determined through reference to public prices or other reasonable measures of fair market value;
2. payments or anything of monetary value from a *non-publicly* traded entity where the aggregate value of the payments received during the 12-month period preceding disclosure, or expected over the next 12 months, exceeds \$5,000;
3. Equity Interests of any value in a non-publicly traded entity;
4. payments received from an organization other than the Institute relating to intellectual property rights and interests (for example, patents and copyrights); and
5. travel related to institutional responsibilities that is reimbursed or sponsored by an organization *other than* a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

For clarity, the NIH has specifically advised that Investigators, including subrecipient Investigators, MUST disclose ALL financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country). (See [NIH NOT-OD-18-160: Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests](#). March 30, 2018)

The term “Significant Financial Interest” or “SFI” does not include the following types of financial interests received by an Investigator:

1. salary, royalties, or other remuneration paid by the Institute to the Investigator if the Investigator is currently employed or otherwise appointed by the



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Institute, including intellectual property assigned to the Institute and agreements to share in royalties related to such rights;

2. 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 those vehicles;
3. income from seminars, lectures, or teaching engagements sponsored by, and service on advisory or review panels for, a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

#### 4. Policy Statement

##### A. Disclosure

Investigator(s) (including any person responsible for the design, conduct or reporting of the funded research) must disclose any SFI at the following time(s):

1. prior to submitting a funding proposal to any PHS agency or the NSF;
2. annually during the period of the award;
  - a. within thirty (30) days of discovering or acquiring any new SFI during the term of a grant; and
  - b. within thirty (30) days following reimbursement of travel expenses by a third party; or, if travel costs are paid directly by the third party, within thirty (30) days of the completion of the trip (see Section I.G.5 for a description of travel costs that do not have to be disclosed). When disclosing an SFI that is reimbursed or sponsored travel, the Investigator must detail, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and duration, and the monetary value.



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The Research and Administrative Services (RAS) department will maintain disclosure forms, to be completed by each Investigator, which will require the Investigator to disclose reportable SFIs, or certify that he or she has no such interests. Upon submission of a grant application, the Institute must certify that it has received the Investigators' disclosure forms. Any real or perceived financial conflict of interest will be resolved under this policy, before PHS funds are expended. For all grant submissions subsequent to the initial application, or at least annually, Investigators must submit an updated statement of any changes that have occurred since submitting their most recent disclosure statement or certify that no changes have occurred. Additionally, at any time during the term of the grant, Investigators must submit an updated disclosure statement within thirty (30) days of discovering or acquiring a new SFI.

**B. Review and Implementation**

The Institute's Ethics Administrator, the Vice President, General Counsel, Secretary, & Government Relations, Director of Research and Administrative Services, and the Vice President, Business Development (the "COI Committee"), will review any SFI reported by an Investigator to determine if it is related to the Investigator's PHS or NSF-funded research (this determination may involve discussions with the Investigator). If they determine that the SFI is related to the Investigator's PHS or NSF-funded research, the Ethics Administrator, with the other members of the COI Committee and the Investigator, will develop a FCOI management plan for approval by the President & CEO. Examples of conditions or restrictions that might be imposed to manage FCOIs include, but are not limited to:

1. public disclosure of SFIs; for research projects involving human subjects, disclosures of the SFI directly to participants;
2. monitoring of research by independent reviewers;
3. modification of the research plan;
4. change of personnel or personnel responsibilities on the project, or disqualification from participation in all or a portion of the research funded by the granting agency;
5. divestiture of SFIs; or
6. severance of relationships that create actual or potential FCOIs.



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The aim of a management plan is to ensure open and timely dissemination of research results, protect trainees, and preserve the integrity of the research. The Investigator will be asked to acknowledge in writing that he or she understands and will comply with any conditions imposed by the President & CEO for managing or eliminating a FCOI. Should he or she decline or fail to agree to these conditions, the Institute will take appropriate disciplinary action, including without limitation suspending the Investigator's research and, with requisite approval of NIH, designating a substitute Investigator.

If the President & CEO reports an SFI, the chair of the Board of Trustees will consult with the standing COI Committee, and determine if the financial interest constitutes a potential FCOI. With concurrence of the Executive Committee of the Board of Trustees, the chair will implement measures to manage or eliminate any FCOI of the President & CEO consistent with PHS policy.

In all cases the COI Committee will monitor, on an ongoing basis until the completion of the impacted PSH or NSF funded research project, the Investigator's compliance with the conditions mandated by the President & CEO in any established management plan.

C. Subrecipients (Applicable to PHS-funded research only)

The PHS rules require the Institute to take reasonable steps to ensure that subcontractors or subrecipients comply with the federal rules. Therefore, when the Institute carries out the PHS-funded research through a subrecipient, the Institute will incorporate, as part of a written agreement with the subrecipient, terms that 1) require the subrecipient to maintain a FCOI policy that complies with federal requirements and 2) establish that the subrecipient's FCOI policy will apply to the subrecipient Investigators.

If the subrecipient's policy will apply, the subrecipient must report any FCOIs to the Institute within forty-five (45) days of identification so that the Institute can report them to the PHS in a timely manner (see Section II.E below for additional information on reporting).

Alternatively, if the Institute's FCOI policy will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of SFIs to the Institute. Such time periods shall be sufficient to enable the Institute to comply with timely review, management, and reporting obligations under the federal rules as described in Section II.E.



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If the Institute is a subrecipient of PHS funds, this policy will apply to the required FCOI review, rather than the policy of the subawarding organization.

D. Public Access of Disclosed SFIs (Applicable to PHS-funded research only)

The Institute will make available to the public upon request information concerning any SFI disclosed to the Institute that meets the following three criteria:

1. The disclosed SFI is still held by an Investigator of an active PHS-funded project;
2. The Institute determines that the SFI is related to the PHS-funded research; and
3. The Institute determines that the SFI is a FCOI.

The Institute will respond within five (5) business days of receipt of a request for public disclosure. The response shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI (dollar ranges, as set forth in the PHS rules, may be used), 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. The Institute will note in its written response that the information provided is current as of the date of correspondence and is subject to updates on at an annual basis, or within sixty (60) days of the identification of new FCOI. The requester must ask for any such updates if s/he desires them. FCOI information will remain available for three (3) years from the date the information was most recently updated.

E. Reporting

Prior to the Institute's expenditure of grant funds from the PHS, it will report to the PHS any FCOIs found by the Institute that have not been eliminated, and, along with certain other details required by the PHS, will provide assurance that the FCOI has been managed. NSF requires reporting of conflicts of interest only when the Institute is unable to satisfactorily manage, reduce, or eliminate a conflict of interest. Wistar may be required, by law or by conditions





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imposed by a sponsor, to report an FCOI and also any failure to report an FCOI to the affected project sponsors.

When FCOIs are identified during the term of the grant for an Investigator newly participating in the project, or the Institute identifies a new FCOI for an existing Investigator, the Institute will report such FCOIs to the PHS within sixty (60) days of identification.

The Institute shall provide the PHS with the status of a reported FCOI and any changes to the management plan annually, if applicable, until the completion of the project.

Each report to the PHS must include sufficient information to enable the agency to understand the nature and extent of the FCOI and to assess the appropriateness of the management plan. The required information includes:

1. project number;
2. name of Principal Investigator of the funded research;
3. name of Investigator with FCOI;
4. name of the entity in which the Investigator has a FCOI;
5. nature of the FCOI (e.g. equity, consulting fee, travel reimbursement, honorarium);
6. value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,000; 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;
7. a description of relationship of the SFI to the PHS-funded research and the basis for the Institute's determination that the SFI conflicts with the research; and



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8. a description of key elements of the Institute's FCOI management plan, including;
  - a) role and principal duties of the conflicted Investigator in the research;
  - b) conditions of the management plan;
  - c) how the management plan is designed to safeguard objectivity in the research project;
  - d) how the management plan will be monitored to ensure Investigator compliance; and
  - e) other information as needed.

NIH issued a notice on April 18, 2014 ([NOT-OD-14-081](#)) that beginning April 25, 2014 grantees must use an improved eRA Commons module to submit FCOI reports. The notice also described changes regarding the timeline that reminders are sent to the Signing Official and when the reporting module is available prior to reporting deadlines, but the deadlines remained unchanged. In addition, revised FCOI reports following retrospective FCOI reviews disclosing new SFI or changes to a management plan may be submitted up to 150 days after submitting an original report.

F. Retrospective Review

Whenever the Institute identifies an SFI that was not disclosed in a timely manner by the Investigator, or for whatever reason was not timely reviewed by the Institute, the Institute will determine whether the SFI constitutes a FCOI within sixty (60) days thereafter and implement an appropriate management plan.



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If the FCOI was not identified or managed in timely manner, as when 1) the Investigator failed to disclose a SFI that subsequently was found by the Institute to constitute a FCOI, 2) the Institute failed to review or manage such FCOI, or 3) the Investigator failed to comply with the FCOI management plan, the Institute shall complete a retrospective review of the Investigator's activities and the PHS-funded research project. The purpose of the retrospective review, which must occur within 120 days of the Institute's determination of noncompliance, is to determine whether any PHS-funded research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

The Institute will document the retrospective review, which documentation must include, but not necessarily be limited to, all of the following key elements: project number and title; name of principal investigator, name of the Investigator with the FCOI; the name of the entity with which the Investigator has a FCOI; reasons for the retrospective review; detailed methodology used for the retrospective review, review findings and conclusions.

As appropriate, the Institute will update any previously submitted FCOI report with information describing how the FCOI will be managed going forward.

If bias is found after a retrospective review, the Institute will promptly notify the PHS and follow up with a mitigation report. The mitigation report must include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias. The Institute will monitor the investigator's compliance with the management plan on an ongoing basis until completion of the PHS- or NSF-funded research project.

G. Enforcement and Sanctions for Noncompliance

If an Investigator fails to comply with the provisions of this policy, or with any conditions for managing or eliminating a FCOI mandated by the President & CEO, the President & CEO will discuss the violation with the Investigator and attempt to remedy it informally. If the President & CEO is unable to reach a resolution, he or she shall impose appropriate sanctions up to and including suspension or termination of the Investigator.



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#### H. Training

Prior to engaging in any research project, all Investigators must complete training on the Investigator's obligations under this policy and repeat the training at least every four years. Training must be completed immediately (i) if this policy is revised to the extent that it affects Investigators' obligations; (ii) when an Investigator is new to the Institute; or (iii) when the COI Committee mandates refresher training, e.g. when the Institute finds an Investigator to have violated this policy or any applicable management plan.

#### I. Record Keeping

The Institute will maintain records relating to (i) all Investigator disclosures of SFI; (ii) measures implemented to manage or eliminate FCOIs; and (iii) all actions related to a retrospective review, if applicable, for at least three (3) years from the date of submission of the final grant expenditure report, or longer where applicable, unless any litigation, claim, audit or other action involving the records is commenced before the end of the three-year period, in which case, records will be retained until completion of the action and resolution of all issues.

#### J. Related Guidance

1. 42 CFR part 50 subpart F: Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is Sought.
2. NOT-OD-14-081: Notice of NIH Improving the Financial Conflict of Interest (FCOI) Module for Submission of FCOI reports to NIH Beginning April 25, 2014.
3. Wistar policy 50.POL.001: Disclosure of Potential Conflicts of Interest - Policies and Procedures
4. NOT-OD-18-160: Financial Conflict of Interest: Investigator Disclosures of Foreign Financial Interests. March 30, 2018



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K. History

1. Effective: October 1, 1995
2. Revised August 24, 2012
3. Revised January 22, 2015
4. Revised and reformatted November 30, 2018
5. Revised to reflect NOT-OD-18-160: May 28, 2019
6. Dates in header updated/corrected: July 30, 2019