

Financial Conflict of Interest and Disclosure Policy for Federally Funded Research at Illinois Wesleyan University

The federal government requires that the institution establish and administer a financial conflict of interest and disclosure policy for investigators who conduct research funded by federal grants. Illinois Wesleyan's implementation policy related to financial conflict of interest is below. Following the policy are guidelines related to financial conflict of interest for specific funding agencies.

POLICY

The IWU Faculty member must complete a *Financial Conflict of Interest Disclosure Form* along with the External Grant Proposal Review Form when proposal will be to a federal funding source. When funding is awarded for research under NSF, NIH or other federal entities, the *Financial Conflict of Interest Disclosure Form* should be completed either on an annual basis, or as new reportable significant financial interests are obtained. The IWU policy will apply to sub-awardees, contractors or collaborators, unless their institutional policy meets regulation requirements.

Enforcement: The designated official who will review and make determination is the Provost and Dean of Faculty and/or the Vice-President for Business and Finance. In the event that a determination is made that a FCOI exists for a federally funded award, they will also determine the management plan for the FCOI to be in compliance with regulations. In the event of an unmanageable FCOI for an NSF award, the University shall submit appropriate reporting to NSF/OGC. For any identified FCOI involving an NIH funded award, reports shall be submitted as outlined in Appendix A, "*Submission of Initial and Annual FCOI reports during an Ongoing NIH-funded Research Project*."

Sanctions: In the event that this policy is not followed, the Provost and Dean of Faculty shall determine the sanctions imposed in accordance with the [IWU Faculty Handbook](#).

Records: The University shall maintain records within the GFR Office of all financial disclosures and of all actions taken to resolve Financial Conflicts of Interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any action involving those records, whichever occurs later.

AGENCY SPECIFIC GUIDANCE

The requirements for the above policy depends on the funding agency and are outlined below.

NSF Regulation: (Reference: NSF Award and Administration Guide)

- 1) NSF requires each grantee organization employing more than fifty persons to maintain an appropriate written and enforced policy on conflict of interest and that all conflicts of interest for each award be managed, reduced or eliminated prior to the expenditure of the award funds. If the

organization carries out agency-funded research through subawardees, contractors, or collaborators, the organization must take reasonable steps to ensure that:

- a) the entity has its own policies in place that meet the requirements of this policy;
 - b) or investigators working for such entities follow the policies of the primary organization.
- 2) An organizational conflict of interest policy should require that each investigator disclose to a responsible representative of the organization all significant financial interests of the investigator (including those of the investigator's spouse and dependent children):
- a) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or
 - b) in entities whose financial interests would reasonably appear to be affected by such activities.
- 3) The term "investigator" means the principal investigator, co-principal investigators/co-project directors, and any other person at the organization who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.
- 4) The term "significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

- a. salary, royalties or other remuneration from the applicant organization;
 - b. any ownership interests in the organization, if the organization is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
 - c. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
 - d. income from service on advisory committees or review panels for public or nonprofit entities;
 - e. an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: **does not exceed \$10,000** in value as determined through reference to public prices or other reasonable measures of fair market value, and **does not represent more than a 5% ownership interest in any single entity**; or
 - f. salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve-month period.
- 5) An organizational policy must ensure that investigators have provided all required financial disclosures at the time the proposal is submitted to NSF. It must also require that those financial disclosures are updated during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.
- 6) An organizational policy must designate one or more persons to review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any,

should be imposed by the organization to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

- 7) Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include, but are not limited to:
 - a. public disclosure of significant financial interests;
 - b. monitoring of research by independent reviewers;
 - c. modification of the research plan;
 - d. disqualification from participation in the portion of the NSF-funded research that would be affected by significant financial interests;
 - e. divestiture of significant financial interests; or
 - f. severance of relationships that create conflicts.
- 8) If the reviewer(s) determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.
- 9) The organizational policy must include adequate enforcement mechanisms, and provide for sanctions where appropriate.
- 10) The organizational policy must include arrangements for keeping NSF's Office of the General Counsel appropriately informed if the institution finds that it is unable to satisfactorily manage a conflict of interest.
- 11) When OGC is notified of an unmanageable conflict of interest by an awardee, OGC will conduct the following review:
 - a) Examine a copy of the organization's conflict of interest policy to ascertain if the policy includes procedures for addressing unmanageable conflicts.
 - b) Contact the awardee organization's representative to determine what actions the organization plans/has taken with respect to the reported unmanageable conflict of interest, ensuring consistency with their conflict of interest policy.
 - (c) Request confirmation from the awardee when proposed actions have been accomplished.
- 12) Organizations must maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

PHS/NIH Regulation (Reference: 42 CFR Part 50, Subpart F)

"Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought."
(PHS/NIH regulations are more restrictive than NSF – have a \$5,000 de minimis reporting requirement, require training, differing definition of reportable financial interests and more onerous reporting requirements.)

When applying for funding, by checking the “I Agree” box on the NIH’s SF424 (R&R) Cover component, the Authorizing Organization Representative certifies compliance with the requirements of 42 CFR part 50, Subpart F, including that:

1. There is in effect at the organization a written and enforced administrative process to identify and manage, reduce or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought.
2. Prior to the expenditure of any NIH fund awarded under a new award, the organization will inform NIH of the existence of any conflicting financial interests of the type covered by 42 CFR 50.605 and assure that the interest has been managed, reduced or eliminated in accordance with the regulations.
3. The institution will continue to make similar reports on subsequently identified conflicts within 60 days of identification.
4. When the institution determines that a financial conflict of interest exists (see #2 and # 3 above), the Institution must notify NIH through the FCOI module in the eRA Commons of its existence and provide the following info.
 - a. Grant number and Principal investigator
 - b. Name of investigator with FCOI; and
 - c. Distinguish which method was used to protect the PHS funded research from bias (i.e., managed, reduced, eliminated).
5. When requested, the Institution will make information available to NIH regarding all identified conflicting interests and how these interests have been managed, reduced, or eliminated to protect the research from bias.

Each Investigator (as defined by the regulation), including sub-recipient Investigator(s), must complete training prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances:

1. Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
2. An Investigator is new to an Institution
3. An Institution finds that an Investigator is not in compliance with the Institution’s Financial Conflict of Interest policy or management plan.

This regulation covers all financial interests that have monetary value, whether or not the value is readily ascertainable.

The 2011 revised regulation defines a “*Significant Financial Interest*” as follows:

“(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, 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 \$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, 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 \$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."

Investigators are required to **disclose** their Significant Financial Interests (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities:

1. no later than at the time of application for NIH-funded research;
2. within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and
3. at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.

IWU's Grants and Foundation Relations Office must review all financial disclosures by Investigators and determine whether any Significant Financial Interest is related to NIH-funded research and a Financial Conflict of Interests exists by making a reasonable determination that the Significant Financial Interest: could be affected by the NIH-funded research or is in an entity whose financial interest could be affected by the research. The GFR Office may involve the Investigator to determine whether the Significant



Financial Interest is related to the NIH-funded research. Final determination will be made by the Provost/Dean of Faculty and/or the Vice-President for Business and Finance.

When determination is made that FCOI exists, IWU's GFR Office will provide to the NIH, prior to the expenditure of any funds under a NIH-funded research project, an FCOI Initial Report regarding any Investigator Significant Financial Interest found by the University to be a Financial Conflict of Interest in accordance with the regulation. IWU will also provide an FCOI report whenever an Investigator does not timely disclose a Significant Financial Interest or whenever the University, for whatever reason, does not review a disclosed Significant Financial Interest and then determines that a Financial Conflict of Interest exists. For any Financial Conflict of Interest previously reported by the University, the GFR Office of IWU shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan.