Policy title	Category
Policy on Financial Conflict of Interest related to funding under the Public Health Service (PHS, U.S. Dept of Health and Human Services)	Academic Affairs Advancement
Owner Advancement	**Approved by** Ad Council

Policy statement

Nebraska Wesleyan University (NWU) wishes to assure objectivity in research or educational projects supported by external sources through funds awarded directly to NWU as grants or contracts, or indirectly to NWU via subcontracts through other institutions. It is important to ensure reasonable expectation that the design, conduct, and reporting of the outcomes of research or educational projects will be free from bias resulting from financial conflict of any and all senior/key personnel, extending also to certain of their family members.

This policy applies to NWU faculty or staff who are defined as “Investigators” within a project proposed or approved for Public Health Service (PHS) funding as per the definitions in the Code of Federal Regulations: 42 CFR Part 50 Subpart F. It is intended to comply with current requirements for PHS-funded research (including NIH, the National Institutes of Health) as posted during July 2013 at:

http://grants.nih.gov/grants/policy/coi/index.htm

This NWU policy incorporates by reference 42 CFR Part 50 Subpart F in its form posted as of July 15, 2013 at:

http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&sid=f67ea01984581d3934103b50… &node=42:1.0.1.4.22&idno=42.

Procedure for NWU’s compliance for federal regulations

Training for Investigators

Prior to engaging in research related to PHS-funded projects for which NWU holds a grant or is a subrecipient under contract with another institution, NWU Investigators must review and complete a training module about financial conflict of interest available at **http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm** (or the module’s updated and replacement version as made available.) Upon completing the training, Investigators should print and save their certification page for attachment to the Disclosure form described below. Training shall be completed once every four years by Investigators.

Disclosure by Investigators

Investigators must complete the written disclosure form associated with this NWU policy and submit it to the Director of Sponsored Programs. The President shall act as the designated institutional official for NWU. On behalf of the President, the Director of Sponsored Programs will make initial review of the disclosure forms and document their completion as part of institutional files for federally-funded projects.

Disclosure forms shall be completed annually by Investigators on continuing projects, but shall be updated within 30 days of the Investigator’s discovering or acquiring a new significant financial interest (i.e., such as through inheritance, purchase, or marriage to a person with significant financial interest.)

In cases where NWU is the primary applicant for PHS funding, the Investigator must complete a disclosure form at the time of proposal submission. In such cases the form will be held in a sealed envelope by the Director of Sponsored Programs until funding is awarded, at which time it will be reviewed by the President prior to expenditure of funds.

Determination and Recording of “significant financial conflict”

As the designated institutional official for NWU, the President will determine whether any significant financial interest disclosed is related to the PHS-funded research, and if so, whether it is a financial conflict of interest. A financial conflict of interest exists when Nebraska Wesleyan University, through its designated official, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The Director of Sponsored Programs will maintain records related to Investigators' disclosures and the institutional review and response to disclosures for three years following final expenditures reporting on a project or other duration specified by 42 CFR Part 50 Subpart F.

Management and Reporting of a financial conflict of interest

The President will be responsible for developing and implementing a management plan to address what has been determined to be a financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest can range from NWU's public disclosure of the financial conflicts of interest, to monitoring of the research project by an independent party, to modification of the research plan and/or personnel, to elimination of the financial interest.

In cases where a conflict of interest has been determined, NWU must submit to the awarding agency (or to the grantee institution which has issued a subaward to NWU) a Financial Conflict of Interest Report to include the significant financial interest found to be a conflict of interest, and the assurance that NWU has implemented a management plan in accordance with CFR Part 50 Subpart F. If the conflict has been eliminated, NWU need not submit such a report.

If the conflict continues, NWU must submit annual reports about its management for the duration of the research project.

Public access to information

This NWU policy shall be posted for access to the general public on the NWU website. In addition, in the event that an identified conflict of interest continues to exist and is under management, certain information shall be available to the public on the NWU website as dictated by 42 CFR Part 50, Subpart F for the duration required.

Governing policy

U.S. Government Printing Office - Electronic Code of Federal Regulations

As found at

http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&sid=f67ea01984581d3934103b50…: 1.0.1.4.22&idno=42

as of July 15, 2013

PART 50—POLICIES OF GENERAL APPLICABILITY

Subpart F—Promoting Objectivity in Research

AUTHORITY: 42 U.S.C. 216, 289b-1, 299c-4; Sec. 219, Tit. II, Div. D, Pub. L. 111-117, 123 Stat. 3034.

SOURCE: 76 FR 53283, August 25, 2011, unless otherwise noted.

§ 50.601 Purpose.

This subpart promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

§ 50.602 Applicability.

This subpart is applicable to each Institution that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement and, through the implementation of this subpart by the Institution, to each Investigator who is planning to participate in, or is participating in, such research; provided, however, that this subpart does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an Institution, is applying for, or receives, PHS research funding, PHS Awarding Components will make case-by-case determinations on the steps to be taken, consistent with this subpart, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a financial conflict of interest of the individual.

§ 50.603 Definitions.

As used in this subpart:

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator 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, for example, collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant financial interest means:

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.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Related file(s)

Disclosure of Financial Interest

Last revised date
July 15, 2013