

	Title: Northwest Indian College Policy: Financial Conflict of Interest in Research Funded by PHS or NSF	Policy # POL-709
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Approved By:	College President's Signature 	Date Approved: 01/12/2022
Effective Date: 01/13/2022	Board of Trustees President's Signature 	Date Approved: 01/12/2022

709.1 POLICY STATEMENT

It is the policy that Northwest Indian College (NWIC) assure that all Investigators of grant awards are accountable to NWIC for the proper management of the grant-sponsored project or program. Investigators are also responsible to keep the NWIC Office of Research and Sponsored Programs (ORSP) informed of all changes and correspondence with the sponsoring agency. Investigators must also comply with funders criteria. Research funded by the Public Health Service (PHS) or National Science Foundation (NSF) must meet all Federal and NWIC requirements to comply with:

- **Title 42 Code of Federal Regulations Part 50 Subpart F – Promoting Objectivity in Research (42 CFR 50 Subpart F)** — for PHS-funded research; and
- **Proposal & Award Policies & Procedures Guide (PAPPG), Chapter IX.A, Conflict of Interest Policies** — for NSF-funded research.

709.2 PURPOSE

The purpose of this policy is to provide a reasonable expectation that the design, conduct, and reporting of research funded by PHS or NSF will be free of bias that could result from Investigator Financial Conflicts of Interest (FCOIs). This policy complies with a federal requirement to receive research funded by PHS or NSF. The policy describes the process and procedures for obtaining disclosures of significant financial interests that would reasonably appear related to the institutional responsibilities by all Investigators in research funded by PHS or NSF, the review of those disclosures, the assessment whether each Investigator has a FCOI, steps to manage all FCOIs, and required reporting to PHS or NSF.

709.3 SCOPE

This FCOI policy applies to all research conducted by NWIC Investigators and subrecipient Investigators that is funded by PHS or NSF. The ORSP will assure that all Investigators are aware of this policy, have access to the policy on NWIC's Web site, and complete a Significant Financial Interest Disclosure Form at least annually during the life of the research and anytime there is a change in those financial interests. Investigators are required to report significant financial interests of self, of the Investigator's spouse/domestic partner, and of the Investigator's dependent children.

709.4 BACKGROUND

As a recipient of federal funds, NWIC is required to comply with all pertinent Federal requirements. All research grants cooperative agreements funded by PHS and NSF require compliance with funding component's FCOI policy. NWIC currently has, and expects to continue to have, several PHS and NSF grants, that are highly important in and integral for the education of many NWIC students.

709.5 RESPONSIBILITY

The ORSP has primary responsibility to: a) maintain a current, documented and enforced FCOI policy, b) assure research grant Investigators are provided a copy of the FCOI policy, c) provide disclosures of significant financial interests, and d) collection of FCOI disclosures and maintaining these records for the designated time period stated in this policy. Investigators are responsible for: a) becoming familiar with the FCOI policy, b) complying with the FCOI policy by completing disclosures annually or as circumstances change, and c) providing accurate information.

709.6 DEFINITIONS

Designated Official (DO): an individual (or individuals) appointed by the president of the College to review disclosures to determine potential significant conflicts of interest.

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

Equity interest: the ownership share of a shareholder in a business or corporation, e.g., stock, stock option, security, or other ownership interest, that exceeds \$5,000 (for PHS-funded research) or exceeds \$10,000 (for NSF-funded research).

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

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

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

Institution: 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: an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on FCOI, 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: the PI/PD 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 NSF, or proposed for such funding, which may include, for example, subrecipient Investigators, collaborators, or consultants.

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

PI/PD: a Principal Investigator or Project Director of a PHS- or NSF-funded research project; the PI/PD is included in the definitions of senior/key personnel and Investigator in this policy.

PHS: the Public Health Service of the U.S. Department of Health and Human Services, and its components to which the authority involved may be delegated, including the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Office of Public Health and Science (OPHS), Agency for Healthcare Research and Quality (AHRQ), Substance Abuse and Mental Health Administration (SAMHSA), Indian Health Service (IHS), and others. [see (U.S. Department of Health and Human Services (DHHS), Office of Grants, **HHS Grants Policy Statement**, p. II-13) and (<https://thefdp.org/default/fcoi-clearinghouse/fcoi-agencies/>)]

PHS Awarding Component and NSF Awarding Component: the organizational unit of the PHS or NSF that funds the research that is subject to this policy.

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

Research: a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health and general science 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). The term includes any activity for which research funding is available from PHS or NSF Awarding Components through a grant or cooperative agreement authorized under the PHS Act or other statutory authority, such as research grant, center grant, career development award, fellowship award, infrastructure award, institutional training grant, or similar.

Senior/key personnel: the PI/PD 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 or NSF by the Institution under this policy.

Significant financial interest:

(The complete definition of “significant financial interest” is under Definitions in 709.7 of this Policy. The threshold limit to be reported is \$5,000 for PHS, and \$10,000 for NSF.)

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - i. Any equity Interest; or
 - ii. Any remuneration received from any non-publicly traded entity; or
 - iii. Any income related to intellectual property rights and interests (e.g., patents, copyrights).
2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities, with certain exceptions.

The term *significant financial interest* does not include several types of financial interests, e.g., salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution.

709.7 FCOI POLICY IN DETAIL

Source Citations:

I. Purpose

42 CFR § 50.601

The primary purpose of this NWIC policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research conducted by NWIC, and that is funded under Public Health Service (PHS) or National Science Foundation (NSF) grants or cooperative agreements, will be free from bias resulting from Investigators having Financial Conflicts of Interest (FCOIs).

The Northwest Indian College (NWIC) requires that all people who are responsible for the design, conduct, or report of research, herein called Investigators, receive a copy of this policy before applying for a research grant or research cooperative agreement and that successful applicants retain it by upon approval for receipt of funds. This policy further requires that all Investigators disclose any significant financial interest of the Investigator, of the Investigator's spouse / domestic partner, and of the Investigator's dependent children, that would reasonably appear to be related to the Investigator's institutional responsibilities.

This policy complies with two primary documents of the federal regulations regarding FCOIs in research:

- **Title 42 Code of Federal Regulation (CFR) Part 50 Subpart F** – for the Public Health Service (PHS);
- **Proposal & Award Policies & Procedures Guide (PAPPG), Chapter IX.A, Conflict of Interest Policies** – for the National Science Foundation (NSF).

This policy also follows several additional Federal documents as appropriate:

- **PHS Grants & Funding – Frequently Asked Questions (FAQs) – Responsibility of Applicants for Promoting Objectivity in Research (2011 Revised Regulations –**
(<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>);

- **NIH Grants & Funding, Financial Conflict of Interest** – (<https://grants.nih.gov/grants/policy/coi/index.htm>); and
- **Title 2 CFR Part 200** – for the National Science Foundation (NSF) (https://www.nsf.gov/pubs/policydocs/pappg20_1/pappg_9.jsp).

II. Definitions.

42 CFR § 50.603 -*verbatim*

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

Financial Conflict of Interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research and/or NSF-funded research.

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

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

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

Institution: 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: an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on FCOI, 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: the PI/PD 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: taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PI/PD: a Principal Investigator or Project Director of a PHS-funded research project; the PI/PD is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS: 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: the organizational unit of the PHS that funds the research that is subject to this subpart.

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

Research: 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: the PI/PD 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:

- (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, and paid authorship); or 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 a 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; 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.

III. NWIC's Structure to Conduct this Policy.

A. Designated Officials

42 CFR § 50.604(e)-(f)

NWIC's Designated Officials regarding FCOIs are responsible to determine whether a FCOI exists and determine the plans to manage such FCOIs. NWIC's Designated Officials:

- Shall, prior to the expenditure of any funds for a new research grant or cooperative agreement funded by PHS or NSF:
 - o conduct a full review of all disclosures of significant financial interests by the Investigators;
 - o determine whether any Investigator's significant financial interest related to their institutional responsibilities is also related to the proposed new PHS-funded or NSF-funded research; and, if so,
 - o make a reasonable determination whether the significant financial interest could be affected by the PHS-funded research or is in an entity whose financial interests could be affected by the research;
- Determine that a FCOI exists or does not exist;
- Manage the FCOI by developing and implementing plans to ensure that the design, conduct, or reporting of the PHS-funded or NSF-funded research remains free of bias due to the FCOI;
- Develop NWIC's Guidelines for Review of significant financial interests and Financial Conflicts of Interest:
 - o Update the Guidelines when new relevant information is obtained; and
 - o Review and update the Guidelines as appropriate and at least every five (5) years, following NWIC's standard procedures to maintain and update NWIC Policies;
- Follow NWIC's Guidelines for Review of significant financial interests and Financial Conflicts of Interest to conduct further evaluation and review of instances of possible significant financial interest to determine if they are FCOIs that need to be managed;
- Conduct advanced training for institutional officials to become Designated Officials;

- With the ORSP, conduct training for Investigators in federal requirements and NWIC's policy regarding FCOIs; and
- Advise the ORSP as it conducts its activities outlined in the list below of its responsibilities regarding significant financial interests and FCOIs.

B. NWIC Office of Research and Sponsored Programs (ORSP)

42 CFR § 50.604(e)

The NWIC Office of Research and Sponsored Programs (ORSP):

- oversees and implements the College's faculty, staff, research, and institutional FCOI Policies and Procedures;
- informs Investigators about NWIC's policy on research FCOIs;
- conducts training for Investigators in federal requirements and NWIC's policy regarding FCOIs;
- assists Investigators in filling out NWIC's forms related to FCOIs;
- ensures compliance with applicable FCOI regulatory requirements;
- provides guidance and support to the NWIC community regarding FCOI policies, systems, standards, and procedures; and
- administers NWIC's disclosure policy and requirements.

IV. Regulatory Requirements

A. Training Requirements.

42 CFR § 50.604(b)

FAQ Section L, p. 37-38

Prior to the appointment of an official to be a Designated Official to conduct and oversee this policy on FCOIs, that person will receive advanced training in this policy by existing Designated Officials and/or by people experienced in FCOIs and this policy.

The NWIC ORSP will inform and provide training for all Investigators of PHS-funded and/or NSF-funded research about the federal definition of significant financial interest as related to the Investigator's institutional responsibilities, 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.

The training will also inform the Investigators of their obligations:

- for disclosure of significant financial interests and FCOIs, and
- under this policy in general.

All Investigators engaged in research related to any PHS-funded or NSF-funded grant or cooperative agreement must complete FCOI training

- prior to engaging in that research, and
- at least every four (4) years.

Training is available from, and will be provided by, ORSP.

Investigators must take the training immediately if:

- NWIC revises this FCOI policy or procedures that affects the requirements of the Investigators;
- The Investigator is new to the Institution; or

- The Designated Officials find the Investigator has not disclosed significant financial interests in a timely manner or is otherwise not in compliance with this policy on FCOI or its management plan.

B. Disclosure, Review, Manage, and Monitor Requirements.

42 CFR § 50.603

42 CFR § 50.604(d)-(g)

42 CFR § 50.605(a)(1)-(4)

Investigators are responsible for engaging in research design, conduct, and reporting that is free from bias resulting from conflicts of interest. Investigators have an obligation to:

- take initial and ongoing FCOI training;
- disclose significant financial interests at least annually during the period of the award as defined in this policy under II. Definitions, in 42 CFR § 50.603, in the FCOI Training, and in NWIC’s Guidelines for Review of significant financial interests and Financial Conflicts of Interest;
- submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring new significant financial interests;
- include significant financial interests of the Investigator’s spouse / domestic partner and of dependent children in their own significant financial interests;
- follow guidelines about the definition of significant financial interest “related to” PHS-funded or NSF-funded research as meaning that the “significant financial interest” could be affected by the PHS-funded or NSF-funded research, or is in an entity whose financial interests could be affected by the research;
- disclose to the Institution those significant financial interests that “reasonably appear related to the Investigator’s institutional responsibilities;”
- update their disclosure at least annually during the life of the research; and
- comply with the requirements to disclose FCOIs and to follow FCOI management plans.

Investigators must disclose their significant financial interests, including those of the spouse / domestic partner and dependent children, that would reasonably appear to be related to the Investigator’s institutional responsibilities. Investigators must disclose this information to the NWIC ORSP before submitting an application for a research grant or research cooperative agreement funded by PHS or NSF. If the research is funded, Investigators must update their disclosure of significant financial interests, and must certify to the Designated Officials that no changes are needed if there is no change since the submission of the application, no later than

- before expenditure of any funds,
- annually during the period of the award, and
- within thirty (30) days of discovering of or acquiring a new significant financial interest.

The procedure to detect and manage FCOIs varies by whether or not the expenditure of funds has begun for a research grant or cooperative agreement funded by PHS or NSF:

1. Before the application for a research grant or cooperative agreement is submitted, or at least before the expenditure of funds has begun, the Designated Officials:
 - a. conduct a full review of all disclosures of significant financial interests by the Investigators, including their spouse / domestic partner, and dependent children;
 - b. determine whether any significant financial interest is related to a PHS-funded or NSF-funded research;
 - c. make a reasonable determination whether the significant financial interest could be affected by the PHS-funded research or is in an entity whose financial interests could be affected by the research;

- d. determine whether the significant financial interests “reasonably appear to be related to the Investigator’s institutional responsibilities;”
 - e. based on those assessments, determine that a FCOI exists or does not exist; and
 - f. if a FCOI does exist, manage the FCOI by working with the team of Investigators to develop and implement plans to ensure that the design, conduct, and reporting of the PHS-funded or NSF-funded research remains free of bias due to the FCOI.
2. After the expenditure of funds has begun, and whenever a new Investigator joins the research or existing Investigators have a change of their significant financial interests or the disclosure of significant financial interest was untimely or delayed, the Designated Officials:
 - a. Conduct steps 1.a. through 1.e., above;
 - b. If a FCOI does exist, within sixty (60) days manage the FCOI by working with the team of Investigators to develop and implement management and monitoring plans to ensure that the design, conduct, and reporting of the PHS-funded or NSF-funded research remains free of bias due to the FCOI;
 - c. Investigate the circumstances of untimely, delayed, or non-disclosure of significant financial interests by an Investigator and/or delayed review by the NWIC system, to determine management plans to increase and achieve compliance with the FCOI procedures (see C. Reporting Requirements to PHS or NSF);
 - d. Develop and implement a management plan to manage the FCOI for the duration of the grant; and
 - e. Investigate and determine if the FCOI resulted in bias in the design, conduct, and reporting of the research (see C. Reporting Requirements to PHS or NSF).
 3. Designated Officials may seek outside consultants’ expertise in FCOI issues, as appropriate.
 4. Irrespective of the expenditure of funds, Designated Officials
 - a. develop NWIC’s Guidelines for Review of significant financial interests and Financial Conflicts of Interest;
 - b. Update the Guidelines when new relevant information is obtained; and
 - c. Review and update the Guidelines as appropriate and at least every five (5) years, following NWIC’s standard procedures to maintain and update NWIC Policies.
 5. Designated Officials follow NWIC’s Guidelines for Review of significant financial interests and Financial Conflicts of Interest to conduct further evaluation and review of instances of possible significant financial interest to determine if they are FCOIs that need to be managed.

C. Reporting Requirements to PHS or NSF.

42 CFR § 50.604(h)
42 CFR § 50.605(a)(3)(iii)
42 CFR § 50.605(b)
42 CFR § 50.606(a)

1. Designated Officials will submit to the funding component of the PHS or NSF the following FCOI reports at the times indicated:
 - a. Prior to the expenditure of funds for the PHS-funded or NSF-funded project, a FCOI Report:
 - i. verifying whether or not any Investigator has a significant financial interest that is a FCOI in relation to the project, and
 - ii. if there is a FCOI, a Management Plan that ensures that the FCOI does not lead to bias in the design, conduct, and reporting of the research, but

- b. if the FCOI is eliminated before any expenditure of funds, no FCOI Report is submitted.
2. Subsequent to the expenditure of funds, if Designated Officials find a FCOI, they
 - a. Submit a FCOI report within sixty (60) days of identifying the FCOI to the funder that describes the FCOI and the Management Plan for the FCOI;
 - b. If bias is found, a Retrospective Review must be conducted;
 - c. The Retrospective Review must be completed and within 120 days and its status reported to the funder; and
 - d. See E. Retrospective Review Requirements for requirements about this retrospective report.

3. The FCOI Report should include at least the following elements:

- a. Project number;
- b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- c. Name of the Investigator with the FCOI;
- d. The role and principal duties of the conflicted Investigator in the research project;
- e. Name of the entity with which the Investigator has a FCOI;
- f. Nature of the financial interests (e.g., equity, consulting fee, travel reimbursement, honorarium);
- g. Value of the financial interests (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; 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;
- h. A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- i. A description of the management plan.

4. The description of the Management Plan should contain at least the following:

- a. The role and principal duties of the conflicted Investigator in the research project;
- b. Conditions of the management plan;
- c. How the management plan is designed to safeguard objectivity in the research project;
- d. Confirmation of the Investigator's agreement to the management plan;
- e. How the management plan will be monitored to ensure Investigator compliance; and
- f. Other information as needed. *42 CFR § 50.605(b)(3)(viii) -almost verbatim*

5. If bias is found, see E. **Retrospective Review Requirements.**

D. Conditions, Remedies, and Restrictions for FCOIs.

42 CFR § 50.604(j)

42 CFR § 50.605(a)(1)-(3)

42 CFR § 50.606(c)

Any instance of Investigator noncompliance may require that the Investigator repeat NWIC's required FCOI training. Additional progressive personnel steps to foster and achieve compliance with this policy are outlined in NWIC's Personnel Policy Manual.

1. NWIC itself determines the Conditions, Remedies, or Restrictions that would be most appropriate to manage the specific research and circumstances causing the FCOI. Conditions or Restrictions that are frequently employed to manage FCOIs include, but are not limited to:
 - i. Public disclosure of FCOIs (e.g., when presenting or publishing the research);

- ii. For research projects involving human subjects research, disclosure of FCOI directly to participants;
- iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- iv. Modification of the research plan;
- v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- vii. Severance of relationships that create financial conflicts.

42 CFR § 50.605(a)(1) -almost verbatim

2. NWIC may also require:

- i. internal or external Reviews of the Investigator’s research, or
- ii. that the Investigator disclose their own nondisclosure of their own FCOI in every publication, presentation, etc., and/or add that information to all past and future publications.

For more details about enforcement, see also **E. Retrospective Review Requirements.**

E. Retrospective Review Requirements.

42 CFR § 50.605(a)(1)

Whenever a FCOI is not identified or not managed in a timely manner, including:

- failure by Investigator[s] to disclose a significant financial interest that is determined by the Institution to constitute a FCOI, or
- failure by NWIC to review or manage such a FCOI, or
- failure by Investigator[s] to comply with a FCOI management plan, then

the Designated Officials will initiate and make a **FCOI Report**, a **Retrospective Report**, and if necessary a **Mitigation Report** to the PHS or NSF funder.

1. The **FCOI Report**, due within sixty (60) days of disclosure, will implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such FCOI going forward and submit a FCOI report to the PHS.
2. The **Retrospective Report** must be completed within 120 days of identifying non-compliance (i.e., the non-disclosure, late disclosure, incomplete disclosure, or NWIC’s non-action on a disclosure). The retrospective review of the Investigator’s activities, NWIC’s activities, and the PHS-funded research project should determine whether any PHS-funded or NSF-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
 - a. NWIC will follow the procedures in NWIC’s Guidelines for Review of significant financial interests and Financial Conflicts of Interest to plan the Retrospective Review.
3. NWIC will fully document the Retrospective Review which must include at least the following key elements:
 - a. Project number;
 - b. Project title;
 - c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - d. Name of the Investigator with the FCOI;
 - e. Name of the entity with which the Investigator has a FCOI;
 - f. Reason(s) for the retrospective review;

- g. Details of the methods used for the retrospective review;
- h. Composition of the review panel;
- i. Documents reviewed;
- j. Findings of the review; and
- k. Conclusions of the review. *42 CFR § 50.605(a)(3)(ii)(B) -almost verbatim*

4. If the Retrospective Review revealed that no bias occurred in the design, conduct, or reporting of research, NWIC must notify the funding component of PHS or NSF to update the previous **FCOI Report** and specify the actions NWIC has taken and will take to manage the FCOI going forward.

5. If, however, the Retrospective Review revealed that bias did occur in the design, conduct or reporting of research, the Institution will

- a. update the previous **FCOI Report**; and
- b. submit a **Mitigation Report** that includes at a minimum:
 - i. key elements documented in the Retrospective Review,
 - ii. a description of the impact of the bias on the research project,
 - iii. extent of harm done,
 - iv. qualitative and quantitative data to support any actual or future harm,
 - v. impact on the research project,
 - vi. extent of harm done, and
 - vii. analysis of whether the research project is salvageable.

42 CFR § 50.605(a)(3)(iii) -almost verbatim

6. Thereafter, the Institution will submit its **FCOI Reports** annually.

F. Subrecipient Requirements.

*42 CFR § 50.604(c)
AI, FAQ Section K, p. 37*

If NWIC is the Primary Recipient of a project that has one or more Subrecipients via a Subaward, NWIC is responsible to:

- Ensure every Subrecipient Institution and Investigator knows about and complies with the federal FCOI regulations;
- Reports identified FCOIs for Subrecipient Investigators to the PHS or NSF;
- Incorporates in the written agreement with a Subrecipient Institution whether the Subrecipient will follow:
 - the Subrecipient’s FCOI policy, or
 - NWIC’s FCOI policy;
- Include in the written agreement time periods to meet disclosure and/or FCOI reporting requirements;
- Monitor every Subrecipient’s compliance with the FCOI regulations and management plans; and
- Report all identified FCOIs to the PHS or NSF.

Subrecipient Institutions that rely on their own FCOI policy must:

- Certify that their FCOI policy complies with the relevant federal regulations; and
- Report identified FCOIs to NWIC in sufficient time to allow NWIC to report the FCOI to the PHS to meet its reporting obligations.

NWIC may incorporate these requirements in the written agreement with the Subrecipient[s].

Subrecipient Institutions that rely on NWIC's FCOI policy must submit all Investigator disclosures of significant financial interests to NWIC in sufficient time for NWIC to review, manage, and report identified FCOIs to the PHS. NWIC may incorporate this requirement in the written agreement with the Subrecipient[s].

G. Public Accessibility Requirements for FCOIs identified for Senior/Key Personnel.

42 CFR § 50.604(a)-(c)
42 CFR § 50.605(a)(5)(i)-(iv)

NWIC ORSP shall maintain an up-to-date, written, enforced policy on FCOI that complies with the regulations 42 CFR 50 Subpart F. ORSP will make this up-to-date policy available via NWIC's publicly accessible Web site.

NWIC ORSP will also make information on FCOIs of senior/key personnel publicly accessible on NWIC's publicly accessible Web site. Only information that meets all three (3) of the following criteria are to be publicly accessible:

1. The significant financial interest was disclosed and is still held by the senior/key personnel for the research project funded by PHS or NSF and identified by the Institution in the grant application, progress report, or any other required report submitted to the funder;
2. NWIC determines the significant financial interest is related to research funded by PHS or NSF; and
3. NWIC determines that the significant financial interest is a FCOI.

The information that the Institution makes available via a publicly accessible Web site or written response shall include, at a minimum, the following:

1. Investigator's name;
2. Investigator's title and role with respect to the research project;
3. Name of the entity in which the significant financial interest is held;
4. Nature of the significant financial interest; and
5. Approximate dollar value of the significant financial interest (the following dollar ranges are permissible):
 - \$0-\$4,999;
 - \$5,000-\$9,999;
 - \$10,000-\$19,999;
 - 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.

NWIC shall update at least annually the information pertaining to the regulations 42 CFR 50 Subpart F that NWIC maintains on its publicly accessible Web site. In addition, NWIC shall update the Web site within sixty (60) days of receipt or identification of information concerning:

- any additional significant financial interests of the senior/key personnel for the PHS-funded research project that was not previously disclosed; or
- upon the disclosure of a significant financial interest of senior/key personnel; or
- upon the disclosure of a significant financial interest of senior/key personnel new to the research funded by PHS or NSF, if the Institution determines that the significant financial interest is related to that research and is a FCOI.

The Web site shall note that the information provided:

- is current as of the date listed;
- is subject to updates on at least an annual basis and within sixty (60) days of NWIC's identification of a new FCOI; and
- shall be maintained on the Web site for at least three (3) years after the most recent update.

See also **F. Subrecipient Requirements.**

H. Maintenance of Records.

42 CFR § 50.604(i)

42 CFR § 50.606(b)

42 CFR § 75.361, Retention requirements for records

NWIC ORSP will retain and maintain all records pertaining to Conflicts of Interest for at least three (3) years from the date of NWIC's Final Expenditures Report to PHS or NSF. If any litigation, claims, or audits opened before three (3) years from the date of NWIC's Final Expenditures Report, ORSP will retain and maintain these records until all litigation, claims, or audits have resolved and final action taken. ORSP will also retain and maintain records of the disclosures related to FCOIs whether the disclosure was by Investigators, NWIC, or others.

NWIC is required to submit, or permit on site review of, all records pertinent to compliance with this policy. ORSP will maintain records per the NWIC Financial Manual, Section 228 Retention of Records.

I. Clinical Research.

42 CFR § 50.606(c)

If the PHS-funded research 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 Institution as required 42 CFR 50 Subpart F, NWIC shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

709.8 RELATED INFORMATION

- A. NWIC Grants Managers Manual
- B. NWIC Financial Manual
- C. NWIC Personnel Policy Manual
- D. Policy 806: Institutional Review Board

709.9 REVIEW DATE

This Policy will be reviewed every five (5) years, per NWIC requirements.