



GREAT LAKES INTER-TRIBAL COUNCIL, INC.

P.O. Box 9, Lac du Flambeau, Wisconsin 54538

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Policy: Financial Conflicts of Interest

A. Purpose

This policy (the "Policy") is intended:

1. To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from an Investigator's (defined herein) financial conflict of interest.
2. To meet the regulatory requirements of 42 CFR Part 50 and 45 CFR Part 94 for Public Health Service (PHS) funded research.

B. Scope

This Policy carries out Great Lakes Inter-Tribal Council, Inc.'s ("GLITC") responsibilities under the Public Health Service ("PHS") Policies on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought, 42 CFR Part 50, Subpart F. This Policy is applicable to any person in an Investigator role (defined below). This Policy is in addition to the Great Lakes Inter-Tribal Council's Conflict of Interest and Ethics policy which governs GLITC's business decisions and actions of individual employees in conducting GLITC business. Any significant variation of this Policy will be approved in advance by General Counsel of GLITC. This policy applies to organizational units and members of the workforce who meet this policy's definition of "Investigator" or are otherwise involved in GLITC's research-related activities, including those which are funded through a research-related grant.

C. Definitions

1. **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.
2. **Significant Financial Interest (SFI)** exists if the value of remuneration received by the Investigator, Investigator's spouse or dependent children that reasonably appear to be related to the Investigator's GLITC responsibilities exceeds \$5,000;

a) Including:

- i. Salary or other payments for services (e.g., consulting fees or honoraria) received in the twelve months preceding disclosure;
- ii. With regard to any publicly traded entity, 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 the 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 Interests" include any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.



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- iii. Regarding any non-publicly traded entity, 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 (and/or the Investigator's spouse and/or dependent children) holds any Equity Interest in such entity regardless of amount; and
 - iv. Income from intellectual property rights owned by the Investigator; or
 - v. Financial interests received from a foreign Institution of higher education or any foreign governmental body of any size or nature.
- b) Excluding:
- i. Salary or other remuneration from GLITC;
 - ii. Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, derived from excluded sources;
 - iii. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions;
 - iv. Unlicensed intellectual property owned by the Investigator that does not generate income and intellectual property owned by GLITC; and
 - v. Income from seminars, lectures, or teaching engagements sponsored by a local, state, or federal government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institute of higher education.
- c) SFI also includes travel, specifically, externally funded reimbursed or sponsored travel that would appear to be related to the Investigator's Responsibilities and not funded by GLITC, and must be disclosed regardless of amount. Such travel expenses need not be disclosed when the expenses are covered by an excluded source.
- d) The threshold of \$5,000 is applied to the aggregation of a)i and a)ii, iii or to a)iv.
3. **Investigator** means any principal investigator and any other person, regardless of title or position, who is responsible for the investigation, design, conduct, or reporting of research, which may include employees, contractors, collaborators, volunteers, or consultants.
4. **Investigator's professional responsibilities on behalf of GLITC (Responsibilities)** means conducting research, submitting patent applications, publication, technical committee membership, teaching as adjunct faculty at an institution of higher education and other responsibilities as assigned by GLITC.
5. **Excluded Source** means a source of remuneration that is excluded from disclosure. With reference to C.2.b) ii and C.2.c) excluded sources are federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

D. General Principals

1. Each such Investigator must:



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- a) **disclose** his or her SFI in non-GLITC entities that would appear to be related to the Investigator's Responsibilities on behalf of GLITC;
 - b) **comply** with an FCOI management plan, if an FCOI is identified; and
 - c) **undergo** FCOI training as set forth herein, and at least once every four years.
2. Disclosure of SFI is essential for GLITC to determine if an FCOI exists, and in cases of an FCOI determine how it will be managed and reported in full compliance with government regulation. Non-disclosure of SFI or non-compliance with an FCOI management plan may subject the Investigator to employment discipline including, without limitation, suspension, or termination of employment.
 3. Investigators who are planning to, assigned to or participating in research or other activity that is either partially or wholly supported by PHS funds must disclose their SFI in a timely fashion, either to a member of the GLITC Administrative Team or the designated GLITC official. The designated GLITC official, in consultation with the GLITC Administrative team, will determine whether the SFI constitutes a FCOI, based on guidance set forth by this Policy. If the SFI is determined to be an FCOI, the GLITC Administrative Team will take actions to discuss and approve the implementation of an FCOI management plan consistent with government regulation and, furthermore, to promptly notify the PHS funding component (e.g., NIH) via an FCOI report.
 4. As a part of the FCOI management plan, the GLITC Administrative Team will decide necessary actions, including requiring certain disclosure in public presentations, Investigator role reassignment, reduction, or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that create financial conflicts. Investigators with an identified FCOI must comply with the FCOI management plan.

E. Protocol for Handling Financial Conflict of Interest

1. This Policy hereby incorporates by reference the "Financial Conflict of Interest in PHS-Funded Projects." Capital terms used herein but not defined have the meaning as set forth in the Financial Conflict of Interest in PHS-Funded Projects policy. This Policy outlines the procedure that will be followed as per regulation (Title 42 CFR 50.601-50.607).
2. This document specifies the FCOI procedures for PHS-funded research that is the step-by-step implementation of this Policy.
 - a) Individuals required to disclose financial interests:

Investigators planning to or participating in research activity that is either partially or wholly supported by PHS funds are required to disclose financial interests ("PHS-funded Investigators").
 - b) Required SFI disclosure:

PHS-funded Investigators are required to disclose SFIs to either a member of the GLITC Administrative Team or the designated GLITC official, as follows:

 - i. Investigators planning to participate in PHS-funded research are required to disclose all SFIs prior to submission of an application for PHS-funded research.
 - ii. Once the research project has been funded, all PHS-funded Investigators shall submit SFI disclosures within thirty days of acquiring any new or increased SFI.



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- iii. When a new Investigator joins an ongoing PHS-funded project, the Investigator shall submit SFI disclosures within thirty days of joining the project.
 - iv. All PHS-funded Investigators shall submit an updated SFI disclosure annually.
 - v. SFI disclosures (except travel) must include the following information:
 - a. Identity of the sponsor/organizer; and
 - b. Nature of SFI (e.g., salary, license income, stock).
 - vi. PHS-funded Investigators shall submit SFI disclosures for externally funded travel prior to submission of an application for PHS-funded research; and for PHS-funded projects within thirty (30) days of externally funded travel and in an annual update. The following travel related information must be disclosed:
 - a. Purpose,
 - b. Identity of the sponsor/organizer,
 - c. Destination, and
 - d. Duration.
- c) Review of disclosures:
- i. All SFI disclosures, including those submitted by a new Investigator who joins an ongoing PHS-funded project, will be reviewed by the designated GLITC official. The review will determine whether a SFI is related to the PHS-funded research and therefore a FCOI. The designated GLITC official may involve the relevant Investigator in the review and request additional information from the Investigator.
 - ii. When a SFI that was not disclosed by a PHS-funded Investigator in a timely manner is identified, the designated GLITC official will determine if FCOI exists, and will develop and implement a FCOI management plan within sixty days after the identification of the SFI. In addition, the designated GLITC official will conduct a retrospective review of SFIs for the PHS-funded Investigator within one hundred twenty days and document the review.
- d) Management of FCOI:
- i. For each disclosure that leads to determination of FCOI, the GLITC Administrative Team will discuss and approve the implementation of a management plan developed by the designated GLITC official. PHS-funded Investigators with an identified FCOI must comply with the management plan. The management plan will include the following elements:
 - a. The role and principal duties of the conflicted PHS-funded Investigator in the research project;
 - b. Conditions of the management plan (see examples below);
 - c. How the management plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the PHS-funded Investigator's agreement to the management plan; and
 - e. How the management plan will be monitored to ensure PHS-funded Investigator compliance.



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- ii. Examples of conditions or restrictions that might be imposed to manage a PHS-funded Investigator's FCOI include, but are not limited to:
 - a. Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s)).
 - b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - c. 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;
 - d. Modification of the research plan;
 - e. Change of personnel or personnel Responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
 - f. Reduction or elimination of the SFI (e.g., sale of an Equity Interest); or
 - g. Severance of relationships that create financial conflicts.

- e) Reporting FCOI to PHS Awarding Component (e.g., the NIH)
 - i. Based on the FCOI management plan, the designated GLITC official will make sure an initial FCOI report is submitted to the PHS-funding component, for example NIH. The report will be submitted, for example using eRA Commons for NIH, and consist of all elements required by the regulation.
 - ii. The FCOI report will be submitted prior to the expenditure of funds under the Notice of Award. FCOIs identified during the period of award will be submitted to NIH within sixty days of identification, including for new Investigators joining an ongoing PHS-funded project.
 - iii. Annual FCOI reports (or revised reports as a result of retrospective reviews) will also be submitted and will include the status of financial conflict, i.e., whether the financial conflict is still being managed or explains why the financial conflict no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

- f) Training for FCOI:

PHS-funded Investigators must undergo training with respect to this Policy and PHS FCOI rules and regulations as follows:

 - i. GLITC will include an overview of these guidelines in the annual grant training;
 - ii. Prior to participating in PHS-funded research, and/or at least once every four years;
 - iii. When the Policy changes in a manner that affects PHS-funded Investigator disclosure or compliance requirements; and
 - iv. If GLITC Administrative Team determines that a PHS-funded Investigator is not compliant with this Policy or an FCOI Management Plan.

- g) Sanctions for violation of this Policy:
 - i. Disclosure of SFI is essential for GLITC to implement its FCOIP. If a PHS-funded Investigator fails to comply with this Policy (with regard for instance to the SFI



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disclosure requirement or implementation of an FCOI management plan), and appears to have biased the PHS-funded research, the GLITC Administrative Team will implement a mitigation plan and require that the Investigator disclose the FCOI in each public presentation of the results of the research, and to remedy previously published presentations with an FCOI disclosure addendum. In addition, the Investigator may be subject to discipline including, without limitation, suspension or termination of employment or contract.

- ii. In any case, the PHS-funding agency will be promptly notified.

h) Retention of records:

Records of financial disclosures and any resulting action will be maintained for three years from the date of submission of the final expenditures report.

i) Subrecipient compliance:

When working with a subrecipient, a written agreement will be put in place to clarify: (a) which organization's (prime awardee or subrecipient) FCOI policy will be followed, and (b) in either case, clarify the timeline for disclosure and reporting. Note that the prime awardee is responsible for monitoring the subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified financial conflicts of interest.

j) Public Accessibility:

- i. As required by PHS regulation, this Policy is being made accessible on GLITC's web site, www.glitc.org
- ii. If a PHS-funded Investigator holds financial interests that are determined to be FCOI, as required by PHS regulation, these will also be posted on the web site, as follows: www.glitc.org/glnarch under the "Compliance" tab
 - 1) Include the minimum elements required by the regulation;
 - 2) Update within sixty days of a newly identified FCOI;
 - 3) Update annually; and
 - 4) Remain available for three years.