

American Indian Higher Education Consortium (AIHEC)
Financial Conflict of Interest Policy (FCOI)
Effective Date: March 1, 2021

Policy Summary

By law, all Investigators applying for and working on award funded research, where required, must disclose significant financial interests (SFIs) that are related to the Investigator's institutional responsibilities. Investigators are ALL persons, regardless of title or position, who are responsible for the design, conduct, or reporting of award funded research proposed for funding, including collaborators and/or consultants. This policy provides the framework to identify, evaluate and correct or remove real, apparent and potential conflicts of interest.

Definitions/Glossary

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 award funded research.

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

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

Investigator – 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 award funded research or proposed for such funding, which may include, for example, collaborators and/or consultants.

Manage – 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 – a project director or principal investigator of an award funded research project.

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. As used in his policy, the term includes any such activity for which research for which funding is available through a grant or cooperative agreement, whether authorized under any 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 PD/PI and any other person identified as senior/key personnel by AIHEC in the grant application, progress report, or any other report submitted to an award funder by AIHEC.

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, 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.

(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 AIHEC.

This Policy Applies to: ALL persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for award funding, including collaborators and/or consultants.

Reason(s) for the Policy

AIHEC complies with regulations pertaining to Financial Conflicts of Interest in award funded research. As an institution that regularly competes for and receives award funding for research, AIHEC is required to have a written and enforced policy on conflict of interest.

The policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. The policy further provides a mechanism for all conflicts of interest for each award to be managed, reduced or eliminated prior to the expenditure of the award funds.

Policy

The Grants Administrator will inform each Investigator of AIHEC's policy on financial conflicts of interest, the Investigator's responsibilities regarding timely disclosure of significant financial interests, and regulations governing any award funded research prior to submitting an application to a funding agency.

Investigator Responsibilities

Each Investigator who is planning to participate in award funded research must disclose to the Grants Administrator, the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for any award funded research. Investigators must complete the appropriate Financial Disclosure Form found in the appendix of this policy. Any Investigator who is participating in any award funded research must submit an updated disclosure of significant financial interest at least annually during the period of the award.

In the event a financial conflict of interest arises during the period of the award, the Investigator is required to notify the Grants Administrator within thirty days of discovering or acquiring a new significant financial interest.

Investigators are required to complete training prior to engaging in research related to any award funded grant, at least every four years thereafter, or AIHEC revises its FCOI policy affecting requirements of Investigators. Training is also required in cases where an Investigator is new to AIHEC and continues to serve as an Investigator in a funded project transferred from another institution to AIHEC. Refresher training is required in the event an Investigator is not in compliance with AIHEC's financial conflict of interest policy or management plan. Financial conflict of interest training is administered and available through the Grants Administrator. Investigators applying for funding from any awarding agency are encouraged to complete financial conflict of interest training.

Investigators Engaged in Subrecipient Research or Engaging Others as Subrecipients

All staff engaged in award funded research as a subrecipient may be required by the awardee institution to comply with the awardee institution's own financial conflict of interest policy. Likewise, in cases where AIHEC serves as the awardee institution in award funded research projects, AIHEC may require subrecipients to comply with AIHEC's financial conflicts of interest policy. In these cases, the awardee institution or subrecipient and AIHEC must incorporate, in a written agreement, whether the financial conflicts of interest policy of the awardee institution or that of the subrecipient will apply to the subrecipient's Investigators.

If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with applicable law. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution.

Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the award funder as required by law. Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee institution. Such time period(s) shall be sufficient to enable the awardee institution to comply timely with its review, management, and reporting obligations.

Significant Financial Interests Identified

The Grants Administrator is designated as AIHEC's institutional official to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the award funded research as detailed above. In the event the Investigator discloses a significant financial interest, the Grants Administrator will notify AIHEC's President & CEO and Vice President of Finance and Administration, who will then evaluate all available evidence to determine if an Investigator's significant financial interest is related to an award funded research project and, if so related, whether the significant financial interest is a financial conflict of interest.

Financial Conflict of Interest Identified

In cases where AIHEC's President & CEO and Vice President of Finance & Administration identify a financial conflict of interest, they are tasked with taking such actions as necessary to manage the financial conflict of interest. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report. Additionally, they must comply with, and provide, initial and ongoing FCOI reports to the award funder.

AIHEC must maintain records relating to all Investigator disclosures of financial interests and AIHEC's review of, and response to, such disclosures (whether or not a disclosure resulted in AIHEC's determination of a financial conflict of interest) and all actions under AIHEC's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the award funder or, from other dates, where applicable.

Management of Financial Conflicts of Interest

The President & CEO is required to develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage financial conflicts of interest when they arise. The following examples are conditions or restrictions that may be imposed by the President & CEO to manage a financial conflict of interest, but they are not limited to:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest 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 financial conflict of interest;
- (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.

Penalties and Enforcement

Regulations require AIHEC to impose sanctions or take other administrative actions where appropriate. AIHEC maintains the right to impose sanctions on Investigators for failure to disclose significant financial interests and for failure to abide by this policy.

Sanctions may include restrictions on future submission of research proposals and other disciplinary actions up to and including dismissal. Investigators have the right to appeal any sanction or disciplinary actions.

Confidentiality

Except to the extent required by law and federal regulations, the information disclosed throughout these processes will be kept confidential. AIHEC, however, is required to report the existence of real or potential conflicts of interest to certain federal agencies.

Reporting of Financial Conflicts of Interest

Prior to AIHEC's expenditure of any funds or at anytime during the course of an ongoing award funded research project, AIHEC shall: review all Investigator disclosures of significant financial interest; determine whether any significant financial interests relate to award funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by AIHEC to constitute a financial conflict of interest; failure by AIHEC to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, AIHEC shall, within 120 days of AIHEC's determination of noncompliance, complete a retrospective review of the Investigator's activities and the award funded research project to determine whether any award funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

AIHEC is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigator with the FCOI; (5) Name of the entity with which the Investigator has a financial conflict of interest; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, AIHEC shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, AIHEC is required to notify the Awarding Component promptly and submit a mitigation report to the Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and AIHEC's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, AIHEC will submit FCOI reports annually, as specified elsewhere in the policy. Depending on the nature of the financial conflict of interest, AIHEC may determine that additional interim measures are necessary with regard to the Investigator's participation in the award funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of AIHEC's retrospective review.

Whenever AIHEC implements a management plan pursuant to this policy, AIHEC shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the award funded research project.

Prior to AIHEC's expenditure of any funds under an award funded research project, AIHEC shall ensure public accessibility, via a written response, to any requestor within five business days of a request of information concerning any significant financial interest disclosed to AIHEC that meets the following three criteria: (A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart; (B) AIHEC determines that the significant financial interest is related to the award funded research; and (C) AIHEC determines that the significant financial interest is a financial conflict of interest.

The information that AIHEC makes available via a written response to any requestor within five business days of a request, 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 significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (the following dollar ranges will be used: \$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.

The written response will contain a note that "the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within

60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.”

Additional Reporting Requirements

Prior to AIHEC's expenditure of any funds under a award funded research project, AIHEC shall provide to the Awarding Component an FCOI report regarding any Investigator's significant financial interest found by AIHEC to be conflicting and ensure that AIHEC has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of awarded funds, AIHEC shall not submit an FCOI report to the Awarding Component.

For any significant financial interest that AIHEC identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing award funded research project (e.g., upon the participation of an Investigator who is new to the research project), AIHEC shall provide to the Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this subpart. Where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), AIHEC also is required to complete a retrospective review to determine whether any award funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, AIHEC is required to notify the Awarding Component promptly and submit a mitigation report to the Awarding Component.

Any FCOI report required under this policy shall include sufficient information to enable the Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of AIHEC's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following: (i) Project number; (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used; (iii) Name of the Investigator with the financial conflict of interest; (iv) Name of the entity with which the Investigator has a financial conflict of interest; (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); (vi) Value of the financial interest (dollar ranges will be used: \$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; (vii) A description of how the financial interest relates to the award funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and (viii) A description of the key elements of the Institution's management plan, including: (A) 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.

For any financial conflict of interest previously reported by AIHEC with regard to an ongoing award funded research project, the Institution shall provide to the Awarding Component, an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the award funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. AIHEC shall provide annual FCOI reports to the Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the Awarding Component.

In addition, AIHEC will maintain all FCOI-related records for at least 3 years from the date the final expenditures report is submitted to the funding agency.

Exclusions and Special Situations

Not applicable

Policy Contact(s)

Responsible Office: Office of Grants Administration

Policy Author: Kathy DePalma, Grants Administrator

Email: kdepalma@aihec.org

Phone: 703-838-0400

Appendix

- I. Financial Conflict of Interest (FCOI) Disclosure Form – Used for all award funded projects included here or as a separate attachment.