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Department:	Organization-Wide Policy	Policy #01-2074
Approved By:	Ethics and Compliance Services	Effective Date: 11/10/2016
Policy Owner:	Ethics and Compliance Services	Last Reviewed: 11/14/2023

**1. Purpose:**

To protect research-related activities against potential risks posed by financial conflicts of interest.

**2. Scope:**

This policy applies to organizational units and members of the workforce who meet this policy’s definition of “investigator” or are otherwise involved in Alaska Native Tribal Health Consortium’s (ANTHC’s) research-related activities, including those which are funded through a research-related grant.

**3. Definitions:**

- 3.1. Financial Conflict of Interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of a research project or program.
- 3.2. Financial Interest: anything of monetary value, whether or not the value is readily ascertainable.
- 3.3. Investigator: the project director or principal investigator and any other person, regardless of title or position, who is responsible for design, conduct, or reporting of research, including collaborators or consultants.
- 3.4. Key Personnel: a research project director or principal investigator (PD/PI) and any other person ANTHC identifies as having significant responsibility in the development of, oversight of, or influence over a research project, including persons identified as having such responsibility in the grant application, progress report, or any other report submitted to a granting agency.
- 3.5. 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 chapter) and product

development (e.g., diagnostic test or drug), and any activity for which research funding is available from a Public Health Service (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.

#### 4. Policy:

- 4.1. Financial Conflicts of Interest (FCOI) Program. ANTHC is committed to maintaining the highest ethical and legal standards and the integrity of its research-related activities. As part of fulfilling this commitment, ANTHC administers a Financial Conflicts of Interest (FCOI) program under this policy, which is consistent with Public Health Service/National Institutes of Health (PHS/NIH) regulations, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” 42 CFR, Part 50, Subpart F (grants and cooperative agreements), and 45 CFR Part 94 (contracts).
- 4.2. Investigator Disclosures.
  - 4.2.1. Training. Investigators must complete training upon joining the ANTHC workforce or prior to engaging research, and then at least every four years. An investigator must also complete training after a policy change that affects FCOI requirements or after a finding of non-compliance by the investigator. Training will include information on this policy and other applicable requirements, including disclosure responsibilities.
  - 4.2.2. Timing. Investigators must submit disclosures:
    - 4.2.2.1. upon joining the ANTHC workforce;
    - 4.2.2.2. before ANTHC’s application for research funding or, if joining the project after application, before beginning research;
    - 4.2.2.3. annually, or more frequently if required by an award or grant; and
    - 4.2.2.4. within 30 days of discovering or acquiring a new significant financial interest.

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4.2.3. Content. Investigators must disclose any “Significant Financial Interests” of the investigator and of the investigator’s spouse and dependent children and any “Reimbursed or Sponsored Travel.”

4.2.3.1. A “Significant Financial Interest” means one or more of the following financial interests of the investigator, the investigator’s spouse, or the investigator’s dependent children that reasonably appears to be related to the investigator's ANTHC responsibilities:

4.2.3.1.1 remuneration received from a publicly traded entity in the 12 months before the disclosure and/or any equity interest in the entity as of the date of disclosure that, when aggregated, exceeds \$5,000. 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; and

4.2.3.1.2 remuneration received from a non-publicly traded entity in the 12 months before the disclosure, that when aggregated, exceeds:

4.2.3.1.2.1. \$5,000, or any equity interest (e.g., stock, stock option, or other ownership interest); or

4.2.3.1.2.2. intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

4.2.3.1.3 The term “Significant Financial Interest” does not include:



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- 4.2.3.1.3.1. salary, royalties, or other remuneration paid by ANTHC to the investigator as a current member of the workforce, including intellectual property rights assigned to ANTHC and related royalty sharing;
  - 4.2.3.1.3.2. 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;
  - 4.2.3.1.3.3. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, or 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
  - 4.2.3.1.3.4. 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.
- 4.2.3.2. “Reimbursed or Sponsored Travel” means any travel paid on behalf of the investigator and not reimbursed by the investigator, related to their institutional responsibilities; provided, however, it does not include travel that is reimbursed or sponsored by a 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. Such disclosures will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

4.2.3.3. Disclosure of other interests may be required where ANTHC has identified such interest as a potential conflict for a particular research project or through a separate conflict of interest policy.

4.3. Institutional Review Committee. The ANTHC Institutional Review Committee (IRC) will be appointed by the President/Chief Executive Officer (CEO) and report to the Research Integrity Committee.

4.3.1. The IRC must solicit and review investigator disclosures to determine if a significant financial interest exists.

4.3.2. If a significant financial interest exists, the IRC must determine if it is related to a research project. A relationship exists when the significant financial interest could be affected by the research or is in an entity whose financial interest could be affected by the research.

4.3.3. Where a significant financial interest is determined to be related to a research project, the IRC must determine whether it constitutes an FCOI. FCOI exists when the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

4.4. Managing Conflicts. If the IRC determines that an investigator (including a sub-recipient investigator) has an FCOI, the Research Integrity Officer will work with the investigator to manage, reduce, or eliminate the conflict by developing and implementing a management plan.

4.4.1. Management Plan. Management plans specify actions that have been and will be taken to manage an FCOI. Management actions may include, but are not limited to:

4.4.1.1. public disclosure of FCOI (e.g., when presenting or publishing the research);

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- 4.4.1.2. for research projects involving human subjects research, disclosure of FCOI directly to participants;
  - 4.4.1.3. appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias from the FCOI;
  - 4.4.1.4. modification of the research plan;
  - 4.4.1.5. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - 4.4.1.6. reduction or elimination of financial interest (e.g., sale of equity interest); or
  - 4.4.1.7. severance of relationships that create financial conflicts.
- 4.4.2. Interim Management Plan. Where an investigator discloses a new significant financial interest during a research project or where an investigator who is new to an ongoing research project discloses a significant financial interest, the Research Integrity Officer will implement an interim management plan until the IRC makes a determination and takes appropriate interim measures with regard to the investigator's project participation.
- 4.4.3. Mismanagement. Mismanagement and significant lapses in managing conflicts in accordance with a management plan will be reported to the Research Integrity Committee and the President/CEO.
- 4.5. FCOI Reports. This section reflects PHS/NIH requirements for initial and ongoing FCOI reports. Additional reporting requirements may be associated with a particular funding source and should also be included in the reporting plan for a research project.
- 4.5.1. Content. FCOI reports will include sufficient information about ANTHC and any sub-recipient investigators to allow the funding agency to understand the nature and extent of the financial conflict and to assess the appropriateness of ANTHC's management plan. FCOI reports typically include at least the following:
    - 4.5.1.1. project number;

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- 4.5.1.2. PD/PI or Contact PD/PI;
- 4.5.1.3. name of the investigator with the FCOI;
- 4.5.1.4. name of the entity with which the investigator has an FCOI;
- 4.5.1.5. nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 4.5.1.6. the dollar range of the value of the financial interest 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;
- 4.5.1.7. a description of the financial interest relation to the research and ANTHC's basis for determining that an FCOI exists; and
- 4.5.1.8. a description of ANTHC's management plan's key elements, including:
  - 4.5.1.8.1 role and principal duties of conflicted investigator in the project;
  - 4.5.1.8.2 conditions of the management plan;
  - 4.5.1.8.3 how management plan safeguards objectivity in the project;
  - 4.5.1.8.4 confirmation of the investigator's agreement to the management plan;
  - 4.5.1.8.5 how compliance with the management plan will be monitored; and
  - 4.5.1.8.6 other information, as needed.
- 4.5.2. Initial FCOI Reports. If an investigator has an FCOI that has not been eliminated before the expenditure of funds, an initial FCOI report will be provided to a funding agency before expenditure of any funds for the research project.

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- 4.5.3. Ongoing Research Project FCOI Report. Where a significant financial interest is identified after the initial FCOI report and is determined to be an FCOI, ANTHC will provide the funding agency an FCOI report within 60 days.
- 4.5.4. Annual FCOI Report. If an initial or ongoing research project FCOI report was made for an ongoing research project, ANTHC will provide the funding agency annual FCOI reports that state whether the financial conflict is still being managed and any changes to the management plan or explain why the FCOI no longer exists.
- 4.5.5. Untimely Disclosures. Where ANTHC identifies a significant financial interest that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed or reported by ANTHC during an ongoing research project, then within 60 days the IRC will review the significant financial interest and determine whether it is related to the research and if an FCOI exists. If an FCOI exists, then ANTHC will implement, on at least an interim basis, a management plan specifying actions that have been and will be taken to manage the FCOI, in accordance with Section 4.4.1, and will conduct a retrospective review in accordance with Section 4.6. Untimely disclosures will also be reported to the Research Integrity Committee.
- 4.6. Retrospective Review. A retrospective review is a review of the investigator’s activities and the research project to determine if any research project, or portion of the project, conducted during the period of noncompliance was biased in design, conduct, or reporting. The Research Compliance Officer will conduct a retrospective review when:
  - 4.6.1. FCOI is not identified or managed in a timely manner, including if due to failure by the investigator to make a timely disclosure;
  - 4.6.2. ANTHC fails to review or manage an FCOI in accordance with this policy or applicable law; or
  - 4.6.3. when an investigator is found to have failed to comply with a management plan.
- 4.7. Retrospective reviews will be completed within 120 days of a noncompliance determination and reported to the Research Integrity Committee and President/CEO.



- 4.8. Documentation. A retrospective review must be documented with a written report that includes, at a minimum:
- 4.8.1. project number;
  - 4.8.2. project title;
  - 4.8.3. PD/PI, or contact PD/PI if a multiple PD/PI model is used;
  - 4.8.4. name of the investigator with the FCOI;
  - 4.8.5. name of the entity with which the investigator has an FCOI;
  - 4.8.6. reason(s) for the retrospective review;
  - 4.8.7. detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
  - 4.8.8. findings of the review; and
  - 4.8.9. conclusions of the review.
- 4.9. Follow-Up. After a retrospective review, ANTHC will submit annual FCOI reports and, if appropriate, update previous FCOI reports specifying actions that will be taken to manage the FCOI going forward. If bias was found, ANTHC will notify the funding agency promptly and submit a mitigation report, which includes, at a minimum:
- 4.9.1. the retrospective review's key elements;
  - 4.9.2. a description of the bias's impact on the project; and
  - 4.9.3. ANTHC's plan of action or actions taken to eliminate or mitigate the effect of the bias.
- 4.10. Public Information.
- 4.10.1. Policy. This policy will be accessible to the public on the ANTHC website, at <https://www.anthc.org>, on the Corporate Compliance page.

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4.10.2. Key Personnel FCOI Information. ANTHC will make available to the public, either on the ANTHC website or by written response to a requestor within five business days, information about an FCOI of an investigator who is part of the “Key Personnel” on an ANTHC research project. This available information will include:

- 4.10.2.1. investigator’s name;
- 4.10.2.2. investigator’s title and role with respect to the research project;
- 4.10.2.3. name of the entity in which the Significant Financial Interest is held;
- 4.10.2.4. nature of the Significant Financial Interest; and
- 4.10.2.5. approximate dollar value of the Significant Financial Interest or a statement that the interest’s value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

4.10.3. Notices. Publicly accessible information will include a statement that the information provided is current as of the date listed (for a website) or the date of the correspondence (for a written request response) and is subject to updates on at least an annual basis and within 60 days of ANTHC’s identification of a new FCOI.

4.11. Sub-Recipients. Where research is carried out through a sub-recipient, such as a subcontractor or partner organization, ANTHC will incorporate relevant information about the sub-recipient’s investigators into its FCOI reports. ANTHC will use written agreements or other arrangements to ensure the sub-recipient timely reports disclosures to ANTHC and meets other applicable requirements.

4.12. Recordkeeping. ANTHC maintains records relating to investigator disclosures of significant financial interests and review of, and response to, such disclosures (whether or not determined to be an FCOI) and all actions under this policy for at least three years from the date the final expenditures report is submitted to the funding agency and for longer if otherwise required. Disclosures concerning the significant financial interests of an individual are subject to public access and shall remain available, for responses to written requests or for posting via ANTHC’s publicly accessible web site, for at least three years from the date that the information was most recently updated.



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4.13. Violation. Any member of the workforce who violates this policy may be subject to discipline or corrective action.

References:

- 1) 42 CFR, Part 50, Subpart F
- 2) 45 CFR Part 94
- 3) 20 U.S.C §1001(a)