

Alaska Community Action on Toxics
Financial Conflict of Interest (FCOI) Policy

Purpose

Identification and management of financial conflicts of interest are necessary to promote objectivity and integrity in Alaska Community Action on Toxic's (ACAT) research efforts. This policy was created to reflect ACAT's dedication to ensuring objectivity and integrity in its research efforts and to comply with NIH regulation 42 CFR 50, Subpart F – *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*.

Who is Covered?

Review of and agreement with the following policy is required for ACAT Investigators, Senior/Key personnel, and Sub-Award recipients involved in Public Health Service (PHS)-funded research.

Definitions

The following definitions are based on the NIH website and are meant as a reference and to provide clarification regarding this policy. Additional definitions can be found in 42 CFR 50.603.

Bias – Prejudice or favor that may affect the design, conduct or reporting of a PHS-funded project.

Disclosure of Significant Financial Interest – 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.

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.

Institution – any domestic or foreign, public, or private, entity or organization (excluding a federal agency). For the purposes of this document the institution refers to ACAT.

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

Investigator – the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

Senior/Key Personnel – the Principal Investigator and any other person identified as senior/key personnel by ACAT in the grant application, progress report, or any other report submitted to the PHS by ACATACAT.

Significant Financial Interest (SFI)

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:
 - a. 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 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;
 - b. 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
 - c. 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 or 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 or 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. This disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
3. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by ACAT to the Investigator if the Investigator is currently employed or otherwise appointed by ACAT, including intellectual property rights assigned to ACAT and agreements to share in royalties related to such rights; any ownership interest in ACAT held by the Investigator, if the institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Training Requirements

All Investigators are required to take part in training prior to engaging in research related to any PHS-funded grant. The training module is provided through the NIH website (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html).

An investigator must retake training without delay without delay if:

1. Any revisions or updates are made to ACAT's FCOI policy.
2. Four years have elapsed since the last training session.
3. An investigator is new to a PHS-funded project.
4. ACAT finds that an investigator is not in compliance with its FCOI policy.

Upon successful completion on the training, Investigators are required to submit a Certificate of Completion to ACAT's Designated Official (DO).

Disclosure

Each Investigator is required to disclose any potential SFI (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meets or exceeds the NIH definition of SFI. Disclosure is required prior to the application of PHS-funded research; and is to be updated and reviewed annually. Additionally, an Investigator is required to disclose any newly discovered or acquired SFI within 20 days.

Responsibilities & Reporting

ACAT's DO will be responsible for soliciting, reviewing, and managing SFI disclosures from all Investigators involved in PHS-funded research prior to application. The DO will review each SFI according to NIH regulation 42 CFR 50.604 and determine whether the SFI is related to the PHS-funded project. If the DO determines there is a FCOI that could affect the design, conduct, reporting or integrity of the research project, a management plan will be written and implemented within twenty days. The DO will then report the FCOI and management plan to the eRA commons website within sixty days. In cases of newly identified FCOI, the DO will submit all required reports to the NIH within sixty days. For all findings of FCOIs a retrospective review of the respective Investigator's activities will be conducted within 120 days to ensure no there was no bias leading up to the FCOI.

To maintain integrity throughout the life of the research project, and to comply with Federal guidelines, SFIs and FCOIs will be reviewed and solicited on an annual basis, at a minimum, by the designated official.

Records Management

All Records relating to Investigators' SFIs and FCOIs will be retained for no less than three years from the date of submission of the final expenditures report for the PHS-funded grant.

Noncompliance

If an Investigator is found to be noncompliant with ACAT's FCOI policy or FCOI management plan, ACAT will complete a retrospective review within 120 days to determine if there was evidence of bias. If bias is found, the DO will create a mitigation plan and submit to NIH as required in NIH regulations. When a FCOI is discovered, the Investigator will be required to disclose the FCOI in each public presentation of the results of

the research and request an addendum to previously published presentations. In severe cases of noncompliance, removal from the research project or termination may be implemented.

Subrecipient Requirements

All subrecipients involved in PHS-funded research must sign a contract agreeing to comply with ACAT's FCOI policy or provide proof that their respective institution is in compliance with Federal regulation 42 CFR 50, Subpart F. All subrecipient investigators will be required to submit to ACAT, proof of completion of the NIH required training.

Accessibility

ACAT's FCOI policy will be available for public viewing on the organizations website. All written requests will be responded to within 5 calendar days.