

## **A. Further Policy Regarding Financial Conflicts of Interest**

The design, conduct, and reporting of research funded under federal grants or cooperative agreements should be free from bias resulting from investigator financial conflicts of interest.

To provide a reasonable expectation of achieving the goal of this policy, Public Health Service (PHS) supported investigators and relevant employees shall complete appropriate training as required under this policy and investigators shall disclose perceived and real conflicts of interest annually and provide new or updated disclosures in a timely manner. ASH shall provide for the elimination or management of financial conflicts.

### **(1). Training Required:**

Relevant ASH employees and investigators will be informed of ASH's Financial Conflict of Interest (FCOI) policy, the requirement to disclose financial interests, and the Federal FCOI regulations. The employees and investigators of ASH shall complete FCOI training provided by ASH prior to beginning any projects for ASH and then every four (4) years thereafter. ASH will utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest [webpage](#) to satisfy some of the training requirements. ASH will provide additional training regarding investigators responsibilities for disclosure of significant financial interest (SFI) and of ASH's specific policy on financial conflicts of interests. Immediate training will be required if ASH revises this policy in a manner that affects employees or investigators, when an employee or investigator is new to ASH, or as a result of a finding of noncompliance with this policy or a management plan.

### **(2). Disclosure Requirement:**

All investigators shall disclose any situation in which they (and a spouse/partner or child) have, or may have, a real or potential significant financial interest as defined and provided for herein. Research should not be undertaken where a significant financial interest is present until a determination and approval has been made pursuant to this policy.

### **(3). Disclosure Frequency:**

- i. Disclosure must be made at the beginning of an investigators' involvement in a PHS research project.
- ii. Disclosure must be made annually. If no significant financial interest is present a disclosure must still be submitted that states "none".
- iii. In addition to the annual disclosure, a new or updated disclosure must be completed in a timely manner whenever a new or potential significant financial interest arises or when a significant change occurs concerning an existing disclosure.
- iv. In any event, disclosure must be made within thirty (30) days of discovery or acquiring a new significant financial interest.

### **(4). Review and Management:**

- i. The ASH Executive Committee (EC) shall appoint and authorize a conflict of interest officer to solicit and review disclosures of SFIs and determine if it is a FCOI.
- ii. Adequate guidelines consistent with the Federal FCOI regulations will be used to determine if an FCOI exists. These guidelines will also determine whether an investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. An FCOI exists when the officer reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property right and interests, and reimbursed or sponsored travel). If an FCOI exists, the officer shall seek input from the investigator and recommend to the EC a suitable action plan ("management plan") to eliminate or manage the FCOI consistent with the objectives of this policy. The management plan shall provide for its periodic review and updating at least annually. Key elements of the management include:
  - 1) Role and principal duties of the conflicted investigator in the research project;
  - 2) Conditions of the management plan;
  - 3) How the management plan is designed to safeguard objectivity in the research project;
  - 4) Confirmation of the investigator's agreement to the management plan;
  - 5) How the management plan will be monitored to ensure investigator compliance; and
  - 6) Other information needed.

In the event that there is no reasonable way to manage a FCOI, the investigator will be prohibited from participating in the related research until such a time as the FCOI is eliminated.

- iii. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
  - 1) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
  - 2) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
  - 3) 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;
  - 4) Modification of the research plan;
  - 5) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - 6) Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
  - 7) Severance of relationships that create financial conflicts.

- iv. The EC shall review the proposed management plan and can approve, modify and approve, or return to the officer for additional work. Final review and determination must be completed prior to the expenditure of any federal funds for the applicable research.
- v. The decision of the EC is final and cannot be appealed by the investigator.

**(5). Violations and Sanctions**

Violations of ASH policies, including the failure to avoid a prohibited activity or disclose a conflict of interest in a timely manner, will be dealt with in accordance with applicable policies and procedures.

**(6). Retrospective Review**

- i. The officer shall complete retrospective reviews of determinations of noncompliance with this policy within 120 days of the determination.
- ii. The retrospective reviews shall be documented; 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 employee/official with the FCOI;
  - 5) Name of the entity with which the employee/official 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.
- iii. Based on the results of the retrospective review, if appropriate, the officer shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.
- iv. If bias is found, the officer is required to notify the awarding agency promptly and submit a mitigation report to the awarding agency. 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 the institution'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, the officer will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, the

officer may determine that additional interim measures are necessary regarding the investigator's participation in the project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of the committee's retrospective review.

**(7). Clinical Research**

In any case in which the Health and Human Services (HHS) determines that a federally funded project of clinical research whose purpose 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 ASH as required by this policy, the committee 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.

**(8). Institutional Reporting**

- i. ASH, through its officer shall provide annual and revised reports of FCOI to PHS/National Institutes of Health (NIH) or other federal agency per the applicable grant/cooperative agreement terms and conditions or federal regulations.
- ii. ASH, through its officer, shall notify the funding agency of bias found in the design, conduct, or reporting of federally funded research including whether investigator failure to comply with this FCOI policy or management plan appears to have caused such bias.
- iii. FCOI records shall be maintained for at least three (3) years from the submission of the final expenditure reports for the pertinent federal funding or longer as required by other policy or regulation.
- iv. FCOI informational requests by the public should be made to the officer. The officer shall respond to requests for FCOI information within five (5) business days as provided for under applicable regulations.

**(9). Subrecipients**

ASH shall require sub-recipient compliance with pertinent FCOI requirements as mandated by federal regulation.

**(10). Definitions**

*Disclosure* means an investigators' disclosure of significant financial interests to ASH.

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

*FCOI Report* means ASH's report of a financial conflict of interest to a federal awarding agency such as HHS-PHS.

*Financial Interest* means anything of monetary value, whether or not the value is readily ascertainable.

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

*Institutional Responsibilities* means an investigators' professional responsibilities on behalf of the institution, 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* means 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 research funded by the federal government, or proposed for such funding, which may include, for example, postdoctoral fellows, graduate students, undergraduate students, collaborators or consultants.

*Manage* means 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* means a project director or principal investigator of a federally funded research project; the PD/PI is included in the definitions of senior/key personnel under this subpart.

*PHS* means 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).

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

*Research* means a systematic investigation, study or experiment designed to develop or contribute to generalized 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 federal 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* means the PD/PI 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* means:

(a) 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 12 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 employee/official/investigator (or the employee/official's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest), or a management or governance position; or

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

(b) Travel:

(i) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the employee/official and not reimbursed to the employee/official so that the exact monetary value may not be readily available), related to their institutional responsibilities;

(ii) 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.

(iii) Disclosure for travel shall include, at a minimum, the purpose of the trip, the identity of the funding agency/organizer, the destination, and the duration. ASH

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 federally funded research.

(c) Exclusions: The term significant financial interest does not include the following types of financial interests:

(i) salary, royalties, or other remuneration paid by ASH to the investigator if they are currently employed or otherwise appointed by ASH, including intellectual property rights assigned to ASH and agreements to share in royalties related to such rights;

(ii) income from investment vehicles, such as mutual funds and retirement accounts, as long as the employee/official does not directly control the investment decisions made in these vehicles;

(iii) 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

(iv) 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.