

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.

- 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

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

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).

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.