Institutional Financial Conflict of Interest Policy
Related to the 2011 Revised Financial Conflict of Interest (FCOI) Regulation
Promoting Objectivity in Research – 42 CFR Part 50 Subpart F
March 2021

Introduction
NIH policy (see NIH GPS Section 4.1.10 Financial Conflict of Interest) requires institutions subject to the requirements of the Financial Conflict of Interest (FCOI) regulation to maintain an up-to-date, written, enforced FCOI policy that complies with the regulation. Given that the American Society for Investigative Pathology (ASIP) receives NIH funding on a regular (often annual) basis, the Society is required to establish, implement, and maintain such a policy. This document represents the ASIP Institutional Financial Conflict of Interest Policy. In further compliance with the requirements, this policy can be found posted to the official ASIP website (https://www.asip.org/). Although available on the ASIP website, this FCOI policy will be made available to any requestor within five business days of a request. FCOI reports regarding identified financial conflicts of interest will be reported to the PHS Awarding Component in accordance with the requirements of the NIH.

The ASIP, as an institution, does not engage in research in the traditional sense of laboratory-based discovery 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...encompassing basic and applied research and product development). Rather, NIH funding to the ASIP is typically through the R13 mechanism to support trainees to attend and participate in ASIP scientific meetings. The Executive Officer serves as Principal Investigator for R13 submissions to the NIH, and also represents the organization’s Signing Official. As such, the ASIP designates its Executive Committee (consisting of the current President, President-elect, Vice President, and Immediate Past President) as an independent body to review any financial conflicts of interest that might affect the Executive Officer. The designation of this group provides controls to prevent self-regulation in these matters by the Executive Officer. The Executive Officer will provide oversight for training of investigators and reporting by senior/key personnel listed in applications submitted by the ASIP.

Training Requirements
The ASIP will inform each investigator of the Society’s policy on financial conflicts of interest, the investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each investigator to complete training regarding financial conflicts of interest prior to engaging in research related to any PHS-funded grant and on a recurring basis (at least every four years), and immediately when any of the following circumstances apply:

(i) The ASIP revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators involved in funded projects.
(ii) An investigator is new to the ASIP.
(iii) The ASIP finds that an investigator is not in compliance with the Society’s financial conflict of interest policy or management plan.

Training of investigators will include (1) definition of financial conflict of interest (significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research), (2) definition of financial interest (anything of monetary value, whether or not the value is readily ascertainable), (3) mechanisms for disclosure of significant financial interests (reporting to the ASIP), (4) responsibilities of the institution (ASIP) for gathering and reporting financial disclosures to the NIH, and (5) mechanisms to remedy financial conflicts of interest involving NIH funding to the ASIP.

Disclosure, Review, and Monitoring Requirements
Investigators planning to participate in activities associated with ASIP-associated PHS-funded research proposals are required to disclose to the Society’s designated official(s) the investigator's significant financial interests (and those of the investigator's spouse and dependent children) no later than the time of application for PHS-funded research. Investigators are required to submit an updated disclosure of significant financial interests at least annually during the period of the award. Such disclosure will include any information that was not disclosed initially to the ASIP, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another institution), and will include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest). Each investigator who is participating in ASIP-associated PHS-funded research is required to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Designated institutional official(s) for the ASIP will consist of the Executive Officer and the Executive Committee (composed of the current President, President-elect, Vice President, and immediate Past President). These designated ASIP officials will solicit and review disclosures of significant financial interests from each investigator who is planning to participate in, or is participating in, the ASIP-associated PHS-funded research. The Executive Officer will provide oversight for training of investigators and coordinate reporting by senior/key personnel listed in applications submitted by the ASIP.

Investigators are required to report financial interests 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 to the ASIP:

(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.

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, 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. The individual institution's FCOI policy will specify the details of this disclosure, which will include 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.

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 the institution, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights; any ownership interest in the institution 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.

The designated ASIP official(s) (Executive Officer and Executive Committee) will evaluate and determine whether an investigator's disclosed significant financial interest is related to the ASIP-associated PHS-funded research and whether the significant financial interest is a financial conflict of interest. An investigator's significant financial interest is related to PHS-funded research when the ASIP, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The ASIP may involve the investigator in the determination of whether a significant financial interest is related to the ASIP-associated PHS-funded research. A financial conflict of interest exists when the ASIP, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The ASIP will take such actions as necessary to manage financial conflicts of interest.

Prior to the ASIP's expenditure of any funds derived from a PHS-funded research project, the designated official(s) will: (a) review all investigator disclosures of significant financial interests, (b) determine whether any significant financial interests relate to PHS-funded research, (c) determine whether a financial conflict of interest exists, and (d) develop and implement a management plan that will specify the actions that have been, and be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

(i) Public disclosure of financial conflicts of interest.
(ii) 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.
(iii) Modification of the research plan, as necessary.
(iv) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
(v) Reduction or elimination of the financial interest (e.g., sale of an equity interest).
(vi) Severance of relationships that create financial conflicts.

Whenever, in the course of an ongoing ASIP-associated PHS-funded research project, an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator discloses a new significant financial interest to the ASIP, the designated ASIP official(s) will, within sixty days: (a) review the disclosure of the significant financial interest, (b) determine whether it is related to PHS-funded research, (c) determine whether a financial conflict of interest exists, and (d) implement, on at least an interim basis, a management plan that will specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, the ASIP may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the ASIP's review.

If the ASIP identifies a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed by the Society during an ongoing PHS-funded research project (e.g., was not timely reviewed), the designated ASIP official(s) will, within sixty days: (a) review the disclosure of the significant financial interest, (b) determine whether it is related to PHS-funded research, (c) determine whether a financial conflict of interest exists, and (d) implement, on at least an interim basis, a management plan that will specify the actions that have been, and will 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 the ASIP to constitute a financial conflict of interest, failure by the Society 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, the ASIP will, within 120 days of the determination of noncompliance, complete a retrospective review of the investigator's activities and the ASIP-
associated PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

Under circumstances where a retrospective review is necessary, the ASIP will document the process by collection of the following information and key elements (at a minimum):

1. Project number.
2. Project title.
3. PD/PI or contact PD/PI if a multiple PD/PI model was employed.
4. Name of the investigator (senior/key personnel) with the FCOI.
5. Name of the entity with which the investigator (senior/key personnel) 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.
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the ASIP will update the previously submitted FCOI report, specifying the actions taken to manage the financial conflict of interest going forward. If bias is found, the ASIP will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will include the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and the Society’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 ASIP will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, the ASIP may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of the ASIP's retrospective review. The ASIP will monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

**NIH Reporting Requirements**

Prior to the ASIP’s expenditure of any funds under a PHS-funded research project, the Society will provide to the PHS Awarding Component an FCOI report regarding any investigator’s (senior/key personnel) significant financial interest found by the ASIP to be conflicting and ensure that the Society has implemented a management plan. In the event that the ASIP identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Society will not be obligated to submit an FCOI report to the PHS Awarding Component.

For any significant financial interest that the ASIP identifies as conflicting subsequent to the Society’s initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an investigator who is new to the research project), the ASIP will provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Society has implemented a management plan. When the FCOI report involves a significant financial interest that was not disclosed in a timely manner by an investigator or was not previously reviewed or managed by the Society (e.g., was not timely reviewed), the ASIP will complete a retrospective review to determine whether any PHS-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, the ASIP will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

All FCOI reports will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the ASIP’s management plan. Elements of the FCOI report will include, but are not necessarily limited to the following:

1. Project number.
2. PD/PI or contact PD/PI if a multiple PD/PI model was employed.
(3) Name of the investigator (senior/key personnel) with the FCOI.
(4) Name of the entity with which the investigator (senior/key personnel) has a financial conflict of interest.
(5) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium).
(6) Value of the financial interest (dollar ranges are permissible: $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.
(7) A description of how the financial interest relates to the PHS-funded research and the basis for the ASIP’s determination that the financial interest conflicts with such research.
(8) A description of the key elements of the ASIP’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 the ASIP with regard to an ongoing PHS-funded research project, the Society will provide to the PHS 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 PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The ASIP will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

Based on the results of the retrospective review, if appropriate, the ASIP will update the previously submitted FCOI report, specifying the actions taken to manage the financial conflict of interest going forward. If bias is found, the ASIP will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will include the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and the Society’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 ASIP will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, the ASIP may determine that additional interim measures are necessary with regard to the investigator’s participation in the PHS-funded research project between the date that the financial conflict of interest or the investigator’s noncompliance is determined and the completion of the ASIP’s retrospective review. The ASIP will monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

If the failure of an investigator to comply with the ASIP’s financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Society will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

**Maintenance of Records**

The ASIP will maintain records relating to all investigator disclosures of financial interests and the ASIP’s review of and response to such disclosures (whether or not a disclosure resulted in the Society’s determination of a financial conflict of interest) and all actions under the ASIP’s policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the.

**Enforcement Mechanisms and Remedies and Non-compliance**

If the ASIP identifies a significant financial interest that was not disclosed in a timely manner by an investigator or was not previously reviewed by the Society during an ongoing PHS-funded research project, the designated ASIP official(s) will, within sixty days: (a) review the significant financial interest, (b) determine whether it is related to PHS-funded research, and (c) determine whether a financial conflict of interest exists. If a financial conflict of interest is determined to exist, the ASIP will implement a management plan that will specify the actions
that have been and/or will be taken to manage the financial conflict of interest going forward. In addition, 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 the Society to constitute a financial conflict of interest, failure by the ASIP 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, the Society will, within 120 days of the determination of noncompliance, complete a retrospective review of the investigator’s activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

If the failure of an investigator to comply with the ASIP’s financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Society will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

Subrecipient Requirements
The ASIP does not carry out PHS-funded research through subrecipient organizations (e.g., subcontractors or consortium members) and so this aspect of the FCOI policy does not apply.

Public Accessibility Requirements
The ASIP will maintain an up-to-date, written, enforced policy on financial conflicts of interest and prior to the expenditure of any funds under a PHS-funded research project, the Society will ensure public accessibility, via a publicly accessible website (https://www.asip.org/) or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the ASIP that meets the following criteria: (a) the significant financial interest was disclosed and is still held by the senior/key personnel, (b) the ASIP determines that the significant financial interest is related to the PHS-funded research, and (c) the Society determines that the significant financial interest is a financial conflict of interest.

The information that the ASIP makes available via https://www.asip.org/ or written response to any requestor within five business days of a request will include 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 (dollar ranges are permissible: $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 information that the ASIP makes available via https://www.asip.org/ will be updated on a regular basis and at least annually. In addition, the Society will update the website within sixty days of the ASIP’s receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Society determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The website will note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Society’s identification of a new financial conflict of interest. If the ASIP responds to written requests for information on financial conflicts of interest, the Society will note in its written response 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 identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the significant financial interests of an individual collected by the ASIP will remain available, for responses to written requests or for posting via the ASIP’s publicly accessible website for at least three years from the date that the information was most recently updated.