

Promoting Objectivity in Research – Financial Conflict of Interest Policy

Reviewed and approved: 7/17/2018

Objective/Purpose:

The purpose of this policy is to outline requirements for promoting objectivity in research in accordance with federal regulation 42 CFR Part 50 Subpart F as related to NIH grants

I. Policy Statement

This policy addresses the responsibilities of the American Association of Neuropathologists (AANP) for ensuring objectivity in research in accordance with 42 CFR Part 50 Subpart F “Promoting Objectivity in Research.” It governs the disclosure of financial interests and the management and reporting of individual financial conflicts of interests in research performed on behalf of the AANP.

This policy provides requirements for the disclosure of financial interests and identification and management of financial conflicts of interest for all research projects for which funding is sought or received from the U.S. Department of Health and Human Services (HHS) and the HHS Public Health Service (PHS).

II. Reason for Policy

This policy provides requirements for the disclosure of significant financial interests that comply with the disclosure requirements of federal regulations. It also establishes the process for the management and reporting of financial conflicts of interest in research.

III. Scope and Audience

This policy applies to Investigators and their family members as defined below in Section IV during the course of conducting research on behalf of the AANP.

IV. Definitions

Institution: For purposes of this policy, Institution refers to the American Association of Neuropathologists (AANP).

Institutional Responsibilities: An Investigator’s professional responsibilities on behalf of the Institution (in the case of this policy – the American Association of Neuropathologists).

Investigator: 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 PHS, or proposed for such funding.

PD/PI: The Project Director or Principal Investigator of a PHS-funded research project; the PD/PI is included in the definition of Senior/Key Personnel and Investigator.

Senior/Key Personnel: The PD/PI and any other person identified as Senior/Key Personnel by the AANP in the grant application.

Research: Any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term includes both basic and applied research and product development.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable

Significant Financial Interest: A financial interest consisting of one or more of the descriptions outlined in Section VI of the Investigator (and those of his/her spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities.

Financial Conflict of Interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research

V. General Provisions

- a. Accessibility: This policy must be available via a publicly accessible website per 50.604(a).
- b. Collaborators and Contractors: In the event that the AANP carries out PHS-funded research through a subrecipient (e.g. subcontractor or consortium members), the AANP must take reasonable steps to ensure that any subrecipient complies with this policy per 50.604(c).
- c. Transparency and Training: The AANP must inform each Investigator of this policy and his/her responsibilities to comply. Additionally, Investigators are required to complete training regarding financial conflict(s) of interest prior to engaging in research related to any PHS-funded grant and at least every four years per 50.604(b). New Investigators must complete training prior to engaging in research related to any PHS-funded grant or provide evidence of having completed the training at another Institution. An Investigator must complete the training immediately if the AANP finds that the individual is not in compliance with this policy or the management plan or if the AANP revises the policy in a manner that impacts the Investigator's responsibilities.

VI. Disclosure of Financial Interests

- a. Timing of Disclosure: Investigators must provide disclosure of financial interests prior to submission of any application for PHS-funded research, annually during the period of PHS-funded research and within 30 days of acquiring new financial interests that require disclosure per 50.604(e). The AANP will review financial relationships to determine if they meet the threshold for significant financial relationships as outlined in Section VI (b).
- b. What to Disclose: An Investigator must disclose the following financial interests that appear to be related to his/her responsibilities with the AANP in accordance with the requirements outlined in 50.603. When providing disclosure, an Investigator must also disclose the financial interests of his/her spouse and dependent children.

- i. Publicly Traded Entity: The value of remuneration (i.e. salary and any payment for services such as consulting fees, honoraria, etc.) received from the entity in the 12-months preceding disclosure **AND** equity interest (e.g. stock, stock option, or other ownership interest) held by the Investigator (or spouse or dependent children) as of the date of disclosure. This is considered a significant financial interest when the value of remuneration and equity interest, when aggregated, exceeds \$5,000.
- ii. Non-Publicly Traded Entity: The value of remuneration (i.e. salary and any payment for services such as consulting fees, honoraria, etc.) received from the entity in the 12-months preceding disclosure **AND** equity interest (e.g. stock, stock option, or other ownership interest) held by the Investigator (or spouse or dependent children) as of the date of disclosure. This is considered a significant financial interest when the total value of remuneration exceeds \$5,000 **OR** when **any** equity interest exists.
- iii. Intellectual Property Rights and Interests: Intellectual property rights and interests must be disclosed as a significant financial interest upon receipt of income related to such rights and interests.
- iv. Sponsored Travel: Any reimbursed or sponsored travel related to an Investigator's institutional responsibilities (i.e. responsibilities associated with the AANP). Disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination and duration. This requirement does not apply to travel for a federal, state or local government agency, an Institution of higher education, an academic teaching hospital, a medical center or a research institution that is affiliated with an Institution of higher education.
- v. Exclusions:
 - 1. Salary, Royalties or Other Remuneration Paid by the AANP.
 - a. This exclusion includes intellectual property rights held by the AANP and any agreements to share in royalties related to such rights.
 - 2. Income from Investment Vehicles
 - a. This exclusion exists as long as the Investigator does not directly control the investment decisions made by these vehicles.
 - 3. Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education, an academic teaching hospital, a medical center or a research institution that is affiliated with an Institution of higher education.
 - 4. Income from service on advisory committees or review panels for a federal, state or local government agency, an Institution of higher education, an academic teaching hospital, a medical center or a research institution that is affiliated with an Institution of higher education.

VII. Review of Financial Interests and Determination of Financial Conflict of Interest

- a. Designation of AANP Official(s) to Review Disclosure of Significant Financial Interests: The AANP will designate individual(s) to review disclosure of significant financial interests. The individual(s) should have the necessary expertise to determine if the significant financial interest is related to the PHS-funded research and whether a financial conflict of interest exists.

- b. Timing: Prior to the expenditure of any funds under a PHS-funded research project, the AANP's designated official(s) must review disclosure of significant financial relationships, determine whether a financial conflict of interest exists and implement a management plan. In the instance of a new Investigator or an existing Investigator who discloses a new financial interest, the AANP must review the information within sixty days to determine if a financial conflict of interest exists and, if so, implement a management plan.
- c. Guidelines for Determination of Financial Conflicts of Interest: An Investigator's significant financial interests are related to PHS-funded research when the AANP 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. A financial conflict of interest exists when an Investigator's significant financial interest(s) could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

VIII. Management of Financial Conflicts of Interest

- a. Management Plans: The AANP will take actions to manage any identified financial conflicts of interest through development and implementation of a management plan. One or more of the following management plans may be enacted:
 - i. Public disclosure of significant financial conflicts of interest
 - ii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research against bias resulting from financial conflicts of interest
 - iii. Modification of the research plan
 - iv. Change of personnel or personnel responsibilities or disqualification of personnel from participation
 - v. Reduction or elimination of the financial interest
 - vi. Severance of relationships that create financial conflicts
- b. Monitoring: The AANP must monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.
- c. Accessibility: The AANP must ensure, prior to expenditure of funds, that the following information regarding significant financial interests is available via a publicly accessible website: Significant financial interests disclosed and held by Senior/Key Personnel related to the PHS-funded research that create a financial conflict of interest. The information provided on the website must include: The Investigator's name, title and role with respect to the research project, name of the entity in which the significant financial interest is held, the nature of the significant financial interest and the approximate dollar value.
 - i. Information on the website must be updated at least annually or within sixty days of the AANP's receipt or identification of information concerning additional significant financial interest of the Senior/Key Personnel.

- ii. The website must 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 sixty days of the identification of new significant financial interests.
 - iii. Information concerning significant financial interests must be available for at least three years following the date that the information was most recently collected and updated.
- d. **Retrospective Review:** If necessary the AANP will conduct a retrospective review and submit a mitigation report per 50.605(a). See Section X – Remediation – Retrospective Review and Mitigation Report.

IX. Reporting of Financial Conflicts of Interest

- a. **Overview:** The AANP will provide initial and ongoing FCOI reports to the PHS as required per 50.605(b). FCOI reports are to be submitted via eRA Commons. See Section VII (b) regarding timing.
 - i. Neither the AANP nor an Investigator may expend research funds unless the designated individual(s) responsible for reviewing significant financial interests has determined that no financial conflict of interest exists or that any financial conflict of interest is manageable in accordance with the terms of a management plan that has been adopted and implemented.
- b. **Elements of FCOI Report:** The FCOI report must include sufficient information to enable the PHS Award Component to understand the nature and extend of the financial conflict and to assess the appropriateness of the AANP's management plan. Elements of the FCOI report include:
 - Project Number
 - PD/PI
 - Name of Investigator
 - Name of Entity (for which FCOI exists)
 - Nature of the Financial Interest
 - Value of the Financial Interest
 - Description of how the financial interest relates to the PHS-funded research and the basis for the AANP's determination that the financial interest conflicts with such research
 - Description of key elements of management plan including:
 - Role and principle duties of the conflicted Investigator in the research project
 - Conditions of the management plan
 - How the management plan is designed to safeguard objectivity in the research project
 - Confirmation of the Investigator's agreement to the management plan
 - How the management plan will be monitored to ensure Investigator compliance
 - Other information as needed

X. Remediation – Retrospective Review and Mitigation Report

- a. **Initiation:** If the AANP determines that a significant financial interest was not disclosed in a timely manner or, for whatever reason, was not previously reviewed during an ongoing PHS-funded research project, the designated official(s) must, within sixty days, review the significant financial interest, determine if a financial conflict of interest exists and implement a management plan.

- b. Retrospective Review: The AANP must also, within 120 days of 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 was biased in the design, conduct or reporting.
 - i. Instances of non-compliance include:
 - 1. Failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest.
 - 2. Failure by the Institution to review or manage such a financial conflict of interest.
 - 3. Failure by the Investigator to comply with the financial conflict of interest management plan.
 - ii. The retrospective review must be documented inclusive of the following information: project number/ project title, PD/PI, investigator's name, name of entity with which financial conflict of interest was found to exist, reason(s) for the retrospective review, detailed methodology used for the retrospective review, findings of the review, and conclusions of the review.
 - iii. If bias is found, the AANP is required to promptly notify the PHS Awarding Component and submit a mitigation report. The mitigation report must 1) include the key elements of the retrospective review, 2) provide a description of the impact of the bias on the research project, 3) outline the plan of action or actions taken to eliminate or mitigate the effect of the bias, and 4) articulate the extent of the harm done.

XI. Administration and Records

- a. Maintenance of Records: The AANP will maintain records relating to all Investigator disclosures of financial interests and the AANP's review of, and response to, such disclosures and all actions for at least three years from the date of final expenditures report is submitted to the PHS. The AANP will adhere to any requests to submit records or permit on site review of all records pertinent to compliance with 42 CFR Part 50 Subpart F.
- b. Application Assurances: Further, in each application for funding, the AANP will certify that 1) the organization has up-to-date, written and enforced administrative processes to identify and manage financial conflicts of interest for research projects for which funding is sought or received, 2) the organization will promote and enforce Investigator compliance with this policy and therefore 42 CFR Part 50 Subpart F, 3) the organization will manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component, 4) the organization will make information available, upon request, to the HHS relating to any Investigator disclosure of financial interests and the AANP's review of, and response to, such disclosure and 5) the organization will fully comply with the requirements of 42 CFR Part 50 Subpart F.

XII. Enforcement

The AANP will enforce this policy to ensure both Institutional and Investigator compliance with 42 CFR Part 50 Subpart F. If the AANP encounters any instances of non-compliance, the organization will immediately take action in accordance with Section X - Remediation – Retrospective Review and Mitigation Report. Appropriate mechanisms and remedies will be implemented as needed.