

Conflict of Interest in Sponsored Programs Policy

Brief Description:	The purpose of this policy is to establish the Alzheimer's Association's conflict of interest (COI) in sponsored programs compliance framework and requirements, primarily as it relates to federally-funded research and sponsored programs activities
Applies to:	All individuals who meet Investigator status on all federally-funded sponsored programs
Effective date:	January 2019
Last review/approved date:	December 2020
Approved by:	Chief Strategy Officer
Policy owner:	Chief Strategy Officer

Introduction

The Alzheimer's Association encourages its staff to seek external sponsored funding and participate in research and sponsored programs. As external sponsors establish their own policies regarding conflict of interest, the Association is expected to manage compliance with these requirements. This Policy establishes the Association's conflict of interest (COI) in sponsored programs compliance framework for federally-funded projects; in particular, this Policy ensures compliance with the United States Public Health Service (PHS) conflict of interest regulations.

Policy Statement

The Alzheimer's Association seeks to promote objectivity in research to ensure that any research or sponsored programs conducted by the Association are free from bias or the appearance of bias. Accordingly, this Policy establishes standards for Association staff engaged in sponsored programs that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from financial interests.

Applicability

This Policy applies to all individuals (Association or third parties) who meet Investigator status (as defined in the Definitions section of this Policy) on all federally-funded sponsored programs. Additionally, if a sponsored program that is not federally-funded has conflict of interest

requirements or in light of other specific circumstances, this Policy may be used to manage potential conflicts of interest on other sponsored programs.

Training and Disclosure

Investigators involved in sponsored programs funded by sponsors subject to this Policy must complete training before engaging in research or sponsored activities and must complete this training every four years thereafter. Additional training may be required if the Association revises its policies or procedures in a manner that changes the requirements or expectations of Investigators and in instances of non-compliance with either this Policy or any conflict of interest management plan.

Investigators are required to disclose any Significant Financial Interests (as defined in the Definitions section of this Policy) that directly relate to their organizational responsibilities, including research, education, outreach, memberships, and other activities related to their field of expertise in advance of proposal submission; within thirty (30) days of discovering or acquiring a new Significant Financial Interest; and at least annually during the period of an award. Note that disclosure is required to be done annually via the Alzheimer's Association's Staff Conflict of Interest Policy.

Review and Management

Significant Financial Interests are reviewed in the context of each relevant research or sponsored project on which an individual is an Investigator; a disclosure of a Significant Financial interest alone does not automatically create a Financial Conflict of Interest. A conflict of interest review will be conducted by the Director of Government Grants, Programs to evaluate whether or not the Significant Financial Interests of the Investigator relate to or could directly and significantly affect the design, conduct, or reporting of research, thus presenting a Financial Conflict of Interest relative to the project.

If a Financial Conflict of Interest determination is made, a conflict of interest management plan will be developed, and will include, at minimum, the role and principal duties of the conflicted Investigator in the project; conditions of the management plan; how the management plan is designed to safeguard objectivity in research; confirmation of the Investigator's agreement to abide by the plan; and a plan for effective monitoring of the proposed management plan.

A conflict of interest management plan is a risk mitigation plan designed to manage, reduce, and/or eliminate the Financial Conflict of Interest, to remove the potential for the Investigator to bias research objectivity. Compliance with Investigator conflict of interest management plans are reviewed at least annually by the Chief Strategy Officer and Director of Government Grants, Programs, and other individuals as deemed appropriate and necessary.

Reporting and Record Retention

The Chief Strategy Officer and Director of Government Grants, Programs will oversee all external conflict of interest reporting in accordance with federal and sponsor regulations and requirements.

For Financial Conflict of Interest determinations related to PHS-funded research, the Association will complete the required reporting prior to the expenditure of any funds for new projects; within sixty (60) days of new Financial Conflicts of Interest identified during the project; and on an annual basis prior to progress report submissions during the project period. Additionally, the Association will make available to the public, upon request, specific information regarding Financial Conflict of Interest determinations for any Senior/Key Personnel. As required, the Association will provide this information within five (5) business days of the request.

All relevant conflict of interest-related records will be maintained for a period of at least three years after any applicable research project's final financial report is submitted to the sponsor or until at least three years after the final action has been taken on a related litigation, claim, or audit.

Noncompliance

Any instances of noncompliance may require additional training or a restriction on the ability to serve as an Investigator on future sponsored programs.

In any instances of noncompliance involving PHS-funded research 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 Association to constitute a Financial Conflict of Interest; failure by the Association to review or manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a conflict of interest management plan, the Association will, within one hundred twenty (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 the research.

Additionally, for instances of noncompliance noted above involving PHS-funded clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Investigator is thereafter required to disclose the Financial Conflict of Interest in each public presentation of the results of the relevant research.

Subrecipients

Any subrecipients (as defined in the Definitions section of this Policy) will be required to comply with any relevant originating sponsor conflict of interest requirements, both for PHS-funded sponsored projects and others as applicable. A subrecipient may follow their own organization's

conflict of interest policy as applicable; in instances where a subrecipient does not have a conflict of interest policy that meets sponsor requirements, the subrecipient must abide by this Policy.

Definitions

All definitions provided are specifically for the purposes of this Policy.

Financial Conflict of Interest: A conflict that exists when the Association reasonably determines that an Investigator's Significant Financial Interest (SFI) is related to a research project and could directly and significantly affect the design, conduct, or reporting of this research.

Investigator: Any individual acting as a 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.

Significant Financial Interest (SFI) is defined as 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) received from a single external entity in the 12 months prior to disclosure:

- Remuneration exceeding \$5,000
- Any equity interest in a non-publicly traded entity, and equity interests in publicly traded entities exceeding a value of \$5,000
- Intellectual property interests exceeding \$5,000
- Sponsored or reimbursed travel exceeding \$5,000

The following items are EXCLUDED and should not be disclosed:

- Remuneration, intellectual property interests, equity in publicly traded entities, or sponsored or reimbursed travel received that aggregates to less than \$5,000 from a single entity in the previous 12 months
- Remuneration or sponsored or reimbursed travel received for lectures, seminars, teaching engagements, or service on advisory committees or review panels relating to federal, state, or local government agencies, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- Unlicensed intellectual property that does not generate income or is administered through an Investigator's home educational institution.
- Equity interests in publicly and non-publicly traded entities in the form of stock ownership through personal retirement accounts and mutual funds, as long as the investigator does not directly control the investment decisions made in these vehicles

NOTE: If the individual under this Policy is an Alzheimer's Association employee, the Association's general conflict of interest policy also applies and no staff person is allowed to accept any remuneration and the definition of a family relationship is also expanded. Any Association staff person must comply with the Association's general conflict of interest policy in addition to this Policy.

Sponsored Programs: Any externally funded project for research, professional service, or training that is conducted at or under the authority of the Alzheimer's Association through a grant, contract, or other agreement mechanism.

Subrecipient: A legal entity that receives a subaward or subcontract from a pass-through entity (PTE) for the purpose of carrying out a portion of a sponsored program; this entity has responsibility for programmatic decision-making and has its performance evaluated based on whether objectives of the programmatic scope of work are met on the project, as opposed to providing routine goods or services.

Procedures

Training

Training can be completed via the National Institutes of Health's COI training module, found [here](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html).

Once completed, send the certificate of completion to Director, Government Grants, Programs for documentation purposes. This training must be completed once every 4 years at minimum; additional training may be requested as appropriate, and as outlined in the Policy Statement.

As part of training, when submitting a disclosure, Investigators will also certify that they have read and understand this Policy.

Disclosure

At the proposal stage and at the time of award issuance, an active disclosure within the last one (1) year period must be on file for all individuals serving as Investigators on relevant projects. Investigators must also disclose within thirty (30) days of acquiring a new Significant Financial Interest (as defined in the Definitions section of this Policy). Additionally, Investigators will receive a notification and request to complete a disclosure on an annual basis during the award period. The required disclosure is completed consistent with the Association's annual staff conflict of interest policy.

As it relates to individuals who meet Investigator status, keep in mind that Senior/Key Personnel are always considered Investigators; other Investigators may include individuals (internal or external to the Association) who are independently responsible for research design, conduct, or

reporting. Investigators are not administrative personnel performing routine, pre-defined, or incidental tasks related to the project.

The disclosure asks about financial interests and outside activities that relate to your role at the Association, not just self-identified conflicts of interest. While any self-identified conflict of interest should be disclosed in all circumstances, responding comprehensively when completing the disclosure enables the Association to demonstrate that any work occurring on a project is free from even the perception that decisions were biased by personal gain.

When disclosing, an Investigator must include any Significant Financial Interests of their spouse and dependent children.

Access to disclosure information and any other relevant follow-up information collected in connection with this Policy will be kept confidential, and only shared with individuals on a very limited and need to know basis.

If any follow-up is needed related to your disclosure as it pertains to the relevant sponsored project, you will receive a response with any questions and/or to advise on next steps.

Review and Management

Prior to an account being assigned for the project and the expenditure of any funds, the Director of Government Grants, Programs will review all Investigator disclosures of Significant Financial Interests (if any are disclosed) to determine whether any relate to the activities under the relevant sponsored program. The Director of Government Grants, in consultation with the Chief Strategy Officer and other individuals as the Chief Strategy Officer deems necessary, will determine whether a Financial Conflict of Interest exists and, if so, implement a conflict of interest management plan.

Prior to an account being assigned for the project and the expenditure of any funds if any "yes" responses have been disclosed, the Director of Government Grants, Programs will review all Investigator disclosures of Significant Financial Interests and determine whether any relate to the activities under the relevant sponsored project. The Director of Government Grants, Programs in consultation with the Chief Strategy Officer and other individuals as the Chief Strategy Officer deems necessary, will determine whether a financial conflict of interests exists and, if so, implement a conflict of interest management plan. Determinations will be made on a project by project basis.

The Director of Government Grants, Programs will also handle reviews and determinations on an ongoing basis, specifically within sixty (60) days of newly-disclosed Significant Financial Interests and the addition of new Investigators to a specific project, as well as on an annual basis during the project period. The Chief Strategy Officer will be consulted as needed.

If a Financial Conflict of Interest determination is made, a conflict of interest management plan will be developed by the Director of Government Grants, Programs and the Chief Strategy Officer, consulting with the Investigator's immediate supervisor and others as appropriate, and

will include, at minimum, the role and principal duties of the conflicted Investigator in the project; conditions of the management plan; how the management plan is designed to safeguard objectivity in research; confirmation of the Investigator's agreement to abide by the plan; and a plan for effective monitoring of the proposed management plan. If required in specific and extreme instances, the Investigator may be prohibited from participating in the research due to the nature, level, and extent of the Financial Conflict of Interest relative to the specific activities.

All Investigators must acknowledge agreement with any applicable conflict of interest management plans. In these instances, a conflict of interest management plan will be discussed with and subsequently provided to the Investigator in writing, and the Investigator will sign and return the signed document to the Director, Government Grants, Programs.

Compliance with Investigator conflict of interest management plans are reviewed at least annually by the Director of Government Grants, Programs and Chief Strategy Officer, as well as by other individuals directly impacted by the work as deemed appropriate and necessary and upon request.

Reporting and Record Retention

The Chief Strategy Officer and Director of Government Grants, Programs will oversee all external conflict of interest in sponsored programs reporting in accordance with federal and sponsor regulations and requirements.

For Financial Conflict of Interest determinations related to PHS-funded research, the Director of Government Grants, Programs will complete the required reporting prior to the expenditure of any funds for new projects; within sixty (60) days of new Financial Conflicts of Interest identified during the project; and on an annual basis prior to progress report submissions during the project period. Additionally, the Association will make available to the public, upon request, specific information regarding Financial Conflict of Interest determinations for any Senior/Key Personnel. As required, the Association will provide this information within five (5) business days of the request. The Chief Strategy Officer and/or Director of Government Grants, Programs will advise other internal stakeholders of this request as appropriate in advance of providing this information.

The Director of Government Grants, Programs will maintain all relevant conflict of interest-related records will be maintained for a period of three years after any applicable research project's final financial report is submitted to the sponsor, or until three years after the final action has been taken on a related litigation, claim, or audit.

Noncompliance

In any instances of noncompliance involving PHS-funded research 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 Association to

constitute a Financial Conflict of Interest; failure by the Association to review or manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a conflict of interest management plan, the Director of Government Grants, Programs, in consultation with the Chief Strategy Officer will, within one hundred twenty (120) days of the Institution's 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 an instance of noncompliance involves PHS-funded clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Investigator is thereafter required to disclose the Financial Conflict of Interest in each public presentation of the results of the relevant research. The Investigator will be notified of this via email communication as well, and be asked to confirm explicit recognition of this requirement.

Subrecipients

Any Subrecipients (as defined in the Definitions section of this Policy) will be required to comply with any relevant originating sponsor conflict of interest requirements, both for PHS-funded sponsored projects and others as applicable.

At the proposal stage, an email indicating the intended subrecipient organizations should be sent to the Director, Government Grants, Programs at least five (5) business days in advance of the proposal submission. Based on the subrecipient organizations involved, Kelly will advise as to whether or not further information is needed from the subrecipient to determine whether or not they will need to follow the Association's Conflict of Interest in Sponsored Programs Policy. If the subrecipient organization will need to follow the Association's Policy, any relevant Investigators at the subrecipient organization will need to complete [training](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) and submit the required [disclosure form](#) (need to insert link).

At the award stage, the subrecipient subaward or subcontract agreement will incorporate terms that establish whether the conflict of interest policy of the Association or that of the subrecipient will apply to relevant Investigators at the subrecipient institution. If the Policy of the Association applies, the subrecipient Investigators will follow all other aspects of this Policy.

Related Resources	
Forms	Conflict of Interest Disclosure Form (insert link here)

Guidelines	<p>For more information regarding the PHS conflict of interest regulations, please refer to the following:</p> <ul style="list-style-type: none"> • Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) • Responsible Prospective Contractors (45 C.F.R. Part 94)
Training materials	<p>In addition to this Policy document, please refer to the NIH's training module here (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)</p>
Questions	<p>Contact K. Joanne Pike, jpik@alz.org</p>