



Alzheon Inc. Financial Conflict of Interest Policy

Introduction

Alzheon Inc. (hereafter “Alzheon”) is committed to the design, conduct, and reporting of research in an objective manner, free from bias or undue influence as a result of financial conflicts of interest (FCOI).

This policy implements U.S. federal requirements pertaining to “Objectivity in Research” disseminated by the Public Health System (“PHS”) 2011 Financial Conflict of Interest (“FCOI”) requirements, related to PHS Organization-funded research, and published in U.S. regulations 42 CFR Part 50, Subpart F.

Purpose

The intent of this FCOI policy is designed to promote objectivity in Alzheon’s PHS-funded research by establishing standards and procedures that provide a reasonable expectation that the design, conduct, and reporting of research performed will be free from bias resulting from Investigator financial conflicts of interest.

Applicability

As such, this policy is applicable to each Investigator who is planning to participate in, or is participating in, such research.

Definitions

Disclosure of significant financial interests: An Investigator’s disclosure of significant financial interests to an Institution (in this instance Alzheon).

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

FCOI report: Alzheon’s report of a financial conflict of interest to a PHS Awarding Component.

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

HHS: The United States Department of Health and Human Services (HHS), and any components of the Department to which the authority involved may be delegated.

Institution: Generally, any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that submits a proposal, or that receives, PHS research funding. For purposes of this policy, Alzheon is the “Institution.”

Institutional Official: The individual, or individuals designated by Alzheon to be responsible for enforcing this policy, reviewing disclosures of SFIs, determining whether disclosures constitute FCOI, and managing such conflicts.

Institutional responsibilities: An Investigator’s professional responsibilities on behalf of Alzheon, and as defined by Alzheon 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: The 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, which may include, for example, collaborators or consultants.

Key Personnel: The PD/PI (Program Director/Principal Investigator) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. “Zero percent” effort or “as needed” are not acceptable levels of involvement for those designated as Senior/Key Personnel.



Manage: 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.

PHS: 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).

PHS Awarding Component: The organizational unit of the PHS that funds the research that is subject to this part.

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. The term encompasses basic and applied research and product development. As used in this part, the term includes any such activity for which research funding is available from a PHS Awarding Component through a contract, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests of the Investigator, the Investigator's spouse/domestic partner and/or the Investigator's dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities (i.e., on behalf of Alzheon).

Significant financial interests include

A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/domestic partner and/or dependent children) that reasonably appears to be related to the Investigator's institutional (i.e., Alzheon) responsibilities:

1. 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;
2. With regard to any non-publicly traded entity (other than Alzheon), 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/domestic partner and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
3. 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 over \$2,500 (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 (i.e., Alzheon) responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by Alzheon, 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. Such disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. 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. Note, Investigators must disclose reimbursed or sponsored travel received from a foreign institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).



The term significant financial interest does not include the following financial interests:

1. Salary, royalties, or other remuneration paid by Alzheon to the Investigator if the Investigator is currently employed or otherwise appointed by the Alzheon, including intellectual property rights assigned to Alzheon and agreements to share in royalties related to such rights;
2. Any ownership interest in Alzheon held by the Investigator; 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;
3. 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;
4. 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.

Responsibilities of Alzheon

Alzheon shall maintain, update, and enforce this Policy, and make it available via a publicly accessible website.

Alzheon shall inform each Investigator of:

1. Alzheon's policy on financial conflicts of interest,
2. The Investigator's responsibilities regarding disclosure of significant financial interests, and
3. The relevant regulations, 42 CFR 50 Subpart F.

Alzheon shall:

1. Assign a designated Institutional Official to review financial disclosure documents, make determination of potential conflicts of interest and execute a management plan as appropriate.
2. Require that each Investigator who is participating in its PHS-funded research complete mandatory training on both Federal and Institutional policies. This is detailed in the mandatory training section.
3. Require that each Investigator who is participating in Alzheon's PHS-funded research submit a disclosure of significant financial interest form, within the timeframe below, to the designated Institution's Official disclosing the Investigator's significant financial interests (and those of the Investigator's spouse/domestic partner and/or dependent children).
 - a. No later than at the time of application for NIH-funded research;
 - b. Within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and
 - c. At least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.
4. Provide guidelines for the designated Institutional Official to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest.
5. Take such actions as necessary to manage financial conflicts of interest. Establish adequate enforcement mechanisms to ensure Investigator compliance. This is outlined in the management and remedies sections.
6. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest), and all actions under the Institution's policy for at least three years from the date of the submission of the final expenditures report.



Responsibilities of the Investigator

Investigators are responsible to:

1. Read the National Institute of Health (“NIH”) Regulations and Code of Federal Regulations (“CFR”) on FCOI.
 - a. NIH Financial Conflict of Interest Overview: <https://grants.nih.gov/grants/policy/coi/index.htm>
 - b. Federal Register Notice for 45 CFR Part 50 Subpart F: https://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
 - c. FCOI Frequently Asked Questions: <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>
2. Complete the NIH tutorial on FCOI prior to completing this form: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html. Forward the tutorial Certificate of Completion to the Alzheon designated Institutional Official.
3. If available, provide additional certification of FCOI training such as the “Conflict of Interest Course” provided through the Collaborative Institutional Training Initiative (CITI) (<https://about.citiprogram.org/en/course/conflicts-of-interest-coi-basic/>) or other equivalent FCOI training (e.g., for Investigators outside of the United States); and forward any such relevant certification to the Alzheon designated Institutional Official.
4. Read Alzheon’s Financial Conflict of Interest Policy located at: <https://alzheon.com/medicines-alzheimers-disease/> and sign and return form attesting to understanding of policy to the Alzheon designated Institutional Official.

Mandatory Training Requirements

1. All Investigators will be required to complete FCOI training on both Federal and Alzheon policies. This training must be completed prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately if any of the following circumstances apply:
 - a. The FCOI Policy or procedures contained within or the PHS Financial Disclosure Form are revised in any manner that affects the requirements of Investigators;
 - b. An Investigator joins Alzheon; or
 - c. Alzheon is made aware of an Investigator who is not in compliance with this FCOI Policy.
2. To fulfill Alzheon’s training requirements, all relevant Alzheon personnel will be required to read through this FCOI Policy and sign to attest to the fact that they have read and understood all policies, rules, and regulations contained within this document, and that they understand their responsibilities as an Investigator to disclose any and all significant financial interests.
3. To fulfill the Federal training requirement, all Alzheon personnel must complete the NIH Office of Extramural Research’s web-based “Financial Conflict of Interest Online Tutorial” (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html). At the end of the tutorial, each person should fill out the Certificate of Completion and follow the instructions for documentation.
4. All records of completion of training requirements will be maintained electronically, filed in the appropriate Alzheon “FCOI Training Documentation” folder, found on a shared drive managed by Alzheon’s designated Institutional Official.

Policy application to subawardees, subcontractors and Affiliates

Subawardees, subcontractors, and other Alzheon affiliates collaborating on PHS funded research will be required to confirm that they have their own FCOI policy in place that conforms to PHS FCOI 2011 Regulations prior to collaboration, or will be required to comply with this FCOI policy.

Management of financial conflicts of interest

Prior to the Institution's expenditure of any funds under a PHS-funded research project, Alzheon’s designated Institutional Official shall review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, take action 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 the:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to IRB, IACUC, Data Safety Monitoring Boards, etc.);
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.

Whenever Alzheon implements a management plan pursuant to this policy, Alzheon shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Whenever, in the course of an ongoing 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 Institution, the designated Institutional Official(s) shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall 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, an Institution 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 Institution's review.

Retrospective Review

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 Alzheon to constitute a financial conflict of interest; failure by Alzheon 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, Alzheon shall, within 120 days of Alzheon'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. Alzheon will document the retrospective review; such documentation shall include, but not necessarily be limited to, all the following key elements:

1. Project number;
2. Project title;
3. PM/PD/PI or contact PM/PD/PI if a multiple PM/PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator 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.



Based on the results of a retrospective review, if appropriate, the Alzheon will update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, Alzheon will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. 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 Alzheon'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 Institution will submit FCOI reports annually, as specified elsewhere in this policy. Depending on the nature of the financial conflict of interest, Alzheon 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 Alzheon's retrospective review.

Reporting

Per PHS FCOI Regulations, Alzheon will submit to the NIH through the eRA Commons FCOI Module both initial and ongoing FCOI reports:

1. Prior to the expenditure of funds;
2. Within 60 days of identifying a new FCOI;
3. Annually during the progress report submission.

Prior to Alzheon's expenditure of any funds under a PHS-funded research project, Alzheon shall provide to the PHS Awarding Component the FCOI report regarding any Investigator's significant financial interest found by Alzheon to be conflicting, at the time of filing, and ensure that Alzheon has implemented a management plan in accordance with this Policy. In cases in which Alzheon identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, Alzheon shall not submit an FCOI report to the PHS Awarding Component.

Any FCOI report required shall include information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan.

Elements of the FCOI report shall include, but are not necessarily limited to the following:

1. Grant number;
2. PD/PI;
3. Name of the Investigator with the financial conflict of interest;
4. Name of the entity with which the Investigator 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 Institution's determination that the financial interest conflicts with such research; and



8. A description of the key elements of the Institution'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 Alzheon with regard to an ongoing PHS-funded research project, Alzheon shall 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 shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists.

For any significant financial interest that Alzheon identifies as conflicting subsequent to Alzheon'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), Alzheon shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this Policy. Where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to 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 Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Remedies

If the failure of an Investigator to comply with Alzheon'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, Alzheon shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to Alzheon on how to maintain appropriate objectivity in the PHS-funded research project.

The PHS Awarding Component and/or HHS may inquire at any time (before, during, or after award) into any Investigator disclosure of financial interests and Alzheon's review of, and response to, such disclosure, regardless of whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest. Alzheon is required to submit, or permit on site review of, all records pertinent to compliance with this Policy. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that Alzheon has not managed the financial conflict of interest in accordance with this part.

In any case in which the HHS determines that a PHS-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 financial conflict of interest that was not managed or reported by Alzheon as required by this subpart, Alzheon shall require the Investigator involved to disclose the financial conflict of



interest in each public presentation of the results of the research and to request an addendum to previously published presentations .

Public Availability of FCOI Disclosures

Prior to Alzheon's expenditure of any funds under a PHS-funded research project, Alzheon shall ensure public accessibility, via written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to Alzheon that meets the following three criteria:

1. The significant financial interest was disclosed and is still held by key personnel as defined in this part;
2. Alzheon determines that the significant financial interest is related to the PHS-funded research; and
3. Alzheon determines that the significant financial interest is a financial conflict of interest.

The information that Alzheon makes available via written response to any requestor within five business days of a request, shall include, at a minimum, 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.

Information concerning the significant financial interests of an individual shall remain available, for responses to written requests for at least three years from the date that the information was most recently updated.

For more information, visit the following:

42 CFR Part 50 Subpart F, 45 CFR Part 94 https://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

NIH FCOI <https://grants.nih.gov/grants/policy/coi/index.htm>

NIH FCOI FAQs <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>

NIH FCOI Tutorial https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html



**Alzheon Inc.
Financial Conflict of Interest Policy
Read & Understand Form**

Individual:

(Name)

(Position)

The individual listed above hereby attests to having read and understood Alzheon, Inc.'s Financial Conflict of Interest Policy, Version 3, dated October 29, 2020.

Any questions on the Policy listed above should be directed to the Alzheon Management Team or emailed to ap@alzheon.com.

Acknowledgment of Self-study and Understanding:

Signature

Date (DD/MMM/YYYY)

Upon completion, please sign and return to the Alzheon designated Institutional Official at email address: ap@alzheon.com