

American Cochlear Implant Alliance

Public Health Service (PHS) Requirements for Financial Disclosures and Conflict of Interest Policy

OVERVIEW

American Cochlear Implant Alliance Foundation (ACI Alliance) is a nonprofit organization whose mission is to advance access to the gift of hearing provided by cochlear implantation through research, advocacy and awareness. ACI Alliance maintains and enforces a general Conflict of Interest policy that requires members of the community to disclose potential or apparent conflicts of interest or commitment so it can effectively manage, reduce, or eliminate such conflicts to maintain objectivity of its activities and research.

ACI Alliance complies with regulations related to the U.S. Public Health Service (PHS) requirements, and other federal agency disclosure and financial conflict of interest (FCOI) regulations (as applicable) to maintain institutional compliance and eligibility for application and receipt of federal funding (e.g., grants, subawards, cooperative agreements).

PURPOSE

The following policy confirms ACI Alliance's commitment to the foundational PHS requirements that promote objectivity in research, ensuring the design, conduct, and reporting of PHS-funded research remains unbiased relative to any conflicting interest of an investigator. That is, ACI Alliance's policy aims to ensure that covered persons will not permit personal interests to conflict, or even appear to conflict, with the interests of the organization. This policy aligns with current federal FCOI regulations [42 CFR 50, Subpart F](#), entitled "Responsibility of applicants for promoting objectivity in research for which PHS funding is sought," as implemented in the 2011 final rule for grants and cooperative agreements.

This policy applies to all staff, Board members, and investigators associated with ACI Alliance who apply for or receive PHS funding by means of a grant, subaward, cooperative agreement, or other funding mechanism administered through the foundation.

DEFINITIONS

Conflict of interest (COI) – any situation in which financial or other personal considerations compromise or appear to compromise an investigator's professional judgment and objectivity in the design, conduct, or reporting of research.

Conflict of Interest (COI) officer – the staff member responsible for supporting the institutional official in implementing this policy

Designated official – either the COI officer or, in complex cases, the Executive Director of ACI Alliance or any other member of the senior administration designated by the Institutional Official; The designated official will review all financial disclosures by Investigators to determine if any significant financial interest relates to NIH-funded research and if financial conflict of interest exists that could affect the integrity of the research.

Employee – staff employed by the ACI Alliance

Entity – any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

Equity interests – stock, stock options, warrants, and other existing or contingent ownership interests in a commercial entity

Family – an Investigator's spouse, domestic partner, and dependent children

Financial conflict of interest (FCOI) – a situation in which the significant financial interest of a Board member, staff member, or Investigator compromises, or could appear to compromise, their judgment or ability to carry out the responsibilities associated with their appointment, including but not limited to the design, conduct, or reporting of NIH-funded research.

Institution - any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives NIH research funding.

Institutional official – the individual at ACI Alliance ultimately responsible for the review of disclosures of significant financial interests and the management of financial conflicts of interest (i.e., the Director of Operations).

Institutional responsibilities – the professional responsibilities of the staff member, Board member, or Investigator on behalf of the Institution (i.e., ACI Alliance), and as defined by the Institution in its policy on Financial Conflict of Interest, which may include 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 (as defined by the 2011 revised regulation).

Investigator – the project director or principal investigator and any other person, regardless of title or position, who has responsibility for the design, conduct, or reporting of research funded by the PHS (or proposed for such funding).

Outside professional activities – compensated and uncompensated activities that fall outside the purview of the Investigator's institutional responsibilities.

Public Health Service (PHS) – associated with the U.S. Department of Health and Human Services (e.g., the National Institutes of Health (NIH), Food and Drug Administration), as outlined on the PHS website at <https://www.federalregister.gov/agencies/public-health-service>

Related entity – any domestic or foreign, public or private, profit/non-profit/governmental organization in which the Investigator or their family holds a significant financial interest

Remuneration – salary and payments for service (e.g., consulting fees, honoraria, paid authorship, cash, in kind gifts, sponsored travel) from entities for which you provide services

Research – as any such activity (described at 42 CFR 50.603) for which research funding is available from a PHS Awarding Component (e.g., NIH) through a grant or cooperative agreement. The definition of the term "Research" provides a non-exhaustive list of examples of the different types of NIH-funding mechanisms to which the regulation applies such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institutional training grant, program project, or research resources award.

Responsible official – oversees the receipt and review of disclosures of significant financial interests of staff and Board members related to (a) proposing, conducting, or reporting of research or scholarship; and (b) research regulatory compliance.

Significant financial interest (SFI) – "a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities." This includes financial interests outside the company held by staff member, Board member, or their family (i.e., spouse, domestic partner, dependent children) that meet any of the criteria for significance in **Table 1** and could reasonably appear to be related to the individual's institutional responsibilities (e.g., research). The institution must determine if the SFI relates to the PHS-supported research or if it can significantly affect the integrity of the research. If identified as compromising or appearing to compromise the research project, then the institution must disclose a FCOI and proceed with a management and reporting plan to the NIH.

Table 1. Definitions of Significant Financial Interests (SFI)

Source	Time period	Criteria for SFI
US or foreign publicly traded entity	12 months	Remuneration $\geq$ \$5,000
US or foreign non-publicly traded entity	12 months	Remuneration $\geq$ \$5,000 <i>or</i> equity interest held by Investigator and/or family $\geq$ \$5,000
Non-profit institution or foreign governmental organization	12 months	Remuneration $\geq$ \$5,000
Royalties or Intellectual property rights and interests	12 months	Receipt of income related to such rights and interests
Sponsored travel for Investigator and/or family	12 months	$\geq$ \$5,000
Investment vehicles (e.g., mutual funds or retirement accounts)	12 months	The Investigator and/or family directly controls the investment decisions made in the investment vehicles

Note. The time frame reflects the twelve-month period preceding or anticipated during participation on the staff or Board of the ACI Alliance, or participation in research as an Investigator. The monetary threshold for a publicly traded entity applies to the aggregated amount of any remuneration received within the 12 months preceding disclosure and the value of any equity interest at the date of disclosure. Examples of intellectual property rights and interests include patents and copyrights.

SFI does not include the following types of financial interests: (a) remuneration from the institution (e.g., salary, royalties); (b) remuneration from authorship of academic or scholarly works, seminars, lectures, or teaching engagements sponsored by governmental agencies, institutions of higher education, medical centers, etc. (as defined at 20 U.S.C. 1001(a)); (c) remuneration paid to an Investigator's family by any entity with no reasonable relation to the Investigator's institutional responsibilities; and (d) equity interests or income from investment vehicles (e.g., mutual funds, retirement accounts), as long as the Investigator does not directly control the decisions for these investments.

If the royalties paid to the Investigator (or his/her spouse and dependent children) satisfy the definition of SFI, then they must be disclosed. However, if the royalties or agreement to share in royalties relate to intellectual property owned by the employing or appointing applicant or awardee Institution and are licensed or potentially licensed through the applicant or awardee Institution (i.e., they are not personally owned by the Investigator), they are considered remuneration from the Institution and would not be considered a Significant Financial Interest of the Investigator. Royalties received by the Investigator from the Institution would be excluded from the definition of Significant Financial Interest if the Investigator is currently employed or otherwise appointed by the Institution.

Unlicensed intellectual property that does not generate income is also excluded from the definition of Significant Financial Interest. Nonetheless, such interests have the potential to become significant and generate income, at which point they would become subject to the regulation. Disclosure requirements and the documentation needed to verify the value of royalties or agreements to share in royalties should be defined by the Institution's Financial Conflict of Interest policy and procedures. (See definition of Significant Financial Interest).

Sponsored travel - travel expenses paid to an Investigator, their family, or on their behalf by a single entity in any 12-month period ONLY if such travel reasonably appears to be related to the Investigator's Institutional Responsibilities. See the PHS Addendum for more information.

INVESTIGATOR REQUIREMENTS

Any person who meets the federal definition of an Investigator (i.e., the project director or principal investigator and any other person who has responsibility for the design, conduct, or reporting of research funded by the PHS, including collaborators and consultants) who plans to or does participate in NIH-funded research is required to disclose to the designated official(s) of the Institution a listing of SFIs (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities. This disclosure should occur:

1. No later than the time of application for PHS-funded research;
2. At least annually during the period of the award; and
3. Within 30 days of discovering or acquiring any new SFI(s) (e.g., through purchase, marriage, or inheritance).*

*The Institution's designated official has 60 days to review the SFI disclosure, determine whether the SFI relates to NIH-funded research, determine whether an FCOI exists and, if so, implement a plan of specify actions to manage the FCOI. If a FCOI exists, the Institution must submit an FCOI report to the NIH within this same 60-day period.

TRAINING REQUIREMENTS

The training requirements follow ACI Alliance's policies and procedures on FCOI and adhere to Regulatory Citation [42 CFR 50.604\(b\)](#). The Research Committee Chair and/or the Executive Director will oversee the process by which Investigators complete training, including informing each Investigator of ACI Alliance's policy, completion of training, and submission of disclosure documents.

Each Investigator (as defined by the regulation), including subrecipient Investigator(s), must complete training prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances:

- Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

"Immediately" means within a timely period, no greater than 60 days.

ACI Alliance requires Investigators to complete an FCOI online tutorial, such as the one available on NIH's Office of Extramural Research Financial Conflict of Interest webpage (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html). Investigators must provide a copy of the FCOI certification to ACI Alliance prior to engaging in NIH-funded research.

The implementation date can precede the date when all Investigators have been trained. If the implementation date falls on the 365th day, it is expected that all Investigators supported by the NIH will complete their training obligations prior to engaging in NIH-supported research or by the issue date of the Notice of Award issued subsequent to the Institution's implementation date.

DISCLOSURE, REVIEW, AND MONITORING REQUIREMENTS

Disclosure requirements

ACI Alliance will designate an Institutional official to solicit disclosures of SFIs of Investigators and their families related to the Investigator's institutional responsibilities (Regulations [42 CFR 50.603](#) and [42 CFR 50.604\(e\)\(1\)-\(3\)](#)).

As indicated in the INVESTIGATOR REQUIREMENTS section, Investigators must disclose SFIs no later than the time of application for PHS-funded research, at least annually, and within 30 days of acquiring new SFIs.

If the SFI relates to reimbursed or sponsored travel that exceeds the de minimis threshold for FCOI (see **Table 1**), Investigators must provide the following details (at a minimum): (a) the purpose of the trip; (b) the identity of the sponsor/organizer; (c) the destination; and (d) the duration of the trip. The disclosure requirement does not apply to travel reimbursed or sponsored by (a) a federal, state, or local government agency; (b) an Institution of higher education as defined at 20 U.S.C. 1001(a); (c) an academic teaching hospital; (d) a medical center; or (e) a research institute that is affiliated with an Institution of higher education.

Review and monitoring requirements

Figure 1 displays ACI Alliance's process to review disclosures of SFIs of Investigators and their families (Regulatory citation [42 CFR 50.605\(a\)\(1\)](#)). This review policy applies to Investigators on a new PHS-funded research project, new Investigators on an existing research project, or existing Investigators who disclose a new SFI.

The Designated official(s) will solicit and review disclosures of SFIs of Investigators and their families, as related to the Investigator's institutional responsibilities, in accordance with [42 CFR 50.604\(d\)](#). The designated official(s) could include the COI officer or another member of senior administration, depending on the circumstances.

Per [42 CFR 50.604\(f\)](#), ACI Alliance will provide adequate guidelines consistent with the regulation for the designated institutional official(s) to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI constitutes a real or perceived FCOI.

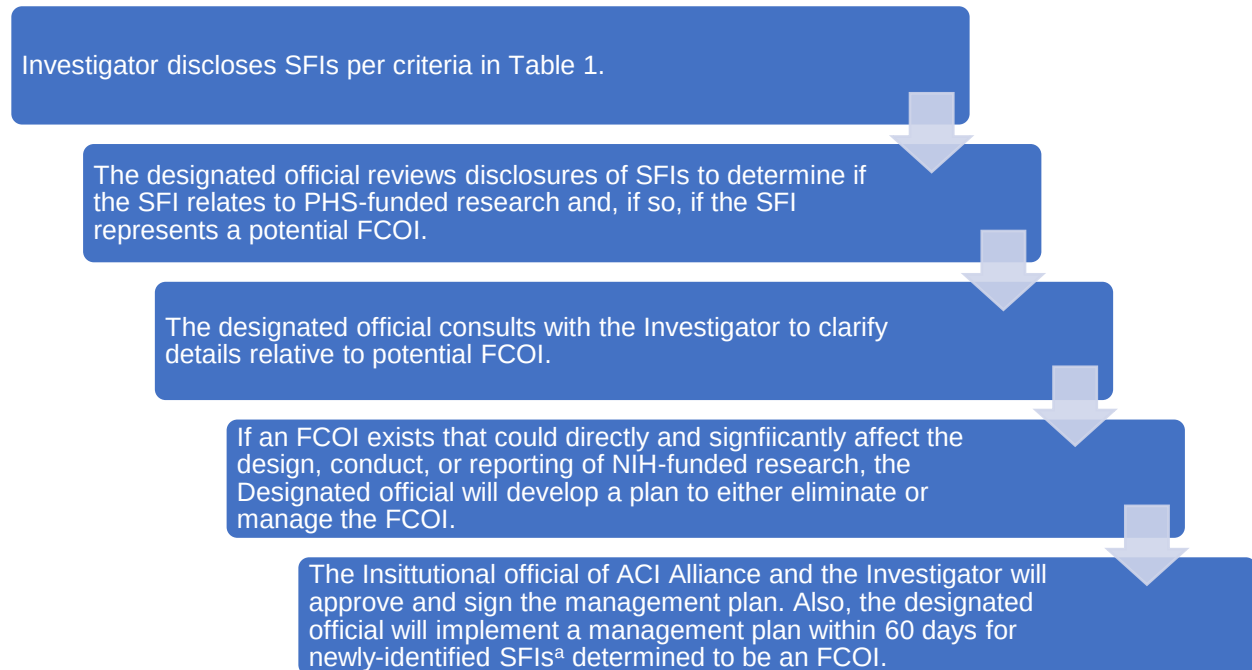
The designated official will clarify potential FCOI with the Investigator.

If a real or perceived FCOI exists, the designated official will develop a management plan, as needed, and submit a recommendation for a plan to the Institutional official of ACI Alliance (i.e., Director of Operations) to either *eliminate* the FCOI (e.g., divestiture of equity interests, change of personnel, modification of the research plan, withdrawal of proposal, termination of sponsored project) or *manage* the FCOI (e.g., public disclosure of FCOI when presenting or publishing research, direct disclosure to participants in human subjects research, appointment of an independent researcher/oversight committee without FCOI to protect the design, conduct, and reporting of research against bias resulting from the FCOI; change of personnel or personnel responsibilities; reduction or elimination of the financial interest; severance of relationships that create financial conflicts). Both the Institutional official of ACI Alliance (i.e., Director) and the Investigator must approve and sign the management plan before expenditure of any funds under a PHS grant, cooperative agreement, subaward, or contract. The review and management plans will follow regulations outlined in [42 CFR 50.605\(a\)\(2\)](#), [42 CFR 50.605\(a\)\(3\) and \(i\) – \(iii\)](#), [42 CFR 50.604 \(g\)](#), and [42 CFR 50.605\(a\)\(4\)](#).

The ACI Alliance may be required by law or by a sponsor to report an Investigator's FCOI or an Investigator's failure to disclose an FCOI to the affected project sponsors.

This policy of disclosure, review, and monitoring requirements applies to annually-disclosed SFIs, SFIs for a new investigator on a new research project, a new investigator on an existing research project, or an existing investigator who discloses a new SFI.

Figure 1. Disclosure review process



^a Newly-identified SFIs could reflect interests not disclosed by the Investigator in a timely manner or those not previously reviewed by the Institution.

REPORTING REQUIREMENTS TO NIH

Submitting FCOI reports to the NIH

ACI Alliance will submit FCOI reports to the NIH in accordance with the regulations (i.e., [42 CFR 50.604\(h\)](#) and [42 CFR 50.605\(b\)](#)).

Initial Reports

Prior to ACI Alliance's expenditure of any funds under a NIH-funded research project, ACI Alliance must provide to the NIH an FCOI report regarding any Investigator SFI found by the ACI Alliance to be an FCOI in accordance with the regulation. ACI Alliance also must provide an FCOI report whenever an Investigator does not timely disclose an SFI or whenever ACI Alliance, for whatever reason, does not review a disclosed SFI they then determine constitutes a FCOI.

Submission of Initial FCOI reports during an Ongoing NIH-funded Research Project

1. ACI Alliance must submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new SFI to the Institution during the period of award.

2. *Whenever* an Investigator does not disclose in a timely fashion a previously existing SFI or ACI Alliance fails to review a previously existing SFI during an ongoing NIH-funded project, ACI Alliance designated official(s) shall, within sixty (60) days: Review the SFI; determine whether it is related to the NIH-funded research; determine whether an FCOI exists. If so, ACI Alliance must implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such FCOI going forward and submit an FCOI report to the NIH.

In addition to the FCOI report, ACI Alliance must, within 120 days of their determination of noncompliance, complete a retrospective review of the Investigator's research activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research.

Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward, as specified in [42 CFR 50.605\(a\)\(3\)\(iii\)](#)

If bias is found, notify the NIH promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effects of the bias ([42 CFR 50.605\(a\)\(3\)\(iii\)](#)). Thereafter the Institution will submit FCOI reports annually.

Annual FCOI Report

For any FCOI previously reported by ACI Alliance, ACI Alliance shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual FCOI reports must be submitted to the NIH (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as when ACI Alliance is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of a project extension with or without funds (see FAQ H.35).

The annual FCOI report will be submitted to NIH separately through the eRA Commons FCOI Module. In addition, please note that the annual FCOI report is not to be submitted as part of the annual progress report nor is it a grant closeout requirement.

Information to include in the FCOI report

All FCOI reports must include sufficient information to enable the NIH to understand the nature and extent of the FCOI and to assess the appropriateness of the Institution's management plan. The regulation provides key elements that must be included in the FCOI report to NIH. These include but are not necessarily limited to the key components listed in **Box 1**.

See the "Management" section for the questions for guidance on the minimum requirements for the management plan.

NIH grant and cooperative agreement award recipients should continue to submit FCOI reports using the electronic Research Administration (eRA) Commons FCOI Module. Once the institution is required to be in full compliance with the regulatory requirements, the additional reporting requirements must be met. Therefore, if the eRA Commons FCOI Module is not updated by the time this occurs, the FCOI report should include an attachment that addresses the minimum elements of the FCOI report as stated above and provided in 42 CFR 50.605(b)(3).

Box 1. Key components of the FCOI report

- Project number;
- PD/PI or Contact PD/PI with multiple PD/PIs
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 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;
- A description of how the financial interest relates to the NIH-funded research and why the Institution determined the SFI conflicts with such research;
- 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.

MAINTENANCE OF RECORDS

In accordance with [42 CFR 50.604\(i\)](#), ACI Alliance will maintain all FCOI-related records that meet or exceed the regulatory requirements, including SFI/FCOI disclosure forms, training certifications, management plans, reports, and all related records of actions taken by ACI Alliance with respect to disclosures of financial interests for at least three years from the date the final expenditures report is submitted to NIH and from other dates specified in 45 CFR 75.361, where applicable (e.g., retaining documents beyond the required three-year period in the case of litigation, claim or negotiation, audit, or other action involving the records until completion of the action and resolution of all issues).

ENFORCEMENT MECHANISMS AND REMEDIES AND NONCOMPLIANCE

Enforcement mechanisms and remedies

In accordance with [42 CFR 50.604\(i\)](#), [42 CFR 50.605\(a\)\(3\)](#) and [42 CFR 50.606\(c\)](#), ACI Alliance has established adequate enforcement mechanisms to ensure Investigator compliance. In the event an Investigator fails to comply with this Policy, putting the integrity of the research at risk, the Institutional Official will report to the NIH (as indicated in this document), but also may take its own action as it deems appropriate. Disciplinary actions may include, but are not limited to, a reprimand, oral or written, private or public; a period of suspension of funding or relevant activities of the Investigator; removal of privileges; or other sanctions or administrative actions in accordance with ACI Alliance Policies and Procedures.

Noncompliance

When an Investigator fails to disclose an FCOI or comply with the Institution's FCOI policy or the management plan, or when ACI Alliance does not review or manage such a FCOI, the Institution shall within 120 days of determination of noncompliance:

1. complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine any bias in the design, conduct or reporting of research;
2. document the retrospective review consistent with the regulation; and
3. document the Institution's determination as to whether any NIH-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the Institution's Financial Conflict of Interest policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research.

The retrospective review will include the following key elements:

1. Project number;
2. Project title;
3. PD/PI;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has an FCOI;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., detailed 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 the retrospective review, ACI Alliance will update any previously submitted FCOI report, as applicable, specifying the actions to be taken to manage the FCOI going forward.

If bias is found during the retrospective review, the Institution shall notify the NIH promptly and submit a mitigation report to the NIH that shall include the following (at a minimum):

1. All information required for the retrospective review (above);
2. Description of the impact of the bias on the research project; and
3. The Institution's plan of action(s) taken to eliminate or mitigate the effect of the bias.

Thereafter, the Institution shall submit FCOI reports annually, in accordance with the regulation ([42 CFR Part 50, Subpart F](#)). Depending on the nature of the Financial Conflict of Interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date that the

Financial Conflict of Interest is identified and the completion of the Institution's independent retrospective review, in accordance with 42 CFR 50.605(a)(3) and 42 CFR 50.605(b)(3).

In addition, if the NIH determines that one of its funded clinical research projects 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 FCOI that was not managed or reported by ACI Alliance, then ACI Alliance shall require the Investigator involved to (a) disclose the FCOI in each public presentation of the results of the research and (b) to request an addendum to previously published presentations.

SUBRECIPIENT REQUIREMENTS

Subrecipient requirements follow regulatory citation [42 CFR 50.604\(c\)](#).

ACI Alliance is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified FCOIs for subrecipient Investigators to the NIH. When applicable, ACI Alliance will establish a written agreement specifying whether the subrecipient will follow the FCOI policy of ACI Alliance or of the subrecipient's institution.

1. If applicable, ACI Alliance will obtain certification from the subrecipient that its FCOI policy complies with the regulation.
2. If applicable, the written subrecipient agreement will include a requirement for the subrecipient to report identified FCOIs for its Investigators in sufficient time to allow ACI Alliance to review, manage and report identified FCOIs to the NIH.
3. If applicable, the written subrecipient agreement will include a requirement to solicit and review subrecipient Investigator disclosures that enable ACI Alliance to identify, manage, and report identified FCOIs to the NIH.

PUBLIC ACCESSIBILITY REQUIREMENTS

ACI Alliance will maintain and post an updated FCOI written and enforced policy that complies with the regulation, available on the ACI Alliance website, in accordance with [42 CFR 50.604\(a\)](#) and the revised [December 2019 NIH Grants Policy Statement, Section 4.1.10](#).

Prior to the expenditure of any funds under a NIH-funded research project, ACI Alliance will ensure public accessibility (either through the Alliance's website or written response within five business days of a request) of information concerning any SFIs disclosed by an Investigator that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by ACI Alliance in the grant application, progress report, or any other required report submitted to the NIH;
2. ACI Alliance determines that the SFI is related to the NIH-funded research; and
3. ACI Alliance determines that the SFI is a FCOI.

The information that ACI Alliance makes available via a publicly accessible Web site or written response will include, at a minimum:

1. Investigator's name;
2. Investigator's title and role with respect to the research project;



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3. Name of the entity in which the SFI is held;
4. Nature of the SFI; and
5. Approximate dollar value of the SFI 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.

This policy will be updated at least annually or within 60 days of a newly identified FCOI, and will remain available for three years from the date the information was most recently updated.

In all cases it is the prime Institution's responsibility to make FCOI information publicly accessible. However, when the subrecipient Investigator is required to comply with the subrecipient's FCOI policy, the subrecipient Institution will also make such information publicly accessible. Therefore, in these situations, the prime Institution may consider including the requirement for the subrecipient Institution to make FCOI information publicly available as part of the written subaward agreement.

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