Acupuncture Care Alliance (ACA)

Financial Conflict of Interest (FCOI) Policy

Effective date: 08/10/2025

Approved by the ACA Board of Directors on: 08/10/2025

Next review: Annually

1. Purpose

The purpose of this Financial Conflict of Interest (FCOI) Policy is to promote objectivity in research funded by the U.S. Public Health Service (PHS), including the National Institutes of Health (NIH), by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS-funded research performed under the auspices of Acupuncture Care Alliance (ACA) will be free from bias arising from an Investigator's conflicting financial interests. This policy implements, and ACA commits to comply with, 42 CFR Part 50 Subpart F (sections 50.601–50.607). If ACA applies for or receives PHS research contracts, ACA will also comply with 45 CFR Part 94.

Because ACA is a small nonprofit with a single employee who may simultaneously serve as Principal Investigator (PD/PI), FCOI Official, Reviewer, and Research Administrator, this policy includes specific safeguards to preserve independence and objectivity when roles overlap. These safeguards include recusal from conflicted determinations, use of a disinterested board member or external reviewer for FCOI evaluations when the PD/PI or FCOI Official is conflicted, independent monitoring of managed FCOIs, and documentation and board approval of management plans.

Through this policy, ACA will:

- Define roles and key terms consistent with 42 CFR 50.603 (e.g., Investigator, Institutional Responsibilities, Significant Financial Interest, Financial Conflict of Interest).
- Require timely FCOI training; complete and up-to-date disclosure of Significant Financial Interests (SFIs); and prompt updates within required timelines.
- Establish a structured process to review SFI disclosures, determine relatedness and FCOI status, implement written management plans before the expenditure of funds, and monitor compliance.
- Meet PHS/NIH reporting obligations, including initial, ongoing (within 60-days), and annual FCOI reports to the awarding component, and conduct retrospective reviews and mitigation when necessary.

- Ensure public accessibility of FCOI information for senior/key personnel as required, and maintain required records for the regulatory retention period.
- Oversee subrecipients to ensure their compliance with Subpart F through written agreements, timely disclosures, appropriate training, and reporting.
- Certify in each PHS application that ACA maintains an enforced, compliant FCOI program and will manage, reduce, or eliminate FCOIs to safeguard research objectivity.

This policy supports ACA's mission to advance acupuncture and integrative medicine research through unbiased scientific inquiry, protects the integrity of research activities, and promotes public trust.

2. Applicability (Scope)

2.1 Activities covered

- This policy applies to all PHS-funded research conducted under the auspices of ACA, whether ACA is the prime awardee or a subrecipient. "PHS-funded research" includes grants and cooperative agreements from NIH and other PHS awarding components (e.g., AHRQ, CDC, HRSA, IHS, SAMHSA, FDA, ASPR) and any PHS-funded subawards issued to ACA by other institutions.
- Research is defined consistent with 42 CFR 50.603 as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge; it encompasses basic and applied research and product development. This policy therefore applies to research projects, cooperative agreements, program/center projects, training and career development awards (where applicable), and multi-site or consortium studies coordinated by or involving ACA.
- Timing: The policy applies from the time of application or proposal (prior to award), throughout the entire period of performance (including no-cost extensions), and through closeout. Certain obligations (e.g., record retention) extend beyond closeout as specified in this policy.
- Note on small business exceptions: The regulatory requirements of 42 CFR Part 50 Subpart F do not apply to Phase I SBIR/STTR applications or awards. ACA is a nonprofit organization and typically not subject to this exception; it is noted here for completeness.

2.2 Individuals covered (Investigators)

This policy applies to all "Investigators," meaning any individual, regardless of title or employment status, who is responsible for the design, conduct, or reporting of PHS-funded research. This includes, but is not limited to:

- Project Director/Principal Investigator (PD/PI) and contact PD/PI
- Co-investigators and senior/key personnel
- Collaborators and consultants whose work can influence the design, conduct, or reporting of the research
- Individuals who enroll subjects, analyze or interpret data, make decisions about publication of results, or write or substantively edit manuscripts or presentations describing PHS-funded research
- Study coordinators, statisticians, methodologists, and laboratory leads with decision-making responsibilities related to the research
- Subrecipient Investigators (domestic or foreign)
- Contractors or independent consultants to ACA who meet the Investigator definition by virtue of their role in the research

Clarifications:

- Individuals whose involvement is purely administrative, clerical, or technical support without the ability to influence the research design, conduct, or reporting are generally not Investigators. ACA will determine Investigator status case-by-case based on actual responsibilities, not job titles.
- Students, trainees, or volunteers are covered if they meet the Investigator definition.

2.3 Family member financial interests

- This policy applies to the Significant Financial Interests (SFIs) of each Investigator and the Investigator's spouse and dependent children, consistent with 42 CFR 50.603. These interests must be disclosed and will be considered in ACA's review and FCOI determinations.

2.4 Subrecipients, consortium partners, and external sites

- This policy applies to subrecipients, subcontractors, subgrantees, and consortium participants engaged in ACA's PHS-funded research, whether domestic or foreign.
- ACA's written agreements with subrecipients will specify whether the subrecipient will follow its own FCOI policy (certifying compliance with 42 CFR Part 50 Subpart F) or will

follow ACA's policy. Agreements will also specify disclosure and reporting timelines that allow ACA to meet PHS/NIH requirements (e.g., review and reporting before expenditure of funds, 60-day reporting for new FCOIs, and annual updates).

- Subrecipient Investigators are subject to the same training and disclosure requirements as ACA Investigators, using either the subrecipient's compliant policy and systems or ACA's systems, as established in the agreement.
- ACA's FCOI obligations extend to all performance sites where PHS-funded research is conducted on ACA's behalf.

2.5 When ACA is a subrecipient

- If ACA is a subrecipient under another institution's PHS award, ACA will comply with the prime awardee's FCOI policy if required by the subaward agreement or, if specified, with this ACA policy. In either case, ACA will meet all applicable disclosure, training, review, management, and reporting obligations within the timelines that enable the prime recipient to comply with PHS requirements.

2.6 Single-employee, multiple-role structure

- ACA currently operates with a single employee who may simultaneously serve as PD/PI, FCOI Official, Reviewer, and Research Administrator. This policy therefore applies to the ACA employee in each of these capacities and includes safeguards to preserve independence and objectivity:
    - If the ACA employee is the Investigator whose SFI is under review (or otherwise has a conflict in the matter), an independent, disinterested reviewer (e.g., ACA's Board Chair or another independent director) will perform the FCOI review and approve any management plan. If needed, ACA will engage an external COI consultant to perform the review.
    - For any managed FCOI involving the ACA employee, ACA will appoint an independent monitor not supervised by the conflicted individual to oversee adherence to the management plan and to review design, conduct, and reporting as appropriate.
    - These oversight arrangements apply equally when ACA is prime or subrecipient and are documented in the FCOI file and, when required, in reports to the PHS awarding component.

2.7 Minimum and broader application

- At a minimum, this policy applies to PHS-funded research as required by 42 CFR Part 50 Subpart F. ACA may elect to apply the same standards to non-PHS-funded research for consistency and best practice; where non-PHS sponsors impose additional requirements, ACA will also meet those requirements.

2.8 No limitation by employment status or payment source

- This policy applies regardless of whether the Investigator is employed by ACA, paid through the PHS award, or engaged as a volunteer or consultant. The determinant is responsibility for the design, conduct, or reporting of PHS-funded research.

3. Definitions

ACA adopts the definitions in 42 CFR 50.603. The following terms are used throughout this policy:

• Institution (ACA)

  o Any domestic or foreign, public or private entity or organization (excluding a federal agency) that is applying for, or has received, PHS research funding. For purposes of this policy, the Institution is Acupuncture Care Alliance (ACA).

  o Reference: 42 CFR 50.603.

• Public Health Service (PHS) and PHS Awarding Component

  o PHS means the Public Health Service of the U.S. Department of Health and Human Services (HHS), including the National Institutes of Health (NIH).

  o PHS Awarding Component means the organizational unit of PHS that funds the research (e.g., an NIH Institute or Center).

  o Reference: 42 CFR 50.603.

• Research

  o A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes basic research, applied research, and product development; it also includes projects involving human participants, clinical interventions (e.g., acupuncture protocols), data analyses, and dissemination of results.

  o Reference: 42 CFR 50.603.

• Investigator

- Any individual, regardless of title or employment status, who is responsible for the design, conduct, or reporting of PHS-funded research. This includes the Project Director/Principal Investigator (PD/PI), co-investigators, senior/key personnel, collaborators, consultants, statisticians, methodologists, coordinators with decision-making authority, and subrecipient Investigators.
- At ACA, "Investigator" also encompasses the ACA employee when acting in multiple institutional roles (e.g., PD/PI, FCOI Official, Reviewer, Research Administrator), to the extent those roles can influence the design, conduct, or reporting of PHS-funded research.
- Reference: 42 CFR 50.603.

• Senior/Key Personnel

- The PD/PI and any other person identified by ACA as senior/key personnel in the grant application, progress report, or other report submitted to the PHS Awarding Component.
- Reference: 42 CFR 50.603.

• Project Director/Principal Investigator (PD/PI)

- The individual designated by ACA to direct the project or program. For multiple-PD/PI projects, "contact PD/PI" is the individual designated as the primary contact with the PHS Awarding Component.
- Reference: 42 CFR 50.603.

• Institutional Responsibilities

- An Investigator's professional responsibilities on behalf of ACA, which may include research, research consultation, teaching, professional practice (e.g., clinical activities tied to the research), administrative duties, internal committee service, and service on panels such as Institutional Review Boards (IRBs) or Data and Safety Monitoring Boards (DSMBs), where applicable.
- Reference: 42 CFR 50.603.

• Financial Interest and Remuneration

- Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

- Remuneration includes salary, consulting fees, honoraria, paid authorship, royalties, in-kind compensation, and other payments for services. Equity interests include stock, stock options, or other ownership interests, whether publicly traded or privately held.
- Reference: 42 CFR 50.603.

• Significant Financial Interest (SFI)

- ACA adopts the definition at 42 CFR 50.603 and NIH clarifications (NIH GPS 4.1.10; NOT-OD-18-160; NOT-OD-19-114).
- An SFI is a financial interest of the Investigator (and of the Investigator's spouse and dependent children) that reasonably appears related to the Investigator's Institutional Responsibilities and consists of one or more of the following (per entity):
  - Publicly traded entities:
    - An SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the disclosure date, when aggregated, exceeds $5,000.
    - 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.
  - Non-publicly traded entities:
    - An SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000; or
    - The Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
  - Intellectual property rights and interests (e.g., patents, copyrights):
    - Disclose upon receipt of income related to such rights and interests (e.g., royalties, license revenue). ACA does not impose a dollar threshold for IP income (NIH FAQ E.20).
  - Reimbursed or sponsored travel related to Institutional Responsibilities:

– Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., paid on behalf of the Investigator and not reimbursed directly) related to Institutional Responsibilities, except for the U.S.-only exclusions listed below. Disclosures must include, at a minimum, the purpose of the trip, the sponsor/organizer, the destination, and the duration. ACA's designated official(s) will determine if further information is needed (including monetary value) to determine whether the travel constitutes an FCOI with PHS-funded research (NIH FAQs E.9, E.24).

- Explicit exclusions from SFI (NIH FAQ D.8; see also E.36, E.37):

  ▪ Salary, royalties, or other remuneration paid by ACA to the Investigator if the Investigator is currently employed or otherwise appointed by ACA (including IP rights assigned to ACA and income from such rights paid by ACA).

  ▪ Any ownership interest in ACA (included for completeness; ACA is a nonprofit).

  ▪ Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions in these vehicles.

  ▪ Income from seminars, lectures, or teaching engagements sponsored by, and income from service on advisory committees or review panels for: a federal, state, or local government agency located in the United States; a United States institution of higher education (as defined at 20 U.S.C. 1001(a)); an academic teaching hospital; a medical center; or a research institute affiliated with a United States institution of higher education. The same exclusion applies to reimbursed or sponsored travel from these U.S. sources.

- Foreign SFI clarification (NOT-OD-18-160; NOT-OD-19-114):

  ▪ Investigators (including subrecipient Investigators) must disclose all foreign financial interests that meet SFI criteria, including income from seminars, lectures, or teaching engagements; income from service on advisory committees or review panels; and reimbursed or sponsored travel received from a foreign entity (e.g., foreign institution of higher education or foreign government at any level). The U.S.-only exclusions above do not apply to foreign sources.

- Reference: 42 CFR 50.603; NIH GPS 4.1.10; NOT-OD-18-160; NOT-OD-19-114; NIH FAQs D.8, E.9, E.20, E.24, E.36, E.37.

• Financial Conflict of Interest (FCOI)

- An SFI that ACA reasonably determines could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- "Directly and significantly" refers to a potential for the SFI to influence decision-making about study design, enrollment, data collection, analysis, interpretation, or dissemination of results.
- Reference: 42 CFR 50.603 and 50.604(f).

• Reimbursed or Sponsored Travel

- Reimbursed travel means travel costs paid to the Investigator; sponsored travel means the travel is paid on behalf of the Investigator and not reimbursed to the Investigator directly so that the exact monetary value may not be readily available.
- ACA does not impose a dollar threshold for travel disclosure; all non-excluded travel must be disclosed regardless of amount (see Section 4.5; NIH FAQs E.9, E.24).
- Exclusions (U.S. only, NIH FAQ D.8): Travel reimbursed or sponsored by a federal, state, or local government agency located in the United States; a United States institution of higher education (20 U.S.C. 1001(a)); an academic teaching hospital; a medical center; or a research institute affiliated with a United States institution of higher education is excluded from SFI disclosure under this policy.
- Required disclosure elements for non-excluded travel: purpose, sponsor/organizer, destination, and duration (ACA may also request estimated/actual cost).
- Reference: 42 CFR 50.603; NIH FAQ D.8.

• Manage or Management of FCOI; Management Plan

- Manage means taking action to address an FCOI, including reducing or eliminating the financial conflict to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- A Management Plan is a written plan that specifies the actions, conditions, and monitoring to manage an identified FCOI (e.g., public disclosure, independent oversight, role modification, divestiture).
- Reference: 42 CFR 50.603.

• Subrecipient; Subaward; Subrecipient Investigator

- Subrecipient is an entity that receives a subaward from ACA to carry out a portion of the PHS-funded research and is accountable to ACA for that performance. A

subaward is the formal legal instrument by which a portion of the PHS-funded research is carried out by another entity.

- Subrecipient Investigator means any Investigator at the subrecipient who is responsible for the design, conduct, or reporting of the subrecipient's portion of the PHS-funded research.

- Reference: 42 CFR 50.603; 50.604(c).

• ACA Designated Official(s); FCOI Official; Reviewer

- The institutional official(s) designated by ACA to solicit and review SFI disclosures, determine relatedness and FCOI status, develop and oversee management plans, and perform required reporting to the PHS Awarding Component.

- Given ACA's single-employee structure, when the designated official is conflicted or is the Investigator under review, ACA will assign review and approval to a disinterested board member or an external reviewer to preserve independence.

- Reference: 42 CFR 50.604(d).

• Disclosure of SFI

- An Investigator's disclosure of Significant Financial Interests to ACA using ACA's disclosure mechanisms and timelines (initial, annual, and within 30 days of acquiring or discovering a new SFI).

- Reference: 42 CFR 50.604(e).

• Retrospective Review; Bias; Mitigation

- Retrospective Review: The documented review conducted by ACA when an SFI was not disclosed in a timely manner, not reviewed or managed in a timely manner, or when an Investigator failed to comply with a Management Plan, to determine whether research design, conduct, or reporting was biased.

- Bias: A prejudice to the integrity of the research such that the design, conduct, or reporting of the research has been, or may have been, affected.

- Mitigation: Additional actions taken if bias is found, including updating the management plan, reanalyzing data, or other corrective measures, and submission of a mitigation report to the PHS Awarding Component.

- Reference: 42 CFR 50.605(a)–(b).

• Clinical Research (for remedies in noncompliance)

- Research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment (including acupuncture or related integrative procedures when studied as treatments).
- Additional public disclosure and publication addendum requirements apply if such research is biased due to noncompliance.
- Reference: 42 CFR 50.605(c).

• Immediate Family (for purposes of SFI)

- As used in Subpart F, this policy treats the Investigator's "spouse and dependent children" as the immediate family members whose interests must be disclosed and considered in SFI determinations.
- Reference: 42 CFR 50.603.

• Entity (for SFI disclosures)

- Any domestic or foreign, public or private organization, company, or body corporate, including for-profit corporations, private or public universities outside the excluded categories for travel, trade or professional associations, foundations, or startups, whose financial interests could be affected by the Investigator's research activities.

• Value Ranges (for reporting and public accessibility)

- When reporting the approximate value of an SFI to PHS or in public statements, ACA will use regulatory dollar ranges or state that the value cannot be readily determined:
  - $0–$4,999
  - $5,000–$9,999
  - $10,000–$19,999
  - Amounts between $20,000 and $100,000 by increments of $20,000
  - Amounts above $100,000 by increments of $50,000
- Reference: 42 CFR 50.604(a) and 50.605(b).

4. Investigator Responsibilities and Disclosure Requirements

4.1 Duty to know and comply

- Investigators must read, understand, and comply with this policy and with 42 CFR Part 50 Subpart F.
- Investigators must disclose Significant Financial Interests (SFIs) completely and on time; cooperate with relatedness and FCOI determinations; comply with any Management Plan; and provide prompt updates when circumstances change.
- Investigators must ensure their disclosures cover their own interests and those of their spouse and dependent children, and that they relate the disclosures to their Institutional Responsibilities.

4.2 Training requirements (42 CFR 50.604(b))

- Required timing:
    - Before engaging in any PHS-funded research at ACA.
    - At least every 4 years thereafter.
    - Immediately (as soon as practicable) when:
        - ACA revises this policy in a manner that affects Investigator responsibilities;
        - The Investigator is new to ACA or newly assumes Investigator responsibilities on a PHS-funded project; or
        - ACA determines the Investigator is not in compliance with this policy or with a Management Plan.
- Content:
    - Definitions of Investigator, Institutional Responsibilities, SFI (including exclusions), FCOI.
    - Disclosure obligations and timelines; travel disclosure rules and exclusions.
    - Relatedness and FCOI determinations; elements of Management Plans; monitoring.
    - NIH/PHS reporting, retrospective review, and mitigation requirements.
    - Remedies for noncompliance, including additional public disclosure for biased clinical research.
- Acceptable training:

- NIH FCOI tutorial (preferred) or equivalent ACA-approved training. Investigators must retain and provide completion certificates to ACA.

- Subrecipients:
    - Subrecipient Investigators must also complete compliant FCOI training before engaging in PHS-funded research and at least every 4 years (or upon trigger events), whether under ACA's policy or the subrecipient's own compliant policy.

4.3 Disclosure obligations and timing (42 CFR 50.604(e))

- Who must disclose:
    - All Investigators responsible for the design, conduct, or reporting of PHS-funded research conducted under ACA's auspices, including subrecipient Investigators, must disclose SFIs related to their Institutional Responsibilities. Disclosures must include the SFIs of the Investigator's spouse and dependent children.
- When to disclose:
    - Initial disclosure: No later than at the time of application for PHS-funded research (new, resubmission, or renewal). If an Investigator is added to an active award, disclosure is due before engaging in the research and in time for ACA to complete review and any required reporting before expenditure of PHS funds on that Investigator's activities.
    - Annual updates: At least annually for the duration of the award period (including no-cost extensions). Annual updates must reflect the preceding 12 months and anticipated changes.
    - Within 30 days of new SFI: Within 30 calendar days of discovering or acquiring a new SFI (e.g., through purchase, option exercise, gift, inheritance, marriage, consulting agreement, speaking honoraria, sponsored/reimbursed travel, licensing/royalty payments).
- Special routing for ACA's single-employee structure:
    - When the ACA employee is the Investigator, they must submit their SFI disclosure to the designated independent reviewer (e.g., ACA Board Chair or external COI reviewer) rather than to themselves in their FCOI Official role.

4.4 What to disclose (content and data elements)

For each external entity with which the Investigator (or the Investigator's spouse/dependent children) has an SFI that reasonably appears related to the Investigator's Institutional Responsibilities, provide:

- Entity identification:
    - o Legal name of the entity; contact information (if known); country of incorporation or operation (if outside the U.S.).
- Nature of the financial interest:
    - o Remuneration (salary, consulting fees, honoraria, paid authorship, in-kind payments).
    - o Equity/ownership interests (publicly traded or non-publicly traded stock, stock options, warrants, partnership or LLC interests).
    - o Intellectual property rights and interests (patents, copyrights, licenses), with income upon receipt (e.g., royalties, milestone payments).
    - o Sponsored or reimbursed travel related to Institutional Responsibilities (see 4.5). ACA does not impose a dollar threshold for non-excluded travel; all such travel must be disclosed regardless of amount (see Section 4.5; NIH FAQs E.9, E.24).
- Value or value range:
    - o The approximate value of remuneration and/or equity interest, stated in dollar ranges or as "value cannot be readily determined." For publicly traded equity, use current public price or reasonable measures of fair market value.
- Relationship to ACA duties and the PHS-funded research:
    - o A brief description of how the entity and the SFI relate to the Investigator's Institutional Responsibilities; and, if known, whether the entity's financial interests could be affected by the PHS-funded research (e.g., the entity sponsors related products or services, supplies materials, stands to benefit from research outcomes).
- Aggregation and thresholds:
    - o Publicly traded entities: Aggregate remuneration received from the entity in the preceding 12 months plus current equity value; disclose if the aggregate equals or exceeds $5,000.
    - o Non-publicly traded entities: Disclose any equity interest (no de minimis) and any remuneration in the preceding 12 months that exceeds $5,000.

- Intellectual property: Disclose related income upon receipt (e.g., royalty distributions).

• Exclusions (do not disclose as SFI):

- Salary, royalties, or other remuneration paid by ACA to the Investigator while currently employed or appointed by ACA (including IP rights assigned to ACA and related income paid by ACA).

- Income from investment vehicles (e.g., mutual funds, retirement accounts) if the Investigator does not directly control the investment decisions.

- Income from seminars, lectures, or teaching engagements, and income from service on advisory or review panels, sponsored by: a federal, state, or local government agency located in the United States; a United States institution of higher education (20 U.S.C. 1001(a)); an academic teaching hospital; a medical center; or a research institute affiliated with a United States institution of higher education. The same exclusion applies to reimbursed or sponsored travel from these U.S. sources.

- Note: These U.S.-only exclusions do not apply to foreign sources. Income or travel from foreign institutions of higher education or foreign governments (including provincial/local/equivalent) must be disclosed when SFI criteria are met (see NOT-OD-18-160; NOT-OD-19-114).

• Documentation:

- Provide supporting documentation upon request (e.g., consulting agreement, cap table, license agreement, royalty statement, travel itinerary/invoice, W-2/1099).

4.5 Travel disclosure requirements

• Travel that must be disclosed:

- All reimbursed or sponsored travel related to Institutional Responsibilities that is paid for or arranged by an external entity that is not an excluded sponsor (see below), regardless of dollar amount. ACA does not impose a dollar threshold for travel disclosure (NIH FAQs E.9, E.24).

- Provide: purpose of the trip, sponsor/organizer, destination, and duration. If requested, Investigators will also provide the estimated or actual monetary value to support FCOI review. ACA's designated official(s) may request additional details if needed to determine relatedness and whether an FCOI exists.

• Exclusions from travel disclosure (U.S. only; NIH FAQ D.8):

- Travel reimbursed or sponsored by a federal, state, or local government agency located in the United States; a United States institution of higher education (as defined at 20 U.S.C. 1001(a)); an academic teaching hospital; a medical center; or a research institute affiliated with a United States institution of higher education.

• Foreign travel:

- Foreign travel is disclosable when sponsored/reimbursed by foreign institutions, governments (including provincial/local/equivalent), companies, or other foreign entities; the U.S.-only exclusions above do not apply to foreign sources (NOT-OD-18-160; NOT-OD-19-114).

• Examples requiring disclosure:

- Travel paid by professional societies or associations not affiliated with a United States institution of higher education; nonprofit foundations; for-profit companies (e.g., device or software vendors); foreign governments or foreign universities not meeting the U.S. exclusion criteria; trade associations; or continuing education companies.

• Note:

- If ACA later adopts a $5,000 per-entity de minimis for travel (as permitted by NIH FAQs), ACA will revise this section and the disclosure form accordingly.

• References:

- NIH FAQ D.8; NIH FAQs E.9, E.24; NOT-OD-18-160; NOT-OD-19-114.

4.6 Form and submission of disclosures

- Forms:
  - Use ACA's SFI Disclosure Form for initial and annual disclosures, and the Event-Based Update for new SFIs acquired during an award. Subrecipient Investigators will use their own institution's forms if following their policy, or ACA's forms if following ACA's policy.
- Method and recipient:
  - Submit disclosures electronically to the ACA FCOI Official. If the ACA employee is the Investigator, submit disclosures directly to the designated independent reviewer (Board Chair or external COI reviewer) to preserve independence.
- Certification:

    - Each submission must include a certification that the information is true, complete, and accurate to the best of the Investigator's knowledge, that the Investigator has read this policy, and that the Investigator agrees to comply with any Management Plan.

- Submission prerequisite:
    - Investigators may not engage in the design, conduct, or reporting of a PHS-funded project until ACA has verified training, received initial SFI disclosures, completed relatedness/FCOI determinations, implemented any required management plan, and, if applicable, submitted the initial FCOI report.
- Deadlines:
    - Initial: by the time of application (and before engaging in the research).
    - Annual: by the date specified by ACA each year during the award period (ACA will set deadlines to align with RPPR or other sponsor reporting cycles).
    - Event-based: within 30 calendar days of acquiring or discovering a new SFI.

4.7 Cooperation with review, management, and monitoring

- Investigators must:
    - Provide additional information reasonably requested by ACA to assess relatedness and determine whether an SFI is an FCOI.
    - Refrain from participating in any research decisions that could be affected by a disclosed SFI unless and until ACA approves a Management Plan allowing specific roles.
    - Comply with all conditions of any Management Plan (e.g., public disclosure, independent oversight, modification of roles, divestiture).
    - Facilitate monitoring activities and provide periodic certifications of compliance as required by ACA.
- Publications and presentations:
    - When required by a Management Plan or as part of mitigation after noncompliance, disclose the existence of an FCOI in manuscripts, abstracts, posters, slide decks, and oral presentations that report results from the PHS-funded research.

4.8 Subrecipient Investigator responsibilities

- If a subrecipient follows its own compliant FCOI policy:
    - Subrecipient Investigators must complete training, make timely SFI disclosures to their institution, and ensure their institution provides ACA with FCOI reports and assurances in time for ACA to meet PHS reporting deadlines (prior to expenditure of funds and within 60-days for newly identified FCOIs).
- If a subrecipient follows ACA's policy:
    - Subrecipient Investigators must complete training and submit their SFI disclosures to ACA on ACA's forms and timelines; ACA will review, determine relatedness and FCOI status, implement Management Plans, and submit required FCOI reports to PHS.

4.9 Clarifications on relatedness and scope

• Relatedness standard and FCOI determination (42 CFR 50.604(f)):

o Disclose SFIs that "reasonably appear related" to the Investigator's Institutional Responsibilities (not just to a specific grant). ACA will determine whether each disclosed SFI is related to a specific PHS-funded (e.g., NIH-funded) project and whether it constitutes an FCOI.

o Designated official(s) role: The ACA designated official(s) is responsible for assessing the relatedness of SFIs to PHS/NIH-funded research and determining whether an SFI is an FCOI. As allowed by regulation, the designated official(s) may involve the Investigator in making the relatedness determination.

o Relatedness test: An SFI is "related" when the designated official(s) reasonably determines the SFI (1) could be affected by the PHS/NIH-funded research; or (2) is in an entity whose financial interest could be affected by the PHS/NIH-funded research.

o FCOI determination: A Financial Conflict of Interest exists when the designated official(s) reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. "Significantly" means the financial interest would have a material effect on the research.

• No de minimis for travel:

o Non-excluded sponsored/reimbursed travel must be disclosed regardless of dollar value (NIH FAQs E.9, E.24).

• Foreign relationships:

- Disclose all foreign SFIs consistent with NOT-OD-18-160 and NOT-OD-19-114. The U.S.-only exclusions in NIH FAQ D.8 do not apply to foreign sources. SFIs involving foreign institutions, companies, or governments are subject to the same disclosure rules as domestic SFIs when SFI criteria are met.

• References:

- 42 CFR 50.604(f); NIH FAQs D.8, E.9, E.24; NOT-OD-18-160; NOT-OD-19-114.

4.10 Interim limitations prior to determination

- If an Investigator discloses an SFI that could reasonably be related to a PHS-funded project and ACA has not yet completed its review, ACA may temporarily limit or reassign the Investigator's role in affected activities until a determination is made and, if needed, a Management Plan is in place.

4.11 Data accuracy and updates

- Investigators must ensure disclosures are accurate, complete, and promptly updated. Failure to disclose, delayed disclosure, or inaccurate disclosure may result in enforcement actions (see Enforcement and Sanctions) and required reporting to the PHS awarding component.

4.12 Special procedures for ACA's single-employee structure

- When the ACA employee serves as both Investigator and FCOI Official:
  - The employee will submit disclosures to the designated independent reviewer.
  - Relatedness/FCOI determinations and any Management Plan approval will be performed by a disinterested board member or external reviewer.
  - Any active Management Plan will include independent monitoring by a person not supervised by the conflicted Investigator.
  - All steps, decisions, and approvals will be documented.

4.13 Examples to guide disclosure (non-exhaustive)

- Disclose:
  - Consulting fees from a manufacturer of acupuncture needles, devices, or software used in the research.
  - Equity in a startup developing digital tools or devices for acupuncture research or practice.

    - Royalties from a patented method, device, or software potentially used in the project.
    - Sponsored travel to speak at a conference organized by a professional society not affiliated with an academic institution, if the topic overlaps with the Investigator's ACA duties.
- Generally excluded (do not disclose as SFI under Subpart F):
    - Salary paid by ACA; royalties paid by ACA on ACA-assigned IP.
    - Travel paid by an accredited university or an affiliated academic medical center.

5. Review and Determination Process

5.1 Designation and independence

- FCOI Official: ACA designates an institutional official (FCOI Official) to solicit, receive, and review SFI disclosures; determine relatedness and FCOI status; develop and oversee management plans; and coordinate required reporting to the PHS awarding component.
- Independence safeguards for ACA's single-employee structure:
    - If the designated FCOI Official is also the Investigator whose SFI is under review, or otherwise has a conflict, ACA will assign the review and approval to a disinterested board member or engage an external COI reviewer. This assignment will be documented in the file.
    - For any FCOI managed under these circumstances, ACA will appoint an independent monitor not supervised by the conflicted individual to oversee compliance.

5.2 Intake and completeness screening

- Upon receipt of an SFI disclosure (initial, annual, or event-based), the FCOI Official screens for completeness and may request clarifications or supporting documentation (e.g., consulting agreements, equity summaries, royalty statements, travel itineraries).
- The FCOI Official confirms that the disclosure encompasses the Investigator's spouse and dependent children and covers the preceding 12 months.
- If the Investigator is new to a project or has acquired a new SFI, the FCOI Official prioritizes review to meet regulatory timelines.

5.3 Relatedness assessment (SFI to Institutional Responsibilities and to the specific PHS-funded project)

• Step 1 (Institutional Responsibilities): Determine whether each disclosed SFI reasonably appears related to the Investigator's Institutional Responsibilities at ACA (e.g., research, teaching, professional practice, administration, committee service).

• Step 2 (PHS/NIH-funded project): For SFIs related to Institutional Responsibilities, determine whether the SFI is related to any PHS-funded (e.g., NIH-funded) research project on which the Investigator is responsible for the design, conduct, or reporting. An SFI is "related" when the designated official(s)/FCOI Official reasonably determines the SFI (1) could be affected by the PHS/NIH-funded research; or (2) is in an entity whose financial interest could be affected by the PHS/NIH-funded research (42 CFR 50.604(f)). For example, the entity makes, markets, or competes with a product, device, software, method, or service that is studied, used, licensed, or reasonably could be affected by study findings. The designated official(s) may involve the Investigator in determining relatedness.

• Documentation: The designated official(s)/FCOI Official prepares a written relatedness determination for each SFI, noting the rationale, information reviewed, and any input from the Investigator.

5.4 FCOI determination

• For each SFI determined to be related to a PHS-funded project, the designated official(s)/FCOI Official evaluates whether the SFI could directly and significantly affect the design, conduct, or reporting of the research. "Significantly" means the financial interest would have a material effect on the research (42 CFR 50.604(f)). The designated official(s) will document the FCOI determination and the rationale.

• Considerations include:

    o Magnitude and nature of the SFI (remuneration level, equity type and value, IP income, sponsored travel patterns).

    o Investigator's role and principal duties on the project (protocol design, subject enrollment, data analysis, access to outcomes, authorship).

    o How the entity's financial interests could be influenced by study outcomes, endpoints, or secondary uses of data.

    o Presence of existing safeguards (e.g., independent statisticians, DSMB, blinded analyses).

• Classification outcomes:

    o Not related to Institutional Responsibilities: No further action for that SFI under this policy.

- Related SFI but no FCOI: No FCOI found; monitoring and/or transparency may be recommended as a precaution.
- FCOI: The SFI could directly and significantly affect the research; a written Management Plan is required before expenditure of funds (for initial disclosures) or within the regulatory window (within 60 days) for new SFIs identified during an ongoing award.

5.5 Timelines and interim actions (42 CFR 50.604–50.605)

- Before expenditure of funds: For SFIs disclosed at application or prior to award, ACA will complete relatedness and FCOI determinations, implement any required Management Plan, and submit any required FCOI report to the PHS awarding component before expending PHS funds.
- Newly acquired or newly identified SFI during an active award: Within 60 calendar days of identification, ACA will complete relatedness and FCOI determinations, implement at least an interim Management Plan, and submit any required FCOI report. If the SFI was not timely disclosed or not timely reviewed/managed, ACA will also conduct a retrospective review per Section 6.
- Interim limitations: Pending determination and plan approval, ACA may temporarily restrict or reassign the Investigator's roles that could be affected by the SFI (e.g., enrollment decisions, data analysis, procurement, communications with the entity).
- Pre-award timeliness: If a timely relatedness/FCOI determination or management plan cannot be completed, ACA will delay the Investigator's participation and/or delay expenditure of funds on the affected activities until all requirements are met.

5.6 Information sources and consultation

- In addition to the Investigator's disclosures, the FCOI Official may consult:
  - Grant applications, scopes of work, protocols, consent forms, and data analysis plans.
  - Budgets and purchasing plans (to assess vendor relationships).
  - Public information on entities (SEC filings, websites, press releases).
  - IRB or DSMB chairs, independent statisticians, or subject-matter experts.
- The Investigator may present relevant facts but will not participate in the FCOI determination vote or decision.

5.7 Management plan development (42 CFR 50.605(a)(3))

- If an FCOI is identified, ACA will develop a written Management Plan tailored to the risks and the Investigator's role. Each plan will include, at a minimum:
    - Investigator's role and principal duties in the research.
    - Conditions and restrictions to manage the conflict, which may include:
        - Public disclosure of the FCOI in presentations, manuscripts, abstracts, posters, trial registries, and on ACA's website, as appropriate.
        - Disclosure to the IRB and, when human participants are involved, to prospective research participants in consent documents.
        - Modification of the research plan (e.g., introduce blinding, independent data analysis, restrict access to interim outcome data).
        - Change of personnel or responsibilities (e.g., the conflicted Investigator may not be the primary decision-maker for enrollment, randomization, endpoint adjudication, data analysis, or manuscript first authorship).
        - Independent monitoring by an external or internal reviewer not supervised by the conflicted Investigator, with defined frequency and scope (e.g., quarterly audit of data integrity, adverse event reporting, endpoint analysis).
        - Establishment of information barriers (e.g., no involvement in procurement or vendor selection related to the entity; no access to competitors' proposals; firewalling of price/cost data).
        - Divestiture or reduction of the financial interest; or severance of conflicting relationships.
        - Restrictions on receiving additional remuneration or equity from the entity during the project without prior approval.
    - How the plan safeguards objectivity of the research (specific rationale linking conditions to identified risks).
    - Monitoring procedures, responsible monitor, and review frequency.
    - Confirmation of the Investigator's agreement to comply (signature or electronic acknowledgment) and the plan's effective date and duration.
    - Procedures for plan modification or termination if circumstances change.

- Independence safeguards when roles overlap:
    - If the conflicted Investigator is also the FCOI Official, the plan must be approved by a disinterested board member or external reviewer, and monitoring must be conducted by an independent monitor not under the conflicted individual's supervision.

5.8 Monitoring, compliance certification, and modifications

- Ongoing monitoring: The assigned monitor or FCOI Official will verify compliance at intervals specified in the plan (e.g., quarterly or at defined project milestones) and after any major project change (protocol amendments, staffing changes).
- Investigator certifications: The Investigator will provide periodic written certifications of adherence to plan conditions and promptly report any deviations.
- Noncompliance: Deviations are addressed immediately; corrective actions may include plan amendment, increased monitoring, additional disclosures, role changes, or suspension from specific activities. If noncompliance results in untimely identification or management of an FCOI, ACA will initiate a retrospective review per Section 6.
- Plan modification or termination: Plans may be modified or terminated if the SFI is eliminated, the Investigator's role changes, or risk diminishes. All changes must be documented and, if required, reported to the PHS awarding component.

5.9 Documentation and records

- For every disclosure reviewed, ACA will maintain:
    - The disclosure form and supporting materials.
    - The relatedness determination and rationale.
    - The FCOI determination and rationale (if applicable).
    - The final Management Plan and any modifications.
    - Monitoring reports, Investigator certifications, and any corrective actions.
    - Approvals by independent reviewers or the board when independence safeguards were invoked.
- Records will be retained consistent with Section 10 (Record Retention) and regulatory requirements.

5.10 Communication and coordination

- Internal communication:
    - For human subjects research, the IRB (if applicable) will receive the Management Plan and any updates. Consent documents will include required disclosures when mandated by the plan.
    - Project leadership and relevant staff will receive role-specific instructions (e.g., recusal lists for procurement).
- External reporting:
    - ACA will submit initial, ongoing (within 60-days), and annual FCOI reports to the PHS awarding component in accordance with 42 CFR 50.605. Details of report content and timing are specified in the NIH/PHS Reporting section of this policy.

5.11 Subrecipient determinations

- If a subrecipient follows its own compliant FCOI policy:
    - The subrecipient conducts relatedness and FCOI determinations for its Investigators and provides ACA with FCOI reports and assurance of management in time for ACA to meet PHS reporting deadlines.
- If a subrecipient follows ACA's policy:
    - ACA conducts the relatedness and FCOI determinations, issues Management Plans, and monitors compliance for the subrecipient's Investigators.
- In both cases, ACA will ensure that determinations and plans are in place before expenditure of funds on the subrecipient's work and that updates are received within 60-days for newly identified FCOIs.

5.12 Decision outcomes and notices

- Written outcome notice to the Investigator will state:
    - Whether each SFI is related to Institutional Responsibilities and to the specific PHS-funded project.
    - Whether an FCOI exists.
    - Any required conditions, including a Management Plan with effective date, monitoring, and reporting requirements.
    - Appeal or reconsideration process (if any), which does not delay compliance or required reporting timelines.

- If no FCOI is found, ACA may still impose precautionary measures (e.g., public disclosure or recusal from certain decisions) to protect objectivity.

5.13 Examples of tailored conditions (non-exhaustive)

- If the SFI involves equity or paid consulting with a device/software company whose product is used in the study:
    - The Investigator may provide subject-matter input but will not participate in vendor selection, price negotiations, data analysis, or endpoint adjudication. An independent statistician performs primary analysis; an external monitor audits data integrity quarterly; public and participant disclosures are required.
- If the SFI is IP income (royalties) from a technique evaluated in the research:
    - The Investigator will be recused from primary outcome selection and data interpretation; a blinded analysis is conducted by an independent analyst; public and consent disclosures are required; manuscript drafting is reviewed by a non-conflicted co-author or editorial committee for bias.

6. Retrospective Review and Mitigation

6.1 Triggers for retrospective review (42 CFR 50.605(a)(3)) ACA will initiate and complete a documented retrospective review whenever any of the following occur:

- An Investigator fails to disclose a Significant Financial Interest (SFI) in a timely manner and ACA later determines the SFI is related to PHS-funded research and constitutes a Financial Conflict of Interest (FCOI).
- ACA fails to review or manage an identified FCOI in a timely manner (e.g., the Management Plan was not implemented before the Investigator engaged in the relevant activities).
- An Investigator fails to comply with an approved Management Plan (e.g., violates recusal conditions, omits required disclosures in manuscripts/presentations, receives disallowed remuneration).
- A subrecipient fails to make timely SFI disclosures, or the subrecipient's FCOI was not managed in a timely manner, and the SFI is related to the subrecipient's portion of ACA's PHS-funded research.

6.2 Immediate actions upon identification of untimely disclosure or noncompliance

- Date of identification: ACA will document the date on which it determines that an SFI related to PHS-funded research constitutes an FCOI and that the FCOI was not identified

or managed in a timely manner, or that a Management Plan was violated. This is the "date of identification" for timeline purposes.

- Interim management plan: As soon as practicable after the date of identification, ACA will implement an interim Management Plan to manage the FCOI going forward while the retrospective review is conducted (e.g., immediate role restrictions, independent monitoring, public and participant disclosure as applicable).
- 60-day reporting: Within 60 calendar days of identifying the FCOI (if not previously reported), ACA will submit an initial or updated FCOI report to the PHS awarding component via the eRA Commons FCOI Module and ensure a Management Plan is in place, consistent with Section 5 and 42 CFR 50.605(b)(2).
- Independence safeguards: If the conflicted Investigator is also ACA's FCOI Official, the retrospective review will be assigned to a disinterested board member or external COI reviewer, and monitoring will be conducted by an independent monitor not under the conflicted Investigator's supervision.

6.3 Retrospective review timeline (42 CFR 50.605(a)(3))

- Completion deadline: ACA will complete the retrospective review within 120 calendar days of the date of identification.
- Scope of review period: The review covers all PHS-funded research conducted during the time period of noncompliance (i.e., from the date the SFI was acquired or should have been disclosed, or from the date a Management Plan should have been in place, through the date interim management began).

6.4 Required elements of the retrospective review record ACA will prepare a written retrospective review report that includes, at a minimum:

- Project number and title.
- PD/PI or contact PD/PI.
- Name of the Investigator with the FCOI.
- Name of the external entity(ies) with which the Investigator has the SFI/FCOI.
- Reason(s) for the retrospective review (e.g., late disclosure, delayed management, plan noncompliance).
- Key dates: date the SFI was acquired or discovered; date the SFI should have been disclosed; date ACA received disclosure; date ACA identified the FCOI; date interim management began.

- Detailed methodology used for the review, including:
    - What records were examined (e.g., protocols, IRB submissions, data sets, analysis plans, meeting minutes, emails, manuscripts, abstracts, presentations, purchase records).
    - Which activities and time periods were evaluated.
    - Who conducted the review and their independence from the conflicted Investigator.
- Findings and conclusions:
    - Whether the design, conduct, or reporting of any portion of the PHS-funded research was biased by the FCOI during the period of noncompliance.
    - The extent and nature of any identified bias and affected outputs (e.g., data analyses, decisions, publications, presentations).
- Management plan updates (if any) needed to ensure objectivity going forward.

ACA will maintain this documentation and provide it to HHS/PHS upon request.

6.5 Actions following the retrospective review (42 CFR 50.605(a)–(b))

- If no bias is found:
    - ACA will update the FCOI report to the PHS awarding component, as needed, to reflect the completion of the retrospective review and any adjustments to the Management Plan. ACA will continue annual FCOI reporting for the duration of the award.
- If bias is found:
    - Mitigation report (prompt submission): ACA will promptly submit a Mitigation Report to the PHS awarding component. The report will include:
        - All key elements from the retrospective review (Section 6.4).
        - A description of the impact of the bias on the project (e.g., data integrity, analysis, conclusions).
        - A detailed plan of action to eliminate or mitigate the effect of the bias on the project (e.g., reanalysis of data by an independent statistician, additional enrollment or controls, additional independent monitoring,

errata or corrections to abstracts/manuscripts, disclosure to collaborators and sponsors).

- Updated FCOI report: ACA will update the FCOI report with the Management Plan modifications and specify how compliance will be monitored going forward.
- Clinical research remedy (42 CFR 50.605(c)): If the biased research is clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment (including acupuncture):
  - The Investigator must disclose the FCOI in each public presentation of the research results.
  - The Investigator must request an addendum to previously published presentations or publications to disclose the FCOI and address any necessary corrections.

6.6 Notifications and internal coordination

- IRB and human participants: For human subjects research, ACA will notify the IRB of the retrospective review outcome and any mitigation steps. If required by the Management Plan or IRB, ACA will inform current or prospective participants of the FCOI through consent addenda or public notices.
- Collaborators and subrecipients: ACA will inform relevant collaborators, subrecipients, and performance sites of any required changes to roles, data handling, or disclosures.
- Journals and conferences: Where bias affects published or submitted work, ACA will notify journal editors or conference organizers as needed to implement corrections, retractions, or addenda.

6.7 Public accessibility updates (42 CFR 50.604(a))

- For any FCOI held by senior/key personnel, ACA will ensure public accessibility of required information prior to the expenditure of funds and will update it within 60-days of identifying a new FCOI and at least annually thereafter. If the Management Plan is modified following the retrospective review, public information will be updated accordingly and maintained for at least 3 years from the most recent update.

6.8 Subrecipient noncompliance

- If a subrecipient's SFI was not disclosed or managed in a timely manner:
  - ACA will require the subrecipient (if using its own policy) to conduct a retrospective review in accordance with 42 CFR 50.605(a)(3) and to provide ACA

with the review documentation and any mitigation report so ACA can meet its reporting obligations to the PHS awarding component.

- If the subrecipient follows ACA's policy, ACA will conduct the retrospective review or direct an independent reviewer to do so.
- ACA will ensure initial/updated FCOI reports, mitigation reports (if bias is found), and annual updates are submitted to the PHS awarding component on the required timelines. ACA may take contractual remedies, including suspension of subrecipient activities, if necessary to protect research objectivity.

6.9 Timelines summary (from date of identification)

- Implement interim Management Plan: immediately/as soon as practicable.
- Submit initial or updated FCOI report (if not previously submitted): within 60 calendar days.
- Complete retrospective review and documentation: within 120 calendar days.
- If bias is found: promptly submit a Mitigation Report and update the FCOI report/Management Plan; implement corrective actions without delay.
- Continue annual FCOI reporting for the duration of the award and update public disclosures within 60-days when applicable.

6.10 Corrective measures and preventive actions

- Corrective measures may include increased monitoring, modification of roles, additional blinding, independent reanalysis, divestiture, severance of conflicting relationships, supplemental disclosures, and training.
- Preventive actions may include policy clarifications, targeted training, process adjustments (e.g., earlier pre-award screening), and enhanced subrecipient oversight.

6.11 Recordkeeping (42 CFR 50.604(i); see Section 10)

- ACA will maintain all records related to retrospective reviews, mitigation reports, updated Management Plans, FCOI reports, and monitoring for at least three (3) years from the date of submission of the final expenditure report for the award (or longer if required by audit, litigation, or other federal record retention rules). Records will be made available to HHS upon request.

6.12 Examples (illustrative)

- Late SFI disclosure (equity in device vendor): Interim plan restricts the Investigator from procurement and data analysis; independent statistician takes over analysis; retrospective review finds no bias; FCOI report updated; plan continues with quarterly monitoring.
- Management Plan violation (undisclosed paid talk): Interim plan imposes stricter disclosure and recusal from public communications; retrospective review finds potential influence on interpretation; mitigation includes independent reanalysis, addendum to slides and a manuscript disclosure; clinical presentation includes FCOI disclosure moving forward.

7. Training Requirements

7.1 Authority and purpose

- Authority: 42 CFR 50.604(b) requires that each Investigator complete FCOI training before engaging in PHS-funded research, at least every four years, and immediately when certain conditions occur.
- Purpose: Ensure Investigators understand their obligations to disclose Significant Financial Interests (SFIs), comply with management plans, and uphold research objectivity; ensure ACA can meet its review, management, reporting, public accessibility, and recordkeeping responsibilities.

7.2 Who must complete training

- All Investigators responsible for the design, conduct, or reporting of PHS-funded research conducted under ACA's auspices, including:
    - PD/PI and contact PD/PI
    - Co-investigators and senior/key personnel
    - Collaborators and consultants who can influence the research
    - Statisticians/methodologists with decision-making roles
    - Study coordinators with authority over design, conduct, or reporting
    - Subrecipient Investigators (domestic or foreign) who meet the Investigator definition
- Clarification: Administrative or technical staff without influence on design, conduct, or reporting are not Investigators and are not required to complete FCOI training under this policy, though ACA may provide awareness training as a best practice.

7.3 Timing of training (must be met before participation)

- Initial training:
    - Complete before engaging in any PHS-funded research activities at ACA (e.g., protocol development, subject enrollment, data analysis, manuscript drafting).
    - Recommended to complete at or before application/just-in-time to avoid delays in starting work.
- Refresher training:
    - At least every four (4) years, measured from the date of the last completed FCOI training accepted by ACA.
- Trigger-based training (immediate):
    - When ACA revises this policy in a way that affects Investigator responsibilities, disclosure requirements, or management.
    - When an Investigator is new to ACA or newly assumes Investigator responsibilities on a PHS-funded project.
    - When ACA determines that an Investigator is not in compliance with this policy or an FCOI Management Plan.
- Subrecipient timing:
    - Subrecipient Investigators must complete compliant training before engaging in the subrecipient's portion of the PHS-funded project and at least every four years thereafter (or upon triggers), using their institution's compliant program or ACA's program, as specified in the subaward.

7.4 Training content Training must cover, at a minimum:

- Regulatory framework:
    - 42 CFR Part 50 Subpart F (50.601–50.607) and, when applicable, 45 CFR Part 94.
- Definitions and scope:
    - Investigator; Institutional Responsibilities; Research; SFI (with thresholds and exclusions); FCOI; Reimbursed/Sponsored travel and exclusions; Senior/Key personnel; Subrecipients.
- Disclosure duties and timelines:

    - Initial disclosures (by application/just-in-time or before engaging), annual updates, and 30-day updates for newly acquired/discovered SFIs; the scope of SFIs (Investigator, spouse, dependent children); travel disclosure elements; exclusions.
- Review and determination:
    - How ACA assesses relatedness of SFIs to Institutional Responsibilities and to specific PHS-funded projects; how FCOI determinations are made; independence safeguards for ACA's single-employee structure.
- Management plans and monitoring:
    - Required elements; common conditions (public disclosure, role modification, independent monitoring, information barriers, divestiture); compliance certification; consequences for deviations.
- Reporting to PHS/NIH:
    - Initial FCOI report before expenditure of funds; updated reports within 60-days for newly identified FCOIs; annual FCOI reports; required content; eRA Commons FCOI Module.
- Retrospective review and mitigation:
    - Triggers; 120-day completion; mitigation reports; clinical research remedy for biased safety/effectiveness studies (public disclosures and publication addenda).
- Public accessibility and records:
    - Posting of the policy; public availability of certain FCOIs for senior/key personnel; value ranges; three-year public availability; record retention requirements.
- Subrecipient responsibilities:
    - Policy election (their policy or ACA's), training requirements, SFI disclosure/reporting timelines, and flow-down terms.
- ACA-specific safeguards:
    - Procedures when the PD/PI is also the FCOI Official; use of a disinterested board member or external reviewer; independent monitoring; documentation standards.
- Practical case studies:

- Scenarios relevant to acupuncture/integrative research (e.g., consulting with a device vendor, royalty income from techniques used in a study, sponsored travel by a professional society).

7.5 Approved training resources

- Primary option (preferred):
  - NIH FCOI
    Tutorial: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html (retain completion certificate).
- Equivalent programs:
  - ACA may accept completion of an equivalent, PHS-compliant FCOI training program (e.g., CITI Program FCOI course) if completed within the preceding 4 years and accompanied by:
    - The completion certificate; and
    - An ACA attestation that the Investigator has read ACA's current FCOI policy and completed an ACA-provided knowledge check on ACA-specific procedures and safeguards.
- ACA-provided modules:
  - ACA may provide supplemental training (slides, webinars, policy briefings) focused on ACA-specific procedures, subrecipient requirements, and independence safeguards. Completion of these modules may be required in addition to the NIH tutorial.

7.6 Delivery and accessibility

- Formats:
  - Online self-paced modules, live webinars, or in-person briefings (as feasible).
- Accessibility:
  - Materials will be accessible in English. For subrecipients whose primary language is not English, ACA will work with the subrecipient to ensure comprehension (e.g., translated materials, interpreter support).
- Verification:

- Training completion is evidenced by a certificate and/or recorded attestation and knowledge check results.

7.7 Verification, eligibility to participate, and enforcement

- Eligibility prerequisite:
  - Investigators may not engage in the design, conduct, or reporting of PHS-funded research until ACA verifies completion of required FCOI training.
- Single-employee safeguard:
  - When the ACA employee (who may be PD/PI and FCOI Official) completes training, the ACA Board Chair or an external compliance reviewer will verify the training record to preserve independence.
- Subrecipients:
  - If the subrecipient uses its own policy, the subaward must require certification that each subrecipient Investigator completed compliant FCOI training before engaging, and that records will be made available to ACA upon request.
  - If the subrecipient follows ACA's policy, the subrecipient Investigators must complete ACA's training and provide certificates before engaging.
- Enforcement:
  - Failure to complete required training on time will result in suspension of the Investigator's participation in PHS-funded activities under ACA, withholding of funds for affected tasks, and, if necessary, notification to the PHS awarding component if noncompliance affects award conditions. Retraining is required before resumption of duties.

7.8 Tracking and reminders

- ACA will maintain a training roster listing each Investigator's last completion date and the next due date (four-year cycle or earlier if a trigger occurs).
- Automated or manual reminders will be sent at least 60 and 30 days before training expiration and immediately upon a trigger event (e.g., policy revision).

7.9 Documentation and recordkeeping

- Records retained for each Investigator:

    - Name and role on the project; date of training completion; training provider/program and version; certificate or completion proof; ACA-specific knowledge check results or attestation (if applicable); verifying official; and next due date.

- Subrecipient records:
    - Subrecipient's certification of compliance; list of covered Investigators; training completion dates; and agreement to provide records upon request.
- Retention period:
    - At least three (3) years from the date ACA submits the final expenditure report for the applicable award, or longer if otherwise required by federal recordkeeping rules (e.g., audit, litigation hold). See Section 10.

7.10 Quality assurance and updates

- Annual review:
    - ACA will review training content annually and update promptly to reflect changes in 42 CFR Part 50 Subpart F, NIH guidance, or ACA procedures.
- Post-incident updates:
    - Following any noncompliance or retrospective review that reveals training gaps, ACA will refine training materials and, where appropriate, require targeted retraining for affected Investigators.

7.11 Acknowledgment

- Each Investigator must acknowledge in writing (or electronically) that they have:
    - Completed the required FCOI training;
    - Read and understood ACA's FCOI policy; and
    - Agree to comply with disclosure timelines, Management Plans, and all related procedures.

8. Subrecipient Compliance

8.1 Authority and responsibility

- Authority: 42 CFR 50.604(c)–(d) requires the awardee Institution (ACA) to take reasonable steps to ensure that any subrecipient Investigator complies with the PHS FCOI regulations through written agreements that specify which FCOI policy applies and

establish timelines for disclosures, reviews, and reporting so the awardee can meet PHS deadlines. If a PHS-funded contract is used, 45 CFR Part 94 applies.

- Responsibility: ACA remains responsible for overall compliance for the PHS-funded project. ACA must ensure that subrecipient FCOIs are identified, managed, and reported to the PHS awarding component on time, and that appropriate training, public accessibility, and record retention requirements are met by the responsible party.

8.2 Definitions and applicability

- Subrecipient: An entity (domestic or foreign) that receives a subaward from ACA to carry out a substantive portion of the PHS-funded research and is accountable to ACA for programmatic outcomes.
- Contractor/vendor: Provides goods or routine services within normal business operations; not typically subject to Subpart F via subaward flow-down. However, any individual consultant who will be responsible for the design, conduct, or reporting of PHS-funded research is treated as an Investigator and must comply with FCOI requirements under ACA's policy.
- Subrecipient Investigator: Any individual at the subrecipient who is responsible for the design, conduct, or reporting of the subrecipient's portion of the PHS-funded research.

8.3 Policy election (which policy applies) Each subaward will specify, in writing, one of the following:

- Subrecipient's policy applies:
    - The subrecipient certifies that it has an FCOI policy compliant with 42 CFR Part 50 Subpart F (and 45 CFR Part 94 if applicable), and agrees to fulfill all Investigator training, disclosure, review, management, reporting, public accessibility, and recordkeeping obligations under that policy.
- ACA's policy applies:
    - The subrecipient agrees to comply with ACA's FCOI policy and procedures. Subrecipient Investigators will complete training per Section 7 and submit SFI disclosures directly to ACA for review, management, and reporting.

Note: ACA will not proceed with a subaward until policy election is documented and all pre-expenditure conditions (e.g., FCOI reports, management plans) are satisfied.

8.4 Required subaward terms (42 CFR 50.604(c)) Each subaward agreement will include, at minimum:

- Policy election and certification:
    - Identification of the policy to be followed (subrecipient's or ACA's).
    - If subrecipient's policy applies, a certification of compliance with 42 CFR Part 50 Subpart F and 45 CFR Part 94 (as applicable), and that the subrecipient's policy is actively enforced.
- Disclosure and reporting timelines to enable ACA's compliance:
    - Initial (pre-expenditure) timing:
        - If the subrecipient's policy applies: The subrecipient will provide ACA with any identified FCOIs and the corresponding FCOI report elements sufficiently prior to the expenditure of funds so ACA can submit the initial FCOI report to the PHS awarding component before funds are spent on the subrecipient's work.
        - If ACA's policy applies: Subrecipient Investigators will submit SFI disclosures to ACA before engaging in the research. ACA will complete relatedness/FCOI determinations, implement a written management plan (if needed), and submit any required FCOI report before funds are spent.
    - Newly identified FCOIs during the award:
        - If the subrecipient's policy applies: For any FCOI identified after award start, the subrecipient must provide ACA with an FCOI report within sufficient time for ACA to submit a report to PHS within 60 calendar days of identification.
        - If ACA's policy applies: Subrecipient Investigators must disclose newly acquired/discovered SFIs to ACA within 30 calendar days; ACA will complete review, implement or update management within 60 calendar days of identification, and submit any required FCOI report within that same 60-day window.
    - Annual updates:
        - For any previously reported FCOI, subrecipient will provide ACA with information necessary for ACA to submit annual FCOI reports for the duration of the project (e.g., with or before the RPPR).
- Content of subrecipient FCOI information provided to ACA:
    - Grant/contract number; PD/PI or contact PD/PI.

    - Name of conflicted Investigator and role on the project.
    - Name of the external entity and the nature of the SFI (e.g., equity, consulting, IP income).
    - Approximate value of the SFI using regulatory ranges, or a statement that value cannot be readily determined.
    - Description of how the SFI relates to the PHS-funded research and rationale for the FCOI determination.
    - Key elements of the management plan, including the Investigator's role/duties, conditions and restrictions imposed, how objectivity is safeguarded, Investigator's agreement to comply, and how compliance will be monitored.
- Training requirements:
    - Subrecipient Investigators must complete compliant FCOI training before engaging in the PHS-funded work, at least every 4 years thereafter, and immediately upon triggers (policy revision affecting responsibilities; new to the project; or noncompliance).
- Public accessibility:
    - If the subrecipient's policy applies: The subrecipient is responsible for public accessibility of identified FCOIs for its senior/key personnel (website posting or 5-business-day written response) consistent with 42 CFR 50.604(a), and must keep such information available for at least 3 years from the most recent update.
    - If ACA's policy applies: ACA will handle public accessibility for subrecipient senior/key personnel whose FCOIs it determines and manages.
- Record retention and access:
    - The subrecipient must retain all FCOI-related records (disclosures, determinations, management plans, monitoring, training) for at least 3 years from the date of submission of the final expenditure report for the prime award (or longer if required for audit or litigation), and must provide such records to ACA or HHS upon request.
- Notification of noncompliance:
    - The subrecipient must promptly notify ACA of any Investigator noncompliance with its FCOI policy or with a management plan that affects the subrecipient's

portion of the project, and cooperate with required retrospective review and mitigation steps to enable ACA's timely reporting to PHS.

- Flow-down:
    - The subrecipient must flow down these FCOI requirements to any lower-tier subrecipients carrying out a substantive portion of the PHS-funded research.

8.5 Pre-award and just-in-time procedures

- Subrecipient commitment:
    - At proposal or just-in-time, ACA will obtain a signed Subrecipient Commitment Form documenting: policy election; certification of compliance (if subrecipient's policy applies); list of subrecipient Investigators; training status; and the subrecipient's point of contact for FCOI.
- Screening and readiness:
    - For subrecipients following ACA's policy, SFI disclosures from subrecipient Investigators must be submitted to ACA before subaward execution. ACA will complete all reviews, implement any required management plans, and submit any required FCOI reports before allowing the subrecipient to begin work or incur costs.

8.6 Monitoring and compliance verification

- Risk-based oversight:
    - ACA will apply enhanced oversight to higher-risk scenarios, including: foreign subrecipients; entities with limited compliance infrastructure; projects involving human participants; subrecipients reporting FCOIs; or prior noncompliance history.
- Verification tools:
    - Written attestations of training completion and policy compliance.
    - Review of subrecipient FCOI policies for regulatory alignment and effective dates.
    - Copies or summaries of subrecipient FCOI determinations and management plans.
    - Desk reviews or site visits focused on adherence to management plan conditions (e.g., role restrictions, independent data review).

    - Periodic check-ins (e.g., quarterly) to confirm no new SFIs or FCOIs and continued training compliance.

- Independence safeguard for ACA's single-employee structure:
    - If the ACA employee is conflicted or otherwise lacks independence to evaluate a subrecipient's FCOI matter, ACA will assign oversight to a disinterested board member or engage an external COI reviewer/monitor.

8.7 Reporting mechanics and timelines (ACA's obligations to PHS)

- Initial FCOI report: For any subrecipient Investigator's FCOI, ACA submits an FCOI report to the PHS awarding component (via eRA Commons for NIH) prior to the expenditure of funds on the subrecipient's activities affected by the FCOI.
- New FCOI identified during the award: ACA submits an updated FCOI report within 60 calendar days of identification (based on information provided by the subrecipient or ACA's own determinations if using ACA's policy).
- Annual FCOI report: ACA submits an annual report for each previously reported FCOI for the duration of the project, including status and any changes in the management plan.
- Retrospective review and mitigation: If untimely disclosure/management occurs at the subrecipient, ACA ensures a retrospective review is completed within 120 days and submits a mitigation report if bias is found. Subrecipient must provide the documentation necessary for ACA to meet these deadlines.

8.8 Special considerations

- Foreign subrecipients:
    - Subject to the same requirements. Agreements should address language, data privacy laws, and local institutional structures. If public web posting is impracticable, subrecipient must meet the 5-business-day written response alternative.
- SBIR/STTR exception:
    - The Subpart F requirements do not apply to Phase I SBIR/STTR applications or awards. However, if ACA is the prime on a non-SBIR award and issues a subaward to a small business, Subpart F applies to that subrecipient. ACA will verify applicability during subaward negotiation.
- Human subjects research:

    - Where a subrecipient conducts human subjects research, the IRB must receive FCOI management plans as applicable, and consent documents must include FCOI disclosures when required by the plan.

- Consultants:
    - Individual consultants engaged directly by ACA (not through a subrecipient agreement) who meet the definition of Investigator are subject to ACA's policy: they must complete training and submit SFI disclosures to ACA, and ACA will manage and report any identified FCOIs.

8.9 Remedies for subrecipient noncompliance

- Contractual remedies (as appropriate to protect research objectivity and meet regulatory deadlines):
    - Withholding of payment pending corrective action.
    - Suspension of subrecipient activities related to the affected project tasks.
    - Replacement of conflicted personnel or modification of roles.
    - Increased monitoring or imposition of additional conditions.
    - Termination of the subaward for cause.
    - Reporting of material noncompliance to the PHS awarding component as required.
- Corrective actions:
    - Require immediate implementation of an interim management plan, completion of retrospective review and mitigation (if applicable), retraining, and documentation.

8.10 Public accessibility responsibilities (42 CFR 50.604(a))

- If the subrecipient's policy applies:
    - The subrecipient is responsible for making FCOI information for its senior/key personnel publicly accessible (via website posting or written response within 5 business days) and for maintaining such information for at least 3 years from the most recent update. ACA may request evidence of compliance (e.g., URL, response log).
- If ACA's policy applies:

- ACA is responsible for public accessibility of FCOI information for the subrecipient's senior/key personnel whose FCOIs ACA determines and manages.

8.11 Record retention and access (42 CFR 50.604(i))

- Subrecipients must maintain FCOI-related records for at least 3 years from the date of submission of the final expenditure report for the prime award (or longer if required) and provide access to ACA, HHS, or auditors upon request. ACA will maintain corresponding records in its own files per Section 10.

8.12 Required notifications

- Immediate notification by the subrecipient to ACA of:
  - Any newly identified FCOI.
  - Any Investigator noncompliance with FCOI policies or a management plan.
  - Any event triggering a retrospective review or mitigation.
- ACA will, in turn, meet all PHS notification/reporting deadlines and requirements.

8.13 Sample subaward FCOI clause (summary) Each subaward shall, at minimum, include language substantially similar to:

- Policy election: "Subrecipient shall [certify compliance with its own FCOI policy compliant with 42 CFR Part 50 Subpart F / comply with ACA's FCOI policy]."
- Training: "Subrecipient Investigators shall complete compliant FCOI training before engaging in the project, at least every 4 years, and immediately upon triggers."
- Disclosures and reporting: "Subrecipient shall provide ACA with [SFI disclosures if ACA's policy applies / FCOI reports if Subrecipient's policy applies] sufficiently in advance to permit ACA to submit initial FCOI reports before expenditure of funds, updated reports within 60-days, and annual FCOI reports. Reports shall include all elements required by 42 CFR 50.605(b)."
- Public accessibility: "The party whose policy applies is responsible for public accessibility of identified FCOIs for senior/key personnel per 42 CFR 50.604(a)."
- Records and audits: "Subrecipient shall retain FCOI records for at least 3 years from the date of submission of the final expenditure report for the prime award and provide access upon request to ACA and HHS."

- Noncompliance: “Subrecipient shall promptly notify ACA of any noncompliance requiring a retrospective review or mitigation; ACA may impose corrective actions including withholding, suspension, or termination.”

8.14 Documentation

- ACA will maintain, for each subrecipient:
    - The subrecipient commitment form and policy election/certification.
    - List of subrecipient Investigators and training completion evidence.
    - All SFI disclosures provided to ACA (if ACA’s policy applies) and ACA’s determinations/management plans.
    - All subrecipient FCOI reports (if subrecipient’s policy applies) and evidence of public accessibility.
    - Copies of management plans and monitoring reports.
    - Communications related to noncompliance, retrospective reviews, and mitigation.
    - Copies of subaward FCOI clauses and any amendments.

9. Public Accessibility

9.1 Authority and commitment

- Authority: 42 CFR 50.604(a) requires Institutions to make their FCOI policy publicly accessible and to make information concerning identified Financial Conflicts of Interest (FCOIs) held by senior/key personnel publicly accessible prior to the expenditure of PHS funds, with defined content, timelines, and retention.
- Commitment: ACA will provide transparent public access to its FCOI policy and to required information about identified FCOIs to promote objectivity in PHS-funded research.

9.2 Public posting of ACA’s FCOI policy

- ACA will post an up-to-date, written, and enforced FCOI policy on a publicly accessible page of its website, without charge or login requirement:
    - URL: https://acupuncturecare.org/fcoi/Acupuncture-Care-Alliance-FCOI-Policy.pdf

- The posted policy will include the effective date, last revised date, and contact information for ACA's FCOI Official.
- ACA will update the posted policy promptly upon material revision and retain prior versions internally for records.

9.3 Public accessibility of identified FCOIs for senior/key personnel

- Scope of public information:
    - ACA will make publicly accessible information concerning identified FCOIs that:
        - Are held by senior/key personnel (as identified in the PHS application, progress report, or other PHS report); and
        - Have been determined by ACA to be related to a PHS-funded project and to constitute an FCOI; and
        - Pertain to research conducted under ACA's auspices (including, if applicable, subrecipient senior/key personnel when ACA's policy applies).
- Timing:
    - Information will be made publicly accessible prior to the expenditure of PHS funds on the project activities to which the FCOI relates.
    - Information will be updated:
        - At least annually for the duration of the project; and
        - Within 60 calendar days of ACA's identification of a new FCOI for the senior/key personnel.
- Retention on the public site or in response files:
    - Publicly accessible FCOI information will remain available for at least three (3) years from the date of the most recent update.

9.4 Required content elements (exactly as specified by regulation) For each identified FCOI held by senior/key personnel, ACA will make publicly accessible the following:

- Investigator's name (senior/key personnel).
- Investigator's title and role with respect to the research project (e.g., PD/PI, co-investigator, statistician).
- Name of the external entity with which the Investigator has the financial conflict.

- Nature of the Significant Financial Interest (e.g., equity interest, consulting fees, honoraria, paid authorship, intellectual property income).
- Approximate dollar value of the SFI expressed in ranges, or a statement that the value cannot be readily determined. The ranges used will be:
    - $0–$4,999
    - $5,000–$9,999
    - $10,000–$19,999
    - Amounts between $20,000 and $100,000 by increments of $20,000
    - Amounts above $100,000 by increments of $50,000
- ACA will not disclose exact dollar amounts; names of spouses or dependent children; confidential contract terms; or proprietary information beyond the elements required by regulation.

9.5 Methods of public access

- Website posting:
    - ACA will maintain a publicly accessible web page containing the required FCOI information for senior/key personnel. The page will be linked from ACA's main research or compliance page and will not require a password or user registration.
    - ACA's website at: https://acupuncturecare.org/fcoi/Acupuncture-Care-Alliance-FCOI-Policy.pdf
    - If no FCOIs are identified for senior/key personnel, the page will state that no identified FCOIs exist as of the current date.
- Written response within five business days:
    - ACA will satisfy public access either by website posting or by written responses within five (5) business days. As of the effective date, ACA will provide FCOI information by written response to requests sent to:
        - Email: contact@acupuncturecare.org
        - Mail: Acupuncture Care Alliance, Attn: FCOI Official, 24202 Sylvan Glen Rd Unit D, Diamond Bar, CA 91765
    - The written response will include all required content elements (see 9.4) and the date of the most recent update.

- ACA will maintain a log of public requests and responses (see 9.9).

9.6 Accuracy, independence, and quality control

- Accuracy review:
  - Before posting or issuing a written response, ACA will verify that the FCOI information is complete and accurate and corresponds to the current, approved Management Plan.
- Independence safeguard for ACA's single-employee structure:
  - When the ACA employee is both the PD/PI and FCOI Official, a disinterested board member or an external COI reviewer will verify the public posting or written response for accuracy and completeness prior to release.
- Updates and corrections:
  - If an error is identified in posted or released FCOI information, ACA will correct it promptly and note the correction date in the posting or response log.

9.7 Subrecipients and public accessibility

- When the subrecipient's policy applies:
  - The subrecipient is responsible for making FCOI information for its senior/key personnel publicly accessible (website or five-business-day response) in accordance with 42 CFR 50.604(a).
  - ACA's subaward will require the subrecipient to provide ACA, upon request, with the URL of its public posting or with a copy of the written response used to satisfy requests.
  - ACA may link to the subrecipient's FCOI information page from ACA's site for public convenience.
- When ACA's policy applies:
  - ACA will make publicly accessible the required FCOI information for the subrecipient's senior/key personnel whose FCOIs ACA determines and manages, following the same timelines and content requirements described in this section.

9.8 Disclosures in publications and presentations

- When required by a Management Plan or as part of mitigation following noncompliance, the conflicted Investigator must disclose the existence of the FCOI in:

    - Manuscripts, abstracts, posters, slide decks, and oral presentations reporting results of the PHS-funded research.

- For biased clinical research evaluating the safety or effectiveness of a drug, device, or treatment (including acupuncture), ACA will require public presentation disclosures and requests for addenda to prior publications, as described in Section 6 (consistent with 42 CFR 50.605(c)).

9.9 Recordkeeping for public accessibility

- ACA will maintain:
    - The current public posting (and archived prior versions), with effective and update dates.
    - A request/response log for written requests, including requestor contact, date received, date responded (must be within 5 business days), and the content provided.
    - Verification records showing review/approval by the independent verifier when the ACA employee is the conflicted senior/key personnel.
- Retention:
    - Public accessibility records will be maintained for at least three (3) years from the date of the most recent public update for the associated FCOI, and otherwise consistent with Section 10 (Record Retention).

9.10 Privacy and limitations

- ACA will disclose only the minimum elements required by regulation. ACA will not publicly disclose:
    - Exact dollar amounts;
    - Names of spouses or dependent children;
    - Personal addresses or contact information; or
    - Confidential or proprietary details of agreements.
- The presence of an FCOI indicates that a Significant Financial Interest has been identified and is being managed under an approved Management Plan; it does not imply wrongdoing.

9.11 Accessibility and usability standards

- The FCOI policy and FCOI information page will be:
    - Accessible without payment, registration, or special software;
    - Presented in a clear, searchable, and printable format (e.g., HTML and/or PDF);
    - Reasonably accessible to persons with disabilities (e.g., screen-reader compatible).

9.12 Example public FCOI information statement (for ACA website)

- "Acupuncture Care Alliance (ACA) is committed to promoting objectivity in PHS-funded research. In accordance with 42 CFR 50.604(a), ACA provides public access to information about Financial Conflicts of Interest (FCOIs) identified for senior/key personnel on ACA's PHS-funded projects. The information includes the Investigator's name; title and role on the project; the name of the external entity; the nature of the Significant Financial Interest; and the approximate value of the SFI (reported in regulatory dollar ranges) or a statement that the value cannot be readily determined. Information is updated at least annually, within 60-days of identifying a new FCOI, and remains available for at least three years from the most recent update. Requests may be submitted to contact@acupuncturecare.org or by mail to ACA's FCOI Official."

10. Record Retention

10.1 Authority and scope

- Authority: ACA will maintain records related to this policy in accordance with 42 CFR 50.604(i). For grants and cooperative agreements, retention follows 45 CFR 75.361 (HHS Uniform Guidance). If ACA ever conducts PHS-funded research under contract, comparable retention periods under 45 CFR Part 94 and applicable federal acquisition regulations will apply.
- Scope: Records encompass all Investigator disclosures of financial interests and ACA's review of, and response to, such disclosures, whether or not a PHS-funded award is made, and all actions taken under this policy or pursuant to 42 CFR Part 50 Subpart F (including retrospective reviews and mitigation).

10.2 Types of records retained ACA will maintain, at minimum, the following categories of records:

- Policy and governance
    - Current and prior versions of ACA's FCOI policy with effective dates and revision history.

    - Standard operating procedures (SOPs), checklists, and templates used to implement this policy.
    - Board or committee minutes, resolutions, and approvals related to FCOI determinations and management plans (including recusal records).
    - Designations of the FCOI Official and any independent reviewer/monitor assignments used for independence safeguards.
- Investigator training and eligibility
    - Training completion certificates; training rosters; dates; program/provider and version; ACA-specific attestations/knowledge checks; verification records (including independent verification when the ACA employee is conflicted).
- Disclosures and related intake
    - All Significant Financial Interest (SFI) disclosure forms (initial, annual, event-based 30-day updates), including those of subrecipient Investigators when ACA's policy applies.
    - Supporting materials and correspondence (e.g., consulting agreements, equity summaries, royalty statements, travel details).
    - Documentation that disclosures include the interests of spouses and dependent children.
- Review and determination
    - Completeness/intake checklists.
    - Written relatedness analyses (SFI to Institutional Responsibilities and to specific PHS projects).
    - FCOI determinations and rationales (including documentation when an SFI is determined not to be an FCOI).
    - Conflict classification and risk assessments.
- Management and monitoring
    - Final Management Plans and any amendments, including Investigator acknowledgments.
    - Monitoring plans; monitor assignments; monitoring reports; Investigator periodic certifications of compliance; corrective action records.

    - Communications to IRBs, DSMBs, journals, conference organizers, collaborators, and participants (e.g., consent language) when required by a plan.

- Reporting to PHS/HHS
    - Initial, updated (within 60-days), and annual FCOI reports (e.g., eRA Commons confirmations/receipts for NIH).
    - Correspondence with the PHS awarding component or HHS (questions, clarifications, directives).
- Retrospective review and mitigation (if applicable)
    - Date of identification; interim management actions.
    - Retrospective review reports with required elements (scope, methodology, records examined, timeframes, findings, conclusions).
    - Mitigation reports (if bias is found), including impact analysis and corrective plan.
    - Updated Management Plans and related monitoring after mitigation.
- Public accessibility
    - Current and archived website postings of the policy and FCOI information for senior/key personnel.
    - Public request/response logs (requests received, date responded—within 5 business days—and content provided).
    - Independent verification records for public postings/responses when the ACA employee is the conflicted senior/key personnel.
- Subrecipients and consultants
    - Subrecipient commitment forms; policy election and certification (subrecipient's policy vs. ACA's).
    - Subaward FCOI clauses and amendments; flow-down certifications; lists of covered subrecipient Investigators.
    - Subrecipient FCOI policies (or links), training attestations, and FCOI reports when their policy applies.
    - SFI disclosures from subrecipient Investigators when ACA's policy applies, and ACA's determinations/management/monitoring.

    - Evidence of subrecipient public accessibility (URL or sample response) if their policy applies.
- Procurement and recusal (as applicable to conflict management)
    - Recusal lists; access/firewall controls; vendor selection records where FCOI conditions restricted roles or access.

10.3 Retention periods

- Funded PHS awards (grants/cooperative agreements): Retain all records listed above for at least three (3) years from the date ACA submits the final expenditure report (Final FFR) to the PHS awarding component for the applicable award. For multi-year projects, the three-year clock runs from the Final FFR for the overall project, not the annual RPPR.
- Unfunded applications and proposals: Retain records relating to SFI disclosures and ACA's review/response for at least three (3) years from the date the proposal is formally withdrawn or from the date of the non-funding decision.
- Subrecipients: When ACA is the prime, subrecipient FCOI records retained by ACA are kept on the same schedule as the prime award (at least 3 years from the prime award's Final FFR). Subrecipients must retain their own FCOI records on that same timeline and provide access to ACA and HHS upon request.
- Extensions and exceptions (whichever is later):
    - If any litigation, audit, or claim is initiated, or if an HHS request for records is received, retain all pertinent records until the action is resolved and final, even if this extends beyond three years.
    - If records are transferred to HHS or another federal entity, retain copies until ACA receives written confirmation that retention by ACA is no longer required.
    - For equipment/real property or program income records subject to longer retention under 45 CFR 75.361–.372 or other applicable rules, retain for the longer period if FCOI records are embedded.
    - For clinical research subject to IRB or human subjects record retention that exceeds three years, ACA will retain overlapping FCOI records for the longer of the two periods.
- Contracts (if applicable): For PHS-funded research under contract, ACA will apply the retention period specified by 45 CFR Part 94 and applicable acquisition regulations

(generally at least three years after final payment/closeout), or longer if required by audit/litigation.

10.4 Security, privacy, and confidentiality

- Confidentiality: FCOI records often contain personally identifiable information (PII) and sensitive financial details (including spouse/dependent child information). ACA will:
    - Limit access to authorized individuals only (FCOI Official; designated independent reviewer/monitor; necessary leadership; IRB/DSMB if applicable; auditors; HHS/PHS upon request).
    - Use role-based access controls and maintain an access log for electronic records.
    - Encrypt electronic records at rest and in transit; keep paper records in locked storage.
    - Prohibit unauthorized disclosure or secondary use of FCOI data, except as required by regulation (e.g., public accessibility for senior/key personnel, or production to HHS).
- Independence safeguards: When the ACA employee is the conflicted Investigator, independent reviewers/monitors will have appropriate access to the necessary records; this access will be documented.
- Secure transfer: ACA will transmit FCOI reports via approved sponsor systems (e.g., eRA Commons) or encrypted channels. Records provided to HHS will be transmitted using secure, agency-approved methods.

10.5 Organization and format of records

- Indexing: Organize records by award number and Investigator, with cross-references to subrecipients and related management plans.
- Version control: Maintain version histories for policies, Management Plans, and key determinations; date-stamp all significant actions and decisions.
- Completeness: Each FCOI record should contain the end-to-end chain: disclosure(s) → intake → relatedness/FCOI determination → Management Plan → monitoring/compliance → reporting → (if applicable) retrospective review/mitigation → public accessibility artifacts.

10.6 Access by HHS/PHS and other oversight entities

- Upon request, ACA will provide FCOI-related records promptly to HHS, the PHS awarding component, and authorized auditors or oversight bodies. ACA will follow any deadlines specified by the requesting agency.
- ACA will not assert confidentiality to withhold records from HHS/PHS; however, ACA will coordinate to protect PII to the extent permitted by law.

10.7 Public accessibility records

- ACA will keep:
    - Current and prior versions of the public FCOI information page(s).
    - Documentation of the dates of posting/updates.
    - Public request/response logs and copies of responses.
- Public accessibility records will be retained for at least three (3) years from the date of the most recent public update for the associated FCOI.

10.8 Subrecipient record retention and access

- Subaward terms will require subrecipients to:
    - Retain all FCOI-related records for at least three (3) years from the date of submission of the Final FFR for the prime award (or longer if required by audit/litigation).
    - Provide ACA, HHS, or auditors access to such records upon request and within timeframes that allow ACA to meet PHS deadlines.
    - Document and provide evidence of public accessibility compliance when their policy applies (e.g., URL, exemplar response).

10.9 Secure destruction at end of retention

- When the applicable retention period (including any extensions) concludes, ACA will securely destroy or dispose of records:
    - Paper: cross-cut shredding or certified secure destruction.
    - Electronic: media sanitization consistent with NIST SP 800-88 (or successor guidance), with deletion verified and logs retained.
- Destruction will not be performed if a litigation hold, audit, claim, or agency request is pending.

10.10 Single-employee operational notes

- Independent verification: When the ACA employee is the conflicted Investigator, the independent reviewer/monitor's approvals and oversight notes will be preserved with the record and verified by the Board Chair or designee.
- Separation of duties (documented): Where feasible, ACA will document any separation-of-duties steps taken (e.g., independent statistician assignments) and retain those records with the Management Plan file.

11. Enforcement and Sanctions

11.1 Policy statement and authority

- ACA enforces this policy to protect research objectivity and public trust. Investigators must comply with 42 CFR Part 50 Subpart F and this policy.
- Authority: Under 42 CFR 50.605 and 50.606, ACA must manage, reduce, or eliminate Financial Conflicts of Interest (FCOIs), conduct retrospective reviews and mitigation when required, and report to the PHS awarding component. HHS/PHS may impose remedies for institutional or Investigator noncompliance, including special award conditions, suspension, or other enforcement actions.

11.2 What constitutes noncompliance (examples, non-exhaustive)

- Failure to disclose Significant Financial Interests (SFIs) completely, accurately, or on time (initial, annual, within 30 days of acquiring a new SFI).
- Failure to complete FCOI training before engaging in PHS-funded research, at least every four years, or immediately when triggered by policy changes, new Investigator status, or noncompliance.
- Failure to comply with any condition of an approved Management Plan (e.g., role restrictions, public disclosures, independent monitoring, information barriers).
- Failure to cooperate with ACA's FCOI review, monitoring, or reporting processes (e.g., refusing to provide requested documentation).
- Failure to implement required subrecipient oversight steps or to flow down required terms to lower-tier subrecipients.
- Submission of false or misleading information in disclosures, certifications, or FCOI-related communications.

- Subrecipient noncompliance with its own compliant FCOI policy or with ACA's policy when elected.

11.3 Detection and reporting of concerns

- Reporting channels: Concerns about potential noncompliance may be reported to ACA's FCOI Official at contact@acupuncturecare.org. If the FCOI Official is the subject of the concern, report to the ACA Board Chair or an external COI reviewer designated by the Board.
- Good-faith protection: ACA prohibits retaliation against any person who reports a concern in good faith or participates in a related inquiry.

11.4 Immediate risk control measures (upon suspected or confirmed noncompliance)

- Upon identifying a potential violation, ACA may immediately:
    - Implement an interim Management Plan with appropriate restrictions (e.g., recusal from enrollment, analysis, procurement; independent monitoring).
    - Suspend the Investigator's participation in affected portions of the project.
    - Temporarily withhold or restrict expenditures under ACA's control for affected activities.
    - Notify the IRB (if applicable) and confer on participant protections.
    - For subrecipients, withhold payments or suspend affected subaward work pending corrective action.

11.5 Fact-finding and determination

- ACA will promptly gather relevant facts, including disclosure records, communications, protocols, data analysis plans, and any relevant contracts or financial documents.
- The Investigator will be given an opportunity to respond and provide additional information. This does not delay the implementation of interim safeguards.
- Independence safeguards: If the ACA employee is the subject of the matter, a disinterested board member or external COI reviewer will conduct or oversee the fact-finding and determination.

11.6 Corrective action planning

- If noncompliance is substantiated, ACA will adopt a written Corrective Action Plan (CAP) that may include:

- Completion of overdue disclosures or training.
- Implementation or tightening of a Management Plan (e.g., additional monitoring, role changes, information barriers).
- Divestiture of conflicting interests or termination of conflicting relationships.
- Public and participant disclosures as appropriate.
- Reanalysis of data by an independent statistician or replication/confirmation steps.
- For subrecipients: policy alignment steps, staff retraining, revised subaward terms, and enhanced reporting cadence.

11.7 Sanctions (graduated, proportionate to risk and history)

- ACA may impose one or more of the following:
  - Written warning and mandatory retraining or counseling.
  - Temporary or permanent removal from specific project roles or decision-making.
  - Suspension from participation in some or all PHS-funded activities at ACA.
  - Withholding of funds under ACA's control for affected activities; for subrecipients, withholding payments or imposing special conditions.
  - Requirement to divest the financial interest or terminate the conflicting relationship as a condition of continued participation.
  - Replacement of the Investigator as PD/PI or senior/key personnel (subject to sponsor approval).
  - Termination of the Investigator's involvement in the project and, if necessary, recommendation to terminate the subaward or consultant agreement.
  - Referral to appropriate authorities if false statements or research misconduct are suspected (e.g., under 42 CFR Part 93), and cooperation with any resulting inquiry.
- ACA will consider aggravating and mitigating factors, including whether noncompliance was intentional, repeated, or resulted in actual bias.

11.8 Required retrospective review and mitigation (42 CFR 50.605(a)–(b))

- If noncompliance results in untimely disclosure or management of an FCOI, or a violation of a Management Plan, ACA will:
    - Implement an interim Management Plan immediately/as soon as practicable.
    - Submit an initial or updated FCOI report to the PHS awarding component within 60 calendar days of identifying the FCOI (if not previously reported).
    - Complete a retrospective review within 120 calendar days of the date of identification and document all required elements.
    - If bias is found, promptly submit a Mitigation Report and implement corrective actions to eliminate or mitigate the bias, and update the FCOI report with any revised Management Plan.

11.9 Clinical research remedy (42 CFR 50.605(c))

- If noncompliance results in bias in PHS-funded clinical research whose purpose is to evaluate the safety or effectiveness of a drug, device, or treatment (including acupuncture):
    - The Investigator must disclose the FCOI in each public presentation of the research results, and
    - The Investigator must request an addendum to previously published presentations or publications to disclose the FCOI and address necessary corrections.

11.10 Notifications to PHS/HHS and cooperation (42 CFR 50.605–50.606)

- ACA will provide all required FCOI reports (initial, within 60-days for newly identified FCOIs, and annual) and, when applicable, retrospective review documentation and mitigation reports to the PHS awarding component via eRA Commons (for NIH).
- Remedies under 42 CFR 50.606: ACA acknowledges that, in the event of Investigator or institutional noncompliance, the PHS awarding component or HHS may impose special award conditions, suspend funding for the Investigator or the project, or take other enforcement actions. ACA will cooperate fully with any inquiries or directives and enforce any required conditions on the Investigator.

11.11 Subrecipient noncompliance (prime award responsibilities)

- If a subrecipient fails to comply with applicable FCOI requirements or timelines:

- ACA will require immediate corrective actions, including interim management, retrospective review, mitigation (if bias is found), and retraining.
- ACA may withhold payments, suspend the subrecipient's activities, require personnel changes, impose special conditions, or terminate the subaward for cause.
- ACA will ensure timely submission of required reports to the PHS awarding component and maintain all related records.

11.12 Appeals and reconsideration

- An Investigator may request reconsideration of sanctions or CAP terms in writing within a timeframe specified by ACA (e.g., 10 business days). A disinterested board member or external reviewer will consider the request.
- Appeals do not delay implementation of interim or required safeguards, reporting to PHS, or corrective actions necessary to protect research objectivity or participant safety.

11.13 Coordination with oversight bodies

- IRB/DSMB: For human subjects research, ACA will notify the IRB and DSMB (if applicable) of relevant noncompliance, Management Plans, retrospective review outcomes, and mitigation steps. Consent documents may be amended to include FCOI disclosures when required.
- Journals and conferences: ACA will coordinate with editors or organizers to issue corrections or addenda when needed.
- Collaborators and performance sites: ACA will inform partners of role changes, monitoring requirements, or other conditions needed to manage or mitigate bias.

11.14 Independence safeguards for ACA's single-employee structure

- When the ACA employee is the Investigator or the subject of enforcement:
  - A disinterested board member or external COI reviewer will lead the fact-finding, approve the CAP, and oversee sanctions.
  - An independent monitor not supervised by the conflicted individual will verify ongoing compliance.
  - All steps and approvals will be documented contemporaneously.

11.15 Documentation and record retention

- ACA will document all noncompliance evaluations, interim measures, determinations, CAPs, sanctions, communications with PHS/HHS, retrospective reviews, mitigation reports, and subsequent monitoring. Records will be retained consistent with Section 10.

11.16 Communication with the Investigator

- ACA will provide written notice describing the nature of the noncompliance, required interim protections, the CAP and any sanctions, reporting obligations to PHS/HHS, and the Investigator's responsibilities and appeal option.

11.17 Education and prevention

- Following any confirmed noncompliance, ACA will evaluate process gaps and update training, procedures, or templates. ACA may require targeted retraining for affected personnel and subrecipients.

12. NIH/PHS Reporting (42 CFR 50.605)

12.1 When ACA must submit an FCOI report

- Initial report (prior to expenditure of funds): For any identified FCOI related to a PHS-funded project (including subrecipient Investigators when ACA's policy applies), ACA will submit an FCOI report to the PHS awarding component before expending any PHS funds on the project activities to which the FCOI relates.
- New FCOI during an active award: Within 60 calendar days of identifying an FCOI for an Investigator on an active award (e.g., due to a newly acquired SFI or newly determined relatedness/FCOI), ACA will submit an updated FCOI report and implement a management plan.
- Following retrospective review: If a retrospective review is required due to late disclosure/management or plan noncompliance, ACA will update prior FCOI reports as needed; if bias is found, ACA will submit a Mitigation Report (see Section 6).
- Annual FCOI report: For each previously reported FCOI, ACA submits an annual FCOI report for the duration of the project (e.g., with or before the RPPR or at extension), providing the status of the FCOI and any changes to the management plan.

12.2 Content of each FCOI report For each Investigator with an identified FCOI, ACA will include the elements required by 42 CFR 50.605(b):

- Project/award information: grant or cooperative agreement number; project title; PD/PI or contact PD/PI.
- Investigator: name of the conflicted Investigator.

- Entity: name of the external entity with which the Investigator has the SFI.
- Nature of the SFI: e.g., equity/ownership interest, consulting fees/honoraria, paid authorship, intellectual property rights and interests (including royalties), or reimbursed/sponsored travel (if managed as part of the FCOI).
- Approximate value of the SFI: expressed in regulatory dollar ranges ($0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000 and $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the value cannot be readily determined.
- Relatedness and FCOI rationale: description of how the SFI relates to the PHS-funded research and the basis for ACA's determination that the SFI is an FCOI (i.e., could directly and significantly affect the design, conduct, or reporting of the research).
- Key elements of the management plan:
    - Investigator's role and principal duties in the project.
    - Conditions and restrictions imposed to manage the FCOI (e.g., public/participant disclosures, role changes, independent monitoring, information barriers, divestiture).
    - How the plan safeguards research objectivity.
    - Confirmation of the Investigator's agreement to the plan.
    - How compliance will be monitored (responsible monitor and frequency).

12.3 Submission method and timing

- NIH awards: ACA will submit FCOI reports via the eRA Commons FCOI Module by the deadlines listed above.
- Other PHS awarding components: ACA will follow the component's specified system and deadlines (if not in eRA Commons).
- Subrecipients:
    - If the subrecipient follows its own compliant policy, it must provide ACA with timely FCOI information so ACA can submit reports on the required timelines.
    - If the subrecipient follows ACA's policy, ACA will make the determinations and submit the reports.

12.4 Updates after retrospective review and mitigation

- If a retrospective review is required, ACA will document completion within 120 days of the date of identification (see Section 6) and update FCOI reports as necessary.
- If bias is found, ACA will promptly submit a Mitigation Report containing the elements required by 42 CFR 50.605(b)(3) and update the FCOI report with any revised management conditions.

12.5 Annual reporting details

- For each previously reported FCOI, ACA's annual report will:
    - State whether the FCOI is still being managed or explain why it no longer exists.
    - Note any changes in the management plan since the last report.
    - Confirm ongoing compliance monitoring.

12.6 Public accessibility cross-reference

- ACA's public accessibility obligations for senior/key personnel FCOIs (content, timing, and retention) are described in Section 9 and are separate from FCOI reports submitted to PHS.

13. Funding Applications and Certifications (42 CFR 50.604)

13.1 Certifications in each PHS application/proposal By submitting a PHS application or proposal, ACA certifies that it:

- Has in effect and enforces a written FCOI policy that complies with 42 CFR Part 50 Subpart F and, if applicable, 45 CFR Part 94 (for contracts).
- Will promote objectivity in research by establishing standards to ensure that the design, conduct, and reporting of PHS-funded research will be free from bias arising from Investigator financial conflicts of interest.
- Will inform and train Investigators as required; solicit, review, and manage Significant Financial Interests; and submit required FCOI reports to the PHS awarding component.
- Will make information about identified FCOIs for senior/key personnel publicly accessible prior to the expenditure of funds and will update it as required.
- Will make FCOI-related records available to HHS/PHS upon request, and will retain records for the required period.
- Will ensure subrecipient compliance via written agreements specifying which FCOI policy applies and setting timelines that allow ACA to meet PHS reporting deadlines.

13.2 Application materials and public URL

- ACA will include, when requested, the public URL where its current FCOI policy is posted (see Section 9).
- Upon Just-in-Time or pre-award request, ACA will provide confirmations of Investigator training and disclosure status and will complete FCOI reviews and reporting prior to the expenditure of funds.

13.3 Assurances for additions of Investigators post-award

- When new Investigators are added to a PHS-funded project, ACA will ensure training and disclosures are complete, and any required FCOI review/management/reporting occurs before those Investigators engage in the research.

14. Designated Officials and Policy Administration

14.1 FCOI Official and contact

- FCOI Official: Haven Hau Tran (ACA's sole employee) is designated to solicit and review SFI disclosures, determine relatedness and FCOI status, develop and oversee management plans, and coordinate required reports to the PHS awarding component.
- Contact:
    - Email: contact@acupuncturecare.org
    - Phone: (949) 878-5656
    - Mailing address: 24202 Sylvan Glen Rd Unit D, Diamond Bar, CA 91765

14.2 Independence safeguards for ACA's single-employee structure

- When the FCOI Official is also an Investigator with an SFI under review or otherwise has a conflict:
    - Independent reviewer: The ACA Board Chair (or another disinterested director) or an external COI reviewer will perform the relatedness/FCOI determination and approve any management plan.
    - Independent monitor: For any managed FCOI in this scenario, ACA will appoint an independent monitor not supervised by the conflicted individual to oversee compliance and review research design, conduct, and reporting as appropriate.

    - Documentation: ACA will document the assignment of the independent reviewer and monitor, all determinations, and all oversight actions.

14.3 Role of the Board of Directors

- Oversight: The Board provides oversight of the FCOI program, approves management plans when independence safeguards are invoked, and reviews summary reports on FCOI compliance at least annually.
- Authority: The Board (or a disinterested committee) may impose conditions or sanctions to ensure compliance and research objectivity.

14.4 Coordination with IRBs/DSMBs and research compliance

- For human subjects research, ACA will share FCOI management plans and updates with the IRB and DSMB (if applicable) to ensure participant protections and research integrity.
- ACA will align FCOI management with other compliance requirements (e.g., human subjects protections, data and safety monitoring, data sharing).

14.5 Policy administration

- ACA will maintain procedures, templates, and forms (e.g., SFI disclosure forms, event-based updates, management plan templates, subrecipient commitment forms, public-access response templates) to administer this policy efficiently.
- ACA will review and update these tools as regulations or institutional practices change.

15. Effective Date, Approval, and Policy Review

15.1 Effective date and approval

- Effective date: 08/10/2025
- Approved by: ACA Board of Directors on 08/10/2025

15.2 Review and revision

- Review cadence: This policy will be reviewed at least annually and updated as needed to reflect regulatory changes, NIH/PHS guidance, or ACA operational changes.
- Material revisions: Material revisions that affect Investigator responsibilities will trigger immediate retraining for Investigators per Section 7.

15.3 Distribution and accessibility

- Distribution: ACA will provide this policy to all Investigators engaged in PHS-funded research and to subrecipients following ACA's policy, and will post the policy on ACA's website (see Section 9).
- Version control: ACA will maintain version control and archive prior versions internally.

16. Appendices and Forms (incorporated by reference)

- Appendix A: Investigator SFI Disclosure – Initial/Annual (Form ACA-FCOI-F01)

  https://acupuncturecare.org/fcoi/ACA-FCOI-F01.pdf
- Appendix B: Event-Based SFI Update – 30-Day New/Changed Interest (Form ACA-FCOI-F02)

  https://acupuncturecare.org/fcoi/ACA-FCOI-F02.pdf
- Appendix C: FCOI Management Plan Template (Form ACA-FCOI-F03)

  https://acupuncturecare.org/fcoi/ACA-FCOI-F03.pdf
- Appendix D: Subrecipient Commitment and FCOI Compliance (Form ACA-FCOI-F04)

  https://acupuncturecare.org/fcoi/ACA-FCOI-F04.pdf
- Appendix E: Public FCOI Webpage Text (ACA-FCOI-F05)

  https://acupuncturecare.org/fcoi/ACA-FCOI-F05.pdf
- Availability: ACA will maintain these appendices as separate, fillable documents and link them from this policy and ACA's compliance page. Current versions can be requested from contact@acupuncturecare.org.