Executive Summary of Revisions & Comparison		
Section / Topic	**Previous Version (FCOIG Policy 26-27 FINAL)**	**Revised Document (Reformatted Draft) & Regulatory Impact**
Definitions & Scope	Included basic $5,000 SFI thresholds and standard travel exclusion language.	Added **Senior/Key Personnel** definition; clarified non-public equity (SFI regardless of value); added 12-month IP income aggregation ($5,000 threshold); and explicitly mandated disclosure of foreign SFIs.
Duty to Disclose	Covered annual disclosures, 30-day new SFI updates, and pre-proposal disclosures.	Added 42 CFR § 50.604(e)(2) mandate for Investigators joining ongoing projects midway to disclose prior to participating; added travel disclosure specifics (destination, duration, value).
IO Authority & Management Plans	Delegated review to RCOIC and deans without listing required core management elements.	Established IO sole authority for relatedness and FCOI determinations; prohibited conflicted Investigators from participating in final determinations; added **6 required internal management plan elements**.
NIH Reporting & Interim Plans	Included general 60-day reporting language without listing required data fields or interim plan components.	Incorporated the mandatory **60-day interim requirement** for newly disclosed/unreviewed SFIs during ongoing awards; itemized all **8 required elements** for Initial/Mid-Award FCOI reports.
Retrospective Reviews	Contained 120-day retrospective review requirement and inline narrative elements.	Separated Retrospective Review Reports into a distinct subsection and itemized all **9 required statutory elements** under 42 CFR § 50.605(a)(3).
Clinical Trials & Public Access	Lacked specific clinical trial corrective disclosure mandates and public access update rules.	Added mandatory public disclosure and formal errata/addenda requests for unmanaged clinical trial FCOIs (42 CFR § 50.606(c)); mandated written public responses within 5 business days, updated **annually and within 60 days** of new FCOIs.
Record Retention & Subrecipients	Baseline 3-year record retention and subrecipient flow-down statement.	Added mandatory extension phrase (*"...or until resolution of any audit, litigation, or claim..."*); cited 42 CFR § 50.604(c) and required explicit reporting timeframes in subaward agreements.
Investigator Training	Mandated annual training frequency.	Updated training cycle to federal standard: **every four (4) years**, or immediately upon policy revision, new appointment, or non-compliance.

Section 8.0 – Financial Conflict of Interest for Research and Grants Policy

Policy Statement

Arkansas Colleges of Health Education (ACHE) will conduct all affairs in accordance with the highest legal, ethical, and moral standards. To promote objectivity in research and ensure that the design, conduct, and reporting of NIH and Public Health Service (PHS) grant-funded research will be free from bias, ACHE is committed to avoiding financial conflicts of interest (FCOI) that may compromise the integrity of research and the safety of human research subjects.

This policy complies directly with federal regulations **42 CFR Part 50 Subpart F** (for grants and cooperative agreements) and **45 CFR Part 94** (for contracts), which govern FCOI requirements for PHS-funded research.

This policy applies to all **"Investigators"**—defined as any individual, regardless of title or position, who is responsible for the design, conduct, or reporting of NIH or PHS-funded research.

Because ACHE encourages its members to engage in outside activities and relationships that enhance its missions, real or perceived conflicts of interest may arise. The keystone of an effective program for identifying and dealing with financial conflicts of interest is full disclosure of those financial interests that reasonably appear related to one's institutional responsibilities. This policy provides guidance for the mandatory disclosure by Investigators of their Significant Financial Interests (SFIs).

After disclosure, ACHE will make an informed judgment about a particular activity and require appropriate oversight, limitations, or prohibitions to manage, reduce, or eliminate the conflict in accordance with this procedure. This policy deals with financial conflicts of interest of individual Investigators. Financial conflicts of interest related to research that are institutional in scope are covered by the ACHE Conflict of Interest Policy (APM, Administration, Section 1.5).

Application and Purpose

The purpose of this Financial Conflict of Interest policy is to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported or the welfare of human research subjects. This policy is intended to supplement but not replace corporate bylaws or any applicable state and federal laws governing conflict of interest.

This policy shall apply to Investigators on any sponsored agreement that is in preparation, has been submitted to a sponsor, or is currently funded, and to Investigators involved in institutionally sponsored research.

Definitions

- **Compensation:** Includes direct and indirect remuneration as well as gifts or favors that are not insubstantial. A financial interest is not necessarily a conflict of interest. A person who has a financial interest has a conflict of interest only if the appropriate governing board or official decides that a conflict exists.
- **Equity Interest:** Stock, stock options, warrants, partnership, or other ownership interests. Excluded from this definition are equity interests held in publicly-traded mutual funds or retirement programs where the investment is not under the direct control of the Investigator or family member.
- **Family Member:** An Investigator's spouse and dependent children.
- **Financial Conflict of Interest (FCOI):** A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS/NIH-funded research.
- **Financial Interest:** Anything of monetary value or potential monetary value, whether the value is readily ascertainable. A person has a financial interest if the person has, directly or indirectly, through business, investment, or family:
    - An ownership or investment interest in any entity with which ACHE has a transaction or arrangement;
    - A compensation arrangement with ACHE or with any entity or individual with which ACHE has a transaction or arrangement; or
    - A potential ownership or investment interest in, or compensation arrangement with, any entity or individual with which ACHE is negotiating a transaction or arrangement.
- **Human Subjects Research and Clinical Investigations:** Any activity that meets either (a) the Department of Health & Human Services definitions of both "research" and "human subjects" or (b) the Food & Drug Administration (FDA) definitions of both "clinical investigation" and "human subjects." These activities require review and approval by the Institutional Review Board (IRB).
- **Indirect Interest:** As defined in §4-33-831(b) of the Arkansas Nonprofit Corporation Act, a director of the corporation has an indirect interest in a transaction if (1) another entity in which the director has a material interest or in which the director is a general partner is a party to the transaction, or (2) another entity of which the director is a director, officer, or trustee is a party to the transaction.
- **Institutional Official (IO):** The individual with authority and responsibility for overseeing implementation of this regulation and for ensuring consistent administrative review of Disclosure Statements.
- **Institutional Responsibilities:** An individual's professional responsibilities on behalf of ACHE including, but not limited to, activities such as research, consulting for outside entities, teaching, professional practice, committee memberships, administration, extension or outreach, as well as service on institutional panels such as Institutional

Animal Care and Use Committees (IACUC), Institutional Biosafety Committees (IBC), Institutional Review Boards (IRB), or Data and Safety Monitoring Boards (DSMB).

- **Interested Person:** Any board trustee, officer of the corporation, faculty, staff, contractor, consultant of ACHE, or member of a committee with governing board delegated powers, who has a direct or indirect financial interest.
- **Investigator:** The Project Director/Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS/NIH-funded research, or proposed for such funding, which may include collaborators, subrecipients, or consultants. The Institutional Official, in consultation with the PD/PI, shall determine whether an individual meets the definition of Investigator. Graduate students generally are not considered investigators; postdoctoral scholars and fellows may be considered investigators if designated as such on a case-by-case basis.
- **Manage:** Taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- **Outside Entity:** Any entity recognized by law through which business for profit is conducted (including sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership, or trust) or non-profit organization (including association, foundation, charitable organization, etc.).
- **Public Health Service (PHS):** An operating unit of the U.S. Department of Health and Human Services (HHS) that includes all PHS Awarding Components (e.g., NIH, CDC, SAMHSA, HRSA).
- **Remuneration:** All salary and wages, including professional income from non-ACHE faculty practice plans, consulting fees, speaking fees, honoraria, paid authorship, travel reimbursement, gifts, licensing revenue, royalties for books, publications, reports, or equity interests. Excluded is ACHE salary and equity held in publicly-traded mutual funds or retirement programs not under direct Investigator control.
- **Research:** A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research such as bench work, clinical trials, product development, or other creative activity.
- **Research Conflict of Interest Committee (RCOIC):** The institutional committee that evaluates disclosures and makes recommendations on courses of action designed to manage, reduce, or eliminate conflicts of interest in research.
- **Senior/Key Personnel:** The PD/PI and any other person identified as senior/key personnel by ACHE in the grant application, progress report, or any other report submitted to the NIH/PHS by ACHE.
- **Significant Financial Interest (SFI):** A financial interest consisting of one or more of the following interests of an Investigator (and those of their spouse and dependent children) that reasonably appears related to the Investigator's institutional responsibilities:

    1. **Publicly Traded Entities:** Any remuneration received from the entity in the 12 months preceding the disclosure aggregated with the value of any equity interest in the entity as of the date of disclosure that exceeds **$5,000**.

2. **Non-Publicly Traded Entities:** Any remuneration received from the entity during the 12 months preceding the disclosure that exceeds **$5,000**, or **any equity interest** held in the entity regardless of value.
3. **Intellectual Property Rights and Income:** Income received during the 12 months preceding the disclosure related to intellectual property rights and interests (e.g., patents, copyrights, trademarks, licensing agreements, or royalty payments) that exceeds **$5,000** from a single entity. Intellectual property rights assigned to ACHE and agreements to share in royalties related to such rights are excluded.
4. **Reimbursed or Sponsored Travel:** Reimbursed or sponsored travel (i.e., travel paid on behalf of the Investigator rather than reimbursed directly) that reasonably appears related to institutional responsibilities, when the aggregate value from a single entity exceeds **$5,000** during the preceding 12 months. Disclosures must include purpose, sponsor/organizer, destination, duration, and estimated value. Excluded is travel reimbursed or sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.
5. **Exclusions from Significant Financial Interest:** SFI does not include:
    - Salary, royalties, or remuneration paid by ACHE if currently employed or appointed by ACHE;
    - Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, U.S. institution of higher education, teaching hospital, medical center, or affiliated research institute;
    - Income from service on advisory committees or review panels for a U.S. federal, state, or local government agency, U.S. institution of higher education, teaching hospital, medical center, or affiliated research institute;
    - Income from investment vehicles, such as mutual funds and retirement accounts, provided the Investigator or family member does not directly control investment decisions; and
    - Any ownership interest in ACHE held by the Investigator, if ACHE is acting as a commercial or for-profit organization for research purposes.

Note: Financial interests received from foreign institutions of higher education or foreign governments must be disclosed as Significant Financial Interests.

Procedures and Responsibilities

Section I. Duty to Disclose

In connection with any actual or possible conflict of interest, an interested person must disclose the existence of the financial or indirect interest and be given the opportunity to disclose all material facts.

- **A. Annual Disclosure:** Each covered individual shall complete an annual Financial Interests Disclosure Statement, whether or not they have financial interests to report, including interests of their spouse and dependent children.
- **B. Newly Acquired or Discovered SFIs:** In accordance with 42 CFR § 50.604(e)(2), each Investigator participating in an active PHS/NIH-funded research project shall submit an updated Disclosure Statement within **thirty (30) days** of acquiring or discovering a new SFI.
- **C. New Employees & Investigators Newly Joining Projects:** New employees required to disclose shall submit a Disclosure Statement within **thirty (30) days** of employment. Any Investigator newly assigned to an ongoing PHS/NIH-funded research project midway through the award period must submit a Disclosure Statement **prior to participating in or engaging in** the research.
- **D. Pre-Application Disclosure:** Covered individuals shall submit a Disclosure Statement prior to submitting any proposal seeking external funding or participating in research, regardless of funding source.
- **E. Sponsored Travel Disclosure:** PHS/NIH-funded Investigators shall disclose each instance of reimbursed or sponsored travel meeting the threshold within **thirty (30) days** of travel completion, detailing purpose, sponsor, destination, duration, and monetary value.

Section II. Research Conflict of Interest Committee (RCOIC)

A. Membership

1. The RCOIC is appointed by the President/CEO and reports to the IO.
2. The RCOIC shall consist of a minimum of five (5) members.
3. A majority of members shall be faculty without administrative appointments.
4. Non-ex-officio members shall serve staggered three (3)-year terms.

B. Responsibilities

1. Review real or perceived FCOI cases referred by the IO and recommend courses of action to manage, reduce, or eliminate conflicts.
2. Maintain written meeting minutes and submit reports to the IO as requested.

Section III. Disclosure Statement Review Procedures

A. IO Authority and Determination: The Institutional Official (IO) or designated official(s) is solely responsible for conducting the administrative review of all Disclosure Statements.

1. **Relatedness:** An SFI is related to PHS/NIH-funded research when the IO reasonably determines that the SFI could be affected by the research or is in an entity whose financial interest could be affected.

2. **FCOI Determination:** An SFI constitutes an FCOI when the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.
3. **Documentation:** The IO shall document the basis for each determination in accordance with 42 CFR § 50.604(f). Administrative reviews shall be completed within **60 days** of submission.

B. Investigator Participation & Separation of Duties: An Investigator may provide clarifying information and documentation during preliminary review to assist the IO. However, in accordance with 42 CFR § 50.604(f), the Investigator **shall not participate** in the final institutional determination of whether an SFI constitutes an FCOI. No individual may participate in the administrative review of their own disclosure.

C. Timing of Authorization: An FCOI case shall be satisfactorily resolved and a final decision rendered by the IO before any funds may be expended from a sponsored award and before IRB approval can be granted for human subjects research.

Section IV. Management and Reporting of Financial Conflicts of Interest

A. Institutional Action Steps

ACHE must submit an initial FCOI report to the NIH prior to the expenditure of any funds under an NIH award. When the IO determines that an SFI constitutes an FCOI, the IO shall notify the Investigator and the appropriate dean/director to determine the appropriate action:

1. **Determination of No FCOI:** If, after review, the IO determines that the disclosed SFI **does not** constitute an FCOI, that determination shall be documented in writing, recorded in the administrative system, and no further management or elimination action will be required.
2. **Elimination of FCOI:** If an actual FCOI exists and the Investigator and dean/director agree to eliminate the conflict through divestiture or severance of relationships, they shall document the agreement in writing and submit it to the IO. The IO must confirm elimination prior to authorizing fund expenditures.
3. **Management of FCOI:** If elimination is not feasible, the Investigator shall develop a management plan in consultation with the dean/director and Office of Research. The IO may approve the plan or refer it to the RCOIC for review.

B. Required Elements of Management Plans

All approved management plans must include, at a minimum:

1. Role and principal duties of the conflicted Investigator in the research project;
2. Specific conditions and restrictions imposed to manage the conflict;
3. Explanation of how the plan is designed to safeguard objectivity in the research;
4. Ongoing monitoring schedule and designated responsible official;
5. Mandatory reporting requirements and Investigator certification/agreement; and
6. Specific consequences for non-compliance.

C. RCOIC Review & Recommendation Options

Funding authorization is contingent upon both IO approval and submitting the initial FCOI report to NIH. When reviewing a referred case, the RCOIC may recommend conditions or restrictions, including:

- Public disclosure of SFIs in scientific publications (e.g., manuscript disclosure blocks), oral presentations (e.g., introductory slides), and informed consent forms;
- Independent monitoring of research by objective reviewers;
- Modification of the research plan;
- Disqualification from participation in all or part of the research;
- Divestiture of SFIs or severance of conflicting relationships.

Unless a shorter sponsor deadline applies, the Investigator must submit any written response or objections to the RCOIC proposal within **five (5) business days** of receiving the proposal.

D. Ongoing Compliance Monitoring

Investigators with active management plans must submit annual and final implementation reports. The Office of Research shall monitor Investigator compliance through:

1. Mandatory annual implementation reports;
2. Independent verification of public disclosures in publications and presentations; and
3. At least one random or scheduled administrative audit during the award period.

Section V. Institutional Reporting Requirements and Record Retention

A. Reporting to NIH

- **Initial Report:** Prior to expenditure of funds, ACHE shall submit an FCOI report to the NIH regarding any identified FCOI.
- **Mandatory 60-Day Interim Requirement:** Whenever an SFI is not disclosed or reviewed in a timely manner, ACHE's IO must within **sixty (60) days** review the SFI, determine if an FCOI exists, implement an **interim management plan**, and submit an FCOI report to NIH; this applies when a new Investigator joins an ongoing project or an existing Investigator discloses/acquires a new SFI during the period of award. An interim management plan will be implemented immediately for any new SFI disclosed during an award period. **Interim Management Plans shall include:**
    - Monitoring schedule;
    - Designated responsible official;
    - Mandatory reporting requirements;
    - Investigator certification;
    - Specific consequences for non-compliance;
    - Role and principal duties of the conflicted Investigator;
    - Conditions of the plan (e.g., independent oversight, public disclosures);

- Explanation of how the plan is designed to safeguard objectivity in the research;
- Confirmation of Investigator agreement; and
- How the plan will be monitored.

- **Required elements of Initial and Mid-Award Reports:**
  - Required elements (8) include -

    1. Grant/Contract/Project Number,
    2. Title
    3. PD/PI or Contact PD/PI,
    4. Name of Investigator with FCOI,
    5. Name of Entity with FCOI,
    6. Nature of SFI (e.g., Equity, Remuneration),
    7. Value Range of SFI (<$5k, $5k-$10k, etc.) or statement that value cannot be readily determined,
    8. Description of how SFI relates to PHS research and basis for FCOI determination,

- **Retrospective Review & Report:** In cases of non-compliance (e.g., late disclosure or unreviewed SFI), ACHE shall complete a retrospective review within **one hundred twenty (120) days** to determine if research was biased (42 CFR § 50.605(a)(3)(iii)).
  - If an FCOI exists but no bias is found, ACHE will submit an updated FCOI report. If bias is found, ACHE shall notify the NIH promptly and submit a formal Mitigation Report.

- **Required elements of Retrospective Reports:**
  - Required elements (9) include-

    1. Grant/Contract/Project Number,
    2. Grant/Contract/Project Title
    3. PD/PI or Contact PD/PI,
    4. Name of Investigator with FCOI,
    5. Name of Entity with which the Investigator has an FCOI,
    6. Reason(s) for the retrospective review
    7. Detailed Methodology used for the retrospective review (e.g. panel composition, documents reviewed)
    8. Findings of the review,
    9. Conclusions of the review

- **Annual FCOI Report:** For any active FCOI, ACHE shall submit an annual FCOI report through eRA Commons simultaneously with non-competing continuation progress reports or project extensions.

B. Clinical Research Corrective Disclosure

In accordance with **42 CFR § 50.606(c)**, if HHS determines that a PHS/NIH-funded clinical research project evaluating drug, device, or treatment safety/effectiveness was conducted by an Investigator with an unmanaged FCOI, ACHE shall mandate that the Investigator:

1. Disclose the FCOI in every public presentation of research results; and
2. Request formal errata, addenda, or corrections for all previously published presentation materials or manuscripts to explicitly disclose the FCOI.

C. Public Accessibility Mechanism

In accordance with **42 CFR § 50.604(f)(5)(i)**, prior to fund expenditure, ACHE shall ensure public accessibility of Senior/Key Personnel FCOIs by providing a written response to any requestor within **five (5) business days** of receiving a written request. Information provided in written responses must be **updated at least annually** and within **60 days** of discovering/identifying any new FCOI.

Responses shall include: Investigator Name, Title/Role, Entity Name, Nature of SFI, and Approximate Value Range. Written public request records shall be retained for at least **three (3) years** from the date last updated or provided.

D. Document Retention

Records of all SFI disclosures, review files, and institutional management actions shall be retained by the IO for at least **three (3) years** following the submission date of the final narrative and financial reports to the sponsor or until resolution of any audit, litigation, or claim involving the records, whichever is longer.

Section VI. Subrecipient Compliance

When ACHE carries out PHS/NIH-funded research through a subrecipient (subcontractors or collaborators), ACHE shall execute a written agreement, including specific timeframes, establishing whether subrecipient Investigators will follow:

1. **Subrecipient's Own FCOI Policy:** The subrecipient must certify that their policy complies with 42 CFR Part 50 Subpart F/45 CFR Part 94, and 42 CFR 50.604(c). The subrecipient must specify deadlines for subrecipient Investigators to report identified FCOIs to ACHE with sufficient time to enable ACHE to meet its 60-day NIH reporting deadline; or
2. **ACHE's FCOI Policy:** If the subrecipient lacks a compliant policy, subrecipient Investigators shall comply with ACHE's written policy and submit SFI disclosures according to timelines specified in the subaward agreement (allowing sufficient time for ACHE to meet 60-day reporting obligations).

Section VII. Training Requirements

Pursuant to federal regulations, all Investigators must complete FCOI training prior to engaging in PHS/NIH-funded research. Training must be repeated every **four (4) years**, or immediately when:

- ACHE FCOI policy is substantially revised;
- An Investigator is newly appointed to ACHE; or
- An Investigator is found non-compliant with this policy or an approved management plan.

Section VIII. Enforcement and Sanctions

Violations of this policy include intentionally providing incomplete or misleading information, failing to disclose required SFIs, or non-compliance with management plans. Sanctions may include administrative suspension of grant submissions, suspension of active award expenditures, formal admonition, public disaffirmation of research, agency notification, or employment termination.

Section IX. Document History and Approvals

- **Related References:** 42 CFR Part 50 Subpart F; 45 CFR Part 94; NSF Award & Administration Guide Ch. IV.A
- **Review by Counsel:** Approved by Office of General Counsel
- **Policy Owner:** Office of Research
- **Approval Date:** 08.12.2022 | **Revised:** 07.23.2026 | **Effective:** 07.23.2026 | **Next Review Due:** 06.30.2027