

Title: Conflicts of Interest - Research (Enterprise)		Published Date: 08/06/2025
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I. PURPOSE

Advocate Health (AH) shall establish and implement processes to ensure Significant Financial or Outside Interests (SFOIs) held by Investigators and/or Research Leaders do not create unmanaged Conflicts of Interest that may affect their primary obligation to design, conduct, review and/or report scientifically sound and ethical Research. This policy outlines requirements for the disclosure, review, management, reporting and monitoring of Significant Financial or Outside Interests (SFOI) related to Research.

II. SCOPE

A. This policy applies to all applicable Individuals at entities owned, operated, and controlled by Advocate Health.

B. Out of Scope:

1. Individual Management Plans - Unrelated to Research

Individuals may have management plans in place with general conditions and restrictions that must be followed, apart from and in addition to, any management plan related to a study-specific conflict of interest.

2. Continuing Medical Education

For activities related to accredited continuing education including continuing medical education (CME), additional or alternative disclosure and management requirements may apply. In such cases, the requirements outlined in the [Standards for Integrity and Independence in Accredited Continuing Education](#) may supersede or supplement the expectations outlined in this policy. Individuals involved in continuing education accredited by Advocate Health should consult with the Interprofessional Continuing Education team if there are questions at cme@aah.org.

3. Federally-Funded Grants – Unrelated to Research

Conflicts of Interest - Research (Enterprise)

For federally funded grants that are not for Research, Advocate Health defers to the federal agency's regulations/rules for SFOI disclosure, management and reporting (see Compliance and Integrity Department Procedure: SFOI Disclosures Related to Federally Funded Grants Deemed Out of Scope for the Enterprise Conflicts of Interest in Research Policy in Cross References Section).

III. DEFINITIONS/ABBREVIATIONS

- A. **Conflict of Interest (COI)** means a situation in which an Individual or an Individual's Immediate Family Member has a Significant Financial or Outside Interest (SFOI) that interferes with, compromises or gives the appearance of compromising the design, conduct or reporting of ongoing or proposed Research.
- B. **Conflict of Interest in Research Committee (CIRC)** means the group charged with:
 - 1. Establishing thresholds at which a SFOI is deemed to create a Conflict of Interest.
 - 2. Recommending management conditions and restrictions based on various circumstances and thresholds.
 - 3. Making final determinations when the conflicted individual, or others responsible for implementation, do not agree with COI determinations or proposed management plans.
 - 4. Delegating authority to the Designated Official to perform the required SFOI reviews, management determinations, reporting and overall processes as required by this policy.
- C. **Conflict of Interest Management** means conditions and restrictions the Individual must follow to manage a Conflict(s) of Interest and mitigate the associated risk of the conflict.
- D. **Conflict of Interest Disclosure** means the reporting of Significant Financial or Outside Interests (SFOI) held by an Individual or Immediate Family Member using the tool provided by the Institution to report these Interests.
- E. **Designated Official** means an Individual designated to develop, coordinate, and oversee compliance with the policy on Conflicts of Interest in Research.
- F. **Equity Interest** includes any stock, stock options or personal business ownership interest. The value of equity interest is determined through reference to public prices or other reasonable measures of fair market value.
- G. **External Entity** means a person or organization that:

Conflicts of Interest - Research (Enterprise)

1. has a business relationship (can include research) or has the potential to have a business relationship with the Institution; and/or
 2. offers comparable products and/or services as the Institution.
- H. **Financial Conflict of Interest (FCOI)** is a situation in which the Institution, through its Designated Official(s), reasonably determines that an Investigator's SFOI is related to a federally funded research project and could directly and significantly affect the design, conduct, or reporting of federally funded research.
- I. **Immediate Family Member** means an individual who is related to you by blood, adoption, marriage or is a domestic partner.
- J. **Institution** means entities owned, operated, and controlled by Advocate Health including Wake Forest University School of Medicine (WFUSM).
- K. **Institutional Responsibilities** are activities that derive or descend from one's professional standing or expertise and/or job duties/activities that are conducted on behalf of the Institution, or if not employed by the Institution, conducted on behalf of another employer.
- L. **Interim Report** means the report submitted by the Principal Investigator to the Conflict of Interest in Research Committee (CIRC) on an ongoing basis that provides updated information related to the management plan throughout the duration of the study.
- M. **Investigator** means a project director, Principal Investigator, key personnel or any other person, regardless of title or position, involved in the design, conduct, or reporting of Research.
- N. **Organizational Conflict of Interest per** the Department of Energy's Interim Policy on Conflict of Interest cites 2 CFR 200.318(c)(2) which means a situation where because of relationships with a parent company, affiliate, or subsidiary organization, the non-Federal entity is unable or appears unable to be impartial in conducting a procurement action involving a related organization.
- Other agencies often cite 48 CFR Subpart 9.5 (Federal Acquisitions Register; FAR) in their definition of Organizational Conflict of Interest which means situations where an individual's service or work on behalf of a US government agency or other funding sponsor may provide the Institution with an unfair competitive advantage when others apply for a funding opportunity with that agency or sponsor.
- O. **Position of Authority** means fiduciary duty or other similar position with an External Entity, e.g., officer or leadership positions, whether paid or unpaid.
- P. **Principal Investigator** means the lead researcher on a specific project.
- Q. **Related to the Research** means there is a Significant Financial or Outside Interests (SFOI) held that could influence or appear to influence the outcome of Research.

Conflicts of Interest - Research (Enterprise)

- R. **Remuneration** means payment for services, not otherwise identified as a salary received as an employee, from an External Entity (e.g., consulting fees, honoraria, paid authorship, fees for speaking, board member fees, royalty payments, etc.).
- S. **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences Research.
- T. **Research Leader** means an individual responsible for direct oversight of the Institution's Research. This includes individuals with Research review/oversight responsibility, and others as deemed appropriate.
- U. **Retrospective Review** is an internal review of a study to determine if the ongoing federally funded research was biased in its design, conduct or reporting due to the non-disclosure or timely management of a FCOI.
- V. **Significant Financial or Outside Interest (SFOI)** means:
 - 1. **Financial Interests:** Anything of monetary value received/held by an Individual or an Immediate Family Member including:
 - a) **Remuneration:** Compensation from an External Entity, direct, indirect, or "in kind" (goods or services rather than cash or cash equivalents) and may include, but is not limited to, salary, fees, honoraria, royalty payments, expense reimbursement and Sponsored Travel.
 - b) **Equity Interest:** Any equity interest such as stock, stock options or personal business ownership that is not part of a retirement account or mutual fund over which the Individual does not have direct control.
 - c) **Intellectual Property:** a work or invention to which one has rights, and for which one may apply for a patent, copyright, or trademark and may receive royalties where fees are paid by an External Entity in exchange for the use of intellectual property/rights.
 - 2. **Outside Interest** means a position of authority where an Individual performs fiduciary duties such as a board director/officer or serves in another position such as consultant or speaker for an External Entity whether paid or unpaid.
- W. **Sponsored Travel** means travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available. It does not include travel sponsored by the Institution or Investigator's employer if other than the Institution.

- X. **Subrecipient** is a party that receives a subaward from a recipient or another subrecipient under a Federal financial assistance award and is accountable to the recipient or subrecipient for the use of the Federal funds provided by the subaward.

IV. **POLICY**

A. **Required Disclosures**

1. All Investigators and Research Leaders shall disclose Significant Financial or Outside Interests annually, within the time frame prescribed by the Institution's Compliance and Integrity Department.
2. All Investigators and Research Leaders shall update their annual disclosure within thirty (30) days of discovering or acquiring a new SFOI.
3. All Investigators must disclose study-specific SFOIs for studies submitted to the Office of Sponsored Programs (OSP), Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) at the time of funding proposal or application submission and as required during annual review of active studies.

B. **Disclosure Review**

1. The Conflict of Interest in Research Committee (CIRC) oversees COI management of studies submitted to OSP, IRB or IACUC.
2. The CIRC establishes thresholds at which a SFOI creates a Conflict of Interest (COI), recommends COI management conditions or restrictions based on various circumstances and thresholds and serves as an appeal body.
3. The Compliance and Integrity Department, as delegated by the CIRC, reviews all study-specific disclosures to determine if a SFOI meets the Institutional and/or federal sponsor criteria for COI management.

C. **COI Management**

1. Significant Financial or Outside Interests (SFOIs) of Investigators and Research Leaders determined to create a COI must be managed to the extent that the SFOI no longer affects the design, conduct or reporting of the Research.
2. If a COI is identified in Research involving human subjects, the Institutional Review Board (IRB) and the Compliance and Integrity Department will conduct their respective reviews in parallel. The IRB

Conflicts of Interest - Research (Enterprise)

will withhold final approval pending the completion of the COI review and receipt of recommendations for management. The IRB can add additional conditions or restrictions to manage a COI but cannot remove conditions or restrictions designated for COI management by the Compliance and Integrity Department.

D. **Appeals**

Individuals who disagree with determinations that a SFOI creates a COI or with the proposed COI management conditions and restrictions may appeal the decision to the CIRC.

E. **Management Plan Monitoring**

Monitoring will be performed as stipulated in the Conflict of Interest management plan. Any individual(s) conducting monitoring must not hold any COI related to the disclosed SFOI.

F. **Confidentiality**

Conflict of Interest disclosure forms, review information and any related management plans are considered to be confidential information that should be maintained by the Compliance and Integrity Department in a secure manner. Release by the Compliance and Integrity Department of information disclosed in the conflict of interest review process, including management plans, will be limited to those with a need to know for research or business purposes.

G. **Non-Compliance**

Non-compliance includes but may not be limited to:

1. Failure to complete the required research SFOI training as part of the annual disclosure process.
2. Failure to respond to a request to complete a SFOI disclosure statement.
3. Failure to disclose a potential SFOI on their submission to OSP, IRB or IACUC or update their SFOI disclosure as requested.
4. Failure to acknowledge a COI management plan.
5. Failure to comply with the conditions and restrictions to manage a COI.
6. Failure to eliminate or divest from a SFOI when it has been determined by the CIRC that a Conflict of Interest cannot be managed, and elimination/divestiture is a condition of participating in the research.

Individuals who are non-compliant may receive administrative actions and sanctions as deemed appropriate by leadership and the CIRC.

H. **Public Health Service Funded Research and Other Federal Sponsors**

Conflicts of Interest - Research (Enterprise)

The Institution will comply with all requirements for applicants and recipients of Public Health Service (PHS) funds as detailed at 42 CFR 50 and 45 CFR 94, and any other federal agency's COI requirements including, but not limited to, the National Science Foundation (NSF), the National Aeronautics and Space Administration (NASA), and the Department of Energy (DOE), regarding the disclosure, review, management and reporting of interests.

1. Prior to the expenditure of funds and within 60 days of any subsequently identified FCOI on federally funded research:
 - a) Designate an Institutional official(s) to solicit and review disclosures of SFOIs from each Investigator who is planning to participate in, or is participating in, the federally funded research. The Designated Official is responsible for determining if a Significant Financial or Outside Interest exists, and whether or not it constitutes a Financial Conflict of Interest (FCOI) per applicable federal regulation.
 - b) The Institution shall adhere to its publicly available policy and provide reports regarding identified FCOI to the federal sponsor in accordance with the Institution's own standards and within the timeframe prescribed by the regulation.
2. The Institution will ensure that each Investigator is informed of its policy on FCOI, the Investigator's responsibilities regarding disclosure of SFOIs, and of the applicable federal regulations. Each Investigator is to complete training regarding FCOI requirements prior to engaging in research related to any federally funded contract and at least every four years, and immediately when any of the following circumstances apply:
 - a) The Institution revises its FCOI policies or procedures in any manner that affects the requirements of Investigators.
 - b) An Investigator is new to the Institution.
 - c) The Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan.
3. If an Investigator carries out federally-funded research through a subrecipient (e.g., subcontractors, or consortium members), the Institution will take reasonable steps to ensure subrecipient Investigator compliance through:
 - a) A written agreement with the subrecipient that establishes whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

Conflicts of Interest - Research (Enterprise)

- b) The Institution will provide FCOI reports to the federal sponsor, as required, regarding FCOIs of all subrecipient Investigators consistent with the applicable regulation.
- 4. If an Investigator's SFOI is related to federally-funded research:
 - a) The CIRC or Designated Official determines if the SFI could affect the federally-funded research or is in an entity whose financial interest could be affected by the research.
 - b) The CIRC or Designated Official determines if an FCOI exists when the SFOI could directly and significantly affect the design, conduct, or reporting of the federally-funded research.
- 5. Identification of an FCOI initiates development and implementation of a management plan by the CIRC and, if necessary, a Retrospective Review and mitigation report pursuant to the applicable regulation.
- 6. The Institution provides initial and ongoing FCOI reports to the federal sponsor as required by the applicable regulation. As federal agencies may have differing requirements, reporting of FCOIs will be responsive to the standards and guidelines set by those agencies.
- 7. The Institution maintains records relating to all Investigator disclosures of SFOIs, the CIRC's review of, and response to, such disclosures, and all actions under Institutional policies or Retrospective Review, if applicable, for at least three years from the date of the final expenditure of funds.
- 8. The Institution maintains enforcement mechanisms and provides sanctions and other administrative actions to ensure Investigator compliance as appropriate.
- 9. The Institution ensures public accessibility, via written response to any requestor within five business days of a request, for information concerning an SFOI disclosed to the Institution that meets the following four criteria:
 - a) The federal sponsor regulations/rules mandate this public accessibility requirement.
 - b) The SFOI was disclosed and is still held by Investigator.
 - c) The Institution determines that the SFOI is related to the federally-funded research.
 - d) The Institution determines that the SFOI is a FCOI.
- 10. The information available via written response to any requestor within five business days of a request shall include, at a minimum, the following:
 - a) Investigator's name

Conflicts of Interest - Research (Enterprise)

- b) Investigator's title and role with respect to the research study
 - c) Name of the entity in which the SFOI is held
 - d) Nature of the SFOI, and
 - e) The approximate dollar value of the SFOI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
11. In addition, when sponsor terms require it, Investigators may be asked about additional relationships or activities that create other potential Organizational Conflicts of Interest with respect to procurement decisions and/or the Institution's ability to 1) render impartial assistance to the government, 2) perform work under an awarded contract in an objective way or creates an unfair competitive advantage for the Institution in seeking funding. Required disclosures may include, but are not limited to, instances of providing Advisory and Assistance Services (A&AS) or Systems Engineering and Technical Assistance (SETA) to U.S. federal agencies.

V. PROCEDURE

- A. The Compliance and Integrity Department shall review study-specific SFOIs for studies submitted to the OSP, IRB or IACUC.
- B. Submitted disclosures with reported SFOIs shall be reviewed by the Compliance and Integrity Department to determine whether any constitute a Conflict of Interest as it relates to the research study under review.
- C. If a Conflict of Interest is identified, the Compliance and Integrity Department shall determine the appropriate COI management conditions or restrictions necessary to manage the risks associated with the Conflict of Interest as it relates to the research study under review.
- D. Conflict of Interest determinations and management conditions and restrictions will be communicated to the Principal Investigator and appropriate study team members.
- E. Formal management plans require CIRC review and approval. Approved management plans shall be sent to the conflicted individual, the responsible leader, any applicable study team members providing oversight, and the Chair of the CIRC for signature. Formal management requires the Principal Investigator to submit an Interim Report to the CIRC at least annually.

VI. CROSS REFERENCES

Conflicts of Interest - Research (Enterprise)

Compliance and Integrity Department Procedure: SFOI Disclosures Related to Federally Funded Grants Deemed Out of Scope for the Enterprise Conflict of Interest – Research Policy

VII. RESOURCES AND REFERENCES

Department of Energy (DOE)-Interim Conflict of Interest Policy Requirements for Financial Assistance, FAL 2022-02

National Aeronautics and Space Administration (NASA) -Conflicts of Interest Policy, GCAM and T & C

National Science Foundation – Conflict of Interest Policies, PAPPG Chapter IX

Public Health Services (PHS) Regulations *42 CFR, Part 50, Subpart F* and *45 CFR, Part 94*

Standards for Integrity and Independence in Accredited Continuing Education

VIII. ATTACHMENTS

None