

American College of Rheumatology (ACR) Investigator Financial Conflict of Interest (FCOI) Policy

The American College of Rheumatology (“ACR”) seeks to ensure the integrity of its research and to comply with the federal Public Health Service’s (“PHS”) requirements for institutions that seek research funding. PHS has implemented regulations (Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought) (“FCOI Regulations”) to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. The FCOI Regulations are applicable to institutions that apply for or receive PHS grants or cooperative agreements for research and to each investigator planning to participate in or participating in such Research. This American College of Rheumatology Investigator Financial Conflict of Interest Policy (the “FCOI Policy”) is implemented to fulfill ACR’s responsibilities under the FCOI Regulations to maintain an up-to-date, written, enforced policy and process on investigator financial conflicts of interest. Important definitions for terms used in this FCOI Policy can be found in Appendix A hereto.

Who Must Comply with this FCOI Policy?

All Investigators planning to or participating in PHS-funded Research are required to disclose to ACR his/her known Significant Financial Interests (as described below) that reasonably appear to be related to the Investigator’s Responsibilities. This would include those of his/her spouse or domestic partner and dependent children, alone or in combination.

The Signing Official is responsible for ensuring that ACR complies with all of ACR’s obligations under the FCOI Regulations.

What Should be Disclosed?

Using the Significant Financial Interest Disclosure Form attached as Appendix B hereto, each of the Significant Financial Interests should be disclosed, including those of the Investigator’s spouse or domestic partner and dependent children, alone or in combination to the extent such Significant Financial Interest *reasonably appears to be related to the Investigator’s Responsibilities*. In the interest of full transparency, Investigators should err on the side of disclosure.

Significant Financial Interests (including those of the Investigator’s spouse or domestic partner and dependent children, alone or in combination) within the scope of the FCOI Regulations include:

(a) For publicly traded entities, foreign or domestic, if income or value of any equity interest in excess of \$5,000 (in the aggregate) is received during the twelve months preceding the disclosure;

(i) Examples of income include salary, any payment for services not otherwise identified as salary such as consulting fees, honoraria, paid authorship.

Examples of equity interest includes any stock, stock option, or other ownership interest, based on public prices or other reasonable measures of fair market value.

(b) For non-publicly traded companies, foreign or domestic, if income in excess of \$5000 (in the aggregate) is received during the twelve months preceding the disclosure, or **when any equity interest** is held (e.g. stocks, stock options, or other ownership interests); or

(c) If any income is received from Intellectual property rights and interests (e.g., patents, copyrights, license fees, royalties). The filing of a patent application in the field of funded research also should be disclosed.

(d) Sponsored/Reimbursed Travel. Travel paid by any entity **other than** US Federal, state, or local governments, US-based institutions of higher education, academic teaching hospitals, medical centers, or research institutes associated with institutions of higher education must be disclosed. Paid travel by foreign academic institutions **must be** reported. Travel disclosures will include, at a minimum, the purpose of the trip, identity of the sponsor/organizer, destination, and duration. ACR, or its designees will determine if further information is needed, including a disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded Research.

(e) Significant Financial Interest **DOES NOT** include the following types of financial interests:

(i) Salary, royalties, or other remuneration paid by ACR to the Investigator if the Investigator is currently employed by ACR or otherwise appointed by ACR, including intellectual property rights assigned to ACR and agreements to share in royalties related to such rights.

(ii) Income from investment vehicles, such as mutual funds, ETF's, retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

(iii) Income from seminars, lectures, or other teaching engagements, or from service advisory panels or review panels from a federal, state, or local government agency, US Institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

When Should Significant Financial Interests be Disclosed?

Each Investigator shall submit disclosures of Significant Financial Interests (using the attached Significant Financial Interest disclosure form) to the Signing Official as follows:

- Annually;

- Within Thirty (30) days of an Investigator discovering or acquiring (e.g. through purchase, marriage, or inheritance) any Significant Financial Interest; and
- At the time of the application for PHS-funded research.

The Signing Official shall ensure that annual update disclosure forms are sent to and promptly returned by each Investigator. (One annual disclosure is sufficient to cover all ongoing PHS awards). Investigators shall also provide a disclosure form from time to time as requested by ACR.

What are the requirements for Investigators?

The Investigator is responsible for:

- Following this FCOI Policy;
- Prior to submission to PHS of an application for a research grant, identifying to the Signing Official (1) all Investigators anticipated to be participating in the Research, (2) those who are Senior/Key Personnel and (3) those who are Subrecipients and the institution(s) employing them.
- Completing the Mandatory Investigator Conflict of Interest Training prior to engaging in Research and at least every four (4) years thereafter or immediately if:
 - An Investigator is new to ACR;
 - This FCOI Policy changes in a manner affecting Investigator's Responsibilities; or
 - ACR finds that an Investigator is non-compliant with this FCOI Policy.
- Submitting to ACR's Signing Official prior to the expenditure of PHS funds a listing of his/her known Significant Financial Interests (and those of his/her spouse, domestic partner and dependent children) on the attached Significant Financial Interest Disclosure Form.
- During the period of the award, updating all Significant Financial Interest Disclosure Form according to this FCOI Policy, either on an annual basis or within 30 days of the acquisition or discovery of a new Significant Financial Interest.

An Investigator is non-compliant and in violation of this FCOI Policy, if an Investigator fails to:

- Submit an annual Significant Financial Interest Disclosure Form or provide an update to the annual Significant Financial Interest Disclosure Form by the deadlines established by ACR;
- Provide ACR with written acknowledgement of a management plan; and/or

- Provide ACR with requested documentation regarding compliance with a management plan.

What are the requirements for ACR?

ACR will maintain an up-to-date, written, enforced FCOI policy that complies with the Regulations and make the policy publicly accessible. ACR through its Signing Official, shall have the following additional responsibilities:

- Soliciting and reviewing Significant Financial Interest Disclosure Forms;
- Determining whether an Investigator's Significant Financial Interest is related to ACR's PHS-funded research and, if so related, whether the Significant Financial Interest is a Financial Conflict of Interest
- Developing and implementing management plans, as needed to manage FCOIs for Investigators and subrecipients, if applicable;
- Submitting initial, annual, and revised FCOI reports to the PHS Awarding Component in accordance with the Regulations;
- Completing retrospective reviews when there is noncompliance with this FCOI policy and updating any previously submitted FCOI report, if required after the retrospective review is complete;
- Submitting mitigation reports when bias is found as a result of the retrospective review.

What are the Signing Official's responsibilities?

The Signing Official is responsible for ensuring that ACR complies with all of ACR's obligations under the FCOI Regulations. This includes, without limitation, reviewing all Significant Financial Interest Disclosure Forms received from Investigators, making the requisite determinations as described below, monitoring and taking any subsequent action, including without limitation reporting FCOI.

Disclosure Review

Prior to ACR's expenditure of funds or, with respect to an ongoing PHS-funded project, within sixty (60) days of receiving a Significant Financial Interest Disclosure Form, the Signing Official shall review all disclosure forms and determine whether:

1. An Investigator's Significant Financial Interest is related to ACR's PHS-funded Research; and
2. If so related, whether the Significant Financial Interest is a FCOI.

(a) A FCOI exists when the Signing Official reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of ACR's PHS-funded Research. In determining whether there is an FCOI, the Signing Official will consider all relevant factors and information, including but not limited to:

(i) The nature of the Research;

(ii) The magnitude of the financial interest and degree to which it relates to the Research;

(iii) The extent to which the interest could be directly and substantially impacted by the Research; and

(iv) The degree of risk to the human subjects, if any, that is inherent in the Research protocol.

(b) Prior to making the decision whether an FCOI exists, the Signing Official may:

(i) Impose interim measures;

(ii) Ask the Investigator to submit additional information; and

(iii) Meet or communicate with the Investigator. The Investigator may be encouraged to suggest procedures, protocols, or other measures designed to manage the FCOI.

(1) Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

a. Public disclosure of FCOI (e.g., when presenting or publishing the Research);

b. For Research involving human subjects, disclosure of FCOIs to Research participants;

c. Monitoring of the Research by independent reviewers;

d. Modification of the Research plan;

e. Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the Research;

f. Reduction or elimination of the financial interest; and/or

g. Severance of relationships that create such conflicts.

3. If a Significant Financial Interest is a FCOI, the Signing Official shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI Report regarding the FCOI and manage the FCOI by implementing a management plan. However, if the FCOI is identified and eliminated prior to the expenditure of any PHS-awarded funds, no FCOI report need be submitted.

(a) An FCOI Report shall include the elements described in 42 CFR §50.605(b)(3)

(b) The management plan shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward. As part of the management plan, the Signing Official shall:

(i) Monitor ongoing Investigator compliance; and

(ii) Submit annual updates to the PHS Awarding Component at the time and in the manner specified by the PHS Awarding Component, both until the completion of the PHS-funded Research project to which the FCOI relates.

4. The Signing Official shall submit Initial, Annual and Revised FCOI reports to PHS Awarding Component

(a) The Signing Official shall send initial, annual, and revised FCOI reports to the PHS Awarding Component as required by the Regulation:

(i) Prior to the expenditure of the funds

(ii) Within sixty (60) days of identification for an Investigator who is newly participating in the project;

(iii) Within sixty (60) days for new or newly identified FCOIs for existing Investigators

(iv) At least annually (at the same time as when ACR is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable until the completion of the project.

(v) Following a retrospective review to update a previously submitted FCOI Report, if appropriate.

Noncompliance and Remedies

Whenever the Signing Official, identifies a Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Signing

Official during an ongoing PHS-funded Research project (e.g., was not timely reviewed or reported by a subrecipient), the Signing Official shall within sixty (60) days of the determination of non-compliance:

- Review the Significant Financial Interest;
- Determine whether it is related to ACR's PHS-funded Research;
- Determine whether a FCOI exists; and, if so:
- Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.
- If applicable, conduct a retrospective review as described below.
- If applicable, submit a mitigation report as described below.

Retrospective Review

In addition, whenever a FCOI is one that was not identified, reviewed or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest that is determined by the Signing Official to constitute a FCOI; failure by the Signing Official to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, the Signing Official shall, within 120 days of the Signing Official's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research.

The retrospective review described above shall be documented consistent with FCOI Regulations (42 CFR §50.605(a)(3)(ii)(B)) and include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

- Findings of the review; and
- Conclusions of the review

Based on the results of the retrospective review, if appropriate, the Signing Official shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found during the course of the review, the Signing Official will promptly notify the PHS Awarding Component (which may take its own action and/or require further action by ACR and/or the Investigator, as it deems appropriate) and submit a mitigation report consistent with the FCOI Regulations (42 CFR §50.605(a)(3)(iii)).

Mitigation Report

If after the retrospective review, the Signing Official determines that bias is found within the design, conduct, or reporting of the PHS-funded research, the Signing Official shall promptly notify the PHS Awarding Component and submit a mitigation report. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the Research project and the ACR's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the Research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, ACR will submit FCOI reports annually. Depending on the nature of the FCOI, ACR may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded Research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of ACR's retrospective review. Whenever the Signing Official implements a management plan pursuant to this part, the Signing Official shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

For clinical Research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical Research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment was designed, conducted, or reported by an investigator with an FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the Investigator shall disclose the FCOI in each public presentation of the results of the Research (such as articles, manuscripts and oral presentations) and ACR shall request an addendum to previously published presentations.

The Signing Official may impose sanctions for noncompliance which may include, but is not limited to, the following:

- Failure to make timely, full or accurate disclosures;
- Failure to provide information requested;
- Failure to update a disclosure form as necessary; or
- Failure to comply with a management plan.

For ACR employees, sanctions may include suspension or dismissal, denial of eligibility to engage in the Research at issue or other appropriate penalties. Such sanctions may require giving notice of relevant information to funding agencies, professional bodies or journals, or the public. The Signing Official will determine what sanctions, if any, are to be applied.

What are the requirements for subrecipients?

The Signing Official shall ensure, in writing, that Subrecipient Investigators either comply with this FCOI Policy or that their institution(s) provides assurances to enable ACR to fulfill the requirements of this FCOI Policy.

If applicable, the Signing Official shall obtain a certification from the Subrecipient that its FCOI Policy complies with the Regulations. If applicable, the Signing Official shall include in the written Subrecipient agreement a requirement for the Subrecipient to report identified FCOIs for its Investigators in a time frame that allows ACR to report identified FCOIs as required by the FCOI Regulations. Alternatively, if applicable the Signing Official shall include in the written agreement a requirement to solicit and review Subrecipient Investigator disclosures that enable ACR to identify, manage, and report identified FCOIs.

Subrecipients shall comply with this policy and shall also complete the mandatory Investigator Conflict of Interest Training prior to engaging in Research.

Public Accessibility Requirements

This FCOI Policy will be posted on ACR's publicly accessible website, as required by the FCOI Regulations.

Prior to expending any funds under a PHS-funded grant or cooperative agreement, ACR shall ensure public accessibility, via a publicly accessible website or written response to any requestor within five (5) business days of a request, of information concerning any significant financial interest disclosed to ACR that meets the following three criteria:

- The Significant Financial Interest was disclosed and is still held by the Senior/Key Personnel as defined by 42 CFR §50.605(a)(5)(i)(A)-(C);
- ACR determines that the Significant Financial Interest is related to the PHS funded Research; and
- ACR determines that the Significant Financial Interest is a FCOI.

The information that ACR makes available via their publicly accessible website or written response to a requestor, such response to be postmarked or dated (if replying by electronic means) within five (5) business days, shall include, at a minimum that information required to be provided under the FCOI Regulations (42 CFR §50.605(a)(5)(ii)). If ACR responds to written requests for the purposes of this FCOI Policy, ACR will note in its written response that the information

provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of ACR's identification of a new FCOI, which should be requested subsequently by the requestor.

ACR shall update the website within sixty (60) days of ACR's receipt or identification of information concerning any additional Significant Financial Interest of the Senior/Key personnel for the PHS-funded Research project that was not previously disclosed, or upon the disclosure of a Significant Financial Interest of Senior/Key personnel new to the PHS-funded Research project, if ACR determines that the Significant Financial Interest is related to the PHS-funded Research and is a FCOI. The website shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within sixty (60) days of ACR's identification of a new FCOI.

Information concerning Significant Financial Interest of an individual shall remain available, for responses to written requests or for posting via ACR's publicly accessible website for at least three (3) years from the date that the information was most recently updated.

Maintenance of Records and Records Requests

The Signing Official shall maintain all disclosure forms and related records of review of, response to such disclosures (whether or not a disclosure resulted in the Signing Official's determination of a FCOI) and all actions under this FCOI Policy or retrospective review, if applicable, for at least a period of three (3) years from the date the final expenditures report is submitted to the PHS (or, where applicable, from other dates specified in 45 CFR Part 75.361 for different situations).

ACR may be asked to provide records related to this FCOI Policy, including disclosure forms, to the Department of Health and Human Services or other federal agencies or entities. ACR will provide the requested information and make any other disclosures necessary to comply with this FCOI Policy or as required by law. Such records may be requested and provided whether or not the disclosure resulted in a determination that an FCOI existed.

APPENDIX A: KEY DEFINITIONS¹

1. Disclosure refers to the Investigator's disclosure of Significant Financial Interests to ACR.
2. Federally funded Research or PHS-funded Research means any Research funded by the Public Health Service (PHS) of the U.S. Department of Health and Human Services and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH). Other federal agencies include the National Science Foundation (NSF), Department of Defense (DOD), and Department of Energy (DOE).
3. Financial Conflict of Interest (FCOI) means that a Significant Financial Interest disclosed by an Investigator could directly and significantly affect the design, conduct or reporting of ACR's PHS-funded Research.
 - (a) An FCOI exists when ACR, through its Signing Official, reasonably determines that: (i) a significant financial interest could directly and significantly affect the design, conduct or reporting of the PHS-funded Research, or (ii) the significant financial interest could be affected by the PHS-funded Research; or (iii) the significant financial interest is in an entity whose financial interest could be affected by the Research. ACR may involve the Investigator in the Signing Official's determination of whether a Significant Financial Interest is related to the PHS-funded Research.
4. Investigator refers to the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
5. Investigator's Responsibilities mean an Investigator's professional activities on behalf of ACR including, but not limited to, Research, research consultation, teaching, professional practice, ACR committee memberships and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
6. Manage means taking action to address a FCOI, which can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct and reporting of Research will be free from bias.
7. Regulations or FCOI Regulations refers to 42 CFR Part 50 Subpart F, Promoting Objectivity in Research (grants) and 45 CFR Part 94 (contracts). Refer to the Additional Resources listed on Appendix C to the FCOI Policy for links to these federal Regulations.
8. FCOI Report refers to ACR's report of an identified FCOI to a PHS Awarding Component.

¹ These definitions can also be found at 42 CFR §50.603.

9. Research means a systematic investigation, study or experiment or a conference funding request designed to develop or contribute to generalizable knowledge relating broadly to public health or agriculture, and encompasses basic, translational and applied research. Research includes any activity for which research funding is available regardless of the source, including a research award, career development award, center grant award, conference grant, fellowship award, infrastructure award, institutional training grant, program project award or research resources award.
10. Senior/Key Personnel means the Principal Investigator or Project Director and any other person identified as senior/key personnel by ACR in the sponsored research application, progress report or any other report submitted to the funding agency.
11. Signing Official is the person responsible for the procedures under this FCOI Policy and providing these services on behalf of ACR, but the Signing Official may designate one or more individuals to assist in any or all of these responsibilities and/or may delegate any or all of these responsibilities to one or more individuals.
12. Subrecipient is defined as all non-ACR Investigators who are receiving funding awarded to ACR, including but not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub awardees.

**APPENDIX B:
SIGNIFICANT FINANCIAL CONFLICT OF INTEREST DISCLOSURE FORM**

Persons completing this form are expected to have read and understood the American College of Rheumatology (“ACR”) Investigator Financial Conflict of Interest Policy (“FCOI Policy”). If you have any questions regarding that policy, please contact _____ at _____.

Disclosure Type:

- Initial Submission
- Annual Update
- Project Specific

1. Do you, your spouse, domestic partner or dependent children have a Significant Financial Interest (SFI) (as defined in the FCOI Policy) that would reasonably appears to be related to your Responsibilities (as defined in the FCOI Policy)?

Yes

No

If yes, please describe on a separate page the nature and extent of your/their affiliation.

If yes, and if the Significant Financial Interest relates to Sponsored/Reimbursed Travel, please provide the following:

1. The Purpose of the Trip;
2. The Identity of the Sponsor/Organizer;
3. The Destination; and
4. The Duration;

2. Do you, your spouse, domestic partner or dependent children have an SFI in any business or legal entity whose financial interests would reasonably appear to be related to your Responsibilities (as defined in the FCOI Policy)?

Yes

No

If yes, please describe on a separate page the nature and extent of your/their affiliation.

I certify that:

I have read the American College of Rheumatology (“ACR”) Investigator Financial Conflict of Interest (“FCOI”) Policy, and I have made all required financial disclosures.

Signature _____

Date: _____

Printed name: _____

*For Program Leaders, Principal Investigators and Project Directors **Only**: I have made every effort to ensure that all Investigators (see Key Definitions in American College of Rheumatology (“ACR”) Investigator Financial Conflict of Interest (“FCOI”) Policy for definition) responsible for the design, conduct, or reporting of the Research have submitted disclosures.*

Signature _____

Date: _____

Printed name: _____

Project Title: _____

Project Sponsor: _____

Comments (if any):

**APPENDIX C:
ADDITIONAL RESOURCES**

- ACR Point of Contact: [Name; Email Address]
- NIH Grants & Funding: Financial Conflict of Interest
- NIH Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- NIH Training about FCOIs
- Promoting Objectivity in Research Federal Regulations