



UL Research Institutes

Financial Conflict of Interest (FCOI) Policy

As an applicant for and/or recipient of Public Health Service (PHS) grants or cooperative agreements, UL Research Institutes (ULRI) is required to ensure that the design, conduct, and reporting of PHS-funded Research is bias free and in compliance with PHS financial conflict of interest requirements located at 42 CFR Part 50.

I. APPLICABILITY AND RESPONSIBILITY

- A. This policy is applicable to all UL Research Institutes investigators, personnel, contractors, sub-contractors, and collaborators who participate in PHS-funded Research.
- B. The Senior Vice President and Chief Research Officer (Designated Institutional Official) will be responsible for the management and implementation of this policy. An alternative responsible official may be designated by the Designated Institutional Official in the event that the Designated Institutional Official has a Significant Financial Interest that requires evaluation.

II. DEFINITIONS

- A. Financial Conflict of Interest (FCOI): A Significant Financial Interest (defined below) that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research.
- B. Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.
- C. Institutional Responsibilities: For the purpose of this policy, Institutional Responsibilities are the Investigator's professional responsibilities on behalf of UL Research Institutes (ULRI), which may include Research, Research consultation, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- D. Investigator: 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.

- E. PHS Awarding Component: The organizational unit of the PHS that funds the applicable Research.
- F. Research: 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. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement.
- G. Significant Financial Interest (SFI):
 - 1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - a. With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, 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 stock, stock options, or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value.
 - b. With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interest).
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

- d. Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's Institutional Responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education. Disclosures regarding reimbursed or sponsored travel must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
2. SFIs do not include the following types of financial interests:
 - a. Salaries, royalties, or other remuneration paid by ULRI to Investigators that are ULRI employees or who are or otherwise appointed by ULRI, including intellectual property rights assigned to ULRI and agreements to share in royalties related to such rights.
 - b. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
 - c. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
 - d. Income from service on advisory committees or review panels for a federal, state, or local government agency an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

III. POLICY

A. Financial Interest Disclosures

1. All Investigators planning to participate in PHS-funded Research must disclose any SFIs (and those of the Investigator's spouse and dependent children) prior to the submission of an application for PHS-funded Research or prior to participating in any PHS-funded Research, whichever is earlier.
2. Each Investigator participating in PHS-funded Research must submit an updated financial disclosure at least annually. Such annual disclosure shall include any information that was not previously disclosed and updated information regarding any previously disclosed SFIs.
3. Each Investigator must submit an updated SFI disclosure within thirty (30) days of discovering or acquiring a new SFI.
4. Disclosures must be provided on the UL Research Institutes (ULRI) FCOI form and must include all information required by the form. Based upon the disclosed information, the Designated Institutional Official will determine whether further information is required. All requests for further information must be promptly addressed by the disclosing Investigator.

B. Financial Interest Reviews

1. Prior to expenditure of any PHS funds and beginning performance of a grant project; or, within sixty (60) days of an SFI disclosure, the Designated Institutional Official will review the SFI to determine if it is related to PHS-funded Research and, if so, determine whether an FCOI exists.
 - a. An SFI will be deemed to be related to PHS-funded Research when the Designated Institutional Official reasonably determines that the SFI could be affected by the PHS-funded Research or the SFI is in an entity whose financial interest could be affected by the Research.

- (i) When reviewing an SFI, the Designated Institutional Official may involve the Investigator in the determination of whether an SFI is related to the PHS-funded Research.
- b. An FCOI exists when the Designated Institutional Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.

C. Reporting of FCOIs

- 1. All FCOIs must be reported to the PHS Awarding Component prior to the expenditure of any PHS funds and within sixty (60) days of any subsequently identified FCOIs. If an FCOI is eliminated prior to the expenditure of any PHS funds, FCOI reports are not required.
- 2. FCOI reports must include, but are not necessarily limited to the following:
 - a. Project number
 - b. Project Director/Principal Investigator (PD/PI) or Contact PD/PI if a multiple PD/PI model is used
 - c. Name of the Investigator with the FCOI
 - d. Name of the entity with which the Investigator has an FCOI
 - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
 - f. Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value

- g. A description of how the financial interest relates to the PHS-funded Research and the basis for ULRI's determination that the financial interest conflicts with such Research
 - h. A description of the key elements of the Institution's management plan, including:
 - (i) Role and principal duties of the conflicted Investigator in the Research project
 - (ii) Conditions of the management plan
 - (iii) How the management plan is designed to safeguard objectivity in the Research project
 - (iv) Confirmation of the Investigator's agreement to the management plan
 - (v) How the management plan will be monitored to ensure Investigator compliance
 - (vi) Other information as needed
3. **Annual Reports.** For any FCOI previously reported by ULRI to a PHS Awarding Component, ULRI must provide an annual FCOI report that addresses the status of the FCOI and any changes to the management plan. The annual FCOI reports must be provided for the duration of the PHS-funded Research project (including extensions with or without funds), in the time and manner specified by the PHS Awarding Component. The annual FCOI report must specify whether the financial conflict is still being managed or explain why the FCOI no longer exists.

D. Retrospective Reviews

1. If an Investigator discloses or ULRI identifies an untimely, unreported, or unreviewed SFI, the Designated Institutional Official shall, within sixty (60) days, review the SFI; determine whether it is related to PHS-funded Research; determine whether an FCOI exists; and, if so then implement a management plan.
2. If an FCOI exists, and if an FCOI is not timely identified, reviewed, or managed in accordance with this policy, or if an Investigator does not comply with a prior FCOI management plan, within one-hundred and twenty (120) days of ULRI's determination of noncompliance, the Designated Institutional Official shall complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine whether any PHS-funded Research conducted during the time period of the noncompliance was biased with respect to the design, conduct, or reporting of such Research.
3. The Designated Institutional Official shall document the retrospective review. Such documentation shall include the:
 - a. Project number
 - b. Project title
 - c. PD/PI or contact PD/PI if a multiple PD/PI model is used
 - d. Name of the Investigator with the FCOI
 - e. Name of the entity with which the Investigator has an FCOI
 - f. Reason(s) for the retrospective review
 - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
 - h. Findings of the review
 - i. Conclusions of the review

4. Based on the results of the retrospective review, if appropriate, ULRI shall update the previously submitted PHS Awarding Component FCOI report, specifying the actions that will be taken to manage the FCOI going forward.
5. If bias is found, ULRI shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include the above elements documented in the retrospective review, a description of the impact of the bias on the Research project, and ULRI's plan of action or actions 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).

E. Management of an FCOI

1. In the event of an FCOI, the Designated Institutional Official shall develop and implement a management plan specifying any actions that have been and will be taken to manage the FCOI.
2. Management plans shall aim to reduce or eliminate the FCOI to ensure (to the extent possible) that the design, conduct, and reporting of Research will be free from bias.
3. Management plans may include, but are not limited to:
 - a. Public disclosure of FCOIs (e.g., when presenting or publishing the Research)
 - b. Disclosure of FCOIs directly to human subjects
 - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI
 - d. Modification of the Research plan
 - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research

- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest)
 - g. Severance of relationships that create financial conflicts
4. Management plans may be implemented on an interim basis, as needed. Interim management plans may be used, when deemed necessary, between the date of the disclosure and the completion of the review. Interim management plans may also be appropriate when an FCOI exists and such FCOI originates from an SFI that was not timely disclosed or was not previously reviewed.
 5. The Designated Institutional Official shall monitor the Investigator's compliance with the management plan on an ongoing basis until the completion of the PHS-funded Research project.

F. Public Disclosure

1. Within five (5) business days of a request, ULRI will provide a written response to a request for information concerning any SFI that:
 - a. Was disclosed and is still held by the project director, principal investigator, or any other persons identified as senior/key personnel in the applicable grant application, progress report, or other PHS report
 - b. ULRI determines is related to the PHS-funded Research
 - c. ULRI determines is an FCOI
2. The information that is made available will include, at a minimum, the following:
 - a. The Investigator's name
 - b. The Investigator's title and role with respect to the Research project
 - c. The name of the entity in which the SFI is held
 - d. The nature of the SFI

- e. The approximate dollar value of the SFI (dollar ranges are permissible:
\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
3. All such public disclosures must note 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 ULRI's identification of a new FCOI. Such updates should be requested subsequently by the requestor.
4. Information must remain available for disclosure for at least three years from the date that the information was most recently updated.

G. Maintenance of Records

1. ULRI shall maintain the following FCOI-related records: all Investigator financial interest disclosures, its review of the disclosed financial interest, its response to the disclosure, its determination of whether the disclosure results in an FCOI, and all actions taken under this policy or under a retrospective review.
2. All records must be maintained for at least three (3) years from the date of the final expenditure report submitted to PHS, throughout the completion of any litigation, claim, negotiation, audit, or other action involving the records, or other dates specified by law, governmental authority, or regulation, whichever is later. ULRI shall make such records available to U.S. Department of Health and Human Services (HHS) representatives, promptly, upon request.

H. Compliance, Enforcement Mechanisms, and Penalties for Non-Compliance

1. In addition to the requirements of this policy, ULRI will take all such actions as the PHS Awarding Component requires.
 2. ULRI and all applicable personnel will submit or permit an on-site review of all records pertinent to this policy, as requested by the PHS Awarding Component and/or the HHS.
 3. If HHS 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 has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported, as required, ULRI shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the Research and to request an addendum to previously published presentations.
 4. Failure to comply with this policy may result in consequences, including and up to removal from the Research or termination.
- I. **Subrecipient Support in PHS Research.** In written agreements with subrecipients or subcontractors, ULRI shall require any subrecipient or subcontractor performing PHS-funded Research to either comply with this FCOI policy or comply with the subrecipient's or subcontractor's FCOI policy.
1. If the subrecipient's/subcontractor's FCOI policy will apply, the subrecipient/subcontractor must certify in the applicable agreement that its policy complies with 42 C.F.R. Part 50, Subpart F. The agreement must also specify the time period(s) for subrecipient/subcontractor reporting of FCOIs to ULRI. In this case, the subrecipient/subcontractor will be responsible for reviewing and managing all SFIs, as applicable, and ULRI will be responsible for reporting FCOIs to the PHS Awarding Component, as applicable.
 2. If ULRI's FCOI policy will apply, the agreement will specify the time period within which the subrecipient/subcontractor must report to ULRI all SFIs. In this case, ULRI will be responsible for reviewing, managing, and reporting subrecipient/subcontractor SFIs, as appropriate and in accordance with this policy.



- J. Training Requirement.** Each Investigator is required to complete training on the applicable FCOI requirements and this policy prior to engaging in PHS-funded Research, at least every four (4) years, and immediately, if ULRI revises this policy such that Investigator's requirements are impacted; (2) an Investigator is new to ULRI; and (3) an Investigator is non-compliant with the FCOI Policy or a management plan.

IV. POINT OF CONTACT

Questions regarding this policy can be directed to Christopher J. Cramer (chris.cramer@ul.org).