



## University of Liberia College of Health Sciences

### Financial Conflict of Interest in Research Policy

Policy/Procedure

#### I. PURPOSE

The purpose of this policy is to ensure research supported by the Public Health Service (e.g., National Institutes of Health [NIH]) at the University of Liberia College of Health Sciences ("ULCHS" or "Institution") is conducted without bias and with the highest scientific and ethical standards, to protect the integrity and credibility of ULCHS, ensuring that public trust in the institution's research and educational activities is preserved. These policies and procedures are designed to meet Federal Department of Health and Human Services regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) which applies to all Public Health Service (PHS) (e.g., National Institutes of Health [NIH]) funded grants, cooperative agreements, and research contracts. ULCHS is responsible to identify, manage, reduce, or eliminate any financial conflicts of interest that may arise because of the financial interests of an Investigator.

#### II. DEFINITIONS - For the purpose of these policies and procedures the following definitions apply.

1. **Financial conflict of interest (FCOI)** - a significant financial interest of the investigator that could potentially influence the design, conduct, or reporting of their PHS-funded research project; essentially, a conflict between their personal financial gain and the integrity of their research findings at ULCHS.
2. **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 award or proposed for such funding, which may include, for example, collaborators or consultants. ULCHS Principal Investigator/Project Director, upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.
3. **Designated Official (DO)** - means the individual who has been designated by ULCHS, to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests. The **DO** has authority to suspend all relevant activities until the financial conflict of interest is resolved or mitigated. For the purposes of this policy, the DO at ULCHS is the Director of the Office of Sponsored Research Services.
4. **Institutional responsibilities** - means the professional activities an investigator performs on behalf of ULCHS (e.g., administration, teaching research, institutional committee membership or consultation).



5. **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. 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). For PHS- Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.
6. **Senior/key personnel** mean the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS/NIH by the Institution. This term is defined only as it relates to the public accessibility requirements described under the section labeled **Public Accessibility to Information Related to Financial Conflict of Interest**.
7. **PHS**: The Public Health Service 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).
8. **NIH**: The biomedical research agency of the PHS
9. **Disclosure** – means a requirement necessary for Researchers to disclose any potential FCOIs to their institution and the PHS.
10. **Management Plan** – means a plan developed to mitigate or eliminate the conflict, which could include modifying the research design, removing the researcher from certain aspects of the project, or recusing themselves from relevant decisions, if a FCOI is identified.
11. **Financial Interest** - means anything of monetary value, whether or not the value is readily ascertainable that could affect the design, conduct, or reporting of PHS-funded research.
12. **Significant Financial Interest (SFI)** means –
  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 appear to be related to the Investigator’s institutional responsibilities performed on behalf of ULCHS.
    - a. Regarding publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve 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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);



equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- b. Regarding non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve 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 option, or other ownership interest); or
  - c. Regarding intellectual property rights and interests (e.g., patents, copyrights), a significant financial interest exists upon receipt of income of greater than \$5,000 related to such rights and interests.
2. The occurrence of any reimbursed or sponsored travel exceeding \$5,000 undertaken by the Investigator and related to the Investigator's institutional responsibilities. It includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. The disclosure requirement excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, and research institutes that are affiliated with U.S. institutions of higher education.

The term Significant Financial Interest does **not** include the following types of financial interests:

1. Salary, royalties, or other remuneration paid by ULCHS to the Investigator if the Investigator is currently employed or otherwise appointed by ULCHS, including intellectual property rights assigned to ULCHS and agreements to share in royalties related to such rights.
2. Any ownership interest in ULCHS, held by the Investigator since ULCHS is a commercial or for-profit organization and such interest is excluded from the SFI definition per the regulation.
3. 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.
4. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education or
5. Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.



Note: Investigators must disclose the occurrence of any foreign or domestic reimbursed or sponsored travel that exceeds \$5,000 (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. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

1. federal, state, or local government agency located in the United States
2. a United States Institution of higher education,
3. an academic teaching hospital,
4. a medical center, or
5. a research institute affiliated with a United States Institution of Higher Education.

**Foreign Financial Interests** – Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country except when excluded in relation to the exclusions outlined above in this policy under Section II. Definitions Part 12 – Significant Financial Interest) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

### III. TRAINING REQUIREMENTS

Each Investigator will be informed about ULCHS Financial Conflict of Interest Policy and be trained on the Investigator's responsibility to disclose foreign and domestic SFIs per this policy and of the FCOI regulation at [42 CFR Part 50 Subpart F](#). FCOI training will occur prior to an Investigator engaging in PHS/NIH-funded research, at least every four years and immediately (as defined below) when any of the following circumstances apply:

1. ULCHS revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators;
2. An Investigator is new to ULCHS research under an NIH award or any other research funding (training is to be completed prior to his/her participation in the research); or
3. ULCHS finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the designated official).

In fulfillment of the FCOI training requirement of the FCOI regulation, ULCHS requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at:



[https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html) in accordance with the requirements and expectations of this Policy. All investigators must print a certification of completion at the end of training and retain it for audit purposes.

#### **IV. DISCLOSURE**

1. Investigator Disclosure:
  - a. At the time of application, the Principal Investigator and all other individuals who meet the definition of “Investigator” must disclose their SFIs to ULCHS designated official. Any new Investigator who, after applying to NIH for funding from NIH or during the course of the research project, plans to participate in the project must similarly disclose their SFI(s) to the designated official promptly and prior to participation in the project.
  - b. Each Investigator who is participating in research under an NIH award must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to ULCHS pursuant to this Policy or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on an NIH-funded project directly as an NIH Grantee and/or indirectly through a sub-award) that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
  - c. Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). In addition, Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.
2. **REVIEW OF SFI DISCLOSURES BY ULCHS DESIGNATED OFFICIAL**
  - a. The designated official will conduct reviews of SFI disclosures. The designated official will review any SFI that has been identified in a disclosure; these interests will be compared to each PHS/NIH research application and/or award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the PHS/NIH funded research and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award. The designated official has been designated as Director of the Office of Sponsored Research Services (contact - [theowayjt@ul.edu.lr](mailto:theowayjt@ul.edu.lr)).

#### **V. GUIDELINES FOR DETERMINING “RELATEDNESS” OF SFI TO PHS/NIH FUNDED RESEARCH AND A FINANCIAL CONFLICT OF INTEREST**

The designated official will determine whether an Investigator’s SFI is related to the research under an NIH award and, if so, whether the SFI is a financial conflict of interest.



**An Investigator's SFI is related to the research when the designated official reasonably determines the SFI:**

- 1. could be affected by the PHS/NIH-funded research; or**
- 2. is in an entity whose financial interest could be affected by the PHS/NIH- funded research.**

The designated official may involve the Investigator in determining whether an SFI is related to the research supported by the award.

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

#### **VI. MANAGEMENT OF SIGNIFICANT FINANCIAL INTERESTS THAT POSE FINANCIAL CONFLICT(S) OF INTEREST**

1. If a conflict of interest exists, the designated official will determine what management conditions and/or strategies will be put in place to manage the FCOI. Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:
  - a. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the Institution's Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.);
  - b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document;
  - 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 financial conflict of interest;
  - 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;
2. If the designated official determines that a conflict exists, it will communicate its determination and the means it has developed for managing the FCOI in writing to the individual, to the relevant Principal Investigator/Project Director, and to the appropriate direct supervisor.



3. No expenditures on an NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated official necessary to manage the Financial Conflict of Interest. The designated FCOI DO of ULCHS will submit the FCOI report to NIH via the eRA Commons FCOI Module.

## **VII. PUBLIC ACCESSIBILITY TO INFORMATION RELATED TO FINANCIAL CONFLICTS OF INTEREST**

1. Prior to the expenditure of any funds under an NIH award, ULCHS will ensure public accessibility by written response to any requestor within five business days of a request of information concerning any SFI disclosed that meets the following three criteria:
  - a. The SFI was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by ULCHS in the award application, progress report, or any other report submitted to the NIH Grantee;
  - b. ULCHS has determined that the SFI is related to the research funded through an award; and
  - c. ULCHS has determined that the SFI is a financial conflict of interest.
2. The information that ULCHS will make available via a publicly accessible Website or in a written response to any request within five days of request 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 Significant Financial Interest is held;
  - d. The nature of the Significant Financial Interest; and
  - e. The approximate dollar value of the Significant Financial Interest in the following ranges: \$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. If ULCHS uses a publicly accessible Website to comply with the public disclosure requirements of the NIH regulations, the information posted will be updated at least annually and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the NIH-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the NIH-funded research project, if it is determined by the designated official that the Significant Financial Interest is related to the research and is a financial conflict of interest.



4. Information concerning an individual's SFI, as limited by this Policy, will remain available for responses to written requests or for posting via ULCHS publicly accessible Web site for at least three years from the date that the information was most recently updated.

## **VIII. REPORTING OF FINANCIAL CONFLICTS OF INTEREST**

Prior to the expenditure of any funds under an award funded by NIH, ULCHS will provide NIH a FCOI report compliant with NIH regulations regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan.

ULCHS will assign an institutional official to serve as the FCOI DO within the eRA Commons FCOI Module. The FCOI DO has the authority to submit FCOI reports to the NIH. The FCOI Module User Guide is available at Financial Conflict of Interest User Guide ([nih.gov](http://nih.gov)).

While the award is ongoing (including any extensions with or without funds), ULCHS will provide NIH with an annual FCOI report that addresses the status of the FCOI (i.e., an indication whether the FCOI is still being managed or if it no longer exists) and any changes in the management plan, if applicable.

For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing NIH-funded research project (e.g., a new SFI is identified for an Investigator who is participating in the NIH-funded research, upon the participation of an Investigator who is new to the research project, etc.), ULCHS will provide to NIH within 60 days of identifying an FCOI, an FCOI report regarding the financial conflict of interest and ensure that ULCHS has implemented a management plan and the Investigator has agreed to the relevant management plan.

The Original (initial) FCOI report will include the information required in the regulation at [42 CFR Part 50.605\(b\)\(3\)](#) or as outlined in [NIH's FAQ H.5. at Frequently Asked Questions \(FAQs\) grants.nih.gov](#).

Additional information on FCOI reporting can be found under this reference: Types of FCOI Reports Summary Chart for NIH and is available at required FCOI reports through [era commons.docx \(live.com\)](#).

## **IX. FAILURE TO COMPLY WITH ULCHS CONFLICT OF INTEREST POLICY APPLICABLE TO PUBLIC HEALTH SERVICE FUNDED AWARD**

1. When an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a FCOI, failure by the Institution to review or manage such an FCOI; and failure by the Investigator to comply with a management plan; ULCHS will within 120 days:
  - a. Complete a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of research;
  - b. Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ I.2. at Frequently Asked Questions





2. If bias is found, ULCHS shall notify NIH promptly and submit a mitigation report to NIH via the eRA Commons FCOI Module that shall address the following:
  - a. Impact of the bias on the research project, and
  - b. ULCHS plan of action or actions taken to eliminate or mitigate the effect of the bias.
  
3. Thereafter, ULCHS shall submit FCOI reports annually to NIH in accordance with the regulations and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest, ULCHS may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of ULCHS independent retrospective review. If bias is not found, no further action is required.

## **X. CLINICAL RESEARCH REQUIREMENTS**

If HHS determines that one of its funded clinical research projects 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 a Financial Conflict of Interest that was not managed or reported by ULCHS, ULCHS shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

## **XI. SUBRECIPIENT REQUIREMENTS**

A subrecipient relationship is established when federal funds flow down from or through ULCHS to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to ULCHS for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to ULCHS terms and conditions, and as such, ULCHS will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation at 42 CFR Part 50 Subpart F.

ULCHS will incorporate, as part of a written agreement with the subrecipient, terms that establish whether ULCHS FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator(s). See the NIH Grants Policy Statement Section 15.2.1 Written Agreement at 15.2 Administrative and Other Requirements ([nih.gov](http://nih.gov)).

If the subrecipient's FCOI policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with ULCHS that its policy is in compliance with the federal FCOI regulation. In this situation, the agreement shall specify the time period for the subrecipient to report all identified FCOI to ULCHS in sufficient time to enable ULCHS to provide timely FCOI reports, as necessary, to the PHS/NIH as required by the regulation (i.e., prior to the subrecipient's expenditure of funds and within 60 days of the subrecipient's identification of an FCOI during the period of an award). Therefore, the written agreement may establish a reporting requirement of FCOI is identified during the period of an award to be submitted to ULCHS within 50 or 55 days of the subrecipient's identification of an FCOI to allow ULCHS to report the FCOI within the 60-day period. The ULCHS assigned FCOI DO will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.



If the subrecipient cannot provide the certification of compliance with the FCOI regulation, the agreement shall state that the subrecipient Investigator is subject to ULCHS FCOI Policy for disclosing SFI(s) that are directly related to the subrecipient's work for ULCHS. Therefore, ULCHS will require the submission of all Investigator disclosures of SFIs to ULCHS. The agreement will include sufficient time period(s) to enable ULCHS to comply timely with its review, management, and reporting obligations under the regulation. When an FCOI is identified, ULCHS will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI Module for any FCOI is identified for a subrecipient Investigator.

## **XII. MAINTENANCE OF RECORDS**

The Institution will keep all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest), and all actions under the Institution's policy or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained by the Institution for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations. ULCHS will retain records for each competitive segment as provided in the regulation.

## **XIII. FAILURE TO COMPLY WITH THIS POLICY**

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Therefore, such Investigators who fail to comply with this policy are subject to discipline, including letters of reprimand, restriction on the use of funds, termination of employment, or disqualification from further participation in any PHS/NIH-funded research, etc., as may be deemed appropriate.

## **XIV. USEFUL FCOI AND NIH RESOURCES**

FCOI Regulation [42 CFR Part 50 Subpart F eCFR: 42 CFR Part 50 Subpart F – Promoting Objectivity in Research](#)

FCOI at [Financial Conflict of Interest | grants.nih.gov](#)

FCOI training at [FCOI Training | grants.nih.gov](#)

FCOI FAQs at [Frequently Asked Questions \(FAQs\) | grants.nih.gov](#).

Foreign grants website at [Information For Foreign Grants | grants.nih.gov](#).

NIH's Welcome Wagon letter at [NIH "WELCOME WAGON" LETTER Information for New Recipient Organizations | grants.nih.gov](#)