

Office of Sponsored Programs

Financial Conflict of Interest for Sponsored Programs Policy

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Responsible Executive: Provost

Affected Parties: All Liberty University (“Liberty” or the “University”) faculty and staff as well as any non-employees applying for, or who receive on behalf of Liberty, federal research funding by means of a sponsored grant or cooperative agreement must comply with this Financial Conflict of Interest for Sponsored Programs Policy (“Policy”).

Reason for Policy: To promote objectivity in research, institutions receiving federal research funding have an obligation to enforce written policies that ensure Financial Conflicts of Interest (“FCOI”) are managed or eliminated. Properly managing FCOI also recognizes the tension between an Investigator’s Institutional Responsibilities, and the benefits to the public good through the transfer of knowledge gained in University research to the private sector. An FCOI is not unusual; it does not imply wrong-doing or inappropriate activities. The University seeks to foster interactions and the establishment of relationships between academia and industry which can cause FCOI to arise, provided such relationships are managed to eliminate real or apparent bias in research.

Policy Statement: In accordance with the federal regulations that promote objectivity in research¹ Liberty requires that all faculty and staff who plan for and manage Sponsored Programs take action to address FCOI in compliance with this Policy. The Policy is intended to reduce or eliminate FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias resulting from an Investigator’s FCOI. The Policy also sets education and training standards for the Liberty academic community about the federal regulations for the disclosure and management of FCOI. This Policy supplements and does not replace Liberty’s other conflict of interest policies, including as set forth in Liberty’s Employee Handbook and Faculty Handbook. While this Policy applies only to Sponsored Programs, the OSP may apply the procedures of this Policy to non-federally funded research programs.

Definitions: This Policy adopts the following definitions:

¹ 42 CFR Part 50, Subpart F, <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>

Awarding Component:

An Awarding Component is the organizational unit of the government that funds the Sponsored Program.

Disclosure:

Disclosure means an Investigator's disclosure of financial interests to the University related to his or her Institutional Responsibilities in Sponsored Programs.

Entity:

An entity is an external business, company, or other such organization, and includes (but is not limited to) any partnership, corporation, limited liability corporation, unincorporated association, or other institution or organization, whether or not it is for-profit, academic, or professional.

Financial Conflicts of Interest or FCOI:

A Financial Conflict of Interest is a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of a Sponsored Program.

FCOI Committee:

If a potential FCOI is determined (as described below), the Provost will appoint an ad hoc FCOI Committee to review the case and decide if the conflict is manageable. Membership of the FCOI Committee will consist of the following: (1) IRB member, (1) IACUC member, (1) Faculty member from the discloser's department, and (1) Faculty member that has no connection to the proposed research; or, such other of members as the Provost deems appropriate in the circumstances. The FCOI Committee will determine what, if any, conditions or restrictions should be imposed by the University to manage actual or potential FCOI arising from disclosed Significant Financial Interests. The FCOI Committee is designed to ensure the integrity of the research performed by Investigators.

FCOI report:

An FCOI report is the University's report of a FCOI to an Awarding Component in compliance with the federal regulations.

Financial Interest:

A financial interest means anything of monetary value received or held by an Investigator or an Investigator's immediate family (spouse and dependent children), whether or not the value is readily ascertainable, including, but not limited to:

- salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works)
- any equity interest (e.g., stocks, stock options, or other ownership interest)

- intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests

Institutional Responsibilities:

Institutional Responsibilities are an Investigator's professional responsibilities on behalf of the University. For example, these professional responsibility activities include, but are not limited to: research, research consultation, teaching, clinical or other professional practices, and service on panels or institutional committees (such as the Institutional Review Board or the Institutional Animal Care and Use Committee).

Investigator:

An Investigator is the principal investigator, project director, co-principal investigator or any other person, regardless of title or position, including students, graduate students, and postdoctoral fellows, who is responsible for the design, conduct or reporting of research, whether funded or proposed for funding, which may include, for example, collaborators or consultants.

Management plan:

A management plan is an action plan to address an 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. The management plan shall meet the United States Department of Health and Human Services Guidelines for Promoting Objectivity in Research. See 42 CFR Part 50, Subpart F, and 45 CFR Part 94.^{2, 3}

PHS:

PHS means 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").

Research:

Research is any systematic investigation, study, or experiment designed to contribute to generalizable knowledge.

Significant Financial Interest or SFI:

A Significant Financial Interest is a Financial Interest consisting of one or more of the following interests of the Investigator and/or his or her immediate family (spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

² <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>.

³ <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94>

- For a publicly traded entity:
 - Any equity interest (stock, stock options or other ownership interest as of the date of disclosure) valued at \$5,000 or more in a single entity;
 - Remuneration valued in the aggregate at \$5,000 or more from a single entity in the last 12 months preceding the disclosure; or
 - A combination of remuneration from and equity interest in an entity which, when aggregated, is valued at \$5,000 or more.
- For a non-publicly traded entity:
 - Any equity interest (e.g., stock, stock option, or other ownership interest as of the date of disclosure); or
 - Remuneration valued in the aggregate at \$5,000 or more from an entity in the last 12 months preceding the disclosure
- For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, paid authorship, and honoraria). Equity interest includes any stock, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.
- Intellectual property rights and interests (e.g., patents, copyrights as of the date of disclosure)
 - Upon receipt of income related to such rights and interests.
- Travel
 - Investigators must disclose the occurrence of any reimbursed or sponsored travel (sponsored travel is 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 in the last 12 months preceding the disclosure.
 - This disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources. Excluded sources include: U.S. federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, and medical centers, or research institutes affiliated with institutions of higher education.
 - The Investigator's reimbursed or sponsored travel disclosure must detail:
 - Purpose of the trip
 - Identity of the sponsor
 - Destination and duration of the trip
 - Total monetary value of the trip

Significant Financial Interest Exclusions:

- Salary, royalties, or other remuneration paid by Liberty to the Investigator if the Investigator is currently employed or otherwise appointed by Liberty;
- Intellectual property rights assigned to Liberty and agreements to share in royalties related to such rights;
- 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;
- 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; or
- Income from service on advisory committees or review panels for a federal, state, or local government agency, institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Sponsored Program:

A Sponsored Program means a federally funded grant or cooperative agreement between an Awarding Component and Liberty.

Subrecipient:

A subrecipient is another party who is assigned part of the obligations and tasks under a Sponsored Program (e.g., a subcontractor or consortium member).

Training:

Each Investigator must complete FCOI training prior to engaging in any research related to any Sponsored Program at Liberty, at least every four years thereafter, and immediately under the following designated circumstances:

- When the University's FCOI policies change in a manner that affects Investigator requirements;
- When an Investigator is new to the University; or
- When the University finds an Investigator noncompliant with this Policy or the management plan for a FCOI.

The training courses are entitled ***Conflicts of Interest*** and will be provided through CITI Program, or as otherwise facilitated by the OSP.

Procedures:

When submitting a funding application to the OSP for a Sponsored Program, any individual meeting the definition of Investigator (see above) must disclose any SFI to the OSP. Please note, some non-federal sponsors also require financial disclosure.

COI Form: The method of disclosing a potential FCOI is the Conflict of Interest Disclosure Form ("COI Form").

a. Each Investigator must complete the COI Form (online), attach all required supporting documentation, and provide it to the Executive Director of the OSP prior to submission of the Sponsored Program application or as required by the terms of the Awarding Component. Required supporting documentation of the SFI that each Investigator must provide includes:

- Name of the entity with which the Investigator has a potential FCOI;
- Nature of the SFI (e.g., equity, consulting fees, travel reimbursement, honoraria);
- Value of the Financial Interest or statement that a value cannot be readily determined; and
- Description of how the Financial Interest relates to funded research.

b. Updates to Disclosure: During the term of the Sponsored Program, the Investigator is required to annually update the disclosure and include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest). If any new SFI arises during the term of the Sponsored Program, the Investigator must notify the Director of the OSP within 30 days of discovery or acquisition (e.g., through purchase, marriage, or inheritance) of such new SFI, so that any conflict resulting from the changed situation can be identified and reported and appropriate measures taken to manage, reduce or eliminate it.

c. Discretionary Disclosure: Regardless of the above minimum requirements, an Investigator, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interests or be perceived to present a conflict of interest in the entity and the Investigator's Institutional Responsibilities. Disclosure is a key factor in protecting the Investigator's reputation and career from potentially embarrassing or harmful allegations of misconduct.

COI Form Evaluation:

Review of Disclosures: The Executive Director of the OSP, or his or her designee, shall conduct an initial review of all financial disclosures prior to the Investigator's expenditure of any funds to determine whether a FCOI exists. A FCOI exists when the Executive Director's review reasonably determines that an SFI could directly and significantly affect the design, conduct or reporting of the proposed Sponsored Program, or could be perceived to do so.

Determination of Conflict: After a review of the COI Form, if a potential FCOI is determined to exist by the Executive Director, the disclosure will be referred to

the FCOI Committee. The FCOI Committee, in cooperation with the Investigator, shall develop a management plan that details proposed steps that will be taken to manage, reduce or eliminate any actual or potential conflict of interests presented by an SFI. At a minimum, the management plan shall address such issues as:

- Public disclosure of the SFI by a written response to any requestor within five business days of a request, and a timely update of such information as requested;
- Review of research protocol by independent reviewers; and
- Monitoring of research by independent reviewers.

SFI's Not Disclosed: The FCOI Committee will review disclosures of SFIs, make determination of FCOIs, and implement a management plan within sixty days whenever there is a SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution.

FCOI Committee Conditions/Restrictions: The specifics of Financial Interests and their relation to the proposed research activity may vary considerably. Therefore, it is not possible to guarantee that research may proceed under a management plan in any or all cases of FCOI.

If an appropriate management plan cannot be developed to achieve the goals of this Policy, the FCOI Committee will determine what conditions or restrictions, if any, should be imposed by the University to manage actual or potential FCOI arising from disclosed SFIs. These conditions or restrictions may include the following:

- Modification of the research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of SFIs; or
- Severance of relationships that create actual or potential FCOI.

Appeal of Decision: Should an Investigator wish to appeal a decision made by the FCOI Committee, he or she may present the appeal to the Provost, who will consider the case and make a final determination after consultation with the FCOI Committee.

Management Directive & Memorandum: The approved management plan and any conditions or restrictions shall be incorporated into a memorandum drafted by the Executive Director of the OSP at the direction of the Provost that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the business enterprise or entity. The memorandum shall be signed by the Investigator and the Investigator's supervisor (usually an academic chair and/or dean of the respective department). The memorandum shall be reviewed and acknowledged by the Investigator's dean or department head. Actual or potential FCOI must be satisfactorily managed, reduced or eliminated in accordance with this Policy prior to accepting any award, or they will be disclosed to the Awarding Component to ensure that the University has implemented a management plan in accordance with the federal regulations.

Record Retention: Records of Investigator financial disclosures and of actions taken to manage actual or potential FCOI shall be retained by the OSP until the later of (i) three years after the final expenditures report is submitted to the PHS (NIH) for the award to which they relate, and (ii) the resolution of any government action commenced during such three-year period involving those records.

Confidentiality: To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be kept confidential; however, the University may make such information available as provided elsewhere in this Policy. If the University provides such information to an outside entity, the University will make reasonable attempts to notify the Investigator.

Violations of Policy: Whenever an Investigator has violated this Policy or the terms of the management plan memorandum, the Executive Director of the OSP shall recommend sanctions to the Investigator's supervising University official.

Treatment of Subrecipients:

Subrecipients from other institutions must comply with this Policy. If the Sponsored Program will be carried out through a subrecipient:

- The subrecipient shall certify in a written agreement that its research FCOI policy complies with the requirements of the applicable federal regulations, and that it will report any FCOI of its Investigators to the University with sufficient time for the University to make a timely report to the Awarding Component;
- If the subrecipient is unable to certify compliance, the subrecipient shall enter into a written agreement that provides legally enforceable terms requiring its Investigators to report SFIs to the University pursuant to this Policy and associated procedures; and
- The agreement must specify the time periods for the subrecipient to report identified FCOI to the University. The time periods must be sufficient for the University to make any reports required by federal regulation.

Retrospective Review: The University is required to conduct a retrospective review within 120 days in those cases of non-compliance with federal regulations but is not required to report the review to the Awarding Component. The University is required to notify the Awarding Component promptly and submit a report to the Awarding Component only in cases where bias is found. The report will address the impact of the bias on the Sponsored Program and the actions the University has taken, or will take, to eliminate or mitigate the effect of the bias.

Responding to Public Requests for Information about Sponsored Programs:

The University shall respond in writing within five business days to requests from the public for information concerning any SFI disclosed to the University if: (i) the SFI was disclosed and is still held by the senior/key personnel (the Investigator or project director and any other person identified as senior/key in the Sponsored Program application or other reports); (ii) the University determines that the SFI is related to the Sponsored Program; and (iii) the University determines that the SFI is a FCOI. The response will be made in writing, postmarked within five business days, and include the Investigator's name, a description of the interest, and its dollar value range as required by the federal regulations.

Institutional Responsibilities:

The Executive Director of the OSP has the responsibility to receive and initially review all COI Forms to determine whether a FCOI exists (including assessing whether or not the Investigator's SFI is likely to directly and significantly affect the design, conduct or reporting of the proposed research, creating a FCOI); make recommendations to the FCOI Committee; work with the FCOI Committee to implement a management plan to be approved by the FCOI Committee; monitor the management plan; and make reports as required by the federal agency rules, policies and requirements.

For an NIH-sponsored project, the University must submit an FCOI report to the NIH within sixty (60) days if during the period of award (i) the University determines that an FCOI exists for an Investigator who is newly participating in the project, or (ii) Within 60 days for new, or newly identified, FCOIs for existing Investigators.

FCOI reports must also be submitted if a PI fails to comply with the Institution's FCOI policy or the FCOI management plan appears to have biased the design, conduct or reporting of the NIH funded research.

Academic chairs and/or deans have the responsibility to acknowledge and sign off on an approved management plan that is incorporated into a memorandum that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the business enterprise or entity.

Deans have the responsibility to review and monitor the research activities in compliance with such memoranda in their departments.

The Provost, or his or her designee, has the responsibility to appoint members of the ad hoc FCOI Committee and to hear any appeals from that committee's findings.

The FCOI Committee has the responsibility to determine what conditions or restrictions, if any, should be imposed by the University on an employee to manage actual or potential FCOI arising from disclosed SFIs.

Sanctions:

Investigators who fail to comply with the requirements of this Policy or with a FCOI Committee management plan shall be subject to appropriate disciplinary action, up to and including termination of employment.

Exclusions: None.

Review Cycle: Every two years or as needed. The Provost will approve all OSP policies.