

## **Financial Conflict of Interest Policy**

### **Overview:**

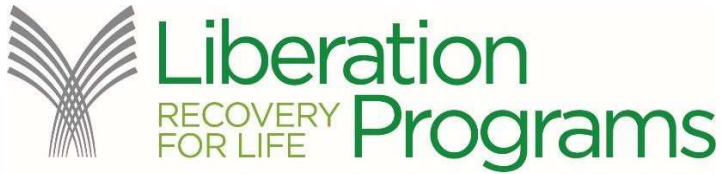
Liberation Programs, Inc.'s Financial Conflicts of Interest (FCOI) Policy protects the objectivity and integrity of the work of Liberation Programs and its individual administrators and staff members. The Policy is designed to ensure that staff members identify, disclose, and appropriately manage or eliminate situations in which their personal or familial interests might otherwise compromise or appear to compromise their objectivity as researchers or administrators. An effective conflict of interest policy helps both to safeguard the work and reputations of Liberation Programs staff members and to ensure the organization's compliance with federal and other regulatory requirements relating to conflicts of interest. The U.S. Department of Health and Human Services (HHS) has issued a final rule in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). This policy addresses the responsibilities of LPI, Investigators, and staff in both safeguarding research objectivity and complying with the requirements of all applicable state and federal regulations.

The Policy requires staff to file disclosure forms annually and to update their disclosures when circumstances change. All "Investigators" must update their forms within 30 days of discovering or acquiring a new financial interest related to their responsibilities.

In addition, the FCOI Policy requires ALL investigators of sponsored research to report financial interests related to their job responsibilities BEFORE filing applications or proposals for external funding.

### **Policy:**

- I. No Research or technology transfer activities occurring at, on behalf of, or through Liberation Programs Inc. shall be adversely affected by the financial interests of persons involved in those activities. Any investigator possessing a financial interest related to their Organizational Responsibilities must disclose the interest to the CFO at least annually and/or prior to participating in a research or technology transfer activity. The CFO is responsible for reviewing disclosures and instituting an adequate plan for the elimination, reduction or management of any identified financial conflicts of interest. The goal of this policy is to protect; research participants, the integrity and credibility of activities related to research and to maintain public trust and confidence in Liberation Programs and its employees.
- II. All Research and technology transfer activity undertaken at Liberation Program's shall be conducted in compliance with the following regulations and policies, as applicable:
  - a. PHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F August 25, 2011);
  - b. PHS regulations on Responsible Prospective Contractors (45 CFR Part 94 August 25, 2011);
  - c. Any applicable State of Connecticut regulations.



- III. Persons failing to comply with this policy shall be subject to sanctions as provided herein.
- IV. **Investigator Responsibilities** - All Investigators are required to:
- A. Disclose financial interests:
    - Annually;
    - Within 30 days of discovering or acquiring a financial interest;
    - In the case of Sponsored or Reimbursed Travel, the disclosure must be made within 30 days of the trip end;
    - Regarding the disclosure of sponsored or reimbursed travel, if an Investigator can reasonably anticipate the occurrence of travel, the Investigator may elect to disclose such travel up to twelve (12) months in advance of the anticipated travel. If an advance disclosure of travel becomes materially inaccurate, the Investigator must provide an updated disclosure within 30 days of the change;
    - Upon direction from the CFO.
  - B. Disclose individual or family members' financial interests that reasonably appear to be related to their Organizational Responsibilities or have any of the following financial interests in an entity that is sponsoring the research, or an entity that is manufacturing the product or service being tested:
    - Any remuneration from the entity in the previous twelve months that exceeds \$5,000, when aggregated for the individual and their immediate family. (Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, or paid authorship);
    - Any equity interest in the entity (equity interest includes any stock, stock option, or other ownership interest);
    - Any intellectual property rights and interests;
    - Any governance or executive relationship with the entity (e.g., founder, board of director, CEO).
  - C. Required Financial Conflict of Interest (FCOI) Training:
    - 1. Liberation Programs offers self-directed, online, FCOI training through the online learning platform Relias. Per Federal regulations and LPI policies, Investigators are required to complete FCOI training:
      - a. At least every 4 years;
      - b. As part of the on boarding process after joining LPI;
      - c. As mandated by LPI, upon determination of non-compliance with this policy or an existing Management Plan;
      - d. When LPI revises this policy in any manner that affects the requirements of investigators;
      - e. As otherwise dictated by LPI.
  - D. Comply with any Management Plan established by LPI.
  - E. **Principal Investigator Responsibilities** - in addition to the responsibilities outlined for all Investigators above, Principal Investigators (PI's) are required



to:

1. Ensure all Investigators involved in a research project, including newly hired Investigators, have a current financial interest disclosure on file prior to their participation in the project;
  - Ensure all Investigators involved in a research project promptly disclose any new or updated financial interests;
  - Ensure all Investigators involved in a research project have completed the FCOI training required under this policy;
  - Identify the Key Personnel on a research project upon request;
  - Indicate, upon submission of a proposal/application to LPI, if they or any project Investigators have a Significant Financial Interest (SFI) that may be related to the proposed project;
  - Indicate, upon submission of a proposal/application to LPI, if they or any project Investigators have a Significant Financial Interest (SFI) that may be related to the proposed project.

#### V. Review of Disclosures

LPI shall review Investigators financial interest disclosures and determine if the financial interest is "significant" and if so, determine if the interest is related to the Investigator's research.

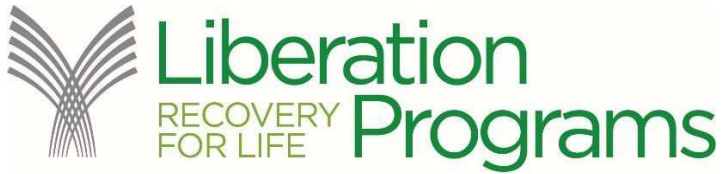
- If additional information is needed during the review process, LPI shall send a request for clarification to the Investigator explaining the details of such request.
- Depending on the nature of the disclosed SFI, LPI may implement measures regarding the Investigator's participation in the research project between the date of disclosure and the completion of the SFI review.

#### VI. Management of FCOI

1. LPI determines the criteria used for, and adequacy of all management plans (low, moderate, and high). FCOI management plans will be created as needed and will address the following key areas: 1) The nature of the conflict; 2) the relatedness of the conflict to the research; 3) the perceived risk to the integrity of the research as a result of the conflict; 4) if applicable, the specific risks to human subjects; 5) if the conflict can be sufficiently managed by a management plan; and 6) the perceived risk to the reputation of the institution.
2. LPI's charge is to review and manage financial conflicts of interest (FCOI) of individual Investigators involved in research at Liberation Programs in accordance with this Policy. LPI Finance Team will develop new and review renewals of FCOI management plans as needed. The Finance team reports to Liberation Programs' Chief Executive Officer.
3. The CFO will share with the other information obtained and determinations made that are relevant to inform and coordinate the work of each committee. In addition,

LPI may seek consultation or escalate a conflict-of-interest issue or management plan to the CEO for review and input.

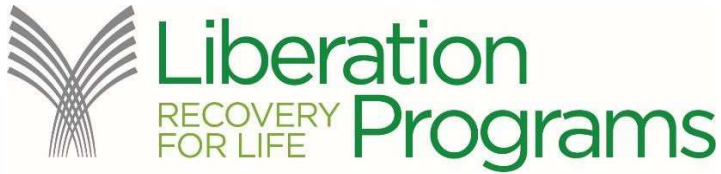
4. If the CFO determines that a reported SFI constitutes an FCOI relating to a research project, it shall develop and implement a Management Plan specifying terms and conditions that have been, or will be, taken that in the reasonable judgement of The CFO or CEO and will reduce or manage the FCOI and may contain one or more of the following terms and conditions:
  - Disclosure of financial interest(s) relating to conflicted research study(ies) in publications, presentations, and any public communication of research results;
  - Disclosure of financial interest(s) relating to conflicted research study(ies) to all research personnel affiliated with and potential human subjects participating in the research;
  - Prohibited from obtaining informed consent of human subject participants;
  - Prohibited from production of data involving subjective scoring or similar methods;
  - Prohibited from conducting data analysis;
  - Prohibited from performing adverse event causation analysis;
  - Provide research personnel with access to a senior staff member;
  - If decision maker, recuse oneself from making future decisions on behalf of LPI relating to financial interest(s);
  - Update financial disclosure within 30 days of known changes;
  - Upon request, provide a Management Plan Compliance Report to LPI;
  - Upon request, make available all research data and results for independent data monitoring;
  - Upon request, provide information for independent review of study design;
  - Prohibited from using LPI assets and facilities relating to conflicted entity(ies);
  - Prohibited from participating in negotiations on behalf of LPI and conflicted entity(ies);
  - Prohibited from disclosing proprietary information belonging to LPI to conflicted entity(ies).
5. In developing a Management Plan, The CFO may conduct factual inquiries and consult with and receive recommendations from such persons as the CFO or CEO.
6. A completed or updated Management Plan will generally serve as such written approval.
7. Investigator must submit FCOI to The Finance Team.
  - FCOI identified due to an updated disclosure after a study is approved, may result in activity holds until the conflict is resolved.
8. The CFO is responsible for reviewing the management plan and the consent form language to ensure whether the financial interest(s) and its management plan adequately protect the rights and welfare of human subjects. They may suggest that;



- Additional actions be taken to minimize risks to human subjects;
  - Changes to the kind, amount, and level of detail of information in the consent form be provided to human subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management terms and conditions applied.
9. For PHS-funded research, the actions detailed above (sections F and G) will be completed prior to the expenditure of any research project funds, or within 60 days of a disclosure of an SFI during the course of a research project by an existing Investigator or an Investigator new to the project.
10. Whenever a Management Plan is implemented, LPI shall take such actions as it deems reasonable to audit and/or monitor compliance with the Management Plan, including obtaining regular reports from individuals and committees charged with oversight responsibilities in connection with FCOI management plans. This audit and/or monitoring of compliance will be conducted until the completion of the research project or until the Management Plan is no longer required.
- VII. Management of Other Interests
- When a disclosure of SFI is determined not to constitute an FCOI, or disclosure of non-SFI related to human subjects research, LPI may determine that some type of management or oversight of the interest is appropriate before certain research activities may proceed. LPI may specify additional terms and conditions to manage these other interests.
- VIII. PHS-Funded Research through Subrecipients

If the PHS-Funded Research or portions of it is carried out through a subrecipient, LPI will take reasonable steps to ensure that any subrecipient Investigator complies with 42 CFR Part 50, Subpart F by incorporating the following as part of the written agreement with the subrecipient:

- Terms that establish whether this policy or the subrecipient's FCOI policy will apply to the subrecipient Investigators;
  - Time period(s) for the subrecipient to report all identified FCOI or for submission of all subrecipient Investigator SFI disclosures to LPI.
- IX. Publicly Accessible Information
11. This policy shall be available via Liberation Programs publicly accessible web site.
12. For PHS-Funded Research, LPI shall make information concerning significant financial interests that meet the criteria below available to the public, upon written request for such information:
- SFI was disclosed and is still held by Senior/Key Personnel (as defined in this policy);
  - LPI determined the SFI is related to a PHS-Funded Research project;
  - LPI determined the SFI constitutes an FCOI;



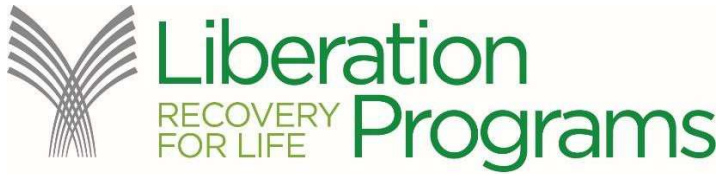
- The above information made available shall consist of the minimum elements as required by 42 CFR Part 50, Subpart F and shall be provided by written response to the requestor;
- The above information shall remain available for public request for at least three years from the date that the information was most recently updated.

X. Retrospective Review of PHS-Funded Research

1. Whenever LPI identifies an SFI that was not disclosed in a timely manner or was not previously reviewed by LPI during an ongoing PHS-Funded Research project, LPI shall within 60 days:
  - Review the SFI;
  - Determine whether it is related to a PHS-Funded Research project;
  - Determine whether an FCOI exists;
  - If LPI determines an FCOI exists, LPI shall implement (at least on an interim basis) a Management Plan that specifies the actions that have been taken and will be taken to manage such FCOI;
2. Whenever an FCOI related to a PHS-Funded Research project is not identified or managed in a timely manner due to non-compliance by LPI or an Investigator, including if an Investigator fails to comply with a Management Plan, LPI shall:
  - Notify the Chief Executive Officer (CEO) via email communication;
  - Within 120 days of non-compliance identification, complete and document a retrospective review of the Investigator's activities and the research project. Documentation of the review will include all elements as specified by 42 CFR Part 50, Subpart F;
  - Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report and specify the actions that will be taken to manage the FCOI moving forward;
  - If bias is found, notify the PHS Awarding Component promptly and develop and submit a mitigation report. The mitigation report shall consist of the minimum elements as required by 42 CFR Part 50, Subpart F;
  - Submit FCOI reports to the PHS Awarding Component annually thereafter for the duration of the research project.

XI. Sanctions and Remedies for Violation of Policy

1. If LPI determines an Investigator has violated this policy, including failure to submit required disclosures or failure to comply with the requirements of a management plan, The CFO shall report the violation to the Chief Executive Officer (CEO). The CEO shall take reasonable steps to respond appropriately to violations, including, but not limited to:
  - Suspending research activity expenditures;
  - Administratively suspending any research study related to the FCOI;
  - Instituting disciplinary measures up to and including suspension or termination.



2. If required to do so, LPI will submit to HHS, or permit on site review of, all records pertinent to compliance with this policy and federal regulations.
3. In the case in which it is determined that a PHS-Funded Research project 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, LPI shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and shall request an addendum to previously published presentations.

## XII. Record Keeping

1. LPI shall maintain records relating to:
  - All Investigator disclosures of financial interests;
  - LPI's review and response to such disclosures;
  - Actions taken under this policy or retrospective reviews.
2. For PHS-Funded Research, these records shall be maintained for at least three years from the date the final expenditures report is submitted to the PHS Awarding Component or as required by 45 CFR 74.53(b) and 92.42(b). For all other research, these records shall be maintained for at least three years from the date of the final expenditures report.

## XIII. Definitions

**Compensation:** means any remuneration, including salary and payment for services not otherwise identified as salary such as consulting fees, honoraria, and paid authorship.

**Covered Persons:** the principal investigator and any other individual involved in the design, conduct, or reporting of funded research, under the Liberation Program's workforce and if applicable, family members.

**Disclosure:** an Investigator's provision of information about their financial interest(s) to Liberation Programs.

**Equity Interest:** any financial interest in the profits of, or stock of, a commercial or non-profit enterprise, a stock option, or any other ownership interest in a commercial or non-profit enterprise.

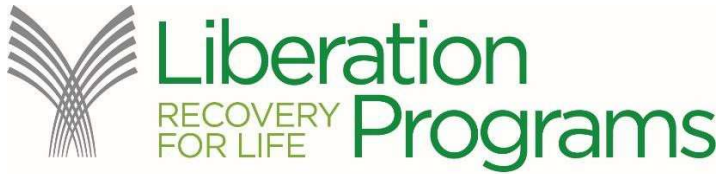
**Entity:** any domestic or foreign, public or private, for profit or non-profit legal entity or organization other than Liberation Programs, any agency of the State of Connecticut, or the federal government.

**Family Member:** an Investigator's spouse, domestic partner, or dependent children.

**Financial Conflict of Interest (FCOI):** a significant financial interest that is related to and could directly and significantly affect the design, conduct, or reporting of the Research.

**Financial Interest:** anything of economic or monetary value, whether or not the value is readily ascertainable, possessed by an Investigator and his/her family member (see definition above).

**Intellectual Property (IP):** IP is defined as ownership and associated right relating to scientific discoveries, technological advances, compilation, and original works. Intellectual Property includes Patents, Trademarks, Copyrights, Trade Secrets and other species such as computer software, Mask Work, printed material, or Tangible Property. The formal



protections provided by Patents, Copyrights or Trademarks may be used to preserve some Intellectual Property from unauthorized use or misappropriation. Intellectual Property is created when something new and valuable has been conceived or developed, or when unusual, unexpected, or non-obvious results have been discovered with existing technology and which can be applied to some useful purpose. Intellectual Property can be created by one person or co-created by several.

**Investigator:** any employee of LPI or staff member of another institution who is engaged in research at facilities owned, leased or operated by LPI and who is responsible for the design, conduct or reporting of research. Investigators typically include, but are not limited to the following roles, the Principal Investigator, Project Director, Co-investigator, and Senior/Key Personnel (see definition of Senior/Key Personnel).

**Management Plan:** a written plan to address a financial conflict of interest to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

**PHS:** the Public Health Service of the U.S. Department of Health and Human Services and any PHS awarding components to which authority may be delegated, including without limitation the National Institutes of Health.

**PHS Awarding Component:** the organizational unit of the Public Health Service that funds Research that is subject to 42 CFR 50, subpart F.

**PHS-Funded Research:** any research or sponsored activity for which funding is available from a PHS awarding component through a grant or cooperative agreement, however authorized, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

**Principal Investigator (PI):** any person designated with the title of "Principal Investigator" of a research or sponsored project having primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration, and implementation.

**Reimbursed Travel:** travel activity for which the travel Expenses are paid directly by the Investigator, who is then reimbursed by an entity for such travel expenses.

**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) and includes any activity for which PHS research funding is available.

**Senior/ Key Personnel:** the program director/principal investigator (PD/PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

**Significant Financial Interest (SFI):** an investigator or family member's financial interest that reasonably appears to be related to an Investigator's Institutional Responsibilities and meets one or more of the following criteria, after accounting for any specified exclusions.





**Financial Conflict of Interest Policy Agreement and Attestation Form**

I, the undersigned (Investigator or Staff member) have received the Liberation Programs, Inc. Financial Conflict of Interest policy and agree to comply with all of the terms and conditions thereof. In addition, I hereby certify and affirm that I have complied with the Financial Conflict of Interest policy and procedure for all periods prior to the date hereof during which I was an Investigator or Staff member, as applicable. This policy is required on an ongoing basis as part of your employment with Liberation Programs, Inc.

Received and accepted by:

Print Name:

Signature:

Date:

**Training Requirement**

In fulfillment of the FCOI training requirements, Liberation Programs, Inc. requires its employees to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at: <http://grants.nih.gov/grants/policy/coi/fcoi-training.htm> in accordance with the requirements and expectations of this Policy. All employees must print a certification of completion at the end of training and send it to the Quality Department for tracking purposes via email. ([Quality@liberationprograms.org](mailto:Quality@liberationprograms.org))