



### **Strategic Sponsored Work**

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## **FINANCIAL CONFLICT OF INTEREST TRAINING**

These adapted excerpts are from the NIH Conflict of Interest tutorial and are related to the LANL PI/key personnel responsibilities under NIH regulations.

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In this tutorial, the term

- "regulation or FCOI regulation" refers to the NIH regulation which applies to both grants and contracts;
  - "investigator" refers to any person named on the budget of a PHS proposal/project;
  - "disclosure" refers to the Investigator's disclosure of financial interests to the [Laboratory]; and
  - "report" refers to the [Laboratory's] report of identified FCOIs to the NIH.
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### **What is the purpose of the Financial Conflict of Interest (FCOI) regulation?**

The FCOI regulation was established to promote objectivity in research by setting requirements to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under NIH grants, cooperative agreements, or contracts will be biased by any conflicting financial interest of an Investigator.

### **Why is it important to comply with the regulation?**

Complying with disclosure requirements ensures that the Laboratory can identify, manage, reduce, or eliminate FCOIs so that the research is unbiased, and the public trust is preserved.

### **Who is covered by this regulation?**

Institutions and Investigators (all persons named on the budget(s) on a PHS proposal or who work on a PHS project) must comply with the regulation. The regulation applies to Laboratory proposals to, or projects for, any PHS agency for grants or cooperative agreements for research or research contracts whether in response to a solicitation or otherwise. However, the regulation does not apply to applications for Phase I support under the Small Business Technology Transfer (STTR) program.

### **What about subrecipient institutions?**

The regulation also applies to Investigators working for sub-grantees/contractors/subcontractors/ collaborators. The NIH regulation's definition of Investigator includes the Investigator's spouse and dependent children.

LANL is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified financial conflicts of interests for subrecipient Investigators to the NIH. LANL must incorporate, as part of the subcontract with a subrecipient, terms that establish whether the Financial Conflict of Interest policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or Financial Conflict of Interest reporting requirements.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to LANL in sufficient time to allow the LANL to report the Financial Conflict of Interest to the NIH to meet its reporting obligations.

Subrecipient institutions that must comply with LANL's policy must submit all Investigator disclosures of Significant Financial Interests to LANL in sufficient time to allow for LANL to review, manage and report identified FCOIs to the NIH. LANL is responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH.

### What if LANL is the subrecipient institution?

For proposals/projects where LANL is not the lead, the lead/contact LANL PI needs to submit a cover sheet and everyone on the proposal/project needs to submit disclosure statements and training certificates to [FCOI@lanl.gov](mailto:FCOI@lanl.gov). Do not submit disclosure statements to other institutions. LANL review your disclosure statement and determine if any FCOIs exist. If FCOIs are identified, a management plan will be put into place and the lead institution of the affected proposal/project will be notified of the FCOI so that they may report it to the sponsor. Letters from LANL attesting to our policy cannot be signed and returned to the lead institution until everyone named on the proposal/project have completed training, submitted disclosures, and any identified FCOIs have been managed.

### Definitions

- A *Financial Conflict of Interest (FCOI)* exists when the Laboratory designated official(s) reasonably determines that a Significant Financial Interest (defined below) could directly and significantly affect the design, conduct, or reporting of NIH-funded research.
- *PHS* refers to the U.S. Public Health Service, a Federal Department of which the CDC, FDA, and NIH are agencies.
- **Institution** refers to any domestic or foreign, public or private, entity or organization (excluding a Federal agency), including the Laboratory, that is the direct and primary recipient of NIH grant funds or that submits a proposal for a research contract whether in response to a solicitation from the NIH or otherwise, and is accountable to NIH for the performance of the project/contract, the appropriate expenditure of grant/contract funds by all parties, and all other obligations of the grantee/awardee, such as compliance with the terms and conditions of NIH grant/contract awards, including FCOI.
- **Investigator** refers to the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the NIH or proposed for such funding, including Investigators working for subgrantees/contractors/subcontractors/collaborators. The term Investigator includes the Investigator's spouse and dependent children.
- *NIH* is the National Institutes of Health, a Federal Agency whose mission is to improve the health of the people of the United States. NIH is a part of the Public Health Service, which is part of the U.S. Department of Health and Human Services.
- The 2011 revised regulation defines a "**Significant Financial Interest**" as follows:
  - 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:
    - With regard to any 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;
    - With regard to any 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, stock option, or other ownership interest); or

- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators also must disclose the occurrence of any 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 their institutional responsibilities; provided, however, that 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, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- The term *significant financial interest* does **not** include the following types of financial interests:
  - salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
  - any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
  - 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, 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.

## Reporting

Under the 2011 revised regulation, Investigators are required to disclose their Significant Financial Interests (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities:

- no later than at the time of application for PHS-funded research;
- within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and
- at least annually, in accordance with the specific time period prescribed by the Institution, 60 days before the annual Progress Report is due

Report by completing a Disclosure Form and submit to [FCOI@lanl.gov](mailto:FCOI@lanl.gov).

## Training

All personnel named on a PHS proposal budget must complete the FCOI training:

- prior to engaging in research related to any PHS funded research, AND at least every four years thereafter;
- when an Investigator is new to the Laboratory; or
- When an Investigator is not in compliance with the FCOI Policy.

The training consists of reading this document and taking the NIH FCOI tutorial which can be found at [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html). (2019 Training website updated)

**Upon completion of the tutorial, print a certificate and retain a copy for your records.** The certificate is good for four years. A copy of the certificate will be required when you submit your Disclosure Statement to a PI on a PHS proposal (whether LANL led or as a sub to another institution).

## Proposal Submission and Funding Release

Per the PHS Policy:

- Significant Financial Interests must be disclosed at the time of proposal submission. Therefore, proposals will not be submitted until the cover letter, all disclosures and training certificates are received.
- Financial Conflicts of Interests must be identified; a management plan put in place and reported to the sponsor prior to the expenditure of funds. Therefore, program codes will not be opened until all disclosures have been updated, new personnel have been trained, and all identified FCOIs have management plans in place and have been reported to NIH.
- Subcontract institutions must verify that they have a FCOI policy in place that adheres to the 2011 FCOI regulation and their FCOIs must be managed and reported prior to their expenditure of funds. Therefore, subcontracts will not be executed by Procurement until subcontract institutions have satisfied these requirements.

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## In Closing

It is vitally important that we - the NIH, the Laboratory, and Investigators - work together to ensure objectivity in research. Responsibilities should be fulfilled thoughtfully and in compliance with all Federal and Institutional requirements. Maintaining objectivity and identifying potentially conflicting financial interests in research will assure that research is unbiased and will maintain the public's trust in the research endeavor. The future of the entire research enterprise depends on the actions that we take today.

In case of questions about a potential conflict and how to ensure objectivity in NIH-funded research, Investigators should consult the Laboratory procedure and/or email [FCOI@lanl.gov](mailto:FCOI@lanl.gov). The National Institutes of Health also has information available on its web site that may be helpful in answering questions related to grants and cooperative agreements <http://grants.nih.gov/grants/policy/coi/index.htm>.