Disclosure of Significant Financial Interests & Management of Financial Conflicts of Interest, Public Health Service Research Awards

Effective: 08/24/12

I. SUMMARY

PURPOSE, SCOPE AND APPLICATION

The federal Department of Health and Human Services (HHS) has determined, pursuant to 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, as revised on August 25, 2011, that effective no later than August 24, 2012, Public Health Service (PHS)-sponsored Investigators shall be subject to specific requirements regarding the disclosure and management of conflicts of interest with regard to research in order to provide a reasonable expectation that PHS-sponsored research will be conducted free of bias resulting from Investigator financial conflicts of interest.

These regulations require the Laboratory to maintain a written policy on conflict of interest disclosure as a condition for receiving PHS awards. Therefore, the Laboratory is obligated to establish this policy consistent with these regulations to require disclosure, and identification and management of financial conflicts of interest for all Investigators supported by PHS (NIH, CDC, FDA, etc.) research awards and other non-federal sponsors that adopt the PHS policy, (for example, American Heart Association and the American Cancer Society).

The PHS policy and this procedure applies to all grants and cooperative agreements with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are for research. These federal requirements are applicable to all proposals for extramural awards submitted to PHS.

Consistent with PHS regulations, this procedure will be made available via a publicly-accessible website (http://www.lanl.gov/projects/feynman-center/resources/fcoi.php). All Los Alamos National Security, LLC (LANS) Investigators (that is, individuals who, regardless of position or title, are responsible for the design, conduct or reporting of PHS supported research, and Investigators seeking PHS research support) shall be informed where this procedure and relevant reporting requirements may be accessed via the web.

II. DEFINITIONS

Designated Official(s)

The Sponsored Research Program Manager and the Technology Transfer Division leader are the Laboratory officials who have been designated to and review Investigators' completed Disclosure of Financial Interest forms and who may determine whether the Investigator has a Financial Conflict of Interest. The various program offices will solicit disclosures from Investigators, on behalf of the designated officials, at the time of proposal submission and annually 90 days before the progress reports are due to the sponsor.

Financial Conflict of Interest

A Significant Financial Interest that is related to the PHS-funded research activity in which the Investigator is engaged and that could directly and significantly affect the design, conduct and/or reporting of PHS-funded research activity.

Institutional Responsibilities
An Investigator's professional responsibilities on behalf of LANS, and as defined by LANS, include, but are not limited to, activities such as research, research consultation, outreach, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator
Any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the PHS-sponsored project. For LANS, this includes any person on the budget of a project funded by PHS or proposed for such funding.

Principal Investigator
An Investigator, who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.

Key Personnel
A PHS research Project Director/Principal Investigator and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Key Personnel are identified in the contract proposal, grant, or contract.

Research
As used in the PHS policy and this procedure, indicates any activity for which research funding is available from a PHS-awarding agency, including but not limited to research grants, cooperative agreements, center grants, infrastructure awards, program projects or research resources awards, and Phase II Small Business Technology Transfer Research (STTR) awards. Excluded from the PHS policy and this procedure, consistent with the underlying federal regulations, are Phase I Small Business Technology Transfer Research (STTR) awards.

Significant Financial Interest (SFI)
Consistent with federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator or the Investigator's spouse and dependent children for the following categories, except in the case of travel:

A. With regard to any publicly-traded entity, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in Paragraph 5, below) 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. Included are salary (other than salary described in Paragraph D, below), consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value.

B. With regard to any non-publicly-traded entity, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in Paragraph D, below) 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, registered domestic partner, or dependent children) holds any equity interest.

C. Intellectual property rights and interests, upon receipt of income, exceeding $5,000 during the twelve months preceding disclosure from such rights and interests. However, Significant Financial Interests do not include royalties received from the Laboratory.

D. In the case of travel, sponsored travel or reimbursements made to or on behalf of, the Investigator, regardless of amount, by a for-profit or non-profit entity related to the Investigator's Institutional Responsibilities. However, Significant Financial Interests do not include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.

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

- Salary, royalties, or other payments made by Los Alamos National Security, LLC (LANS) to a LANS Investigator who is currently employed or otherwise appointed by the Laboratory;
- income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government, agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.
- Income from investment vehicles, such as mutual funds and retirement funds, in which the Investigator does not directly control investment decisions.

III. PROCECURE FOR FOLLOWING PHS FCOI POLICY

A. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

Investigators seeking PHS research funding or receiving PHS research support are required to disclose Significant Financial Interests related to their Institutional Responsibilities.

The requirement that an Investigator disclose a Significant Financial Interest under the terms of the PHS policy does not in and of itself imply the existence of an actual or potential financial conflict of interest. The existence of a financial conflict of interest, based upon the relationship of the Investigators' Significant Financial Interests to the Investigators' Institutional Responsibilities, is determined by a Designated Official(s) with input from the Investigator. If a financial conflict of interest is identified, the Designated Official(s) shall work with the Ethics and Compliance Office and Legal Counsel to recommend additional steps to manage or eliminate the conflict, to the Program and/or Line Manager(s) or designee(s) who is authorized to act on that recommendation.

Investigators as defined by the PHS policy, shall disclose all Significant Financial Interests related to their Institutional Responsibilities, no later than at the time of application for PHS funding.

This initial disclosure responsibility is separate from and in addition to an Investigator's ongoing duty throughout the period of a PHS research award to disclose his or her Significant Financial Interests (and those of his or her spouse and dependent children) related to the Investigator's Institutional Responsibilities:

- Within 30 days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest (with the exception of travel disclosures, noted below); and

- At least annually throughout the period of the award.

- Before joining an ongoing PHS-funded research project new Investigators must submit a disclosure of Significant Financial Interests.

Under the terms of this PHS policy, Principal Investigators must identify all personnel who are named on the budget(s) of the award who are required to disclose Significant Financial Interests.

Sponsored or reimbursed travel may be disclosed:

a) Prospectively listing all anticipated travel (including information about the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration of the trip, as well as any other information that may be required by the campus) for the 12 month period following the filing of the Investigator's annual disclosure form; and/or

b) Within 30 days of the occurrence of travel that either was not listed on the prospective annual travel report pursuant to paragraph a) or that significantly varied in the threshold reporting details from what was listed in the prospective report.

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a subcontract from the Laboratory are expected to comply with the policies and procedures for disclosure and review of a Significant Financial Interests at the institution at which they are employed or, if their institution does not have a conflict of interest policy that complies with the DHHS regulations, they must comply with the Laboratory's policies and procedures for disclosure and review of a Significant Financial Interests related to PHS sponsored awards.

Subawards issued by the Laboratory will ask the subrecipient institution to certify that its policy is in compliance with PHS conflict of interest regulations, and unless the subrecipient does not have a PHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a Financial Conflict of Interest is identified, for sending the Laboratory notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements so that the Laboratory can report the FCOI to the sponsor.

B. REVIEW OF DISCLOSURES; MANAGEMENT PLAN

With each PHS proposal, progress report, incremental funding or extension, Investigators' Significant Financial Interests disclosures will be reviewed by the Designated Official(s) to determine whether there are any Significant Financial Interests that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged.

In the event that the Designated Official(s) conclude that an Investigator's Significant Financial Interest reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded research; or is in an entity whose financial interest could be affected by the research, the Disclosure and appropriate documentation shall be forwarded to the Laboratory's Ethics and Compliance Office (EA-Ethics) for consideration. Legal Counsel (LC) and EA-Ethics would meet with the appropriate personnel (Investigator, Program/Line management) to determine if a conflict does exist. When it is determined that there is a financial conflict of interest, the appropriate Program and/or Line managers (or designees) will work with EA-Ethics and LC to develop a mitigation/management plan including whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest before the support can be accepted.

The management plan is to be implemented prior to the Laboratory's expenditure of PHS funds awarded for the research project, and shall specify the actions that are required to manage the Financial Conflict of Interest, and shall include:

- The role and principal duties of the conflicted Investigator;
- Conditions of the management plan;
- How the plan will safeguard objectivity in the research activity;
- Confirmation of the investigator's agreement to the plan; and
- How the plan will be monitored.

The same review process takes place when an Investigator reports a new Significant Financial Interest.

C. REPORTING TO PHS

Prior to the Laboratory's expenditure of any funds provided under a PHS award, the Laboratory must provide to the PHS funding agency an initial report regarding Investigator Financial Conflict of Interest. If Financial Conflicts of Interest are eliminated before research funds are expended, the Laboratory is not required to submit a report to the PHS funding agency.

During the period of the award, the Laboratory shall, within 60 days of receipt of disclosure of a new or newly-discovered Significant Financial Interest, review the disclosure, determine whether it is related to PHS-funded research, determine whether it constitutes a Financial Conflict of Interest, and if so, implement a management plan and report the Financial Conflict of Interest to the PHS funding agency.

For any Financial Conflict of Interest that the Laboratory reports to a PHS awarding agency, the Laboratory shall provide to the PHS awarding agency an annual Financial Conflict of Interest report that addresses the status of the conflict and any changes to the management plan, for the duration of the project. The annual report shall specify whether the financial conflict is still being managed or explain why it no longer exists. The Laboratory must provide annual reports to the PHS awarding agency for the duration of the project period (including extensions with or without funds).

Within 60 days of determining that a Financial Conflict of Interest exists for a new Investigator who joins an ongoing PHS-funded research activity, the Laboratory must implement a

management plan and submit a report to the PHS funding agency.

In any case in which the Department of Health and Human Services (DHHS) determines that a PHS-sponsored 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 a Financial Conflict of Interest that was not managed or reported by the Laboratory as required by the PHS policy and Federal regulation, the Laboratory shall require the Investigator 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.

D. MONITORING

The management plan put in place by the Laboratory shall specify the way in which the Investigator's compliance with the management will be monitored on an ongoing basis until completion of the PHS-funded research project.

E. RETROSPECTIVE REVIEWS AND MITIGATION REPORTS

When during the course on ongoing PHS-funded research project, the Laboratory identifies a Significant Financial Interest that was not disclosed in a timely manner by an Investigator or which was not previously reviewed, the Designated Official will, within 60 days, review the Significant Financial Interest to determine whether it is related to PHS-funded research activity, determine whether a Financial Conflict of Interest exists, and if so, implement a management plan on at least on an interim basis.

In addition, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an SFI that was later determined to be a Financial Conflict of Interest, or the Laboratory did not review or manage the Financial Conflict of Interest, or the Investigator failed to comply with a previously implemented management plan, the Laboratory must within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research. The purpose of this retrospective review is to determine if the ongoing PHS-funded research was biased in its design, conduct or reporting. The Laboratory will document the retrospective review; such documentation will include the project number; project title; name of Investigator with the Financial Conflict of Interest; name of the entity with which the Investigator has a Financial Conflict of Interest; the reasons for the retrospective review; detailed methodology used for the retrospective review; findings; and conclusions.

Based on the results of the retrospective review, if appropriate, the previously submitted Financial Conflict of Interest report should be updated to specify the actions that the Laboratory will take to manage the identified Financial Conflict of Interest going forward.

If bias was found during the retrospective review, the Laboratory will promptly notify the PHS funding agency and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the Laboratory's plans to eliminate or mitigate the effect of the bias.

F. RECORD RETENTION

Records of financial disclosures and the Laboratory's review of, or response to such disclosures, whether or not a disclosure resulted in the Laboratory's determination of a Financial Conflict of Interest, and all actions under the PHS policy or retrospective review shall be maintained for at least three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report for the subject award or as otherwise required under 45 CFR 74.53(b) and 92.42(b)(pertaining to pending litigation and audits), or where real property and equipment purchased under the award are retained beyond three years, when records are transferred to or maintained by the HHS awarding agency, or indirect cost proposals and cost allocation plans. Records relating to unfunded awards need not be retained.

G. TRAINING

All personnel working named on the budget(s) of a PHS project, must complete NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded project and at least every four years thereafter, while receiving PHS research funding, and at other times as may be required by the Laboratory in accordance with DHHS regulations. PHS-funded Investigators who are new to the Laboratory or who are joining an ongoing PHS Research Activity, must complete the training prior to engaging in research related to any PHS-funded project or provide the certificate of training from their former institution and renew their training at the Laboratory at least every four years thereafter.

H. PUBLIC ACCESS TO INFORMATION

Public requests for information under the PHS regulations and this procedure should be sent to:

FCOI@lanl.gov

or

FCOI Public Information Request
Los Alamos National Security, LLC
Sponsored Research Office, MS C334
Los Alamos, NM 87545

The Laboratory must respond within 5 business days to any request for information about Significant Financial Interests held by Laboratory personnel when the Laboratory has determined that the disclosed Significant Financial Interests are related to the PHS-funded research, and constitute Financial Conflicts of Interest. The 5-day response time shall be measured from the date that the request for information is received at the designated address until the date a response is sent to the requestor.

Disclosure forms, Disclosure Update forms, and Management Plans including determinations of Financial Conflicts of Interest under the PHS policy are public records open to public inspection, under federal law.

I. SANCTIONS

Failure of an individual to file a complete and truthful financial disclosure for pending proposals, or to properly update their disclosure when a new significant financial interest is obtained, or failure to comply with any conditions or restrictions directed or imposed to mitigate or eliminate the conflict of interest, including failure to cooperate with appointed award monitoring bodies, may grounds for discipline. Agreements with consultants who either fail to file a complete disclosure, to properly update their disclosure when a new significant financial interest is obtained or comply with any conditions or restrictions imposed may be terminated. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations or Laboratory policy.

IV. RESPONSIBILITIES

A. INVESTIGATORS, AS DEFINED BY THIS POLICY

- Must disclose all Significant Financial Interests (SFIs) related to the Investigator's Institutional Responsibilities, no later than at the time of application for PHS funding.
- Throughout the period of the PHS research award, must disclose their SFIs, and those of their spouse and dependent children:
    - Within 30 days of discovering or acquiring any new SFI; and
    - At least annually throughout the period of the award.
    - Before joining an ongoing PHS-funded research project new Investigators must submit a disclosure of Significant Financial Interests
- Principal Investigators must fully identify all personnel named on the budget(s) of the award as they are required to disclose SFIs under the terms of this procedure.
- Investigators must complete NIH-compliant training about the Laboratory's PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded project and at least every 4 years thereafter, while receiving PHS research funding and at other times as may be required by the Laboratory under this procedure.
- In cases where the Laboratory has identified a financial conflict of interest held by the Investigator and has implemented a management plan to eliminate, reduce or manage the conflict, must adhere to the terms of the management plan.
- Where DHHS determines that a PHS-sponsored 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 a Financial Conflict of Interest that was not managed or reported by the Laboratory as required by this policy and federal regulation, the Laboratory shall require the Investigator 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.

B. NON-LABORATORY COLLABORATORES, CONSULTANTS, OR SUBCONTRACTORS

Non-Laboratory collaborators, consultants, or subcontract investigators who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from the Laboratory

- Must comply with the policies and procedures for disclosure and review of SFIs at the institution at which they are employed, or, if their institution does not have a conflict of interest policy that is compliant with the DHHS regulations, they must comply with this policy and campus procedures for disclosure and review of SFIs related to PHS-sponsored awards.
- Must comply with all requirements of their institution's (or this) policy that pertain to Investigators, including completing NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded contract and at least every 4 years thereafter, while receiving PHS research funding

C. INSTITUTIONS THAT RECEIVE SUBAWARDS ISSUED BY THE LABORATORY FOR PHS-FUNDED RESEARCH

- In cases where the agreement between the Laboratory and the subrecipient specifies that the subrecipient's conflict of interest policy shall apply:
  - Must certify that the subrecipient's conflict of interest policy complies with the requirements of the DHHS regulations
  - Must review financial disclosures made by Investigators at the subrecipient institution and, if any Financial Conflicts of Interest are identified, send the Laboratory notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.
- In cases where the agreement between the Laboratory and the subrecipient specifies that the Laboratory's conflict of interest policy shall apply, must submit to the Laboratory, within the time period specified in its subrecipient agreement with the Laboratory, all disclosures by subrecipient Investigators of Significant Financial Interests, for the Laboratory's review.

D. DESINGATED OFFICIAL(s)

- Must solicit and review Investigators' SFI disclosures for each PHS proposal, progress report, incremental funding or extension, to determine whether there are any SFIs that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged.
- If an SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded research activity, the Designated Official shall forward the disclosure and appropriate documentation to EA-Ethics for consideration.
- Upon EA-Ethics determination of a Financial Conflict of Interest (see below), must develop a Management Plan specifying actions required to manage the Financial Conflict of Interest, how the plan will safeguard objectivity in the research activity, confirms the investigator's agreement to the plan, and specify the way in which the Investigator's compliance with the management plan shall be monitored.
- Must respond within 5 business days to any request for information submitted in accordance with this policy about SFIs held by personnel when the Laboratory has determined that the disclosed SFIs are related to the PHS-funded research, and constitute Financial Conflicts of Interest.
- Prior to the Laboratory's expenditure of any funds provided under a PHS award (and within

60 days of any subsequently identified financial conflict of interest), must provide to the PHS funding agency an initial report regarding Investigator Financial Conflict of Interest (including financial conflicts of interest of subrecipient investigators in cases where the agreement with the subrecipient institution specifies that they will follow the Laboratory's financial conflict of interest procedure.

- During the period of the award shall, within 60 days of receipt of disclosure new or newly-discovered SFI, must review the disclosure, determine whether it constitutes a Financial Conflict of Interest, and if so, report the Financial Conflict of Interest to the PHS-funding agency. If a Financial Conflict of Interest ceases to exist during the course of the award, updated information about the status of that Financial Conflict of Interest should be reported to the PHS funding agency.
- Must provide an annual Financial Conflict of Interest report to the PHS awarding agency addressing the status of the conflict and any changes to the management plan, for the duration of the project period (including extensions with or without funds).
- Must submit a report to the PHS-funding agency within 60 days of determining that a Financial Conflict of Interest exists for new Investigator who joins an ongoing PHS-funded research activity.
- If the Laboratory is a subrecipient of a PHS award from another institution, must report to that institution any FCOIs that LANS identifies for Laboratory investigators.

E. ETHICS & COMPLIANCE AND LEGAL COUNSEL

- Review documentation from Designated Official
- Meet with the appropriate personnel (Investigator, Program/Line management) to determine if a conflict does exist.
- When it is determined that there is a financial conflict of interest, the appropriate Program and/or Line managers (or designees) will work with EA-Ethics and LC to develop a mitigation/management plan including whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest before the support can be accepted.

F. PROGRAM & LINE MANAGEMENT

- Must determine, based on final recommendation of EA-Ethics and Legal Counsel, the conditions or restrictions that should be placed on the project to eliminate or manage the Financial Conflict of Interest.

G. SPONSORED RESEARCH OFFICE

- If the PHS award is to be conducted thru a subaward, must incorporate as part of a written agreement with subrecipients terms that establish whether the Laboratory procedure or the policy of the subrecipient (which must be compliant with DHHS regulations) will apply to the subrecipient's investigators

V. RELATED INFORMATION

For training, related forms and guidance, please access the Laboratory FCOI website at http://int.lanl.gov/org/padgs/feynman-center/market-transition/fcoi.shtml.

VI. EXTERNAL WEBSITES FOR ADDITIONAL INFORMATION

NIH FCOI Tutorial – http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

NIH FCOI Website – http://grants.nih.gov/grants/policy/coi/index.htm