

Oak Ridge National Laboratory

Policy on Research Integrity

All researchers performing research for the Oak Ridge National Laboratory (ORNL) must conform to the highest standards scientific integrity in designing, conducting, and reporting the results of scientific experiments and research. This expectation includes avoidance of personal conflicts of interest (PCOI), and the appearance of PCOIs, arising from personal and professional relationships and/or financial interests or arrangements.

Applicability

This policy applies to the following individuals, who are referred to as ORNL Staff:

- Investigators employed by UT-Battelle;
- Graduate students and post-doc researchers funded by UT-Battelle and performing research at the Oak Ridge National Laboratory (ORNL); and
- Joint Faculty Appointees and Governor's Chair Appointees performing research at ORNL or funded by UT-Battelle.

References

Applicable guidance for the research integrity and ethical conduct of research includes the following sources:

- ORNL Code on Scientific Integrity
- UT-Battelle Code of Business Ethics Conduct
- ORNL Financial Conflicts of Interest Policy

Requirements

1. ORNL Staff researchers are responsible for ensuring actions they take in connection with the preparation of proposals and the conduct and reporting of research are in conformance with ORNL standards for research integrity.
2. ORNL Staff Principal Investigators are responsible for ensuring that researchers who participate in their projects or programs are aware of the expectations set forth in this policy.
3. Questions regarding research integrity expectations will be directed to the appropriate ORNL Division Director or cognizant Associate Laboratory Director.
4. Procedures in Appendix A will be followed with regard to research proposals submitted to, and research funded by, the Public Health Service (PHS, which includes the National Institutes of Health), whether ORNL is the awardee of PHS funding or ORNL Staff are performing research funded by PHS through another institution.

Appendix A

ORNL Financial Conflicts of Interest Policy

Requirements For Research Proposals Prepared For Submission to, and/or Conducting Research with Funding from, the Public Health Service

I. Introduction

A. Purpose

This Policy (“Policy” or “ORNL Policy”) is designed to ensure compliance with Public Health Service (PHS) requirements for avoiding financial conflicts of interest (FCOIs) in the preparation of proposals to be submitted to PHS elements and in the conduct of PHS-funded research.

Compliance with this policy is mandatory, and noncompliance may result in disciplinary action up to and including termination.

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C. Guidance

42 C.F.R. Part 50, Subpart F

45 C.F.R. Part 94

PHS Final Rule, 76 Fed. Reg. 23255-93 (Aug. 25, 2011)

Questions regarding requirements should be directed to the UT-Battelle Office of General Counsel, (865) 241-4961. Questions regarding ORNL’s processes should be directed to the ALD-EESD.

D. Definitions

The terms used in this Policy have specific definitions that Investigators must be aware of in order to ensure compliance. See Attachment 1 for these definitions.

E. Summary of Responsibilities

1. *Investigators* (including Principal Investigators, project managers, participants in proposal preparation, designated assistants to the ALD-EESD, etc. (see Section II for detailed statements of the requirements)).
 - Before beginning work on a proposal for, or the conduct of research on, PHS-funded research:
 - Read this ORNL Policy, paying particular attention to the Definitions used and the guidance for preparing an SFI Form.
 - Complete the NIH on-line tutorial at http://grants.nih.gov/grants/policy/coi/fcoi_web-based_tutorial.pdf
 - Submit and update SFI Forms as required.
 - Cooperate with the ALD-EESD in identifying SFIs, FCOIs, and appropriate FCOI management actions.
 - Comply with applicable FCOI management plans.
2. *Principal Investigators* (see Section III for a detailed statement of requirements).
 - Obtain approval from the ALD-EESD for: (a) submission of proposals to PHS elements; (b) and/or participation in a PHS-funded project led by another institution.
 - Obtain an Agreement (Attachment 5) from Subrecipients defining the use of this ORNL Policy or another PHS-compliant financial conflict of interest policy to address Financial Conflicts of Interests (FCOI's) in connection with PHS-funded research project.
 - Ensure work using PHS funding is not commenced until SFI Forms have been reviewed by the ALD-EESD and FCOI determinations are made.
 - Collect all required SFI Forms and submit them to the ALD-EESD in a timely manner.
 - Monitor compliance with FCOI management plans.
 - Immediately forward any public requests for Investigator financial information to the ALD-EESD for action.
 - Cooperate with the ALD-EESD in identifying SFIs, FCOIs, and appropriate FCOI management actions.
 - Comply with applicable FCOI management plans.
3. *ALD-EESD* (see Section IV for a detailed statement of requirements).
 - Maintain and enforce this Policy, and post it on a website accessible by the public.
 - Approve ORNL proposals for submission to any element of the PHS.
 - Promptly review all SFI Forms and take appropriate action when FCOIs are identified.
 - Conduct and document a retrospective review when an SFI Form is not submitted or reviewed in a timely manner.
 - Submit a report from the retrospective review to the awarding agency as required.

- Respond in writing to public requests for Investigator financial disclosure information within 5 working days of receipt by ORNL.
- Maintain records as required by this Policy.

II. Approval of Work for PHS Agencies

A. *Approval of Proposals submitted by ORNL.*

All proposals to be submitted by ORNL for funding by any element of the PHS (including the National Institutes of Health) must be approved by the Associate Laboratory Director for Energy and Environmental Sciences Directorate (ALD-EESD) prior to submission. Requests for approval must include a completely SFI Disclosure Form ("SFI Form", Attachment 2) from each Investigator (see definitions, Attachment 1) who participated in the planning and/or preparation of the proposal and/or who has been identified as a participant in the research.

B. *Approval for Receipt of PHS Funding from Another Institution.*

1. ORNL is responsible for applying this Policy when ORNL Investigators perform research funded by the PHS, regardless who PHS funding is awarded to. The ALD-EESD is ORNL's "Designated Official" for ensuring compliance with this Policy and PHS FCOI management requirements.
2. Approval from the ALD-EESD must be obtained prior to commencing any proposal planning or preparation or research in collaboration with, in support of, or funded by another institution that has received PHS funding for the project.
3. To ensure compliance with this Policy when another institution has the lead, the ORNL Principal Investigator (PI) for the project must provide the ALD-EESD the following information and documents before commencing PHS-funded work:
 - a. Name of the lead institution.
 - b. Name and contact information for the lead institution's PI or other official.
 - c. Project name and identifying number used by the PHS.
 - d. Role of ORNL in the project (e.g., ORNL staff named in the proposal, providing research support, etc.)
 - e. Anticipated timeframe for ORNL's participation in the project.
 - f. Anticipated level of funding ORNL will receive.
 - g. A description of ORNL's research and deliverables in sufficient detail to allow reasonable determinations regarding the existence of potential FCOI's.
 - h. Any agreement or subcontract terms entered into with the lead institution regarding compliance with PHS FCOI requirements.
 - i. Completed SFI Forms from each Investigator.
4. If there is no designated ORNL PI, the individual Investigator(s) who intend to participate in the research will comply with the requirements set forth in subparagraphs 2 and 3, above.

III. Investigator Responsibilities

Investigator Responsibilities. These requirements apply to each Investigator who participates in the planning or preparation of a research proposal to be submitted to the PHS by ORNL or by another institution, and/or who will participate or is participating in research funded in whole or in part by the PHS (except proposals for, and work under, SBIR/STTR Phase 1 grants). Each Investigator must:

1. Read this ORNL Policy and complete the NOH on-line tutorial at:
http://grants.nih.gov/grants/policy/coi/fcoi_web-based_tutorial.pdf:
 - a. Before participating in the preparation of a proposal for PHS funding or performing PHS-funded research (whichever first occurs); and
 - b. Subsequently review these materials:
 - (1) Not less frequently than every 3 years if the Investigator is continuing to perform research funded by the PHS; and
 - (2) As directed by the PI, including whenever an event described in Attachment 4 occurs.
2. Execute an SFI Form that disclosing all SFIs. These forms must be subsequently updated:
 - a. Within 10 days of acquisition of a new SFI by the Investigator, his/her spouse, or a dependent child, by any means (*e.g.*, acquisition by marriage, inheritance, purchase, gift, etc.). Failure to meet this requirement in a timely manner may result in ORNL taking immediate protective action, including suspending the Investigator's participation in the research and submitting a noncompliance report to the PHS; and
 - b. Annually during the performance of work funded by the PHS in accordance with a schedule established by the Principal Investigator, whether or not there has been any change in SFIs.
3. Provide completed SFI Forms to the PI or to his or her designated assistant.
4. Cooperate with the ALD-EESC in identifying SFIs, FCOIs, and appropriate FCOI management actions.
5. Comply with any issued FCOI management plan throughout the duration of the PHS-funded work.

IV. Principal Investigator Responsibilities

Principal Investigator (PI) Responsibilities. In addition to the Investigator's requirements set forth in Section III, each PI will comply with the following additional requirements:

1. Obtain approval from the ALD-EESD to submit research proposals prepared for submission to elements of the PHS. In addition, when ORNL is not the submitting party, obtain approval from the ALD-EESD to participate in proposal preparation and/or PHS-funded research, as described in Section II, above.
2. Collect SFI Forms as required:
 - a. Prior to submitting a proposal to the ALD-EESD for approval, collect completed SFI Forms from each Investigator (see definition in Attachment 1) who participated in the planning or preparation of the proposal, and submit the Forms to the ALD-EESD as part of the proposal approval package (but not as part of the proposal). Also submit a list of all identified Investigators.
 - b. Before or after proposal submission, but in any case prior to beginning PHS-funded work, collect SFI Forms from any other Investigators who have been identified as participants in the research after the proposal was submitted, and submit them to the ALD-EESD for review. Also submit an updated list of Investigators.

Note: PHS-funded work cannot commence until the ALD-EESD has reviewed all SFI Forms and resolved any FCOIs arising from any disclosures.
 - c. During the course of the research project, collect an SFI Form from any Investigator added to the project after the initial SFI Forms were submitted to the ALD-EESD within 20 days of the Investigator commencing work on the project. Submit these forms, and a revised list of Investigators, to the ALD-EESD within 10 days of collection. FCOI reviews must be completed by the ALD-EESD within 60 days of the investigator having begun work on the project, so time is of the essence in meeting this requirement.
 - d. During the course of the research project, collect annual SFI Forms from each Investigator according to a schedule established by the PI and submit the completed forms to the ALD-EESD within 10 days of collection.
 - e. Provide the ALD-EESD an initial list of all Investigators participating in the project, and a revised list whenever:
 - i. New Investigators are added to the project; and/or
 - ii. Investigators complete their work in the project and no longer are participating.
3. Clarify and document FCOI management responsibilities with Subrecipients, using the form in Attachment 5.

4. Collect FCOI determinations from any Subrecipients that have a PHS-compliant FCOI policy and provide them to the ALD-EESD for review and filing.
5. During the course of the research project, advise Investigators if/when an event described in Attachment 4 has occurred and ensure they perform the required review.
6. For the duration of the PHS-funded work, monitor continuing compliance with any FCOI management plans that are issued as a result of FCOI determinations, and promptly report any non-compliance to the ALD-EESD.
7. Ensure the ALD-EESD receives any requests from the public for disclosure of SFI information within 1 day of receipt by ORNL.
8. Cooperate with the ALD-EESC in identifying SFIs, FCOIs, and appropriate FCOI management actions.
9. Comply with any issued FCOI management plan throughout the duration of the PHS-funded work.

Note: Attachment 6, *Principal Investigator Checklist*, may be helpful in tracking compliance with these requirements, but use of the checklist is not required.

V. ALD-EESD Responsibilities

A. *ALD-EESD Responsibilities.*

1. Serve as the ORNL Designated Official for purposes of the PHS requirements regarding the identification and management of FCOIs.
2. Read the on-line tutorial at: http://grants.nih.gov/grants/policy/coi/fcoi_web-based_tutorial.pdf.
3. To the extent desired and appropriate, identify designees in writing to perform defined requirements in this Policy on behalf of the ALD-EESD.
4. Ensure designees read this Policy and the on-line tutorial referenced above and submit SFIs for each project the designee provides assistance. Review the forms for FCOIs and take appropriate action before the designee begins providing assistance for the project.
5. Approve, require revision of, or disapprove proposals prepared for submission to the PHS.
6. Advise PIs if/when any of the following events occur to ensure compliance with the requirements set forth in Attachment 4:
 - a. ORNL revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators; or
 - b. ORNL finds that an Investigator is not in compliance with this Policy or a FCOI management plan.
7. Review SFI Forms, as set forth in Section B., below.
8. Prepare FCOI management plans and send them to the awarding agency, with a copy to lead institutions when ORNL is a Subrecipient, as required.
9. Review FCOI reports submitted by Subrecipients and take appropriate action to ensure research conducted at ORNL is not tainted by an FCOI.
10. Ensure this Policy is posted on a publicly accessible website, update the posting on the website annually, and post SFI Forms for Investigators who are key/senior personnel on the website prior to spending PHS funds.
11. Collect and maintain records as required in Section IV.D., below.
12. Provide the funding agency updated lists of current Investigators at least annually.

B. *Guidance for Review of SFI Forms.*

1. Initial SFI reviews. As soon as possible after initial SFI Forms are submitted to the ALD-EESD for review, but in any event prior to the expenditure of any PHS funding on the

project, the ALD, as the Institutional Official, will determine whether any of the disclosed SFIs constitute an FCOI. This determination will be made using the guidelines set forth in Attachment 3 to this Policy.

2. Subsequent SFI reviews. After research using PHS funding has commenced, SFI Forms will be submitted by:
 - a. Newly-assigned Investigators;
 - b. Investigators who acquire new SFIs; and
 - c. All Investigators, as annual SFI updates.

These Forms must be reviewed by the ALD-EESD within 60 days of submission to determine whether any of the disclosed SFI constitutes an FCOI.

3. FCOI determinations. If an FCOI is identified, the following steps will be completed prior to any expenditure of PHS-provided funding, or within 60 days of submission of an SFI Form after work has commenced:
 - a. The ALD-EESD will consult with the ORNL Office of General Counsel in determining an appropriate FCOI management plan.
 - b. FCOI management plans will be prepared as necessary and signed and adhered to by the disclosing Investigator. In addition, the ALD-EESD will provide the PI a copy of the FCOI management plan so the PI can monitor compliance throughout the project.
 - c. The ALD-EESD will timely submit FCOI reports to the PHS component that awarded funding, in accordance with 42 C.F.R. §50.605(b).

C. *Retrospective Reviews, Public Disclosure Policy, and Enforcement.*

1. Retrospective Reviews. If, for any reason, a requirement for reporting SFIs as established by this Policy is not completed in a timely manner, or if an SFI Form is not properly and timely reviewed, a FCOI management plan is not timely prepared, or if an Investigator fails to comply with a management plan, the ALD-EESD shall ensure that the review, interim actions, and reporting requirements in 45 C.F.R. §94.5(a)(3) are evaluated for applicability and complied with as appropriate.
2. Public Disclosure. Upon receipt of a request for information regarding financial disclosures by an Investigator, the ALD-EESD or his or her designee will analyze the request using the criteria set forth in 42 C.F.R. §50.605(a)(5)(i) and respond in writing within 5 business days after receipt. If the criteria are met, the written response will include the information required by §50.605(a)(5)(ii).
3. Enforcement. Investigators who fail to comply with applicable requirements in this policy may be disciplined, up to and including termination, in accordance with ORNL disciplinary policies.

- D. *Records.* All relevant records for each NIH-funded project will be retained at the office of the ALD-EESD for a period of 3 years after receipt of final funding for the project. Relevant records consist of all of the following documents as they pertain to PHS-funded projects:

1. Agreements with Subrecipients or other institutions receiving PHS funding regarding the applicability of this Policy to a PHS-funded research project.
2. All SFI Forms;
3. Written determinations that an FCOI exists and FCOI management plans;
4. All FCOI reports;
5. All documentation related to any retrospective review or other investigation pertaining to FCOIs involving Investigators participating in PHS-funded research projects;
6. Public requests for Investigator financial information and responses to the requests.

These records shall be maintained for a period of 3 years after the final expenditure report is submitted to the PHS, or as required by rules in 45 C.F.R. §§74.53(b) and 92.42(b), or as required by the ORNL records retention policy, whichever is longer.

VI. Attachments

Attachment 1, Definitions

ALD-EESD means the ORNL Associate Laboratory Director for the Engineering and Environmental Sciences Directorate, or his or her designee(s).

FCOI means “financial conflict of interest”.

Financial conflict of interest (FCOI) means an SFI that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable, that is owned by the Investigator or his or her spouse or dependent children.

Investigator means ORNL Staff who are in the roles of program manager, project director and/or principal investigator in a PHS-funded research project, and any other ORNL Staff regardless of title or position, who are responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, and all designees assisting the ALD-EESD in FCOI matters.

Investigator also means employees of all Subrecipients who are not ORNL employees but:

1. Participate in the design, conduct, or reporting of research funded by the PHS, or proposed for such funding; and
2. Are not subject to a PHS-compliant financial conflict of interest policy through an institution other than ORNL.

NIH means the National Institutes of Health.

ORNL means the Oak Ridge National Laboratory.

ORNL Staff means all employees of UT-Battelle and:

1. Graduate students and post-doc researchers funded by UT-Battelle and performing research at the Oak Ridge National Laboratory (ORNL);
2. Joint Faculty Appointees and Governor’s Chair Appointees, regardless of employer, receiving funding directly or indirectly from ORNL; and
3. ORNL emeritus researchers and others performing services for ORNL on a voluntarily basis.

PHS means the Public Health Service, and the term includes the NIH.

Principal Investigator includes project managers/directors and others responsible for the research project.

Senior/key personnel means the PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the PHS .

SFI means significant financial interest as described in Attachment 2.

SFI Form means the form at Attachment 2 to this Policy.

Subrecipient means any institution, business, individual, collaborator, partner, consortium member, or other entity that receives PHS-sourced funding from ORNL to plan, perform or manage research, including reporting of research results. In context, the term may include ORNL when it receives PHS funding from another institution.

UT-Battelle means the management and operating contractor for ORNL.

Attachment 2

ORNL Significant Financial Interest (SFI) Disclosure Form

Note: Reportable "financial interests" do NOT include: (1) salary, royalties, or other remuneration paid by your employer; (2) income from investments you do not directly control (e.g., 401(k) accounts, mutual funds); and (3) income from lectures, seminars, teaching engagements, or service on advisory committees or review panels, **but only if** the remuneration is paid by a federal, state, or local government or by an accredited institution of higher education.

Printed name: _____ Badge No. _____

A. Declarations:

1. Within the last 3 years, I have read Appendix A to the ORNL Policy on Research Integrity and completed the PHS/NIH on-line tutorial.
2. This form does ___ does not ___ disclose any changes from my most recent prior SFI form.

B. I hereby disclose the following "Significant Financial Interests"* held by me, my spouse, or my dependent children:

None _____

1. Name of entity: _____ Type of interest: _____

2. Name of entity: _____ Type of interest: _____

3. Name of entity: _____ Type of interest: _____

4. Name of entity: _____ Type of interest: _____

5. Name of entity: _____ Type of interest: _____

6. Name of entity: _____ Type of interest: _____

7. Name of entity: _____ Type of interest: _____

(Use the back of this form for additional entries)

* See following page for types of reportable financial interests and thresholds for determining whether a financial interest is "significant" and thus requires disclosure.

I certify that the foregoing declarations and disclosures are accurate and complete to the best of my knowledge and belief. I agree to provide an updated form immediately upon acquiring any new significant financial interest.

Signature

Date

Types of Reportable Financial Interests and “Significant” Threshold Amounts *

Type: PTE - Remuneration from a publicly-traded entity. Financial interests are “significant” if total remuneration exceeds \$5,000 received during the preceding 12 months. “Total remuneration” includes salary and any other cash payments over the preceding 12 months plus the value of any equity interest held (stock, stock options, and ownership interests).

Type: NPTE – Remuneration from a non-publicly traded entity. Financial interests are “significant” if total remuneration exceeds \$5,000 received during the preceding 12 months. “Total remuneration” includes salary and any other cash payments over the preceding 12 months, plus the value of any equity interest held (stock, stock options, and ownership interests).

Type: IP – Any amount of income received during the preceding 12 months from intellectual property rights such as patents and copyright (excluding royalties paid by UT-Battelle).

Type: TRVL – Travel. Any reimbursed or sponsored travel during the preceding 12 months, except that travel is not an SFI if it was provided or reimbursed by: any Federal, state or local government agency; or an accredited institution of higher learning. Travel costs or reimbursements paid with ORNL allowable funds constitute payments by the Federal government and need not be listed.

If you have this type of SFI, make one entry on the Form listing TRVL as the “Type” and on an attached separate page with your name, provide the following information for each trip: the name of the entity that provided the travel or reimbursement for the travel; the approximate dates of the travel; the purpose(s) of the travel; the destination(s); and the duration of the trip.

Connection between “Significant Financial Interests” and Employment Responsibilities

Not all SFIs must be disclosed. The disclosure requirement applies to SFIs that “reasonably appear to be related” to the Investigator’s employment responsibilities at ORNL (note: not only responsibilities related to PHS-funded research, but all responsibilities as an ORNL staff member). Investigators can choose to make a determination whether an SFI reasonably appears to be related to such employment responsibilities or, in the alternative, report the SFI without undertaking such an analysis.

In deciding whether an SFI is related to employment responsibilities, the Investigator should consider whether the value of the SFI reasonably could be expected to be influenced – positively or negatively – by the outcome of the PHS-funded project the Investigator is planning, proposing, or working on; or whether a business, institution, or other entity that is associated with the financial interest could be affected. This judgment must be made in good faith, based on the Investigator’s knowledge and belief.

In determining whether a financial interest “appears to be reasonably related,” keep in mind that the following two types of financial interests almost always will meet this threshold.

1. Income from consulting or speaking engagements. In almost all cases, consulting and speaking engagement reasonably appear to be related because these opportunities arise from the Investigator’s expertise that is related to his or her employment.

2. Any income or financial interest in any a business, institution, or other entity that will be performing work under PHS-funded subcontract for the project (e.g., a Subrecipient) is considered reasonably related to the Investigator’s employment.

* For additional information, see the definition of *Significant Financial Interests* at 42 C.F.R. §50.605.

Attachment 3

Financial Conflicts of Interest (FCOIs)

The standard for determining whether an SFI constitutes an FCOI is set forth in 42 C.F.R. §50.604(f). The process and analysis to be used by ORNL for these determinations is as follows.

1. A determination must be made whether an Investigator's SFI is related to PHS-funded research. An Investigator's SFI is deemed to be "related to PHS-funded research" when the ALD-EESD reasonably determines that the SFI:
 - a. Could be affected by the PHS-funded research; or
 - b. Is associated with an entity whose financial interest could be affected by the research.

The ALD-EESD may consult with the Investigator in the making this determination.

2. A determination must be made whether an SFI that is related to PHS-funded research constitutes an FCOI. An FCOI exists when the ALD-EESD, in consultation with the ORNL Office of General Counsel, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
3. If an SFI constitutes an FCOI, the ALD-EESD will ensure an adequate management plan is prepared and implemented in a time manner. Potential strategies for management include, but are not limited to:
 - a. Public disclosure of financial conflicts of interest (*e.g.*, when presenting or publishing the research);
 - b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - 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); and
 - g. Severance of relationships that create financial conflicts.

See 45 C.F.R. §94.5(a)(1) for further Information regarding management plans.

Attachment 4

Events that Trigger a Requirement for Investigators to Review FCOI Materials

In addition to the requirement for an initial reading of the ORNL Policy and the on-line tutorial prior to commencing PHS-funded work, each Investigator must read these materials if/when the following events occur:

- (1) ORNL revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators; or
- (2) ORNL finds that an Investigator is not in compliance with this Policy or an FCOI management plan.

PIs are responsible for advising all Investigators that one of these triggers has occurred and that the review must be completed.

Reference: 42 C.F.R. 50.604(b)

Attachment 5

Agreements With Subrecipients Regarding Responsibility for Complying With PHS Rules

42 C.F.R. §50.604(c)

ORNL must have a written agreement with Subrecipients that establishes whether this ORNL Policy will apply to the Subrecipient's Investigators or whether a financial conflict of interest policy adopted by the Subrecipient will apply.

In order to implement this requirement, the ORNL Principal Investigator will confer with appropriate representatives of the Subrecipient to determine whether Investigators from that institution will be required to comply with that institution's financial conflict of interest policy or this Policy.

After resolving this issue, the PI will obtain a signed copy of the following Agreement on Applicability of Subrecipient Financial Conflict of Interest Policy from the Subrecipient and provide it to the ALD-EESD for record-retention purposes.

Agreement on Applicability of Subrecipient
Financial Conflict of Interest Policy

PHS/NIH Funding Announcement No. _____

Name of Subrecipient
institution, business or
individual ("Subrecipient"): _____

The Parties to this Agreement are the named Subrecipient and UT-Battelle .

UT-Battelle is seeking or has received an award of funding from the Public Health Service (PHS) under the referenced funding announcement to conduct research for the PHS. Subrecipient will receive a portion of this funding from UT-Battelle to support or collaborate on the research project.

PHS requires all Investigators who participate in the design or preparation of proposals and/or the conduct or reporting of PHS-funded research to be subject to, and comply with, a Financial Conflict of Interest Policy that is compliant with PHS rules ("compliant policy") set forth in 42 C.F.R. Part 50, Subpart F, and 45 C.F.R. Part 94. UT-Battelle certifies that it has a compliant policy.

The Subrecipient hereby certifies that it does_____ does not_____ have a PHS-compliant policy.

Signature of authorized Subrecipient representative

Date

Printed name and title

To ensure that PHS requirements are met in connection with this research, the Parties agree as follows:

1. If Subrecipient has a compliant policy, its Investigators shall be subject to that policy for work performed pursuant to the referenced funding announcement. Subrecipient shall provide all identified financial conflicts of interest and related FCOI related management plans to the ORNL Principal Investigator within 30 days of identification.
2. If Subrecipient does not have a compliant policy, it shall direct its Investigators and Principal Investigators to fully comply with the ORNL Financial Conflict of Interest Policy, including but not limited to timely submission of forms and compliance with FCOI management plans.

Subrecipient's Designated Official or other authorized person

Date

UT-Battelle's Designated Official or designee

Date

Attachment 6

Principal Investigator Checklist

A. Before submitting any PHS proposal:

1. Have you identified all Investigators who participated in preparing the proposal and/or will be conducting the initial phases of the work, and provided the ALD-EESD a list of their names (and institutions if not from ORNL)?
2. Have you received completed SFI forms from these Investigators?
3. Have you submitted all SFI forms to the ALD-EESD or his or her designee for review?
4. Has each Subrecipient executed the Agreement (at Attachment 5) to identify which Financial Conflict of Interest policy will apply to its Investigators?
5. Have you received approval from the ALD-EESD to submit the proposal?

B. Before expending any PHS funding:

1. Has the ALD-EESD reviewed all the SFI forms, including those from Subrecipient Investigators when required?
2. Have any FCOIs been identified? If so -
 - a. Have FCOI management plans been prepared and signed for all FCOIs?
 - b. Has an FCOI report been submitted to the awarding PHS agency?
3. Have SFI Forms submitted by PIs and other key/senior personnel been posted on an publicly accessible website?
4. Have you received completed Agreements (Attachment 5) from all Subrecipients?

C. During the conduct of research:

1. SFI Forms
 - a. Have you obtained completed SFI forms from all newly-assigned Investigators within 20 days of their having begun work?
 - b. Have you provided these SFI forms to the ALD-EESD within 5 days of receiving them from them from the Investigators?
 - c. Have you established and communicated a schedule for Investigators to submit updated SGI forms on an annual basis?
 - d. Are you collecting SFI Forms pursuant to the schedule and promptly providing them to the ALD-EESD for review?
 - e. Are up providing the ALD-EESD an updated list of all Investigators who are participating in the project at that time whenever ?

- f. Are you:
 - i. periodically reminding Investigators of the requirement to submit updated SFI forms immediately upon acquiring a new SFI?
 - ii. collecting these forms and submitting them to the ALD-EESD within 5 days?

3. Other Requirements

- a. Have all newly-added Subrecipient institutions, businesses, or consultants executed the Agreement at Attachment 5 before beginning PHS-funded work, and have you submitted these documents to the ALD-EESD?
- b. Are you monitoring compliance with FCOI management plans with appropriate frequency to avoid adverse impacts on the research?
- c. Are you immediately advising the ALD-EESD of any compliance issues regarding this Policy that you become aware of?
- d. Are you immediately forwarding to the ALD-EESD any requests received from the public asking disclosure of SFI or FCOI information?