

NOTE REGARDING PREPARATION OF THIS DOCUMENT AND KEY TO COMMENTS

COGR has prepared this document by taking the base text of the DOE Interim COI Policy and comparing it with the text of the PHS regulations for Promoting Objectivity in Research (“PHS Regulations”). The original text of these documents can be accessed at the links below. The comparison was made on Aug. 27, 2022.

KEY:

- a. The DOE Interim COI Policy is shown in black text.
- b. Text that appears in the PHS Regulations, but not in the DOE Interim COI Policy is shown in **[bracketed red text]**.
- c. Text that appears in the DOE Interim COI Policy and that is materially different from the PHS Regulations is shown in blue underlined text.

AUGUST 27, 2022, COMPARISON OF PHS REGULATIONS FOR PROMOTING OBJECTIVITY IN RESEARCH (42 CFR PART 50, SUBPART F) WITH DEPARTMENT OF ENERGY, INTERIM CONFLICT OF INTEREST (COI) POLICY FOR FINANCIAL ASSISTANCE (FAL 2022-02 (12/20/2021))

**APPENDIX 1
DEPARTMENT OF ENERGY
Interim Conflict of Interest Policy for Financial Assistance**

[PHS Regulations for Promoting Objectivity in Research (42 CFR Part 50, Subpart F)]

[Subpart F – Promoting Objectivity in Research]

I. [§ 50.601] Purpose.

[This subpart promotes objectivity in research by] This DOE Interim Conflict of Interest Policy for Financial Assistance (“DOE Interim COI Policy” or “Policy”) [establishing] establishes standards that provide a reasonable expectation that the design, conduct, and reporting of projects wholly or in part funded under [research funded under Public Health Service (PHS) grants or cooperative agreements] Department of Energy (DOE) financial assistance awards (e.g., a grant, cooperative agreement, or technology investment agreement) will be free from bias resulting from [investigator] financial conflicts of interest or organizational conflicts of interest.

II. [§ 50.602] Applicability.

This [subpart] DOE Interim COI Policy is applicable to each [institution] non-Federal entity

that is applying for or that receives [PHS research funding by means of a grant or cooperative agreement] a DOE financial assistance award and, through the implementation of this [subpart] policy by the [institution] non-Federal entity, to each Investigator who is planning to participate in, or is participating in, [such research; provided however, that this subpart does not apply to SBIR Program Phase I applications.] the project funded wholly or in part under the DOE financial assistance award, and to each non-federal entity sub-recipient under the award. The DOE Interim COI Policy does not apply to Office of Indian Energy and Phase I Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) applications and awards. In those few cases where an individual, [rather than an institution] as opposed to a non-Federal entity, is applying for or receives [PHS research funding] DOE financial assistance funding for a project, DOE program offices [PHS Awarding Components] will make case-by-case determinations on the steps to be taken, consistent with this [subpart] Policy, to provide a reasonable expectation that the design, conduct, and reporting of the project will be free from bias resulting from a financial conflict of interest of the individual or organizational conflict of interest.

III. [§ 50.603] Definitions.

As used in this [subpart] Policy:

Award, financial assistance award or Federal award means the same as the definition provided in 2 CFR for Federal awards.

Contracting Activity means an organizational element that has the authority to award and administer contracting and financial assistance instruments.

Disclosure of significant financial interests means an [Investigator's] individual's disclosure of significant financial interests to [an Institution] a non-Federal entity.

DOE means the U.S. Department of Energy, the National Nuclear Security Administration (NNSA), and any components of the DOE to which the authority involved may be delegated.

DOE program office means the organizational unit of DOE, led by an officer of the Department who has been appointed by the President by and with the advice and consent of the Senate, that funds and/or manages the awards subject to this Policy. For purposes of this Policy, the term DOE program office includes the organization responsible for executing program management functions; the cognizant contracting activity; and the field elements in safety and health, administrative, management, and technical areas.

Financial conflict of interest (FCOI) means a situation in which an Investigator or the Investigator's spouse or dependent children has a significant financial interest or financial relationship that could directly and significantly affect the design, conduct, reporting [of PHS-funded research] or funding of a project.

FCOI report means [an Institution's] a non-Federal entity's report of a financial conflict of interest to [a PHS Awarding Component] the DOE program office.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Institution of Higher Education means the same as the definition provided at 20 U.S.C. § 1001(a).

Investigator means [the project director or] the principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the purpose, design, conduct, or reporting of [research] a project funded by DOE or proposed for funding [which may include, for example, collaborators or consultants] by DOE. DOE program offices have the discretion to expand the definition to include also any person who participates in the purpose, design, conduct, or reporting of a project funded by DOE or proposed for funding by DOE. Such expansion will be specified in the applicable funding opportunity announcement and/or terms and conditions of the financial assistance award.

Investigator's non-Federal entity responsibilities [Institutional Responsibilities] means an Investigator's professional responsibilities on behalf of the [Institution] non-Federal entity, and as defined by the [Institution] non-Federal entity in its policy on financial conflicts of interest, which may include: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Manage means taking action to address a financial conflict of interest, which can include [reducing] mitigating or eliminating the [financial] conflict of interest, to ensure, to the extent possible, that the purpose, design, conduct, and reporting of a project will be free from bias.

[PD/PI means a project director or principal Investigator of a PHS-funded research project, the PD/PI is included in the definitions of senior/key personnel and investigator under this subpart.]

[PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).]

[PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart]

[Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201, et. seq.]

Non-Federal entity means a State, local government, Indian tribe, Institution of Higher Education, nonprofit organization, or for-profit organization that carries out a DOE award as a recipient or subrecipient.

Non-Federal entity's designated official means the individual designated by the non-Federal entity with the authority and responsibility to act on behalf of the non-Federal entity to ensure compliance with the DOE Interim COI Policy.

Organizational conflict of interest means a situation where because of relationships with a parent company, affiliate, or subsidiary organization, the non-Federal entity is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization. 2 CFR 200.318(c)(2).

Potential conflict of interest exists when an impartial observer reasonably believes that actual or apparent past, present, or currently planned interests could constitute a conflict of interest with a project funded under a DOE award.

Principal Investigator (PI) means a principal investigator of a project funded under a DOE financial assistance award; PI is included in the definitions of senior/key personnel and Investigator.

[Research means 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). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.]

Project means the interdependent activities funded wholly or in part under the DOE financial assistance award. A project has a defined start and end point with objectives described in an application or in an approved scope that, when attained, signify completion and achievement of a specific goal, and creation of a unique product, service, or result. For awards that include recipient cost share as part of the approved budget, activities funded with that recipient cost share are included.

Recipient means an entity, usually but not limited to non-Federal entities, that receives a Federal award directly from a Federal awarding agency. The term recipient does not include subrecipients or individuals that are beneficiaries of the award.

Senior/key personnel means the **[PI/PD and] PI**; any other person who significantly influences the design, conduct, or reporting of a project funded under a DOE award; and any other person identified as senior/key personnel by **[the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.]** the non-Federal entity in the application for financial assistance, approved budget, progress report, or any other report submitted to the DOE by the non-Federal entity under this Policy.

Significant financial interest means:

- (1) 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]** non-Federal entity responsibilities:
 - (i) With regard to any foreign or domestic 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;
 - (ii) With regard to any foreign or domestic non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration, not otherwise disclosed as current, pending, or other support, 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);

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) 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 that is not otherwise disclosed in current and pending or other support disclosures, 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] the United States; a domestic Institution of Higher Education; or a domestic research institute that is affiliated with a domestic Institution of Higher Education. The [Institution's] non-Federal entity'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 non-Federal entity's FCOI policy, the [institutional official(s)] non-Federal entity 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 a FCOI with the [PHS-funded research] project funded under the DOE award.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the [Institution] non-Federal entity to the Investigator if the Investigator is currently employed or otherwise appointed by the [Institution] non-Federal entity, including intellectual property rights assigned to the [Institution] non-Federal entity and agreements to share in royalties related to such rights; any ownership interest in the [Institution] non-Federal entity held by the Investigator, if the [Institution] non-Federal entity 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] the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic 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] the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic Institution of Higher Education.

Small Business Innovation Research (SBIR) Program and Small Business Technology Transfer (STTR) Program mean the extramural research programs for small businesses that are run by the DOE Office of Science and the Advanced Research Projects Agency-Energy and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended, and Public Law 102 -564. [For purposes of this subpart the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was

established by Public Law 102-564.]

Subrecipient means an entity, usually but not limited to non-Federal entities, that receives a subaward from a pass-through entity to carry out part of a Federal award, but does not include an individual that is a beneficiary of such award. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency.

IV. **[§ 50.604] Responsibilities of [Institutions] non-Federal entities regarding Investigator financial conflicts of interest.**

Each [Institution] non-Federal entity shall:

(a) Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with [this subpart] the DOE Interim COI Policy, and make such policy available via a publicly accessible website. If the [Institution] non-Federal entity does not have any current presence on a publicly accessible website (and only in those cases), the [Institution] non-Federal entity shall make its written policy available to any requestor within five business days of a request. If, however, the [Institution] non-Federal entity acquires a presence on a publicly accessible website during the time of the [PHS] DOE award, the requirement to post the information on that website will apply within thirty calendar days[.] of the acquisition of the publicly accessible website. If a [an Institution] non-Federal entity maintains a policy on financial conflicts of interest that includes standards that are more stringent than this [subpart] Policy (e.g., that require a more extensive disclosure of financial interests), the [Institution] non-Federal entity shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the [PHS Awarding Component] DOE program office in accordance with the [Institution's] non-Federal entity's own standards and within the timeframe prescribed by this [subpart.] Policy.

(b) Inform each Investigator of the [Institution's] non-Federal entity's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of [these regulations] DOE's Interim COI Policy; and require each Investigator to complete training regarding the same prior to engaging in projects related to any [PHS-funded grant] DOE financial assistance award and at least every four years, and immediately when any of the following circumstances apply:

- (1) The [Institution] non-Federal entity revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- (2) An Investigator is new to a non-Federal entity; or
- (3) A non-Federal entity finds that an Investigator is not in compliance with the non-Federal entity's financial conflict of interest policy or management plan.

(c) If the [Institution] non-Federal entity carries out the [PHS-funded research] DOE award through or with the assistance of one or more [subrecipient (e.g., subcontractors or consortium members)], the [Institution (awardee Institution)] recipient non-Federal entity must take reasonable steps to ensure that each subrecipient Investigator complies with this Policy by:

- (1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflict of interest policy of the [awardee Institution] recipient non-Federal entity or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflict of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this [subpart.] DOE Interim COI Policy and the subrecipient shall make such policy available via a publicly accessible website. If the subrecipient does not have any current presence on a publicly accessible website (and only in those cases), the subrecipient shall make its written policy available to any requestor within five business days of a request. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflict of interest policy of the [awardee Institution] recipient non-Federal entity for disclosing [significant financial interest that are directly related to the subrecipient's work for the awardee Institution;] financial conflicts of interest;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflict of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the [awardee Institution] recipient non-Federal entity. Such time period(s) shall be sufficient to enable the [awardee Institution] recipient non-Federal entity to provide timely FCOI reports, as necessary, to [the PHS] DOE, as required by this [subpart.] DOE Interim COI Policy;

(iii) Alternatively, if the subrecipient's Investigators must comply with the recipient non-Federal entity's financial conflict of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the [awardee Institution.] recipient non-Federal entity. Such time period(s) shall be sufficient to enable the [awardee Institution] recipient non-Federal entity to comply timely with its review, management, and reporting obligations under this [subpart.] DOE Interim COI Policy.

(2) Providing FCOI reports to the [PHS Awarding Component] DOE program office regarding all financial conflict of interest of all subrecipient Investigators consistent with this [subpart] Policy, *i.e.*, prior to the expenditure of funds and within sixty days of any subsequently identified FCOI.

(d) Designate [an institutional official(s)] a non-Federal entity official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the [PHS-funded research.] project funded under a DOE award, including disclosures of subrecipient investigators pursuant to paragraph (c) of this section.

(e) Require that:

(1) [Require that] Each Investigator who is planning to participate in the [PHS-funded research] DOE award disclose to the [Institution's] non-Federal entity's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for the [PHS-funded research.] DOE award. In the event a non-Federal entity seeks to add an Investigator after the time of application, the non-Federal entity must require the Investigator make such disclosures prior to participating in a project funded under a DOE award.

(2) [Require] Each Investigator who is participating in the [PHS-funded research] DOE

award to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the [Institution] non-Federal entity, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the [Institution] non-Federal entity pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a [PHS-funded project] DOE award that was transferred from another [another institution] non-Federal entity), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

(3) [Require] Each Investigator who is participating in the [PHS-funded research] DOE award to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

(4) Each disclosure and updated disclosure be signed and dated by the Investigator and include a certification statement that reads:

I understand that this Disclosure is required to obtain funding from the U.S. Government. I, [Full Name and Title], certify to the best of my knowledge and belief that the information contained in this Disclosure Statement is true, complete, and accurate. I understand that any false, fictitious, or fraudulent information, misrepresentations, half-truths, or omissions of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims, or otherwise. (18 U.S.C. §§ 1001 and 287, and 31 U.S.C. 3729 -3730 and 3801-3812). I further understand and agree that (1) the statements and representations made herein are material to U.S. Government's funding decision, and (2) I have a responsibility to update the disclosures during the period of performance of the award should circumstances change which impact the responses provided above.

(f) Provide guidelines consistent with this [subpart] Policy for the designated [institutional] non-Federal entity's designated official(s) to determine whether an Investigator's significant financial interest is related to [PHS-funded research] a project funded under a DOE award and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to a [PHS-funded research] project funded under a DOE award when the [Institution] non-Federal entity, through its designated official(s), reasonably determines that the significant financial interest could be affected by the [PHS-funded research] project, could affect the project, is in an entity whose financial interest could affect the project, or is in an entity whose financial interest could be affected by the [research] project. The [Institution] non-Federal entity may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the [PHS-funded research.] project funded under the DOE award. A financial conflict of interest exists when the [Institution] non-Federal entity, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the purpose, design, conduct, or reporting of the [PHS-funded research.] project funded under a DOE award.

(g) Take such actions as necessary to manage financial conflicts of interest, including any

financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to [\[§50.605\(a\).\]](#) Section V(a).

(h) Provide initial and ongoing FCOI reports to DOE as required pursuant to [\[§50.605\(a\).\]](#) Section V(b).

(i) Maintain records relating to all Investigator disclosures of financial interests and the [\[Institution's\]](#) non-Federal entity's review of and response to such disclosures (whether or not a disclosure resulted in the [\[Institution's\]](#) non-Federal entity's determination of a financial conflict of interest) and all actions under the [\[Institution's\]](#) non-Federal entity's policy or retrospective review, if applicable, for [\[at least three years from the date the final expenditures report is submitted to the PHS\]](#) [the time period specified in 2 CFR 200.334](#) or, where applicable, from other dates specified in [\[45 CFR 75.361 for different situations.\]](#) [the individual award terms and conditions.](#)

(j) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

(k) Certify, [\[in each application for funding\]](#) [prior](#) to [\[which this subpart applies\]](#) [award](#), that the [\[Institution\]](#) non-Federal entity:

(1) Has in effect an up-to-date, written, and enforced administrative process to identify and manage [\[financial\]](#) conflicts of interest with respect to all projects for which financial assistance funding is sought or received from [\[the PHS.\]](#) DOE;

(2) Shall promote and enforce Investigator compliance with this [\[subpart's\]](#) Policy's requirements including those pertaining to disclosure of significant financial interests;

(3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to [\[the PHS Awarding Component\]](#) DOE consistent with this [\[subpart.\]](#) Policy;

(4) Agrees to make information available, promptly upon request, to [\[the HHS\]](#) DOE relating to any Investigator disclosure of financial interests and the [\[Institution's\]](#) non-Federal entity's review of, and response to, such disclosure, whether or not the disclosure resulted in the [\[Institution's\]](#) non-Federal entity's determination of a financial conflict of interest; and

(5) Shall fully comply with the requirements of this [\[subpart.\]](#) Policy.

V. [\[§50.605\]](#) Management and reporting of financial conflicts of interest.

(a) Management of financial conflicts of interest.

(1) Prior to the [\[Institution's\]](#) non-Federal entity's expenditure of any funds under a [\[PHS-funded research project\]](#) DOE award, the designated official(s) of [\[an Institution\]](#) a non-Federal entity shall, consistent with [\[§50.604\(f\)\]](#) Section IV(f): review all Investigator disclosures of significant financial interests; determine whether any [\[significant financial interests\]](#) of the disclosures relate to [\[PHS-funded research\]](#) the project funded under the DOE award; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. [\[Examples of\]](#) A nonexclusive list of

conditions or restrictions, one or more of which [that] might be imposed to manage a financial conflict of interest, includes [but are not limited to]:

- (i) Public disclosure of the financial conflict of interest (e.g., when presenting or publishing the project);
 - (ii) For projects involving human subjects, disclosure of financial conflicts of interest directly to participants;
 - (iii) Appointment of an independent monitor or oversight committee capable of taking measures to protect the purpose, design, conduct, and reporting of the [research] project against bias resulting from the financial conflict of interest;
 - (iv) Modification of the [research] project plan;
 - (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the [research] project;
 - (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- or
- (vii) Severance of relationship(s) that create financial conflicts of interest.

(2) Whenever, in the course of an ongoing [PHS-funded research] project funded under a DOE award, an Investigator who is new to participating in the [research] project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the [Institution] non-Federal entity, the designated official(s) of the [Institution] non-Federal entity shall, within sixty days: review the disclosure; determine whether it is related to [PHS-funded research] the project funded under the DOE award; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, [an Institution] a non-Federal entity may determine that additional interim measures are necessary with regard to the Investigator's participation in the [PHS-funded research project] project funded under the DOE award between the date of disclosure and the completion of the [Institution's] non-Federal entity's review.

(3) Whenever [an Institution] a non-Federal entity identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the [Institution] non -Federal entity during an ongoing [PHS-funded research project] project funded under a DOE award (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to [PHS-funded research] the project funded under a DOE award; determine whether a financial conflict of interest exists; and, if so:

- (i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such financial conflict of interest going forward;
- (ii)

(A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner, including failure by the Investigator to disclose a significant financial interest that is determined by the [Institution] non-Federal entity to constitute a financial conflict of interest; failure by the [Institution] non-Federal entity to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the [Institution] non-Federal entity shall, within 120 days of the [Institution's] non-Federal entity's determination of noncompliance, complete a retrospective review of the Investigator's activities and the [PHS-funded research project] project funded under the DOE award to determine whether any [PHS-funded research] project activity, or portion thereof, conducted during the time period of the noncompliance, was biased in the purpose, design, conduct, or reporting of such project.

(B) The [Institution] non-Federal entity is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- (1) [Project number] DOE award number;
- (2) Project title;
- (3) [PD/]PI or contact [PD/]PI if a multiple [PD/]PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the [Institution] non-Federal entity shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the [Institution] non-Federal entity is required to notify the [PHS-awarding component] DOE program office promptly and submit a mitigation report to the [PHS-awarding component] DOE program office. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the [research] project, and the [Institution's] non-Federal entity's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the [research] project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the [research] project is salvageable). Thereafter, the [Institution] non-Federal entity will submit FCOI reports annually, as specified elsewhere in this [subpart.] Policy. DOE program offices may, by language in Funding Opportunity

Announcements (FOAs) or by term and condition of award, require more frequent reporting for awards. Depending on the nature of the financial conflict of interest, [an Institution] a non-Federal entity may determine that additional interim measures are necessary with regard to the Investigator's participation in the [PHS-funded research] project funded under the DOE award between the date that the conflict of interest or the Investigator's noncompliance is determined and the completion of the [Institution's] non-Federal entity's retrospective review.

(4) Whenever [an Institution] a non-Federal entity implements a management plan pursuant to this [subpart] Policy, the [Institution] non-Federal entity shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the [PHS-funded research project.] DOE award.

(5)

(i) Prior to the [Institution's] non-Federal entity's expenditure of any funds under a [PHS-funded research project] DOE award, the [Institution] non-Federal entity shall ensure public accessibility, via a publicly accessible website or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the [Institution] non-Federal entity that meets the following three criteria:

(A) The significant financial interest [was disclosed and] is still held by the senior/key personnel as defined by this [subpart] Policy;

(B) The [Institution] non-Federal entity determines that the significant financial interest is related to the [PHS-funded research] project funded under the DOE award; and

(C) The [Institution] non-Federal entity determined that the significant financial interest is a financial conflict of interest.

(ii) The information that the [Institution] non-Federal entity makes available via a publicly accessible website or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0 -\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

(iii)(A) If the [Institution] non-Federal entity uses a publicly accessible website for the purposes of this subsection, the information that the [Institution] non-Federal entity posts shall be updated at least annually. In addition, the [Institution] non-Federal entity shall update the website within sixty days of the [Institution's] non-Federal entity's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the [PHS-funded research project] project funded under the DOE award that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the [PHS-funded research project] project, if the

[Institutional] non-Federal entity determines that the significant financial interest is related to the [PHS-funded research] project and is a financial conflict of interest. The website shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within sixty days of the non -Federal entity's identification of a new financial conflict of interest.

(B) If the [Institution] non-Federal entity responds to written requests for the purposes of this subsection, the [Institution] non-Federal entity will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty days of the [Institution's] non-Federal entity's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the [Institution's] non-Federal entity's publicly accessible website, for at least three years from the date that the information was most recently updated.

(6) In addition to the types of financial conflicts of interest as defined in this Policy that must be managed pursuant to this section, [an Institution] a non-Federal entity may require the management of other conflicts of interest in its policy on financial conflicts of interest, as the [Institution] non-Federal entity deems appropriate.

(b) Reporting of financial conflicts of interest.

(1) Prior to the [Institution's] non-Federal entity's expenditure of any funds under a [PHS-funded research project] DOE-funded project, the [Institution] non-Federal entity shall provide to the [PHS Awarding Component] DOE program office a FCOI report regarding any Investigator's unmanaged or unmanageable significant financial interest found by the [Institution] non -Federal entity to be conflicting [and ensure that the Institution has implemented a management plan in accordance with this subpart.] DOE program offices may, by language in FOAs or term and condition of award, require a non-Federal entity's FCOI report also list any Investigator's significant financial interest found by the non-Federal entity to be conflicting and addressed by a management plan in accordance with this Policy. The non-Federal entity shall provide, on request, FCOI reports and supporting documentation about any significant financial interest found by the non-Federal entity to be conflicting, regardless of whether or not the conflict has been managed, mitigated, or eliminated. In cases in which the [Institution] non-Federal entity identifies a financial conflict of interest and eliminates it prior to the expenditure of [PHS-awarded funds] DOE-awarded funds, the [Institution] non-Federal entity need not submit a FCOI report to the [PHS Awarding Component] DOE program office.

(2) For any significant financial interest that the non-Federal entity identifies as conflicting subsequent to the [Institution's] non-Federal entity's initial FCOI report during an ongoing [PHS-funded research project] project funded under a DOE award (e.g., upon the participation of an Investigator who is new to the project), the [Institution] non -Federal entity shall:

- (i) [Applicable when a DOE program office requires the non-Federal entity to include only unmanaged or unmanageable Investigator FCOIs in the FCOI Report] [provide to the PHS Awarding Component] Provide to DOE within sixty days, an FCOI report regarding the financial conflict of interest [and ensure that the Institution has implemented a management plan in accordance with this subpart] if the non-Federal entity's designated official determines that the FCOI is unmanageable. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the [Institution] non-Federal entity (e.g., was not timely reviewed or reported by a subrecipient), the [Institution] non-Federal entity also is required to complete a retrospective review to determine whether any [PHS-funded research] project funded under a DOE award or portion thereof conducted prior to the identification of the financial conflict of interest was biased in the purpose, design, conduct, or reporting of such project. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the [Institution] non-Federal entity is required to notify the [PHS Awarding Component] DOE program office promptly and submit a mitigation report to the [PHS Awarding Component.] DOE program office.
- (ii) [Applicable when a DOE program office requires the non-Federal entity to include all Investigator FCOIs – including managed and unmanaged/unmanageable FCOIs – in the FCOI Report] Provide to DOE within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the non-Federal entity has implemented a management plan in accordance with this Policy. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the non-Federal entity (e.g., was not timely reviewed or reported by a subrecipient), the non-Federal entity also is required to complete a retrospective review to determine whether any project funded under a DOE award, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the purpose, design, conduct, or reporting of such project. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the non-Federal entity is required to notify the DOE program office promptly and submit a mitigation report to the DOE program office.
- (3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable [the PHS Awarding Component] DOE to understand the nature and extent of the financial conflict, and to assess the appropriateness of the [Institution's] non-Federal entity's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:
- (i) [Project number] DOE award number;
 - (ii) [PD/]PI or Contact [PD/]PI if a multiple [PD/]PI model is used;
 - (iii) Name of the Investigator with the financial conflict of interest;
 - (iv) Name of the entity with which the Investigator has a financial conflict of interest;
 - (v) Nature of any applicable financial interest (e.g., equity, consulting fee, travel

reimbursement, honorarium) and/or applicable external relationships or activities;

- (vi) Value of any applicable financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- (vii) A description of how the financial interest relates to the [PHS-funded research] project funded under a DOE award and the basis for the [Institution's] non-Federal entity's determination that there is a conflict with such [research] project; and
- (viii) [Applicable when a DOE program office requires the non-Federal entity to include all Investigator FCOIs – including managed and unmanaged/unmanageable FCOIs – in the FCOI Report] A description of the key elements of the [Institution's] non-Federal entity's management plan, including:
 - (A) Role and principal duties of the conflicted Investigator in the project;
 - (B) Conditions of the management plan;
 - (C) How the management plan is designed to safeguard objectivity in the project;
 - (D) Confirmation of the Investigator's agreement to the management plan;
 - (E) How the management plan will be monitored to ensure Investigator compliance; and
 - (F) Other information as needed.

(4) For any financial conflict of interest previously reported by the [Institution] non-Federal entity with regard to an ongoing [PHS-funded research project] project funded under a DOE award, the [Institution] non-Federal entity shall provide [to the PHS Awarding Component] DOE with an annual FCOI report that addresses the status of the financial conflict of interest and, if applicable, any changes to the management plan for the duration of the [PHS-funded research project] DOE award. The annual FCOI report shall specify whether the financial conflict is still being managed or if it remains unmanaged/unmanageable. Alternatively, the annual FCOI report shall explain why the financial conflict no longer exists. The [Institution] non-Federal entity shall provide annual FCOI reports to [the PHS Awarding Component] DOE for the duration of the project period (including extensions with or without funds) in the time and manner [specified by the PHS Awarding Component] required by terms and conditions of award.

(5) In addition to the annual FCOI report, DOE may require a non-Federal entity to routinely submit all or some Investigator disclosures of financial interests. Circumstances when DOE may require a non-Federal entity to submit all or some of such Investigator disclosures include but are not limited to:

- (i) As part of monitoring the non-Federal entity's compliance with this Policy;

- (ii) Bankruptcy of the non-Federal entity;
- (iii) Other legal winding down of the non-Federal entity;
- (iv) Acquisition of the non-Federal entity by a foreign entity, where “acquisition” includes a foreign entity obtaining a controlling interest in the non-Federal entity; or
- (v) As otherwise set forth in 2 CFR 200, as amended by 2 CFR 910.

(6) In addition to the types of financial conflicts of interest as defined in this Policy that must be reported pursuant to this section, a non-Federal entity may require the reporting of other [financial] conflicts of interest in its policy [on financial conflicts of interest], as the non-Federal entity deems appropriate.

VI. Responsibilities of non-Federal entities regarding organizational conflicts of interest.

(a) If the non-Federal entity has a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, the non-Federal entity must maintain written standards of conduct covering organizational conflicts of interest. 2 CFR 200.318(c)(2).

(b) The existence of written policies or procedures requiring that certain procurements or transactions be made with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe is an effective manner of mitigating an organizational conflict of interest.

(c) The non-Federal entity must disclose in writing any potential or actual organizational conflict of interest to the DOE program office. The non-Federal entity must provide the disclosure to DOE in an application for financial assistance or prior to engaging in a procurement or transaction using DOE funds with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe. The elements of the disclosure shall include, but are not limited to the following:

- (i) The name, address, and website (as applicable) of the entity that presents a potential or actual organizational conflict of interest;
- (ii) The relationship between the non-Federal entity and the entity at issue;
- (iii) The nature of the anticipated procurement or other transaction with the parent, affiliate, or subsidiary organization; the anticipated value of the procurement or other transaction; and the basis for making the procurement or other transaction with a parent, affiliate, or subsidiary organization;
- (iv) The basis for the non-Federal entity’s determination regarding the existence of an organizational conflict of interest; and
- (v) How the non-Federal entity will avoid, neutralize, or mitigate the organizational conflict of interest.

(d) If the effects of the potential or actual organizational conflict of interest cannot be avoided, neutralized, or mitigated, the anticipated procurement or other transaction using DOE funds may not be made. Where there is an organizational conflict of interest that cannot be

avoided, neutralized, or mitigated, the non-Federal entity must procure goods and services from other sources when using DOE funds.

VII. **[§50.606] Remedies.**

(a) If the failure of an Investigator to comply with [an Institution's] a non-Federal entity's financial conflict of interest policy or a management plan appears to have biased the purpose, design, conduct, or reporting of [the PHS-funded research] the project funded under a DOE award, the [Institution] non-Federal entity shall promptly notify the [PHS Awarding Component] DOE of the failure to comply and of the corrective action taken or to be taken. [The PHS Awarding Component] DOE will consider the situation and, as necessary, take appropriate action, or refer the matter to the [Institution] non-Federal entity for further action, which may include directions to the [Institution] non-Federal entity on how to maintain appropriate objectivity in [the PHS-funded research project.] the project funded under the DOE award. [PHS] DOE may, for example, require [Institutions] non-Federal entities employing such an Investigator to enforce any applicable corrective actions prior to [a PHS award] a DOE award or when the transfer of a [PHS grant(s)] DOE award involves such an Investigator.

(b) [The PHS Awarding Component] DOE may inquire, at any time before, during, or after an award, into any Investigator's disclosure of financial interests and the [Institution's] non-Federal entity's review (including any retrospective review) of and response to such disclosure, regardless of whether the disclosure resulted in the [Institution's] non-Federal entity's determination of a financial conflict of interest. [An Institution] A non-Federal entity is required to submit or permit on-site review of, all records pertinent to compliance with this [subpart.] Policy. To the extent permitted by law, [HHS] DOE will maintain the confidentiality of all records of financial interests. [On the basis of] Based on its review of records or other information that may be available, the [PHS Awarding Component] DOE program office may decide that a particular financial conflict of interest will bias the objectivity of [the PHS-funded research] or adversely impact the project funded under the DOE award to such an extent that further corrective action is needed or that the [Institution] non-Federal entity has not managed the financial conflict of interest in accordance with this [subpart,] Policy. The [PHS Awarding Component] DOE may determine that the imposition of specific award conditions under [45 CFR 75.207, or suspension of funding or other enforcement action under 45 CFR 75.371, is necessary until the matter is resolved.] 2 CFR 200.208 is necessary. The DOE may also take one or more the actions specified under 2 CFR 200.339, as appropriate in the circumstances.

[(c) In any case in which the HHS determines that a PHS-funded 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 Institution as required by this subpart, the Institution shall require the Investigator involved 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.]

(c) If a non-Federal entity fails to disclose an organizational conflict of interest to DOE prior to engaging in a procurement or transaction using DOE funds with a parent, affiliate, or

subsidiary organization that is not a state, local government, or Indian tribe, the costs of such procurement or transaction may be disallowed. If a non-Federal entity fails to disclose an organizational conflict of interest to DOE prior to engaging in a procurement or transaction using DOE funds with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, and the organizational conflict of interest is not avoided, neutralized, or managed, DOE may determine that imposition of specific award conditions under 2 CFR 200.208 is necessary. DOE may also take one or more actions specified under 2 CFR 200.339, as appropriate in the circumstances.

(d) Any false, fictitious, or fraudulent information, or the omission of any material fact, on a disclosure, report, or other record required under this Policy may be subject to criminal, civil, or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Sections 287 and 1001; and Title 31, 3729-3730 and 3801-3812).

[§50.607 Other HHS Regulations that Apply

Several other regulations and policies apply to this subpart. They include, but are not necessarily limited to:

- 2 CFR Part 376 – Nonprocurement debarment and suspension (HHS)
- 42 CFR Part 50, Subpart D – Public Health service grant appeals procedure
- 45 CFR Part 16 – Procedures of the Departmental Grant Appeals Board
- 45 CFR Part 75 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards
- 45 CFR Part 79 – Program fraud civil remedies]

APPENDIX 2

DEPARTMENT OF ENERGY (DOE) Conflict of Interest Policy for Financial Assistance Funding Opportunity Announcement Language

Include the following text in [FOA Section] Part VI:

[FOA section #] Interim Conflict of Interest Policy for Financial Assistance

a. Policy

The DOE interim Conflict of Interest Policy for Financial Assistance (COI Policy) can be found at [Link to FAL]. This policy is applicable to all non-Federal entities applying for, or that receive, DOE funding by means of a financial assistance award (e.g., a grant, cooperative agreement, or technology investment agreement) and, through the implementation of this policy by the entity, to each Investigator who is planning to participate in, or is participating in, the project funded wholly or in part under the DOE financial assistance award. DOE's interim COI Policy establishes standards that provide a reasonable expectation that the design, conduct, and reporting of projects funded wholly or in part under DOE financial assistance awards will be free from bias resulting from financial conflicts of interest or organizational conflicts of interest. The applicant is subject to the requirements of the interim COI Policy and within each application for financial assistance, the applicant must certify that it is, or will be by the time of receiving any financial assistance award, compliant with all requirements in the interim COI Policy. The applicant must flow down the requirements of the interim COI Policy to any subrecipient non-Federal entities.

APPENDIX 3

DEPARTMENT OF ENERGY (DOE)

Interim Conflict of Interest Policy for Financial Assistance Special Term and Condition

[Term #] Interim Conflict of Interest Requirements for Financial Assistance

a. Policy

The DOE interim Conflict of Interest Policy for Financial Assistance (COI Policy) can be found at [Link to FAL]. The interim COI Policy is applicable to all non-Federal entities that receive DOE funding by means of a financial assistance award (e.g., a grant, cooperative agreement, or technology investment agreement) and, through the implementation of this interim COI Policy by the entity, to each Investigator who is planning to participate in, or is participating in, the project funded wholly or in part under the DOE financial assistance award. The interim COI Policy establishes standards that provide a reasonable expectation that the design, conduct, and reporting of projects funded wholly or in part under DOE financial assistance awards will be free from bias resulting from financial conflicts of interest or organizational conflicts of interest. The Recipient is subject to the requirements of the interim COI Policy, and the Recipient must certify that it is compliant with all requirements in the interim COI Policy. The Recipient must flow down the requirements of the interim COI Policy to any subrecipient non-Federal entities.

b. Additional Requirements (optional)

The Recipient is required to disclose, manage, and report conflicts of interest as per the DOE interim COI Policy. In addition, the Recipient is required to: