

## **Administrative Policy No. 12.07**

**Subject:** Financial Conflicts of Interest in U.S. Public Health Service-Funded Research

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**Authorizing Source:** Title 42 of the U.S. Code of Federal Regulations, Part 50, Subpart F, Promoting Objectivity in Research; Title 45 of the U.S. Code of Federal Regulations, Part 94, Responsible Prospective Contractors; and 76 Federal Register 53,256, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors (U.S. Department of Health and Human Services, August 25, 2011)

**Effective Date:** October 5, 2015

**Revised:** December 10, 2020

**Approved By:** **Original signed by Lori Melchiori**  
Senior Director, Office of Policy and Rules

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### **Purpose**

To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of Department of Social and Health Services research that is funded under U.S. public health service grants, contracts, or cooperative agreements will be free from bias resulting from a financial conflict of interest.

### **Background**

Federal regulations at Title 42 of the U.S. Code of Federal Regulations, Part 50, Subpart F and Title 45 of the U.S. Code of Federal Regulations, Part 94, made effective September 26, 2011 with a compliance date of August 24, 2012, require that any Institution receiving or applying for

funding from a public health service awarding component has a policy that complies with these federal regulations.

## Scope

This policy applies to any Investigator who regardless of title or position has any responsibility in the design, conduct, or reporting of department research funded in whole or in part by or under application to a public health service awarding component.

## Definitions

**Conflict of interest management plan:** means a formal plan to take action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of Research will be free from bias.

**Conflict of interest official:** see IRB administrator

**Disclosure of significant financial interests:** means an Investigator's disclosure of significant financial interests to the Department.

**Financial conflict of interest:** means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research funded by the public health service.

**Financial conflict of interest report:** means the department's report of a financial conflict of interest to a public health service awarding component.

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

**Institution:** means any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives, public health service funding for research. The department is considered an Institution.

**Institutional responsibilities:** means an Investigator's professional responsibilities on behalf of the Department, which may for example include the following activities: Research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the Washington State Institutional Review Board or other department boards and committees.

**Investigator:** means the project director, principal investigator, co-investigator, and any other person, regardless of title or position, who has any responsibility in the design, conduct, or reporting of research funded by the public health service, or proposed for such funding, which may include, for example, collaborators or consultants.

**IRB administrator:** means the individual designated by the department as the conflict of interest official with responsibility under this policy for:

1. reviewing all disclosures of significant financial interests;
2. determining whether any significant financial interests relate to public health service-funded research;
3. determining whether a financial conflict of interest exists;
4. developing and implementing a conflict of interest management plan that shall specify the actions that have been taken, and shall be taken, to manage financial conflicts of interest, as applicable; and
5. taking any other such action as may be required to ensure compliance with this policy.

The Institutional Review Board (IRB) administrator is the individual designated by the department with managerial and operational responsibility for the department's human research review section, for the protection of human subjects of research.

**Public health service awarding component:** means any organizational unit of the Public Health Service of the U.S. Department of Health and Human Services that funds or that may fund research that is subject to this policy. Public health service awarding components may include, for example, the Substance Abuse & Mental Health Services Administration, Centers for Disease Control and Prevention, National Institutes of Health, Food and Drug Administration, Indian Health Service (IHS), Health Resources and Services Administration, Agency for Healthcare Research and Quality, and the Agency for Toxic Substances and Disease Registry.

**Public Health Service Act:** means the federal statute codified at title 42 of the U.S. Code, section 201 et seq.

**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 policy, the term includes any such activity for which research funding is available from a PHS awarding component through a grant, contract or cooperative agreement, whether authorized under the Public Health Service Act or other statutory authority. For example; a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

**Senior or key personnel:** means the project director or principal investigator and any other person identified as senior or key personnel by the department in the grant application, progress report, or any other report submitted to the public health service by the department under this policy.

**Significant financial interest:**

A significant financial interest means:

1. A financial interest consisting of one or more of the following interests of an investigator (AND those of the investigator's spouse, dependent children, or other member of the investigator's household) that reasonably appears to be related to the investigator's institutional responsibilities at the department:
  - a. Any remuneration received from a publicly traded entity in the twelve months preceding the disclosure and the value of any equity interest in the publicly traded entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, and paid authorship. Equity interest includes any stock, stock option, or other ownership interest;
  - b. Any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or any equity interest; or
  - c. Intellectual property rights and interests, such as patents and copyrights, upon receipt of income related to such rights and interests.
2. Any reimbursed or sponsored travel related to an Investigator's institutional responsibilities at the department. This does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
3. The term significant financial interest does not include:
  - a. remuneration paid by or intellectual property rights assigned by the department to investigators who are currently employed by the department;
  - b. 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;
  - c. income from seminars, lectures, or teaching engagements sponsored by an entity listed in A.2 above; or
  - d. income from service on advisory committees or review panels for any entity listed in A.2 above.

**Subrecipient:** means any individual or Institution that, through a subcontract or similar arrangement, carries out research on behalf of the department.

### **Policy requirements**

Federal regulations at 42 CFR 50 subpart F and 45 CFR 94 require that the department implement this policy. This policy governs the disclosure of investigators' significant financial interests and the management and reporting of investigators' financial conflict of interest in research performed by the department or its employees or agents. This policy must be kept up-to-date, written, enforced, and made available to the public through the department's publicly accessible website. The federal regulations at 42 CFR 50 subpart F and 45 CFR 94 are made

available [here](#). The 76 Federal Register 53,256, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors (U.S. Department of Health and Human Services, August 25, 2011), is accessible [here](#).

#### A. General provisions

1. Education. An investigator must, before engaging in research, complete training regarding this policy, and must also complete continuing training regarding this policy at least once every four years thereafter. Training information is available [here](#). An Investigator must complete re-training immediately if the department finds that the individual is not in compliance with this policy or the individual's conflict of interest management plan, or if the department revises this policy in a manner that affects the individual's duties.
2. Acknowledgement. An investigator must, before engaging in research, acknowledge that she or he has read this policy and is aware of their responsibilities regarding disclosure of significant financial interests and of the applicable federal regulations. The acknowledgement form is available [here](#).
3. Subrecipients.
  - a. Subrecipients that carry out research on behalf of the department are subject to their own institution's financial conflicts of Interest policies. Any written agreement or similar arrangement between the department and the Subrecipient must include a statement to this effect.
    - i. Subrecipients must certify as part of these agreements or arrangements that the subrecipients' financial conflicts of interest policies comply with the applicable laws listed above in policy requirements.
    - ii. Subrecipients are required to report all identified financial conflicts of interest to the department conflict of interest official:
      1. Not later than the 30th day of initial subrecipient receipt of an agreement or similar arrangement under which the department provides the subrecipient with funds to conduct research, covering the 12 months preceding the date of disclosure;
      2. Annually, no later than thirty (30) days after the anniversary of initial subrecipient receipt of an agreement or similar arrangement under which the department provides the Subrecipient with funds to conduct research;
      3. Not later than the 30th day after discovering or acquiring a new significant financial Interest; and,
      4. Prior to execution of a contract associated with a new significant financial interest.
  - b. If a subrecipient cannot provide the certification required above, then the subrecipient is subject to this policy.

## **B. Disclosure of significant financial interests related to institutional responsibilities**

1. All investigators must disclose significant financial interests that reasonably appear related to their department institutional responsibilities. Disclosure instructions and the significant financial interest disclosure forms are available [here](#).
2. An Investigator must submit or update a significant financial interest disclosure statement:
  - a. not later than the 30th day of initial employment with the department, covering the 12 months preceding the date of disclosure;
  - b. annually, no later than thirty (30) days after the anniversary of initial employment with the department;
  - c. not later than the 30th day after discovering or acquiring a new significant financial interest; and
  - d. not later than at the time of application for PHS funded research.
3. In determining whether a significant financial interest should be disclosed, the Investigator should resolve the doubt in favor of disclosure.

## **C. Conflict of interest official; disclosure statement review**

1. Conflict of interest official
  - a. The department's conflict of interest official is the department's IRB administrator. The conflict of interest official shall, consistent with the applicable federal regulations, perform the duties required by this policy.
  - b. Within thirty (30) days after receipt of an investigator's disclosure of a significant financial interest, the conflict of interest official should determine whether any significant financial interest disclosed is related to research in which the investigator is engaged and if so, whether a financial conflict of interest exists.
2. Expenditure of funds prior conflict of interest determination. Neither the department nor an investigator may expend PHS funds for research that is subject to this policy unless the conflict of interest official has determined that no financial conflict of interest exists or that any financial conflict of interest is manageable in accordance with the terms of a conflict of interest management plan that has been adopted and implemented.
3. Cooperation with institutional review board. The conflict of interest official shall work with the institutional review board (IRB) in the consideration of whether an investigator has a financial conflict of interest concerning human subject research and in the implementation of a conflict of interest management plan.

## **D. Conflict of interest management plan**

1. Management required for financial conflicts of Interest. If the conflict of interest official determines that an investigator has a financial conflict of interest, the conflict of interest official shall develop and implement a conflict of interest management plan governing the investigator's financial conflict of interest.
2. Management plan design. A conflict of interest management plan may impose any condition and prescribe any action necessary to manage a financial conflict of interest, including an action to reduce or eliminate the financial conflict of interest, to ensure that the design, conduct, or reporting of the research is free from bias or the appearance of bias.
3. Monitoring and compliance. Each investigator conducting research under a conflict of interest management plan must comply fully and promptly with the conflict of interest management plan. Each person identified in the conflict of interest management plan as having responsibility for monitoring compliance with the conflict of interest management plan must carefully and fully monitor that compliance until completion of the PHS funded research.

#### **E. Web posting of financial conflict of interest information**

1. Posting of this policy. This policy and each update of this policy must be publicly accessible through the department's publicly accessible web site. The department's website must note that the public can request a list of current financial conflicts of interest through a written request to the conflicts of interest official. This policy is publicly accessible at the department's web [site](#).
2. Posting of information regarding specific financial conflicts of interest.
  - a. For any financial conflict of interest that is found to exist by the conflict of interest official concerning a significant financial interest held by an investigator, the department must in accordance with applicable federal regulations, make the following financial conflict of interest information available to the public. The information must be provided by written response within five (5) business days of a request for this information and must include:
    - i. Investigator name; research title and role;
    - ii. the name of the entity in which the investigator's significant financial interest is held;
    - iii. the nature of the investigator's significant financial interest; and
    - iv. the approximate dollar value of the investigator's significant financial interest 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.
  - b. For all senior or key personnel, this information must be accessible to the public upon written request before expending PHS funds.

#### **F. Certification and reports to PHS**

1. Certification required. Federal regulations require that each department application for funding to the PHS for research to which this policy applies include specific certifications with regard to this policy and financial conflicts of interest. These required certifications are found at 42 CFR 50, subpart F, section 50.604(k)(1)-(4) and 45 CFR 94, Section 94.4(k)(1)-(4). The department may not apply for PHS funding without providing these certifications. These federal regulations may be accessed [here](#).
2. Financial conflict of interest report. Before the expenditure of any PHS funds for research to which this policy applies, the conflict of interest official will make the financial conflict of interest report to the PHS awarding component in compliance with 42 CFR Part 50, subpart F, and 45 CFR Part 94. Financial conflict of interest reporting information is found [here](#).

#### **G. Enforcement**

1. An investigator's compliance with this policy and the disclosure of significant financial interests is a condition of the Investigator's participation as an investigator in PHS funded research.
2. Subrecipients' compliance with this this policy and the disclosure of significant financial interests is a condition of the subrecipients' participation in or funding through department research funded by the PHS.
3. Federal enforcement
  - a. The department is required to notify the PHS of any failure by an investigator or subrecipient to comply with this policy or a conflicts of interest management plan.
  - b. The department is required to notify the public health service of any instance where a financial conflict of interest appears to have biased the design, conduct, or reporting of PHS funded research.
  - c. The PHS awarding component may take enforcement action or require the department to take action appropriate to maintaining objectivity in research.

#### **H. Administration of conflicts policies – records**

1. Oversight and authority. The conflicts of interest official is responsible for overseeing implementation of this policy and may provide additional procedures and supplementary forms, as appropriate, consistent with this policy and applicable regulations.
2. Records
  - a. Department records regarding the disclosures of significant financial interests and the management of conflict of interests, the conflict of interest official's



determinations, and other records of department actions under this policy, shall be retained for the longer of at least six years after:

- i. the date of creation;
  - ii. the date of termination or completion of a research award or contract, or the submission of the final expenditures report, for research identified in a disclosure statement; or
  - iii. the date of final resolution of any investigation, audit, or similar action involving the records.
- b. The office of the conflict of interest official is the centralized repository for significant financial interest disclosure statements, conflict of interest management plans, and related records.
- c. Department records regarding the disclosures of significant financial interests and the management of conflict of interests, the conflict of interest official's determinations, and other records of department actions under this policy may be subject to disclosure under the Public Records Act, chapter 42.56 RCW.

DSHS Official