

**NEW YORK STATE DEPARTMENT OF HEALTH
AND HEALTH RESEARCH, INC.
MANAGING CONFLICTS OF INTEREST IN RESEARCH POLICY**

It is the policy of the Department of Health and its facilities (DOH) and Health Research, Inc. (HRI) to maximize adherence to ethical principles and promote objectivity in research by establishing standards of conduct and procedures to eliminate any conflict of interest that would directly and significantly affect the design, conduct or reporting of research. Failure to comply with this policy may lead to disciplinary action against a DOH or HRI employee or termination of research.

SCOPE

This policy is applicable to any research that the Department of Health (DOH), including the Department's Health Facilities, is engaged in and to each investigator participating in such research. This item is applicable to Health Research, Inc. employees, and may include all consultants, students, interns, and volunteers.

INFORMATION

The federal government has issued regulations requiring all institutions that apply for and receive research funding to implement and maintain a written, enforced policy on conflict of interest in research that is in compliance with the regulations. This policy, together with the document entitled "Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards," comprise DOH and HRI's policy on financial conflicts of interest. DOH and HRI will enforce compliance with this policy and will implement the provisions set out in "Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards" by DOH, HRI, and investigators.

DEFINITIONS

Conflict of Interest means a Reportable Interest that could directly and significantly affect the design, conduct or reporting of research.

Institutional Responsibilities means all professional responsibilities performed in the course of employment.

Investigator means the project director or principal investigator and any other person who is responsible in whole or in part for the design, conduct, or reporting of Research. The term "Investigator" includes the Investigator's spouse and dependent children.

Management Plan means a plan for eliminating, managing, or mitigating an Investigator's Conflict of Interest that the Objectivity in Research Committee determines to exist.

Objectivity in Research Committee means the group designated in accordance with the Department's document entitled "Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards."

Reportable Interest means an interest the Investigator must disclose on the DOH-3995 form and includes the following:

- A. **Reportable Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable, as described below:
 1. one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's professional responsibilities:
 - a. Remuneration received from an entity or its affiliate whose product or process is involved in the Investigator's research or competes with such a product or process, during the twelve months preceding disclosure; or any equity interest in

such entity or affiliate in excess of \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary including honoraria and consulting or speaking fees. An equity interest includes any stock, stock option or other ownership interest.

- b. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights; and/or
- c. Payment of the Investigator's travel-related or other expenses that are related to his/her Institutional Responsibilities by such an entity or affiliate.

2. A Reportable Financial Interest does not include the following interests of the Investigator:

- a. salary, royalties, or other remuneration paid by DOH, HRI or through an affiliation agreement such as the one the DOH maintains with NYPH;
- b. income from publicly traded 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; or
- c. income from seminars, lectures, teaching and service on advisory panels only when the activity is sponsored or paid for only by one or more of the following: a governmental agency, an institution of higher education, an academic teaching hospital or a medical center.

- B. **Reportable Non-Financial Interest** means any other interest that might reasonably be expected to bias the design, conduct or reporting of research (e.g., when the Investigator or the Investigator's spouse is an uncompensated board member or officer of an organization that advocates for or against a treatment involved in, or that competes with a treatment involved in, the research, or when the Investigator participated in the design, development, production or marketing of a product or process involved in the research but does not derive a financial interest in connection with the product or process)

Disclosure Obligations of All Investigators

Whenever an Investigator participates in or plans to participate in research, the Investigator shall submit a DOH-3995, which identifies and provides all requested information about each Reportable Interest (financial or non-financial) that the Investigator has:

- A. Before an application for research funding is submitted; and
- B. Subsequently within 15 days of discovering or acquiring a previously undisclosed Reportable Interest.

An Investigator shall comply with a request for additional information about a Reportable Interest made by the relevant Objectivity in Research Committee, Institutional Review Board, DOH, or HRI.

An Investigator who fails to disclose a Reportable Interest as provided above may be required to receive additional training or be disciplined. If the non-disclosing Investigator is not a DOH or HRI employee, DOH and/or HRI may take appropriate remedial action, including, when DOH and/or HRI considers it necessary to protect the objectivity of the research, requiring the Investigator to withdraw from the research.

Contents of Agreements Pertaining to Investigators Who Are Not Members of the Department's Workforce (Investigators Outside the Department)

Every contract or other agreement under which an Investigator who is not a member of the Department's workforce (outside Investigator) will have language to ensure that any subrecipient Investigator complies with their institutions financial conflict of interest policy which must be consistent with 42 CFR Part 50 Subpart F and 45 CFR Part 94. The subrecipient shall certify as part of the agreement that its policy complies with the regulation. If the subrecipient cannot provide certification, the agreement shall state that subrecipient Investigators are obligated to comply with the provisions of this APPM Item. Such agreement shall also acknowledge that the

non-Department signatory received a copy of this APPM Item and the Department's document entitled "Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards" and that the Department will follow the procedures set forth in such documents. A non-employee Investigator who fails to sign such an assurance shall not be permitted to participate in research in any way.

Training

Each Investigator shall receive a copy of this policy and 42 CFR Part 50, Subpart F, and 45 CFR Part 94, and will be notified that DOH/HRI will maintain a publicly available web site on which it will promptly post the following information on disclosed Conflicts of Interest: the Investigator's name, title and role in connection with the research; the name of the entity in which the Conflict of Interest is held; and the nature of the Conflict of Interest.

In addition, each Investigator is required to complete the National Institute of Health (NIH) Financial Conflict of Interest (FCOI) training tutorial prior to engaging in research related to any grant or contract and at least every four years. To accomplish this, investigators should go to the NIH training website at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> and follow the instructions. Once the Investigator has completed the tutorial, there is an option to print a certificate. Certificates should be printed and forwarded to the Wadsworth Center Office of Research and Technology. It will be the responsibility of each Investigator engaged in research to provide an initial certificate, as well as an updated certificate every four years, in order to maintain compliance with training requirements.

The Objectivity in Research Committee

A. Determining Whether a Reportable Interest is *Related* to the Research

In accordance with the procedures set out in "Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards," the relevant Objectivity in Research Committee or its designee(s) shall review each completed DOH-3995 and determine whether the disclosed Reportable Interests are related to the Investigator's research. If the Committee determines that the Investigator has no Reportable Interest related to a research activity, it shall so inform the Investigator.

An Objectivity in Research Committee shall, at minimum, consider the following factors in determining whether a Reportable Interest is related to the Investigator's research:

- Whether the Reportable Interest could be affected by the research; and
- Whether the research could affect the entity in which the Investigator has a Reportable Interest.

B. Determining Whether a Related Reportable Interest *Creates a Conflict of Interest*

When the Objectivity in Research Committee or its designee(s) determines that an Investigator's Reportable Interest is related to research in which the Investigator is participating, such Committee, acting as a whole committee and not through designees, shall determine whether the related Reportable Interest constitutes a Conflict of Interest. The Objectivity in Research Committee shall make such a determination before any funds are expended on the affected research, other than funds expended exclusively to prepare an application for approval of the research or to obtain funding for the research. If the Committee determines that the related Reportable Interest is not a Conflict of Interest, it shall so inform the Investigator.

An Objectivity in Research Committee shall determine that an Investigator has a Conflict of Interest when a related Reportable Interest could reasonably be expected to directly and significantly affect the design, conduct or reporting of the research. Such determination shall be made based on objective factors, not on the Investigator's character, reputation or past conduct. The Objectivity in Research Committee may consider any information it deems relevant to its inquiry, and the

Investigator shall cooperate fully with the Committee's inquiries into the Investigator's interests and research.

C. Timing of Determinations Concerning New, Amended or Unreviewed Disclosures

When an Investigator discloses a Reportable Interest after the initiation of the research, DOH and/or HRI otherwise becomes aware of such Reportable Interest, or DOH and/or HRI becomes aware that an Objectivity in Research Committee has not previously determined whether the Reportable Interest constitutes a Conflict of Interest, the relevant Objectivity in Research Committee shall, within 60 days of such disclosure or discovery, determine whether the Reportable Interest constitutes a Conflict of Interest.

D. Responsibilities Following a Finding that an Investigator Has a Conflict of Interest

Whenever an Objectivity in Research Committee finds that an Investigator has a Conflict of Interest, it shall manage that conflict through the development, implementation, monitoring and enforcement of a Management Plan.

Management Plans: In developing a Management Plan, the Objectivity in Research Committee may act on its own or in conjunction with the Investigator or another person. The Management Plan must state the specific actions to be taken and the person or organization responsible for each such action. The Objectivity in Research Committee shall require implementation of all the actions which, in its judgment, will eliminate or mitigate the bias that the identified Conflict of Interest has had or is likely to have on the design, conduct or reporting of the research. The following are examples of actions that an Objectivity in Research Committee may consider in preparing a Management Plan; they are not intended to be prescriptive or exclusive:

- Require public disclosure of Conflicts of Interest (e.g., when publishing or presenting the research or disclosure of Conflicts of Interest directly to human subjects involved in the research);
- Appoint an independent monitor empowered to take measures to protect the design, conduct or reporting of the research from bias;
- Modify the plan for conducting or reporting the research;
- Replace the Investigator, change his/her responsibilities for designing, conducting or reporting the research, or disqualify the Investigator from participating in all or part of the research;
- Reduce or eliminate the Reportable Interest;
- Require the Investigator to sever the relationship causing the Conflict of Interest.

A Management Plan that relates to federally-funded research shall require the Investigator to disclose each Conflict of Interest in each publication and presentation of the research and to request an addendum to previously published reports of the research to disclose such Conflict of Interest when the research was conducted to evaluate the safety or effectiveness for humans of a drug, medical device or treatment and DOH/HRI did not manage or report the Investigator's Conflict of Interest to the federal government.

Each Management Plan will include a plan by which DOH/HRI will monitor the Investigator's compliance with the Management Plan.

The Investigator must be given the opportunity to sign the Management Plan approved by the Objectivity in Research Committee. By signing the Management Plan, the Investigator agrees to comply with all of its terms and the requirements of this APPM Item. A Management Plan concerning federally-funded research will be modified if required by the federal government even if the Investigator had agreed to the pre-modified Management Plan.

E. Consequences of, and Actions Following, an Investigator's Failure to Sign or to Comply with a Management Plan

An Investigator's failure to sign, or his/her substantial non-compliance with, a Management Plan, as determined by the Objectivity in Research Committee and/or the Investigator's supervisor, will result in disciplinary action for an Investigator who is a DOH or HRI employee. Refusal to sign the Management Plan or substantial non-compliance with a signed Management Plan by an Investigator, whether or not a DOH or HRI employee, can result in requiring the Investigator to withdraw from all or a part of the research or, in the case of an Investigator who is not a DOH or HRI employee, the removal of the research from DOH and/or HRI. The decision to require removal of the research from DOH and/or HRI must be approved by the Commissioner of Health or his/her designee.

PROCEDURES

- | | |
|-----------------------------------|---|
| Principal Investigator (PI) | <ol style="list-style-type: none"> 1. Whenever an application for research funding is submitted, completes and submits the DOH-3995 form, which requires disclosures of Reportable Interests, as defined herein, applicable to the research project that he/she is proposing. The PI is responsible for assuring that any other Investigator involved with the project also completes the form. 2. Includes the completed form(s) in the standard application package that is processed for DOH and/or HRI approval. |
| Grant Administrator (DOH or HRI) | <ol style="list-style-type: none"> 3. Files the completed form in the application file, if no Reportable Interest is reported. 4. If a Reportable Interest is reported, forwards application to the appropriate Objectivity in Research Committee. |
| Objectivity in Research Committee | <ol style="list-style-type: none"> 5. Determines whether the Reportable Interest is related to the research and, if so, whether it constitutes a Conflict of Interest. If there is no Conflict of Interest, notifies the PI and grants administrator in writing. 6. If there is a Conflict of Interest, develops a Management Plan to manage, reduce, or eliminate the Conflict of Interest. When a Management Plan has been agreed to, notifies any parties that will have a role in the plan, and identifies the individual (usually the PI's supervisor) who is responsible for any oversight or monitoring required. Sends a copy of the Management Plan to the grant administrator. 7. Sends a copy of the Management Plan to the PI. |
| Principal Investigator | <ol style="list-style-type: none"> 8. If in disagreement with the Objectivity in Research Committee, notifies the Center or Division Director of the disagreement and the reasons for the disagreement. |
| Center or Division Director | <ol style="list-style-type: none"> 9. Evaluates all information provided by the Objectivity in Research Committee and decides upon appropriate course of action. If necessary, modifies the Management Plan in a manner that is acceptable to the Objectivity in Research Committee. 10. When the PI and other Investigators, if any, have agreed to the final Management Plan and it is signed |

by the PI, sends a copy of the final Management Plan to the grant administrator.

Grant Administrator

11. Files the final Management Plan in the grant file. If an award is made, notifies the granting agency of the existence of a Conflict of Interest and provides assurance that the conflict is being managed, reduced or eliminated. If a Management Plan has not been agreed to, withdraws the application from further consideration.

UPON OCCURRENCE OF A CONFLICT OF INTEREST AFTER RESEARCH IS INITIATED

Principal Investigator

1. Reports Reportable Interest when it occurs, but not later than 15 calendar days after the occurrence, by filing form DOH-3995 with the grant administrator.

Grant Administrator

2. Forwards Form DOH-3995 to the Objectivity in Research Committee.

Objectivity in Research Committee

3. Proceeds with steps 5-7 above. A Management Plan must be developed and agreed to within 60 days.

Grant Administrator

4. If a Management Plan has been agreed to, notifies the granting agency of the existence of conflict and provides assurance that the conflict is being managed, reduced or eliminated. If a plan has not been agreed to, notifies the sponsor that the grant will be terminated.

**DEPARTMENT OF HEALTH AND HEALTH RESEARCH, INC.
DISCLOSURE OF REPORTABLE INTEREST IN RESEARCH PROJECT**

Investigator: _____
Project: _____ Date: _____

I, my spouse, and my dependent children,

___ HAVE

___ DO NOT HAVE

a **Reportable Interest**. Attach a detailed description of the Reportable Interest, if applicable

Reportable Interest means:

A. **Financial Interest:**

1. one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's professional responsibilities:
 - a. Remuneration (including any payment) received from an entity or its affiliate whose product or process is involved in the Investigator's research or competes with such a product or process, during the twelve months preceding disclosure; or any equity interest in such entity or affiliate in excess of \$5,000;
 - b. Intellectual property rights (e.g., patents, copyrights) related to such an entity or affiliate; and/or
 - c. Payment of the Investigator's travel-related or other expenses by such an entity or affiliate.
2. A Reportable Interest does not include the following interests of the Investigator:
 - a. salary paid by the Department or HRI;
 - b. income from publicly traded 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; or
 - c. income from seminars, lectures, teaching and service on advisory panels or reimbursement of expenses from a governmental agency or an institution of higher education; or

- B. **Non-Financial Interest:** any other interest that might reasonably be expected to bias the design, conduct or reporting of research (e.g., when the Investigator or the Investigator's spouse is an uncompensated board member or officer of an organization that advocates for or against a treatment involved in, or that competes with a treatment involved in, the research, or when the Investigator participated in the design, development, production or marketing of a product or process involved in the research but does not derive a financial interest in connection with the product or process).

I certify that the information provided herein is factual and complete, and agree to immediately report to the grant administrator any Reportable Interest that occurs hereafter during the term of this research project.

Signature: _____ Date: _____

NEW YORK STATE DEPARTMENT OF HEALTH/HEALTH RESEARCH, INC.

INSTITUTIONAL RESPONSIBILITIES TO IMPLEMENT AND ENFORCE OBJECTIVITY IN RESEARCH STANDARDS

APPLICATION: Compliance with this set of procedures is mandatory for every institution and employee engaged in research. Together, this document and the Managing Conflicts of Interest in Research Policy (the Policy) constitute the written and enforced policy required by 42 C.F.R. Part 50, subpart F and 45 C.F.R. Part 94.

DEFINITIONS

The definitions contained in the Policy, which is attached, are adopted by reference. Defined terms are capitalized in this document.

Senior/Key Personnel for a research project means the project director or principal investigator and any other person whom the Department of Health (DOH) or Health Research, Inc. (HRI) identifies as “senior/key personnel” or equivalent in any grant application, progress report or other report DOH/HRI submits to the PHS, the National Science Foundation or any other funding source.

Objectivity in Research Committees

Each institution at which research is planned or conducted and each division of DOH with employees who engage in research will have Objectivity in Research Committee to perform the tasks the Policy sets out for such a committee and any other responsibilities assigned to it. One or more such institutions or Departmental divisions may have a joint Objectivity in Research Committee.

The director of each such institution and Departmental division shall appoint the members of the Objectivity in Research Committee and shall approve their written operating procedures. These responsibilities shall be performed cooperatively by the relevant directors in the case of joint Objectivity in Research Committees.

The written operating procedures of each Objectivity in Research Committee shall, at a minimum, establish the following:

- The number of persons to serve on the Committee, which should be an odd number, and the length of each term of service, including the initial terms of the original committee members established to achieve staggered terms if that outcome is desired;
- The number of persons needed to constitute a quorum;
- That a quorum is needed to determine whether a Reportable Interest is a Conflict of Interest, approve a management plan, determine whether an Investigator is not in substantial compliance with a management plan, and determine the sanctions to be imposed on an Investigator for failing to disclose a Reportable Interest in accordance with the schedule set out in the Managing Conflicts of Interest in Research Policy or to be in substantial compliance with a management plan;

- Rules defining a conflict of interest for members of the Objectivity in Research Committee and governing members' recusal from matters pending before the Committee due to such a conflict of interest.

Retrospective Reviews

The relevant Objectivity in Research Committee or other persons designated by the director, as applicable, shall undertake a retrospective review whenever one of the following events occurs:

- An Investigator does not disclose a Reportable Interest in accordance with the schedule for such disclosures set out in the Policy and the Objectivity in Research Committee determines it is a Conflicted Interest;
- The Objectivity in Research Committee does not review and make a determination in accordance with the relevant schedule set out in the Policy about whether a disclosed Reportable Interest is a Conflicted Interest;
- The Objectivity in Research Committee does not establish a management plan when one is required by the Policy;
- The Objectivity in Research Committee does not determine whether an Investigator's failure to comply with a management plan constitutes substantial non-compliance;
- The Investigator is not in substantial compliance with a management plan to which he/she agreed; or
- The Objectivity in Research Committee or the Department, as relevant, does not take any action to enforce the Investigator's compliance with a management plan following such Committee's finding that the Investigator is not in substantial compliance with the Plan.

When the Objectivity in Research Committee's failure to act triggers the retrospective review, such review shall be performed by persons designated by the director who are not Committee members.

Each retrospective review will be completed within 120 days from when the non-compliance requiring the review is identified.

The purpose of the retrospective review is to determine whether, during the period of non-compliance, any of the affected research was biased in its design, conduct or reporting. The Objectivity in Research Committee or the director's designee, as applicable, shall document every retrospective review. Such record shall include at least the following:

- Project number;
- Project title;
- Project director or principal Investigator or where there is more than one such person, the contact project director or contact principal investigator;
- Name of the investigator with the Conflict of Interest;
- Name of the entity with which the investigator has a Conflict of Interest;
- Reason(s) for the retrospective review;
- Detailed description of the methodology used for the retrospective review (*e.g.*, methodology of the review process, composition of the review panel, documents reviewed);

- Findings of the review;
- Conclusions of the review; and
- Where bias is found to have affected the design, conduct or reporting of research, a detailed action plan to eliminate or mitigate the effect of such bias.

Public Access to Information

DOH and HRI will post the Policy and this document (Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards) in a readily identifiable section of its public web site. The web site will state that taken together, these two documents comprise DOH/HRI's written, enforced policy required by 42 C.F.R. Part 50, subpart F and 45 C.F.R. Part 94.

DOH and HRI will also post the information set out in this section in the same readily identifiable portion of its public web site or provide this information to any person within five days of receipt of a written request for it. The public must have access to such information, by means of posting on a public web site or response to a written request, before any funds are expended in connection with the affected research.

The public shall have access to a record of an investigator's disclosed Conflicts of Interest where the Investigator is a Senior/Key Person and still holds the interest. The publicly accessible record shall include, at minimum, the investigator's name, title and role in connection with the research; the name of the entity in which the Financial Interest is held; the nature of the Conflict of Interest; and the amount of the Financial Interest, which may be reported by ranges, or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Information described in this section that is posted on the DOH and HRI's web site must be updated in accordance with the following schedule:

- Annually;
- Within 60 days of when the Objectivity in Research Committee determines that a previously undisclosed interest of a Senior/Key Person is a Conflicted Interest;
- Within 60 days of when the Objectivity in Research Committee determines that an interest of a Senior/Key Person new to the research creates a Conflict of Interest.

Whether the publicly accessible information described in this section is provided on a web site or by written response to requests, it shall state the date as of which the information is current and describe the schedule for updating such information as set forth above. DOH and HRI shall retain such publicly accessible information for at least three years following the date on which it was most recently updated.

PHS Access to Information

DOH/HRI will promptly make available to the United States Department of Health and Human Services, PHS and the National Science Foundation all information in their possession or to which it has a legal right that relates to any matter covered by the Policy or this Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards document.

Reporting to PHS

This section on submitting reports to PHS applies **only** when **both** an Investigator's Reportable **Financial** Interest is at issue **and** **PHS-funded research** is involved.

Records Retention: With respect to Investigators working on PHS-funded research, DOH/HTI must retain all Investigators' DOH-3995 forms, the findings of the Objectivity of Research Committees concerning the Reportable Financial Interest on each such form, and all actions such Committees and Department management take pursuant to the Policy for at least three years from the date the final expenditures report for the research is submitted to the PHS or, where, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, unless federal law supplies a different records retention rule.

Contents of Financial Conflict of Interest Reports: Each Financial Conflict of Interest report, whether the initial report for a research project or supplemental reports, shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the relevant management plan. At minimum, such reports shall include the following:

- Project number;
- Name of the project director or principal investigator or, if more than one such person has been identified for a research project, the contact project director or principal investigator;
- Name of the investigator with the Financial Conflict of Interest;
- Name of the entity with which the investigator has a Financial Conflict of Interest;
- Nature of the Financial Interest the investigator has in the entity (*e.g.*, equity, debt/bond, consulting fee, travel reimbursement, honorarium);
- Value of the Financial Interest the investigator has in the entity, which may be by ranges, or a statement that the value of the Reportable Financial Interest cannot be readily determined by reference to public prices or other reasonable measures;
- Description of how the Reportable Financial Interest relates to the PHS-Funded research and the basis for the Objectivity in Research Committee's determination that the Reportable Financial Interest conflicts with such research;
- Description of the key elements of the institution's management plan, including: the conflicted investigator's role and principal duties in the research, the conditions and requirements contained in the management plan, how the management plan is designed to safeguard objectivity in the research, confirmation of the investigator's agreement to the management plan, how the management plan will be monitored to ensure the investigator's compliance, and other information as needed.

Initial Financial Conflict of Interest Reports: Before any PHS-awarded funds are expended on a research project, the Department will make Financial Conflict of Interest reports to the PHS Awarding Component concerning any Financial Conflict of Interest the Objectivity in Research Committee determines an Investigator involved in such research has. The report shall include an assurance that the institution has implemented a management plan

in compliance with the Policy. DOH/HRI will not submit a Financial Conflict of Interest report when the investigator's Financial Conflict of Interest has been eliminated before the expenditure of any PHS-awarded funds.

Supplemental Financial Conflict of Interest Reports: When, subsequent to the expenditure of any PHS funds on a research project, the Objectivity in Research Committee finds that an investigator has a previously unidentified Financial Conflict of Interest, DOH/HRI will submit a Financial Conflict of Interest report to the relevant PHS awarding component within sixty days of such finding.

DOH/HRI will also submit supplemental Financial Conflict of Interest reports to the relevant PHS awarding component in the following situations:

- Following a retrospective review, when appropriate, to specify the actions to be taken to manage the Financial Conflict of Interest going forward; and
- Annually for the duration of the PHS-funded research, including extensions with or without funds, with respect to any Financial Conflict of Interest previously reported to the PHS awarding component, which addresses the status of the Financial Interest and any changes to the management plan. The annual update shall state whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. DOH/HRI will comply with instructions from the PHS awarding component concerning the content and submission of these reports.

Mitigation Reports: Where bias is found through a retrospective review or otherwise, DOH/HRI will promptly notify and submit a mitigation report to the PHS Awarding Component, which must include, at minimum, the required elements of the record documenting the retrospective review set forth above as the second bulleted list under "Retrospective Review," a description of the impact of the bias on the research, and DOH/HRI's plan describing the action(s) to be taken to eliminate or mitigate the effect of the bias. The plan of action should address the impact of the bias on the research; the extent of any harm that has or is likely to occur, including any qualitative or quantitative data supporting any actual or future harm; and an analysis of whether the research project is salvageable.