

**INSTITUTE FOR CLINICAL PHARMACODYNAMICS, INC.**  
**POLICY ON CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT FOR**  
**RESEARCH ASSOCIATES**

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## **1 Introduction/Statement of Policy**

Institute for Clinical Pharmacodynamics, Inc. (ICPD) encourages its research staff to seek out and participate in research activities, to consult widely, and to engage in other activities that may benefit not only the participants but also ICPD and the larger public. While ICPD fully recognizes the benefit of such activities, the interests and commitments of the various parties engaged in or affected by research activities, consulting or other interactions with external organizations — the individual, the community, industry, government, and the public — are complex and can create (or appear to create) conflicts of interest. A conflict of interest is not an implication that wrongdoing has occurred, but should be reviewed and addressed as needed to support the atmosphere of free inquiry that ICPD considers vital and ensure that there are no improper influences, potential, actual or apparent, that compromise the conduct of ICPD's research, consulting or other interactions.

Accordingly, ICPD has adopted this policy to identify and address potential, actual, and apparent conflicts of interest and commitment<sup>1</sup>. It is ICPD's policy to ensure that research, consulting, or other such activities are conducted properly, in accordance with all laws and scientific best practices, and consistently with the highest ethical standards that apply to conflicts of interests and objectivity in the conduct of research. A fundamental premise of the policy is that each member of ICPD's research staff has an obligation to act in the best interest of ICPD, and must not let outside activities or outside financial interests interfere with that obligation. Research staff of ICPD must annually disclose any conflicts of interest; this is a continuing obligation which requires prompt, updated disclosure when changes occur. This policy is intended to heighten awareness of the potential for conflicts of interest and commitment, and to establish procedures whereby such conflicts may be avoided or appropriately managed.

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<sup>1</sup> The federal government has issued policies or regulations that require disclosure of actual and potential conflicts of interest. Research sponsored by or implicating the policies of any federal agency must be conducted consistently with applicable federal regulations and guidelines, and these regulations and guidelines will govern in any case where their requirements exceed the ones set forth in this policy. Attachment B to this policy addresses additional requirements applicable to research funded by the federal government.

## **2 Conflict of Interest**

### **2.1 Underlying Principles/Essential Definitions**

The following principles are among those that underlie ICPD's policy on conflicts of interest:

- External activities should not compromise an individual's ability to perform any activities expected of him or her by ICPD. Such external activities should not be impacted by the desire for or expectation of direct or indirect financial advantage.
- An individual should not receive remuneration for the conduct of his or her research or other activity at ICPD except through ICPD or with ICPD's consent.
- All arrangements between ICPD and outside entities under which ICPD will provide support for research will be codified in a written agreement setting forth the expectations of the parties, including funding amounts and other financial arrangements, realistic timetables for mutually agreed objectives, and intellectual property arrangements.
- ICPD is committed to peer-reviewed publication, in order to allow the scientific community benefit from the knowledge gained from ICPD-conducted studies and analyses, and to avoid the introduction of bias into scientific literature. Accordingly, it is ICPD's customary practice that no agreements with external Sponsors under which ICPD will perform research may preclude or require unreasonable delay of publication of research results.
- ICPD's human and material resources, including, for example, research facilities and research personnel, should be used only for ICPD's research and educational purposes, except when other uses are specifically authorized by ICPD.
- An individual should avoid participating directly in negotiation of research agreements, license agreements, equipment purchases, or other arrangements between ICPD and an organization in which the individual has a significant financial interest. If a potential, actual, or apparent conflict of interest has been reported, research staff should not commence any activities until a review of the proposed activities has been completed and a determination has been made that the activities may proceed.

The essential definitions under this policy are:

- "Conflict of interest" means a divergence between an individual's external interests and his or her professional obligations to ICPD such

that an independent observer might reasonably question whether the individual's professional judgment or actions have been actually, potentially, or apparently influenced by considerations of personal gain, financial or otherwise, or professional gain that is not in the best interests of ICPD. Conflicts of interest can arise naturally from an individual's engagement with the world outside ICPD. The occurrence of a conflict of interest does not necessarily imply wrongdoing on anyone's part. When conflicts of interest do arise, however, they must be recognized, disclosed, and either eliminated or appropriately managed. It is also required to designate if the conflicts of interest are with domestic or foreign entities

- "Significant financial interest" means anything of monetary value, including, but not limited to:
  - Salary or other payments for services (e.g., consulting fees or honoraria);
  - Equity interests (e.g., stocks, stock options, or other ownership interests);
  - Reimbursed or sponsored travel (other than travel that is ancillary to a contract between ICPD and a Sponsor for the support of research) that exceeds \$5,000 in value (in the aggregate for each Sponsor) for Public Health Service-funded projects; and
  - Intellectual property rights (e.g., patents, copyrights, and royalties from such rights), upon receipt of income from such rights.
- A significant financial interest does not include:
  - Salary, royalties, or other remuneration received from ICPD during employment with ICPD;
  - Income from seminars, lectures, or teaching engagements sponsored by public entities or institutions of higher education (or certain entities that are affiliated with institutions of higher education);
  - Income from investment vehicles (e.g., mutual funds or retirement accounts) for which the associate does not have direct control relative to investment decisions;
  - Income from service on advisory boards for public entities or institutions of higher education (or certain entities that are affiliated with institutions of higher education);
  - Interests in publicly traded companies that, when aggregated for an associate, an associate's spouse, and an associate's dependent children, is under \$5,000 for the preceding 12 months

(taking into account both the value of any remuneration you received from the company and the value of your equity interest in the company); or,

- Remuneration from non-publicly traded companies that, when aggregated for an associate, an associate's spouse, and an associate's dependent children, is under \$5,000 in the aggregate for the preceding 12 months.

## **2.2 Broad Disclosure Requirement**

Some external activities or economic interests are unlikely to create conflicts of interest because they may not affect the objectivity of ICPD research, financial decisions, or other ICPD activities. Although such situations are unlikely to present a conflict of interest, it is nonetheless in the interests of the individual and ICPD that any external activities with or without economic interest in an entity that has a relationship with ICPD be disclosed. Accordingly, ICPD's disclosure form requires disclosure of any financial interest, no matter how small. The disclosure form also requires disclosure of all significant financial interests, as defined in this policy and on the disclosure form.

Individuals who seek funding from or who work on a project funded by an external Sponsor must comply not only with this policy, but also with that Sponsor's requirements, if any, related to disclosure, management, and avoidance of conflicts of interest.

## **2.3 Categories of Conflict of Interest**

Because the appropriate approach to each situation depends on its specific facts, this policy does not contain an exhaustive list of fixed rules regarding actual, potential, and apparent conflicts of interest. Given the potential complexity of factual circumstances that could give rise to a potential, actual, or apparent conflict of interest, disclosures will be evaluated on a case-by-case basis to determine if there is a prohibited conflict of interest and what action is appropriate.

In evaluating whether a conflict exists, ICPD will look at the actual or perceived risk of the significant financial interest on the integrity of the project and the research being performed. The following factors may be relevant to this analysis:

- Whether the significant financial interest presents any reasonable likelihood of bias affecting the design, conduct, or reporting of the research.
- Any factors or safeguards which mitigate against a reasonable likelihood of bias affecting the design, conduct, or reporting of the

research (e.g., conscientious application of the scientific method, opportunities for parties who do not have a significant financial interest to control all or portions of the project, or provide objective review of results or other measures that result in independent, objective control over the design, conduct or reporting of the research, or other peer review).

- Any unique qualifications of the researcher that are important to the research and the potential benefit of the research to the public.
- Whether the significant financial interest could potentially increase as a result of the outcome of the research.
- Whether the research involves human subjects.

Except as otherwise indicated in this policy, the following types of activities would generally not need to be disclosed:

- Royalties individuals receive from ICPD for published scholarly works and other writings.
- Payments individuals receive under the ICPD Intellectual Property policy.

## **2.4 The Appearance of Improper Relationships or Interests**

In certain cases an objective observer might reasonably perceive improper motivation for a decision even when no such improper motivation actually exists. Such apparent impropriety can undermine the credibility of research and financial decisions and call into question the integrity of an individual, ICPD, or both. For that reason, this policy defines conflict of interest with reference to the reasonable perception of an independent observer. It is therefore important for an individual, in evaluating a potential conflict of interest, to consider how it might be perceived by others. Such apparent impropriety may itself be a conflict of interest under this policy, and the same rigorous evaluation must be applied to situations in which there is potential for such misunderstanding as is applied to situations in which there is potential for actual conflict.

## **2.5 Gifts and Royalties**

While gifts may appear to be a gesture of goodwill and appreciation, and in some instances consistent with customary business practices, gifts generally have an underlying purpose of trying to influence a business decision. Accordingly, it is a violation of this policy for research staff to receive any gift, including entertainment or meals, or favor of more than token value (i.e., \$200) to or from a third party that is in any way connected with any business relationship involving ICPD.

## **2.6 Use of ICPD's Name and Resources**

ICPD's name, facilities, and equipment are to be used solely in furtherance of ICPD's goals and not for the benefit of, or to imply ICPD's support of, any non-ICPD activities. Associates may not use ICPD resources, including facilities, equipment, or confidential information for non-ICPD purposes. ICPD may grant permission to a member of the research staff to use its facilities in pursuit of outside activities or interests, but will usually do so only where there is evidence that the work of the associate will be of significant benefit to ICPD. Confidential information acquired through conduct of ICPD business or research activities may not be used for any purpose other than in the performance of duties for ICPD. Unless specifically authorized by ICPD, an individual may not use the name of ICPD or its letterhead in sponsoring or recommending any commercial service or product, regardless of whether the individual has any interest in the promotion, or in connection with an outside organization, unless the individual's participation in the organization is at the request of ICPD or part of the individual's normal duties for ICPD.



### **3 Conflict of Commitment**

A conflict of commitment occurs when the commitment to external activities of an individual may adversely affect his or her capacity to meet that individual's responsibilities for ICPD. This form of conflict involves a perceptible reduction of the individual's time and energy devoted to ICPD activities. ICPD recognizes, however, that the contributions and activities of an individual to ICPD may extend beyond the work done directly for ICPD. ICPD also understands the desire of an individual, within the constraints set forth below, to earn and accept outside income for activities that do not create a conflict of interest.

An individual employed full-time by ICPD as a member of the research staff must receive approval from ICPD before spending time on consulting or other external activities. Part-time research staff members should disclose any external activities, consulting, or employment to ICPD.

It is important to recognize that each individual's obligations move beyond the letter of these requirements to their spirit. ICPD requires that its research staff meet their research obligations, fulfill their required administrative responsibilities, and remain productively involved in their research and other scholarly pursuits. External activities that compromise or diminish an individual's capacity to meet these obligations represent a conflict of commitment, regardless of how much time an individual devotes to these activities.

## **4 Procedures for Disclosure and Review**

### **4.1 Disclosure**

Responsibility for addressing conflict of interest or commitment rests, in the first instance, with the individual. An essential step in addressing actual, potential, or apparent conflicts of interest or commitment is for the individual involved to make full disclosure of relevant information to ICPD's Compliance Officer, who can then facilitate review of the situation. **The Operations Manager, is the designated Compliance Officer for ICPD.**

All individuals covered by this policy are required annually to submit to the Compliance Officer a disclosure of their external activities, their domestic and foreign significant financial interests and other financial interests implicated by this policy. The annual disclosure must be in writing on the form approved by the Compliance Officer. The current version of the form is Attachment A to this policy. The Compliance Officer shall submit the disclosure forms, and his or her own disclosure, as applicable, to the Board of Directors of ICPD.

Whenever an individual's domestic and foreign significant financial interests or external activities change materially, or whenever an individual becomes aware of current or prospective situations that are likely to raise questions of conflict of interest or conflict of commitment, the individual must update his or her disclosures as soon as possible (but in no event later than 30 days thereafter), in writing. To the greatest extent possible, individuals should attempt to disclose expected changes or newly anticipated conflicts before they occur. Whenever an application for funding of a new research project is submitted, the individual shall certify that he or she has submitted a complete and accurate annual disclosure, and that the new research project does not present potential for any conflicts of interest not already identified in the annual disclosure. If there is any doubt about the existence of a conflict of commitment or conflict of interest, the individual should err on the side of disclosing it. Individuals also may consult informally with the Compliance Officer to resolve questions about possible conflicts.

ICPD will treat the disclosure statements confidentially, unless disclosure is legally required.

### **4.2 Review of Disclosures/Enforcement**

The Compliance Officer shall review all disclosures to determine whether an actual, potential, or apparent conflict of commitment or conflict of interest exists and, if so, provide recommendations to the Board of Directors as to the means by which the conflict should be managed, reduced, or eliminated — such as the individual's abstention from the external activity, modification of the activity, divestment of the interest, and/or monitoring of the activity. Recommendations

will be developed based on the particular facts and circumstances, compelling considerations relating to the benefit of the activity and ICPD's involvement in the activity, and the ability to manage or reduce the conflict in the circumstances. Conflict disclosures for members of the Board of Directors shall be reviewed by the remaining members of the Board, with the subject individual abstaining from the determination (although the individual may provide information to the Board of Directors upon request). In reviewing these matters, the Compliance Officer and the Board of Directors shall be guided by the principles of this policy and may seek advice from such persons as he or she or it may designate. If the Board of Directors determines that an actual, potential or apparent conflict exists, it shall inform the individual in writing, and advise as to how the conflict will be managed, reduced, or whether it must be avoided. A summary of the Board of Directors' determinations shall be made in writing and retained by the Compliance Officer.

Research staff will be bound by any determination made with respect to conflicts of interest or commitment. Failure by an individual to adhere to this policy and any determination made thereunder may be addressed through disciplinary action, as determined by the Board of Directors based on the facts and circumstances.

**ATTACHMENT A: DISCLOSURE FORM FOR RESEARCHERS**

All individuals covered by the ICPD policy on Conflict of Interest and Conflict of Commitment for Employees (the “Policy”) are responsible for filling out and submitting this disclosure form pursuant to the policy. The Policy applies to all research staff.

Implementation of the Policy begins with the completion of this questionnaire on outside activities and financial interests. The questionnaire is divided into six parts.

Parts A and B seek information relevant to possible conflicts of commitment. Parts C, D, E, and F seek information relevant to possible conflicts of interest. Please be sure to include any information that has not previously been disclosed and update any information about any matters that were previously disclosed.

Attach additional sheets if necessary. Completed forms are to be signed in the space provided at the end of Attachment A and submitted to the ICPD Compliance Officer. Associates must modify the information included in this form within 30 days of any significant change in any of the activities to be reported.

Please complete this form before signing it. By signing this form you (1) certify that the information contained in the form is complete and accurate to the best of your knowledge, and (2) acknowledge your continuing obligation to inform ICPD promptly of any change in your outside activities by completing and submitting a new form.

Individual completing form:

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Printed Name

Title

Employment Status: Full-Time\_\_\_\_\_ Part-Time\_\_\_\_\_ Other\_\_\_\_\_

Please check here if your current research as an ICPD associate is supported by federal funds [ ] and list the agencies.

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**PART A: WORK FOR OUTSIDE ORGANIZATIONS**

A.1 During the last 12 months have you worked as an employee of or independent contractor or consultant (paid or unpaid) for any organization (**domestic or foreign**) other than ICPD? (Include, for example, membership on a company's scientific advisory board and seminars or lectures given at for-profit organizations. Do not include seminars, lectures, service on advisory committees or service on review panels for governmental or institutions of higher education.)

Y\_\_\_ N\_\_\_

A.2 Do you expect to do so during the next 12 months?

Y\_\_\_ N\_\_\_

**If you answered NO to both of these questions, please go to Part B.**

A.3 If you answered yes to either of these questions, please provide the following information:

A.3.1 Name of organization (**specify if domestic or foreign**):

\_\_\_\_\_

A.3.2 Number of days you were engaged during the last 12 months:

\_\_\_\_\_

A.3.3 Estimated number of days you will be engaged during the next 12 months:

\_\_\_\_\_

A.3.4 Where you performed the work:

\_\_\_\_\_

A.3.5. Brief description of the work:

\_\_\_\_\_

A.3.6. Describe the relationship between this outside activity and your activities at ICPD:

\_\_\_\_\_

(Use a separate sheet to list and describe additional organizations.)

**PART B: MANAGEMENT AND FIDUCIARY ACTIVITIES**

B.1 During the last 12 months have you had a management or other fiduciary role (including service as an officer, director, or supervisor) in any organization (**domestic or foreign**) other than ICPD?

Y\_\_\_ N\_\_\_

B.1.1 Do you expect to serve in such a capacity during the next 12 months?

Y\_\_\_ N\_\_\_

**If you answered NO to both of these questions, please go to Part C.**

B.2 If you answered yes to either of these questions, please provide the following information.

B.2.1 Name of organization (**specify if domestic or foreign**):

\_\_\_\_\_

B.2.2 Brief description of the business of the organization:

\_\_\_\_\_

B.2.3 Your title:

\_\_\_\_\_

B.2.4 The nature of your responsibilities:

\_\_\_\_\_

B.2.5. The number of days annually you worked and/or expect to work for the organization:

\_\_\_\_\_

(Use a separate sheet to list and describe additional organizations.)

## **PART C: FINANCIAL INTERESTS**

As used in ICPD's Policy, a financial interest generally means an interest in an entity, whether domestic or foreign, other than ICPD, that has monetary value or based on which you receive or expect to receive remuneration.

Significant financial interest is defined as follows:

- Salary or other payments for services (e.g., consulting fees or honoraria);
- Equity interests (e.g., stocks, stock options, or other ownership interests);
- Reimbursed or sponsored travel or gifts; and
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).
- A significant financial interest does not include:
  - Salary, royalties, or other remuneration received from ICPD during your employment with ICPD;
  - Income from seminars, lectures, or teaching engagements sponsored by public entities or institutions of higher education (or certain entities that are affiliated with institutions of higher education);
  - Income from investment vehicles (e.g., mutual funds or retirement accounts) for which you do not direct control relative to investment decisions;
  - Income from service on advisory boards for public entities or institutions of higher education (or certain entities that are affiliated with institutions of higher education);
  - Interests in publicly traded companies that, when aggregated for you, your spouse, and dependent children, is under \$5,000 for the preceding 12 months (taking into account both the value of any remuneration you received from the company and the value of your equity interest in the company); or,
  - Remuneration from non-publicly traded companies that, when aggregated for you, your spouse, and dependent children, is under \$5,000 in the aggregate for the preceding 12 months.

**You MUST answer parts C.1 and C.2 by checking the appropriate box.**

C.1 To the best of your knowledge, do you, your spouse, or dependent children have a significant financial interest in any entity (**domestic or foreign**) that:

Y\_\_\_ N\_\_\_

C.1.1 Sponsors your ICPD research/activities?

Y\_\_\_ N\_\_\_

C.1.2 Would be affected by your ICPD research/activities?

Y\_\_\_ N\_\_\_

C.1.3 Is otherwise involved with your ICPD research/activities?

Y\_\_\_ N\_\_\_

C.2 Could the outcome of your ICPD research/activities affect this significant financial interest (e.g., by increasing its value)?

Y\_\_\_ N\_\_\_

C.3 If you answered yes to any of the questions in C.1 or C.2, please provide the following information:

C.3.1 Name of entity (**specify if domestic or foreign**):

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C.3.2 Nature and/or type of financial interest (e.g., stock ownership, salary) and percentage of ownership. Please indicate whether it is a public or non-public entity, and whether it is a domestic or foreign entity (governing law in another country):

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C.3.3 Value: \_\_\_ \$5,000 or less

\_\_\_ \$5,000-10,000

\_\_\_ \$10,001-20,000

\_\_\_ \$20,001-40,000

\_\_\_ \$40,001-75,000

\_\_\_ More than \$75,000

C.3.4 Please explain how the entity or your interest might be affected by your research/activities.

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(Use a separate sheet to list and describe additional organizations.)

**PART D: OTHER REPORTABLE INTERESTS**

- D.1 To the best of your knowledge, do you, your spouse, or dependent children have any interest not reported in Part C, no matter how small, in regard to which an independent observer might believe there was a conflict of interest under the ICPD policy on Conflict of Interest and Conflict of Commitment?  
Y\_\_\_ N\_\_\_

**If you answered NO to question D.1, please go to Part E.**

D.2 If you answered yes to question D.1, please provide the following information:

D.2.1 Name of Entity in which you hold the interest (**specify if domestic or foreign**):

\_\_\_\_\_

D.2.2 Type of financial interest (e.g., stock ownership, salary) and percentage of ownership. Please indicate whether it is a public or non-public entity and whether it is a domestic or foreign entity (governing law in another country):

\_\_\_\_\_

D.2.3 Value: \$ \_\_\_\_\_

D.2.4 Please describe any possible conflict of interest arising from this interest.

\_\_\_\_\_

(Use a separate sheet to list and describe additional organizations.)

**PART E: WORK WITH TRAINEES**

E.1 Will any student, fellow, or postdoctoral appointee who works under your direction at ICPD be involved in any of the outside activities you identified in Part A or with any of the organizations you identified in Part A, Part B, Part C, or Part D?

Y\_\_\_ N\_\_\_

E.1.1 If you answered yes, please identify such individuals and describe the relationship between the person and the work he or she performs under your direction and your outside interests (e.g., how might the student's work affect your interest in an outside entity).

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**PART F: BUSINESS ARRANGEMENTS**

- F.1 In addition to requiring this annual disclosure, the ICPD policy on Conflict of Interest and Conflict of Commitment provides that individuals covered by the policy and whom perform direct research activities should not participate in ICPD purchasing decisions, contract negotiations, or other ICPD business arrangements with any entity:
- In which the individual, his or her spouse, or dependent children has a significant financial interest (as defined in Part C above); or
  - With which the individual, his or her spouse, dependent children has employment, consulting, management, fiduciary, or similar affiliations.
- F.2 By signing this form individuals are warranting that they have not and will not participate in such arrangements unless they have disclosed these interests or affiliations in advance to the Compliance Officer and received approval to participate.

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Signature

Date

## **ATTACHMENT B: POLICIES APPLICABLE TO RESEARCH FUNDED BY THE PUBLIC HEALTH SERVICE**

In addition to the policies set forth in ICPD's Policy on Conflict of Interest and Conflict of Commitment for Research Associates (the COI Policy), there are additional, specific requirements that pertain to research grants or contracts that are funded by or proposed for funding by the U.S. Public Health Service (PHS), which includes funding provided by the National Institutes of Health (NIH). In the event of a conflict between a provision of the COI Policy and a provision of this Attachment B, the terms of this Attachment B shall apply.

### **1. Definitions**

The definitions that appear in the COI Policy also apply to this Attachment B.

### **2. Disclosure Requirements Pertaining to PHS Funded Projects**

- Prior to submitting a proposal for funding by PHS, each individual who has responsibility for the design, conduct or reporting of the research that is proposed to be funded (Investigator) must have on file a current disclosure form.
- In addition to the annual disclosure requirement required by the COI Policy, disclosure forms must be updated within 30 days of discovering or acquiring any additional significant financial interest, or for any new personnel that are added to ICPD or the project, or anytime ICPD updates its COI Policy in any manner that impacts the requirements on Investigators, or if ICPD determines that an Investigator is not in compliance with the COI Policy (including this Attachment B).
- Disclosures of reimbursed or sponsored travel which is over the amount of \$5,000 in the aggregate, per sponsor, related to their responsibilities performed for ICPD must be disclosed, unless the travel 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. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organization, the destination, and the duration of the travel.
- The Compliance Officer shall review any disclosure forms within the timeframes required by applicable law.

### **3. Determination of Financial Conflicts of Interest**

Upon receipt of a disclosure of a Significant Financial Interest of an Investigator engaged in PHS-funded research, the Compliance Officer will determine (a) whether the Significant Financial Interest is related to the PHS-funded research and, if so related, (b) whether the Significant Financial Interest is a Financial Conflict of Interest (as defined below). An Investigator's Significant Financial Interest is related to PHS-funded research when the Compliance Officer reasonably determines that the Significant Financial Interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. A "Financial Conflict of Interest" is a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of the PHS-funded research.

If during the course of an ongoing PHS-funded project a Significant Financial Interest is disclosed by a new Investigator or an existing Investigator discloses a Significant Financial Interest not previously reported, or it comes to the attention of the Compliance Officer or the Board of Directors of ICPD that a Significant Financial Interest related to the PHS-funded research was not disclosed in a timely manner by an Investigator, the interest shall be reviewed within 60 days and a decision shall be made as to whether the Significant Financial Interest constitutes a Financial Conflict of Interest. If the Compliance Officer determines that a Financial Conflict of Interest exists, the Compliance Officer shall implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be taken, to manage the Financial Conflict of Interest.

### **4. Management Plans**

If a Financial Conflict of Interest is identified pursuant to Section 3 hereof, then, prior to the expenditure of award funds, the Compliance Officer will develop and implement a management plan specifying the actions that have been or will be taken to manage, reduce or eliminate the Financial Conflict of Interest. In the case where a Significant Financial Interest is disclosed by a new Investigator, the management plan will be developed and implemented within 60 days of the disclosure. ICPD will implement guidelines that will provide additional guidance to the Compliance Officer and assist the Compliance Officer in reviewing disclosures, evaluating and managing Financial Conflicts of Interest. The management plan must include any required regulatory elements, such as:

- The role and principal duties of the Investigator with a Financial Conflict of Interest in the project.
- The conditions of the management plan.
- How the management plan is intended to safeguard objectivity in the project.
- The written confirmation of the Investigator with a Financial Conflict of Interest in the project.

- How the management plan will be monitored for compliance.

Determination of the existence of a Financial Conflict of Interest and the means identified for eliminating or managing the conflict will be communicated in writing to the affected Investigator and other appropriate personnel.

The Compliance Officer shall monitor compliance with any management plan implemented pursuant to this section on an ongoing basis until completion of the project.

## **5. Retrospective Review**

Whenever a Significant Financial Interest involving PHS-funded research is not identified in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest or any other reason, then within 60 days the Compliance Officer shall review the Significant Financial Interest to determine whether a Financial Conflict of Interest is present, and, if so, shall implement a management plan. In the event a Financial Conflict of Interest is not identified or managed in a timely manner, then ICPD shall complete a retrospective review of the Investigator's activities and the PHS-funded research. Such retrospective review shall be completed within 120 days of the determination of noncompliance.

The retrospective review will be documented by the individual or committee appointed by ICPD. Such documentation shall include the following elements:

- Project/Contract number and title;
- Principal investigator/project director;
- Name of the Investigator with the Financial Conflict of Interest;
- Name of entity in which the Investigator has a Significant Financial Interest that gives rise to the Financial Conflict of Interest;
- Reason for the retrospective review;
- Detailed methodology used for the retrospective review;
- Findings of the review; and
- Conclusions of the review.

ICPD shall take such actions as are legally required based upon the retrospective review.

## **6. Financial Conflict of Interest Reports to PHS**

Prior to ICPD's expenditure of any funds under a PHS-funded research project, ICPD will provide the PHS Awarding Component with a Financial Conflict of Interest Report ("Report") regarding any Significant Financial Interests, including Significant Financial Interests of sub-recipient Investigators, related to the PHS-funded research that ICPD has found to be conflicting and, to the extent required by regulation, will ensure that ICPD has implemented a management plan as set forth in Section 4 hereof. In addition, during the course of a PHS-funded research project, ICPD will provide the PHS Awarding Component with a Report within 60 days of identifying any Significant Financial Interest that ICPD identifies as conflicting subsequent to its initial Report, as well as an annual report for the duration of the project, indicating whether any previously reported Financial Conflict of Interest is still being managed or whether it no longer exists.

Any Reports will contain all elements required by regulation, which may include:

- Project/Contract number;
- Principal investigator/project director;
- Name of the Investigator with the Financial Conflict of Interest;
- Name of entity in which the Investigator has a Significant Financial Interest that gives rise to the Financial Conflict of Interest;
- Nature of the financial interest;
- Value of the financial interest, within dollar ranges, or if the value cannot be readily determined through reference to public prices or other reasonable measures, a statement to that effect;
- A description of how the financial interest relates to the PHS-funded research and the basis for ICPD's determination that the financial interest conflicts with such research; and
- A description of the key elements of the management plan, including
  - The role and principal duties of the conflicted Investigator in the research project,
  - Conditions of the management plan,
  - How the management plan is designed to safeguard objectivity in the research project,
  - Confirmation of the Investigator's agreement to the management plan,
  - How the management plan will be monitored to ensure Investigator compliance, and
  - Other information as needed.

If a retrospective review is performed as provided for in Section 5 hereof, previously submitted Reports affected by the review will be updated to specify the actions taken to



manage the Financial Conflict of Interest going forward. If the retrospective review finds that the PHS-funded research was biased, ICPD will promptly notify the PHS Awarding Component and submit a mitigation report, which shall include:

- The key elements, which will be itemized, documented in the retrospective review;
- A description of the impact of the bias on the research project; and
- ICPD's plan of action or actions taken to eliminate or mitigate the effect of the bias.

ICPD will submit updated Reports annually to PHS, addressing the status of previously identified Financial Conflicts of Interest and any changes to management plans, including whether the Financial Conflict of Interest is still being managed or, if it no longer exists, an explanation as to why it no longer exists. Reports will be submitted for the duration of the PHS-funded project period.

#### **7. Sub-awardees, Contractors, and Collaborators**

If ICPD will work on PHS-funded research with a sub-grantee, contractor, or collaborator, ICPD will require the sub-recipient to confirm in its written agreement with ICPD that the sub-recipient will comply with the financial conflicts of interest policy of the sub-recipient or ICPD. If the sub-recipient's financial conflicts of interest policy will apply, the sub-recipient shall certify as part of the agreement that its policy complies with PHS regulations, and the agreement with the sub-recipient must identify how financial conflicts of interests will be reported to ICPD consistent with established timeframes, to allow ICPD to review and further disclose to PHS within required timeframes.

#### **8. Public Disclosure of Information**

The Policy shall be available via posting on a publicly accessible website. In addition, prior to the expenditure of any funds under a PHS-funded research project, ICPD will make available, either via a publicly accessible website or by responding within five days to any written request, information concerning any Significant Financial Interest that is determined by ICPD to be a Financial Conflict of Interest held by a principal investigator or project director or any other individual who has been identified by ICPD as key personnel on the PHS-funded project, is related to the PHS-funded research and which is a Financial Conflict of Interest. This information shall include the Investigator's name, title and role with respect to the research project, the name of the entity in which the Financial Conflict of Interest is held, the nature of the Financial Interest, and the approximate dollar amount of the Significant Financial Interest within dollar ranges, or if the value cannot be readily determined through reference to public prices or other reasonable measures, a statement to that effect. This information shall be updated annually, or within 60 days for information concerning Significant Financial Interests that were not previously disclosed, or if ICPD determines that a Significant Financial Interest is a Financial Conflict of Interest.

In situations where the Department of Health and Human Services 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 as required by this Policy, ICPD will require that the Investigator 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.

#### **9. Notification to PHS**

ICPD will promptly notify the PHS Awarding Component if failure of an Investigator to comply with this Policy or a management plan provided for hereunder has biased the design, conduct or reporting of PHS-funded research. This notice will include any corrective action taken.

#### **10. Training**

ICPD shall ensure that its Investigators are trained on the requirements set forth in ICPD's COI Policy and this Attachment B. Individuals shall be trained prior to engaging in any research on a PHS-funded project, at least every four years, and immediately upon the occurrence of the following:

- ICPD revises its policy in a material manner;
- For new Investigators, when they join ICPD; or
- If ICPD determines that an Investigator has not complied with the COI Policy, this Attachment B or a management plan implemented thereunder.

#### **11. Record Retention**

Records relating to all Investigator disclosures of financial interests related to PHS-funded research and ICPD's review of such disclosures, and management of any matters subject to this Policy, will be maintained for at least three years from the date of submission of the final expenditures report under the PHS-funded research or, where applicable, for such longer periods as specified in applicable regulation.