

**ALLEGHENY-SINGER RESEARCH INSTITUTE**  
**Pittsburgh, Pennsylvania**

Policy Manual No. 9170  
Page 1 of 7

**SUBJECT: RESEARCH CONFLICT OF INTEREST POLICY**

**DATE: April 27, 2011**

**PREEMPTION**

This policy rescinds any previous publication covering the same material. Related policies include Intellectual Property, Standards of Research Conduct, and Code of Ethics

**I PURPOSE**

In its endeavors to advance medical knowledge through research, ASRI recognizes its obligation to preserve the integrity of research conducted at ASRI, and to follow policies and practices that assure maintenance of research integrity, ASRI has a related obligation to sponsors of research, including the U.S. Public Health Service and other Federal agencies, to meet published requirements for recipient institutions to maintain and enforce policies for the management of conflicts of interest.

This policy is specifically intended to provide a safeguard against the possibility that the investigator's judgment could be influenced by having a significant financial or personal stake in the business success of a research sponsor or a direct competitor. The policy also stipulates that if potential bias is introduced into the investigator's work, that independent monitoring and evaluation of the investigator's findings will minimize such bias.

- A. **Responsibilities of the Institution**  
ASRI has the responsibility to identify, track and monitor potential conflict of interest (COI) among investigators, faculty and other individuals involved in the conduct of research at WPAHS, and institutional conflicts of interest that may arise in proposed research. ASRI through the WPAHS Research Conflict of Interest Review Committee is responsible to manage and mitigate identified conflicts of interest in research, and to report management and mitigation activities to internal and external bodies as required by regulation
- B. **Responsibilities of the Investigator**  
The investigator is responsible to read, understand and comply with the provisions of this policy. The investigator will disclose any and all potential conflicts of interest by participating in the ASRI COI survey process as outlined in this policy.
- C. **Responsibilities of IRB**  
In addition to the other provisions outlined in this policy, members of the Institutional Review Board (IRB) are required to read, understand and follow the IRB standard operating procedures (SOP's) on managing conflict of interest. IRB members are required to self disclose if they have a conflicting interest in protocols advanced, and to excuse themselves from the consideration of that protocol. The IRB is also responsible to notify the institution and RCOIRC when an

investigator is found to have a previously unrecognized conflict of interest or in any case where proposed research may result in an institutional conflict of interest.

## **II APPLICABILITY**

This policy is applicable to all investigators actively involved in research as defined in this policy.

## **III DEFINITIONS**

**A. ASRI** - Allegheny Singer Research Institute and affiliated entities of WPAHS.

**B. President of ASRI** – refers to the chief executive officer (president, CEO, Vice President) responsible for Allegheny-Singer Research Institute and affiliated entities.

**C. Chair** - refers to the investigator's department chairperson, center director or other unit head in which the research or clinical evaluation is performed or is to be performed.

**D. Research Conflict of Interest Review Committee** refers to a standing committee appointed by the WPAHS Executive Compliance Council which includes among its members President of the Allegheny-Singer Research Institute (ASRI), Vice President/Chief Scientific Officer of ASRI, cross section representation of investigators, VP. Chief Audit and Compliance Officer, Director System Compliance, ASRI Director of Operations, Director of Regulatory Compliance, a representative from the System Legal Office and other members as required to comply with regulations of federal sponsors of research conducted by ASRI. The RCOIRC membership will be limited to 10 members. The ASRI research investigator membership will rotate every two years.

**E. Disclosure Statement** - refers to the ASRI Investigator's Significant Financial Interests Disclosure Statement (Attachment 1).

**F. Significant Financial Interest** - is anything of monetary value given to the Investigator and Immediate Family including but not limited to, salary or other payments for services; equity interests; and intellectual property rights with the exception of:

1. Salary, royalties, or other remuneration from ASRI, or
2. An equity interest in a company that when aggregated is both not more than \$5,000 and is not more than 5% ownership interest; or
3. Salary, royalties or other payment obligations or expectations that when aggregated for the next twelve months, are expected to be not more than \$5,000 including reimbursed expenses.

**G. Immediate Family** - includes spouse, domestic partner and dependent children of the Investigator.

**H. ASRI Investigator** - includes any person (PI, co-investigator, coordinator, research staff) responsible or partially responsible for the design, conduct, outcome or reporting of Research (proposed or funded) under the auspices of the ASRI.

**I. Research** - refers to any systematic effort to generate new generalizable knowledge and includes the clinical evaluation of new drugs, devices, medical products or procedures and other studies. Research encompasses basic and applied research, and product development and evaluation.

**J. Sponsors of Research** - include entities which provide support to Investigators in research projects of mutual interest or in studies involving said entity's products or services.

**K. Conflict of Interest** - occurs when there is a divergence between an Investigator's private interests and his or her professional obligations to ASRI such that an independent observer might reasonably question whether the investigator's professional actions or decisions are compromised by considerations of personal gain, financial or otherwise. A Conflict of Interest depends on opportunities existing within a situation, and not on the actual benefits to or motives of the Investigator.

Conflicts of Interest, actual or apparent, can arise when an Investigator has financial or personal interests directly or indirectly linked to a Sponsor of Research, or an entity which has an interest in the outcome of Research in which he/she is engaged. These interests may compromise, or have the appearance of compromising, an Investigator's professional judgment in conducting, interpreting or reporting research.

Incentives in the form of any type of equity (including stock options) raise a concern of Conflict of Interest. Regardless of the circumstances under which an equity interest is obtained, the perception may exist that it introduces a bias into research. Payments in the form of equity differ from cash compensation based on time expended because of the possibility for the value of the equity to fluctuate based upon anticipated benefits that result from new research findings, which may or may not be later realized. There is also a potential for "insider trading." This situation should be contrasted with financial benefits in the form of royalties paid to an Investigator as a result of patented discoveries. The financial benefit, in the case of royalties, comes after development of the product. If the discovery is not validated and commercially pursued, neither a product nor a financial benefit will be forthcoming.

**L. Conflict of Commitment** - Institutionally employed ASRI Investigators owe their primary allegiance to ASRI, WPAHS and its affiliated entities. Their primary commitment of time and intellectual energies should be to the patient care, education and research programs of the institution. Attempts of Investigators to balance ASRI responsibilities with external activities such as consulting, public service or pro bono work can result in conflicts regarding allocation of time and energies. The WPAHS Consulting Agreements and Related Activities Policy provides guidance to Employed Physicians of WPAHS, Employed Practitioners and Investigators and Physicians in a Leadership capacity receiving stipends from WPAHS on interactions with public or private companies, organizations or other entities with respect to consulting or other relationships and establishes limitations upon both the type of interaction and time commitments that Employed Physicians of WPAHS, Employed Practitioners and Investigators and Physicians in a Leadership capacity receiving stipends from WPAHS may apply toward such activities. Consulting and related activities ("Consulting") may foster the exchange of knowledge and information that leads to advances in medical care, education, and other benefits. However, these activities may 1) interfere with an individual's primary professional obligations, 2) create conflicts of interest, 3) involve use of institutional resources, and 4) generate legal and/or compliance risks for the individual and the Institution. This Policy establishes the terms for acceptable Consulting to ensure that the benefits of these activities can be realized while avoiding any potential issues.

**M. Institutional Conflict of Interest** – The fiduciary responsibility of the institution's investment managers is to maintain a diversified portfolio of holdings. When proposed research involves a company in which the institution has a financial interest, an institutional conflict of interest may be created.

## **IV POLICY STATEMENT**

It is the policy of ASRI that each Investigator who is involved in research shall make full and detailed disclosures to ASRI of any Significant Financial Interests he/she has both annually and at the time of application for funding of the proposed research. Any actual or perceived conflict of interest will be managed by the mechanism provided in this policy to minimize the risk of loss of scientific integrity (real or perceived)

and to insure the unbiased results of the research are made available to the public. Investigators are responsible for filing interim disclosures if any changes occur before the next annual disclosure filing date.

It is the policy of ASRI that each Investigator who is involved in research shall disclose any financial or ownership interest in a company that provides products that will be evaluated in the course of a research project.

It is the policy of ASRI that each Investigator who is involved in research involving human subjects who has a Significant Financial Interest in the sponsor or in an entity which has an interest in the outcome of the research shall state in the patient consent form used in the study that he/she has such Significant Financial Interest.

It is the policy of ASRI that the results of research reported in publications and presentations acknowledge the source of research support. Disclosure of Significant Financial Interest in sponsors or an entity which has an interest in the outcome of the research shall be made by Investigators in articles submitted for publication in accordance with policies of the publishers of journals to which articles are submitted, and in presentations of research.

Investigators are required to cooperate with the RCOIRC in its efforts to determine appropriate action required to manage any potential conflict of interest or commitment, including, but not limited to making disclosures to ASRI and research subjects as appropriate, permitting independent monitoring of Research and publication, refraining from participating in Research, abstaining from equity acquisition / transactions, and / or divestiture.

## **V DISCLOSURE**

All information provided by an Investigator during the disclosures or review process shall be confidential, except as necessary to implement this Policy or as otherwise required by law.

- A. **Annual Statement** – Annually, investigators who are involved in research at ASRI will complete the Conflict of Interest Disclosure Form (Attachment 1). This form shall be submitted to the ASRI Director of Operations. Investigators shall file interim disclosures if any changes occur before the next annual disclosure filing date.
- B. **Extramural Funding Application** – At the time that an application for extramural funding is made, or prior to a clinical trial agreement being negotiated, the investigator shall indicate a potential conflict by checking the appropriate box on the ASRI Internal Review Form for grant submissions, or on the Institutional Review Board protocol form for clinical trials. If a potential conflict exists, the Investigator will be sent a Project Specific Disclosure Form to complete. This form should be returned in a confidential envelope as soon as possible to the ASRI Director of Operations. If it is determined that the situation needs additional review, the procedures stated in this policy will be followed.
- C. **Institutional Review Board** - Disclosure of Significant Financial Interest in sponsors or in an entity which has an interest in the outcome of the research shall also be made on forms provided by the Institutional Review Board (IRB) for approval of a research protocol involving human subjects, to insure that appropriate language is contained in the consent form and to consider additional monitoring to minimize risk of bias. Investigators, Research Staff and IRB members will adhere to IRB Standard Operating Procedures dealing with Conflict of Interest (Attachment 2).
- D. **Sub-recipient Investigators** - At the time of the application submission, the sub recipient Investigator must provide a statement of assurance signed by the appropriate institutional official

verifying that the sub recipient institution has established a written and enforced policy on Conflicts of Interest that is in compliance with federal laws and regulations governing Conflicts of Interest, and that the sub recipient further agrees to adhere to the sponsoring agency guidelines where those guidelines may be more restrictive than their institution's policy.

## **VI PROCESS FOR DISCLOSURE STATEMENTS**

### **A. Initial Review -**

The initial review of disclosure statements is conducted by the ASRI Director of Operations. The results of the initial review by the ASRI Director of Operations are documented on a Review Form (Attachment 3) which is completed and forwarded to the President of ASRI for review and retention. The Investigator shall receive a copy of this review form.

If the financial interest is less than \$5,000 and is not in a private or start up Company, the ASRI Director of Operations may determine that the relationship disclosed by an Investigator is such that there is minimal probability of the Investigator introducing a bias into the research activity. The Disclosure Statement will be forwarded to Research Conflict of Interest Review Committee for review if the ASRI Director of Operations determines that 1) real or apparent Conflict of interest is not resolved to his / her satisfaction; 2) an ownership interest in a private entity is disclosed; or 3) a Significant Financial Interest exceeding five thousand (\$5,000) is disclosed. The referral to RCOIRC should be made along with a proposed mitigation plan.

### **B. Research Conflict of Interest Review Committee – Level II Review**

The next level of review is conducted by the ASRI Research Conflict of Interest Review Committee which is responsible for; 1) providing assistance and advice to Investigators on questions of conflict of interest and commitment; 2) reviewing all Disclosure Statements that reveal Significant Financial Interests exceeding five thousand dollars (\$5,000) and those Disclosure Statements referred following the first level of review; 3) reviewing all Disclosure Statements that reveal any ownership interests in a private entity; and 4) Approving or (where appropriate) developing mitigation plans and making recommendations to the IRB , ASRI and ECC as warranted.

### **C. Institutional Conflict of Interest**

When an Institutional Conflict of Interest is identified by the ASRI administration (includes Directors, Vice President and the President), the ASRI will consult with Finance, Compliance, and Legal as appropriate and bring forth a Recommended Action Plan for the RCOIRC.

## **VII MANAGEMENT OF CONFLICTS**

Each reviewer and the review committee is responsible for reviewing the totality of the relationships between the investigator and the sponsor or other entity which may have an interest in the outcome of the research and determining if the relationships are so financially rewarding or comprehensive as to cause, or appear to cause, a conflict of interest that could jeopardize the integrity of the conduct or interpretation of research or related reporting.

Conflict of Interest

Based upon an objective and confidential evaluation of the Conflict of Interest Disclosure Statement and the proposed research at each stage of review, the reviewer may require certain modifications to minimize the possibility that any relationship between the investigator and sponsor (or other entity), which has an interest in the outcome of the research, will result in a bias of the results of research or create a potential for benefit from insider trading.

The following general principles shall guide the deliberations of reviewers of potential conflicts of interest in developing their recommendations for an appropriate resolution of any such conflict identified:

1. If research is proposed to be conducted by an Investigator who has acquired a Significant Financial Interest in the sponsor of the research, or in another entity which has an interest in the outcome of the research, or in a company that provides products that will be evaluated in the course of the research, such Investigator will be required to agree to the following:
  - a. Divestiture of such ownership; or
  - b. If ownership is not divested:
    - (1) Agreement to refrain from any and all transactions relating to such Significant Financial Interest until one year after the research or related activity is complete and reported or published in a public forum; and
    - (2) Acceptance of additional monitoring of the research (e.g., data acquisition, data analysis and reports pertaining to the research) by qualified individuals not directly involved in the research in manner or process that will insure freedom from individual bias.
2. If an investigator is engaged in research, the results of which could impact the success of any other company, such Investigator shall refrain from acquiring any ownership interest in such company for the duration of the research plus one year after the research or related activity is complete and reported or published in a public scientific forum.
3. If an individual is engaged in research, the results of which could impact the success of a particular company, such Investigator shall refrain from multiple compensated relationships with such company and shall confine his or her relationship to the company to reporting of research and no more than one compensated activity (e.g., consulting, service on advisory board), and such compensation shall not exceed a reasonable payment relative to the services provided. If such payment exceeds \$5,000, the provisions of this policy governing COI will apply
4. If an individual is engaged in a research activity funded wholly or in part by a Federal or other public entity that has published its policies or requirements concerning financial interests of investigators in sponsors, such individual shall comply with the requirements of the funding agency, if these requirements are more stringent than ASRI policy. This includes any reporting requirements pertaining to the potential or actual existence, management, and resolution of any conflicts.
5. The informed consent should include a disclosure language regarding the financial interest relationship with the sponsor

Conflicts of Commitment (See WPAHS Policy on Consulting Agreements and Related Activities)

A conflict can arise when an investigator's obligation to outside professional activities interferes with his or her responsibilities to ASRI or an affiliated entity which employs him / her. The following principles are set forth to help insure that such conflicts do not develop.

1. Consulting arrangements with outside entities cannot compromise the institutional rights to intellectual property as established in the ASRI Intellectual Property Policy.
2. An Investigator may not divert an opportunity for a research grant, contract or other formal research support which otherwise ASRI would have an expectation to obtain, to external entities or other institutions or individuals (including the Investigator) without prior written approval from the President of ASRI.
3. Consulting relationships must not impose restrictions on the Investigator's right to disseminate results in published or other form except for reasonable delays not to exceed 90 (ninety) days for patent filing etc.

**VIII APPEAL/EXTERNAL REVIEW OPTION**

A. Election to Appeal - Investigators who disagree with the recommendations of the reviewers at any level in the review process may appeal decisions to the next level of review. Investigators who disagree with the decisions of the ASRI Research Conflict of Interest Review Committee may elect to appeal the recommendations to the WPAHS Executive Compliance Council (ECC), with or without an external advisory opinion. The decision of ECC is final and will take into consideration the advisory opinion requested, if any.

The Investigator shall submit to the President of ASRI a written statement of election to appeal specifically including:

1. A statement that he/she agrees to abide by the result of the appeal process,
2. A description of the issue to be appealed; and
3. The appeal mechanism requested.

**IX SANCTIONS**

Sanctions for violations of this policy, including failure to disclose Significant Financial Interests and failure to abide by this Policy, including recommendations made following the review process set forth in this Policy, shall include disciplinary action up to and including termination of employment or denial of further opportunities to conduct research.

**ATTACHMENTS INCORPORATED BY REFERENCE**

Attachment 1	ASRI Investigators Annual COI Disclosure Form
Attachment 2	IRB Standard Operating Procedures for COI
Attachment 3	ASRI Conflict of Interest Review Form

Approved for ASRI Policy Manual:



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# Allegheny-Singer Research Institute

## 2011 Conflict of Interest Disclosure

Name: \_\_\_\_\_

### Part A. Disclosure Questions

#### Disclosure Questions Form

#### 1. Corporate Roles with WPAHS

Since January 1, 2010, have you been or are you now serving on a WPAHS Board of Trustees/Board of Directors?

Yes    No

#### 2. Board Committees

Since January 1, 2010, have you been or are you now serving on a WPAHS Board Committee, foundation boards, or other entity boards?

Yes    No

#### 3. If yes to question #2 above, please list all details below.

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

#### 4. Are you engaged in any of the following outside professional activities? Please check all that apply.

- Consulting arrangement with a company  
 Receipt of honoraria from any for-profit organization  
 Service on a scientific or medical/clinical advisory board  
 Service as a Board of Director for an outside company/vendor  
 Founder of a company  
 Have other financial interests with a vendor or organization involved directly in your sponsored research activities  
 On the speakers bureau of a company  
 Performing services as an expert witness  
 None of the above \_\_\_\_\_

#### 5. Owning Stock in or Receiving Royalties from your Research Sponsors

Since January 1, 2010, have you or any member of your immediate family owned either directly or indirectly any stock or stock options in a commercial entity for whom you are conducting sponsored research? Have you received, directly or indirectly, royalties, dividends or payments of any kind from one of your own sponsors; or indirect interests which include equity or funds that are held by the WPAHS for you? Note: You do not have to disclose equity in publicly traded diversified mutual funds.

Yes    No



**6. Stock Holdings and Supply Vendors**

Since January 1, 2010, to the best of your knowledge, have you or any member of your immediate family held stock or other financial interests in any vendor of the WPAHS from which your department makes purchases?

Yes No

**7. Major Purchases by the WPAHS from Research Sponsors, Vendors or Donors**

Since January 1, 2010, have you participated in decisions involving significant purchases for the WPAHS from a commercial company that funds any research or educational activities at the WPAHS?

Yes No

**8. Substantial Gifts to the WPAHS from Research Sponsors**

Since January 1, 2010, have you received or solicited charitable contributions on behalf of the organization from research sponsors?

Yes No

**9. Other Financial Relationships with Research Sponsors**

Do you have any other financial relationships, either direct or indirect, other than #4 through #7 above, with organizations sponsoring clinical research with which you are involved?

Yes No

**10. Outside Compensation**

Since January 1, 2010, does your total outside compensation exceed \$50,000 from consulting, speaking and related activities?

Yes No

**11. Equity Holdings**

To the best of your knowledge, do you hold or have you since January 1, 2010 held in excess of 1% of the equity in any organization which has executed contracts with the WPAHS?

Yes No

**12. Relationships with Non-Profit Organizations**

Since January 1, 2010, does your total outside compensation from **non-profit organizations** exceed \$5,000?

Yes No

**13. Non-Profit Organization Compensation Exceeding \$5,000**

If you responded "Yes" to question #12 above, please list sources of compensation for non-profit organizations exceeding \$5,000 below.

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**14. Other Relationships and Explanations**

Do you have any other relationships with an outside entity or person, whether investment, compensation, referral or otherwise, that could reasonably be perceived by others as influencing the objectivity of your clinical, research or administrative/business decisions as they relate to your WPAHS responsibilities? Or, do you want to provide additional information about any matter that you are disclosing in this submission?

For example, do you own stock, directly or indirectly, in a company that makes medical products that you prescribe for your patients, excluding stock in publicly traded diversified mutual funds? Or do you refer patients for treatment reasons to a member of your family?

Yes    No

**15. ASRI Statement of Financial Interests Form**

Did you or an immediate family member own more than 1% of the equity of any business during the period of 01/01/10 through now? If "yes," you must disclose in Part B.

Yes    No

**If your responses in Part A (Questions 4-15) included any "Yes" answers, please complete Part B.**

**Part B. Financial and Fiduciary Interests (example: compensation, investments)****Financial and Fiduciary Interests Form**

If your responses in Part A (Questions 4-15) included any "Yes" answers, please complete Part B. Please enter the relevant information below for each vendor, activity or service in which you dedicated effort, were compensated or received investments.

Vendor: \_\_\_\_\_

Activity (i.e.- Board of Directors/Partner, Consultant, Scientific Advisory Board, Speaker, Visiting Professor, Expert Testimony/Review, Elected Officer, NIH Study Section, Editor, Author, Fin. Investment Advisor, Honoraria, Other: \_\_\_\_\_

Type of Financial Interest (i.e. - cash, stock options, etc.): \_\_\_\_\_

Explanatory Comments: \_\_\_\_\_

Value of Compensation or Market Value of Stock: \_\_\_\_\_

Days/Year of Duties: \_\_\_\_\_

To determine whether your interest is a "Significant Financial Interest" under the ASRI policy, please confirm the exact nature of your relationship with the research sponsor by answering all of the following questions. In these questions "You" refers not only to yourself but also to members of your immediate family and any vendor/sponsor/source that you or an immediate family member controls or directs.

1. Do you participate in research sponsored by this entity or one of its primary competitors?

Yes No

2. Are you an elected officer, partner, or member of the governing board of this vendor/sponsor/source?

Yes No

3. Do you or any member of your immediate family own stock or stock options (of any value) in this vendor/sponsor/source, or do you receive royalty payments (of any amount) from this vendor/sponsor/source? (You must disclose financial interests that are indirect as well as direct. "Indirect" interests include equity or funds that are held by the ASRI for you or that is paid to members of your immediate family member and any vendor/sponsor/source that you or an immediate family member controls or directs).

Yes No

4. Did or will you RECEIVE cash or non-cash compensation exceeding \$5,000 from this vendor/sponsor/source DURING THE CURRENT 12-MONTH PERIOD (excluding reimbursement of expenses)?

Yes No

If you answered "Yes" to question #1 AND answered "Yes" to questions #2, #3, or #4 regarding this vendor please complete Part C.

**Please submit a Part B page for each Vendor/Sponsor/Source**

Part C. Management Plan

**Management Plan Form**

Sponsor: \_\_\_\_\_

Your responses in Part B indicate that you are participating in Research that is sponsored by the vendor/sponsor/source shown above, and that you have a "Significant Financial Interest" (SFI) in that vendor/sponsor/source.

In answering these questions, explain your relationship with the vendor/sponsor/source (i.e., speaker, scientific advisor, consultant, director, officer), the nature of your Research, and any circumstances that justify your involvement. If you have equity, stocks, or stock options, indicate the number of shares and approximate current value (of both your shares and the company's total shares). Include all information that you believe will assure the WPAHS and ASRI that your participation and role in the Research are justified by the steps that you propose to manage your SFI in this vendor/sponsor/source.

**1. Describe this Research project**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**2. If Human Subjects Research, describe the risk to human subjects in this investigation.**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**3. Describe any unique expertise you have that makes your involvement in the Research essential.**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**4. Describe the nature and amounts of any financial interests that you or a family member has in the Research sponsor.**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**5. Estimate your (or family member's) potential financial gains in the immediate and long-term future in the event the Research is successful.**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**6. What is the extent to which your Research results could be influenced by your (or family member's) financial interests?**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**7. What are the steps you propose to take in this Research project (in its oversight, management, data collection, data analysis, reporting, and/or patient disclosures) to manage the Significant Financial Interest?**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Part D. Honoraria/Consulting****Honoraria/Consulting Form**

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Research Investigators must be familiar with the WPAHS Policy on Consulting Agreements and Related Activities. The ASRI endorses the dissemination of knowledge involving clinical and research developments. In the questions that follow, compensation includes honoraria, consulting fees, lecture fees, stock or stock options, royalties, and "in-kind" compensation. Covered individuals should obtain appropriate departmental approval for any outside professional activities.

If you have received compensation for honoraria, consulting, or any other form of compensation from an outside source, please answer the questions below.

**1. Have you received the compensation for lectures, journal articles, educational tapes, visiting professorships, or services to professional societies or to National Institutes of Health (NIH) study sections?**

Yes    No

**2. Is any part of the compensation coming directly or indirectly from the pharmaceutical, biotechnology, or health industries? Note: Compensation for delivering Accreditation Council for Continuing Medical Education (ACCME)-accredited lectures is NOT considered to come from the pharma/biotech/health industry.**

Yes    No

**3. Is the compensation in exchange for advising financial investment firms or firms that broker for them if it is related to the healthcare industry?**

Yes    No

**4. For any consulting relationships, is there a written contract?**

Yes    No

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Part E. CMS Reporting

**CMS Reporting Form**

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The Center for Medicare and Medicaid Services (CMS) has established disclosure requirements in its Cost Report form, which WPAHS, as a participant in the Medicare and Medicaid programs, must file every year. In addition, the Office of the Inspector General (OIG) has issued compliance guidance applicable to health care providers setting forth disclosure expectations.

*The following questions apply to the period from January 1 through December 31, 2010.*

1. Have you been investigated for, or been alleged of, charged with, or convicted of a criminal offense related to your involvement directly or indirectly of any governmental program, including but not limited to Medicare or Medicaid?

Yes    No

2. If you responded "Yes" to question #1 above, please provide a detailed explanation below.

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3. Have you been excluded or proposed for exclusion from participating as a vendor, supplier, or provider to any government program, including but not limited to Medicare or Medicaid?

Yes    No

4. If you have responded "Yes" to question #3 above, please provide a detailed explanation below.

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**Signature**

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**Date**

<b>ASRI- WPAHS</b>	<b>SOP: Financial Conflicts of Interests of Investigators and Research Staff</b>				
	<b>NUMBER</b>	<b>DATE</b>	<b>AUTHOR</b>	<b>APPROVED BY</b>	<b>PAGE</b>
	SOP-055	12/3/2009	Director, Regulatory Affairs	IRB Chairman	1 of 2

**1 PURPOSE**

- 1.1 This procedure establishes the process to evaluate a report of an individual financial interest of an investigator or research staff Related to the Research or an institutional financial interest Related to the Research.
- 1.2 The process begins when IRB staff notify the COI Officer that an investigator or research staff has reported a financial interest Related to the Research or the COI Officer have detected an institution financial interest Related to the Research.
- 1.3 The process ends when the COI Officer has evaluated the reported interest and communicated the results of this evaluation to the IRB.

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

**3 POLICY**

- 3.1 The Vice President of Research serves as the COI Officer.
- 3.2 For any or all steps of this procedure, the COI Officer may have a committee follow the procedure whenever the COI Officer believes that institutional consensus is needed to make a decision.<sup>1</sup>

**4 RESPONSIBILITIES**

- 4.1 The COI Officer carries out these procedures or ensures that a committee follows these procedures.

**5 PROCEDURE**

- 5.1 Review the reported financial interest and the research protocol.
  - 5.1.1 If the financial interest and research protocol has already been reviewed, and if needed, managed, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.
- 5.2 Determine whether the reported financial interest could directly and significantly affect the design, conduct, or reporting of the Human Research.
  - 5.2.1 If there is no conflict of interest, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.
- 5.3 If a conflict of interest exists, determine under what circumstances, if any, should a conflicted individual (in the case of individual financial interest) or the organization (in case of institutional financial interest) be allowed to participate in:
  - 5.3.1 Subject recruitment?
  - 5.3.2 Prescreening for inclusion/exclusion criteria?
  - 5.3.3 The consent process?
  - 5.3.4 The treatment of subjects, separate from the research interventions or procedures?
  - 5.3.5 Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting?
- 5.4 Create a written management plan, considering the following options:
  - 5.4.1 Public disclosure of the financial interests.
  - 5.4.2 Monitoring of research by independent reviewers.
  - 5.4.3 Modification of the research plan.

<sup>1</sup> These procedures are designed for the majority of institutions that need infrequent reviews of investigator financial interests related to human research and very rare institutional financial interests related to human research. Institutions with frequent review of investigator financial interests should develop objective financial criteria for when committee review is required and establish a standing committee. Institutions with potential institutional financial interests should consider establishing a standing committee with outside representation or rely on an external review.

<b>ASRI- WPAHS</b>	<b>SOP: Financial Conflicts of Interests of Investigators and Research Staff</b>				
	<b>NUMBER</b>	<b>DATE</b>	<b>AUTHOR</b>	<b>APPROVED BY</b>	<b>PAGE</b>
	SOP-055	12/3/2009	Director, Regulatory Affairs	IRB Chairman	2 of 2

- 5.4.4 Disqualification from participation in all or a portion of the Human Research.
- 5.4.5 Divestiture of financial interests.
- 5.4.6 Severance of relationships that create the conflict of interests.
- 5.4.7 Use of an external IRB.
- 5.5 Provide the written management plan to the investigator for comment and review.
- 5.6 Finalize the written management plan.
- 5.7 Provide the IRB staff of the reviewing IRB with the written management plan.
- 5.8 When required provide the final determination to the funding or regulatory agencies.
- 5.9 Maintain a copy of determinations and management plans in the records.
- 6 MATERIALS**
  - 6.1 None
- 7 REFERENCES**
  - 7.1 None



<b>ASRI- WPAHS</b>	<b>SOP: Conflicting Interests of IRB Members</b>				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	SOP-050	3/18/2010	IRB Staff	Director, Regulatory Affairs	1 of 1

- 1 **PURPOSE**
  - 1.1 This procedure establishes the process to identify and manage Conflicting Interest of IRB members.
  - 1.2 The process begins when an IRB member is asked to review a protocol.
  - 1.3 The process ends when an IRB member has either identified a Conflicting Interest and notified IRB staff, or when an IRB member has determined that he or she does not have a Conflicting Interest.
- 2 **REVISIONS FROM PREVIOUS VERSION**
  - 2.1 None
- 3 **POLICY**
  - 3.1 IRB members are responsible to self-identify when they have a Conflicting Interest.
- 4 **RESPONSIBILITIES**
  - 4.1 IRB members (regular and alternate) follow these procedures.
- 5 **PROCEDURE**
  - 5.1 Before reviewing research IRB members are to determine whether they have a Conflicting Interest with research.
  - 5.2 A Conflict of interest may exist when:
    - 5.2.1 the chair or a member or immediate family member (significant other or dependent child) has a primary role in the design or conduct of the study or has a substantial role in the analysis or management of the data
    - 5.2.2 the chair or a member or immediate family member has a financial interest of \$5,000 or more in any agents/devices/enterprises involved in the study under consideration
    - 5.2.3 the chair or a member or immediate family member have authority to enroll prospective subjects for the protocol based on the following factors:
      - 5.2.4 seeks or obtains informed consent of subjects, or performs or directs research interventions and interactions with subjects; and
      - 5.2.5 the chair or member or immediate family member becomes an advocate for and promoter of that protocol
      - 5.2.6 the chair or a member or immediate family member assisted with design of or designed the study
  - 5.3 If an IRB member has a Conflicting Interest for review outside a meeting (e.g., the expedited procedure), he or she is to notify the IRB staff and return all materials.
  - 5.4 If an IRB member has a Conflicting Interest for review of research at a meeting, he or she is to notify the meeting chair, stay in the meeting room only to answer questions about the research, and to leave the meeting room for discussion and voting regarding that research.
  - 5.5 Conflicting Interest for review of research at a meeting will be documented.
- 6 **MATERIALS**
  - 6.1 IRB COI Handout
- 7 **REFERENCES**
  - 7.1 21 CFR §56.107(e).
  - 7.2 45 CFR §46.107(e).

# ALLEGHENY-SINGER RESEARCH INSTITUTE

## Conflict of Interest Review Form

In accordance with the ASRI Policy on Conflict of Interest, the attached Disclosure Statement submitted by \_\_\_\_\_ on \_\_\_\_\_ has been reviewed.

### **LEVEL I Review**

Based on my review of this Disclosure Statement, I have determined that:

- No perceived or actual conflict of interest or commitment is present.
- The Disclosure Statement reveals equity/financial interest of \$5,000 or more and is being forwarded for Level II Review.
- The Disclosure Statement reveals equity/financial interest in a privately held entity and is being forwarded for Level II Review.
- I remove myself from the review of this Disclosure Statement because of my own involvement in the research. Therefore, the Disclosure Statement needs to be forwarded to the President of the ASRI, or his/her designee, for review.
- A perceived or actual conflict of interest is present. The following recommendations are being made to manage this conflict (attach additional sheets if necessary):  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- The Investigator does not agree with the above recommendations for management of the conflict. Therefore, the Disclosure Statement needs to be forwarded for Level II Review.

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Director of Operations Signature

Date

**LEVEL II Review**

Based on the review of this Disclosure Statement, it has been determined that:

- No perceived or actual conflict of interest is present
- A perceived or actual conflict is present. The following recommendations are made to manage this conflict (attach additional pages if necessary):

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Signature of ASRI President

Date

ACCEPTANCE OF RECOMMENDATIONS MADE BY ASRI PRESIDENT:

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Signature of Investigator

Date