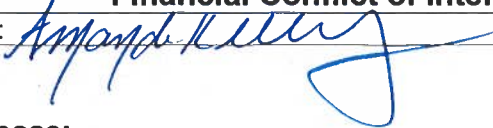


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POLICIES AND PROCEDURES	Do Not Duplicate
Financial Conflict of Interest in Research Policy	
Approved by: 	Revision: Original

1.0 Purpose:

1.1 The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children). This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- National Science Foundation 05-131 Chapter V, 510, Conflict of Interest Policies

2.0 Scope:

2.1 This policy applies to Investigators participating in, or planning to participate in the design, conduct, or reporting of Public Health Service (PHS) or National Science Foundation (NSF) funded research at IIVS.

This policy does not apply to applications and awards supported under the Small Business Innovation Research Phase I Program or the Small Business Technology Transfer Phase I program.

If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) or National Science Foundation (NSF) funds be subcontracted by IIVS to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

3.0 Definitions:

- 3.1 IIVS Officer** - The IIVS official responsible for the implementation of this policy, including the solicitation and initial review of disclosures of significant financial interest from research Investigators.
- 3.2 Conflict of Interest Management Plan or Management Plan** - Written plan developed to manage conflicts by mitigating, reducing or eliminating Financial Conflicts of Interest so that the design, conduct or reporting of research is free from bias or the appearance of bias.
- 3.3 Entity** - Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) from which an Investigator (and/or the Investigator's spouse and/or dependent children) receives remuneration, or in which any person has an ownership or equity interest.
- 3.4 Financial Interest** - Anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children whether or not the value is readily ascertainable.


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- 3.5 Financial Conflict of Interest** - A Significant Financial Interest (SFI) related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.
- 3.6 Institution** - Any domestic or foreign, public or private, entity or organization (excluding a Federal Agency) that is applying for, or receives, PHS or NSF research funding.
- 3.7 Institutional Official** - The individual who is legally authorized to act for the institution, and on behalf of the institution.
- 3.8 Institutional Responsibilities** – An Investigator’s professional responsibilities on behalf of IIVS including, but not limited to, activities such as research, research consultation, teaching, professional/clinical practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Institutional Animal Care and Use Committees or Data and Safety Monitoring Boards, etc.
- 3.9 Investigator** – The project director/principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or a proposal for PHS or NSF funding, including persons who are subcontractors, collaborators or consultants.
For example, this definition includes the principal investigator, co-investigators, research coordinators, research associates, collaborators and consultants, and may include research assistants and students as identified by the PD/PI depending on their specific roles and responsibilities.
- 3.10 Management** - Actions taken to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, and to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- 3.11 PD/PI** - Project director or principal investigator of a research project.
- 3.12 Public Health Service (PHS) Awarding Component** - The organizational unit of the PHS that funds the research (e.g., National Institutes of Health).
- 3.13 Research** - A systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research through which an investigator collects data through intervention or interaction with animal or human subjects, or from identifiable private information. The term encompasses basic and applied research and product development. The term also includes any such activity for which research funding is available from a PHS or NSF Awarding Component through a grant or cooperative agreement, whether authorized under the PHS, NSF, or other statutory authority.
- 3.14 Senior/Key Personnel** - The Project Director/Principal Investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS or NSF by the Institution under this subpart.
- 3.15 Significant Financial Interest (SFI) –**
1. A financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator’s spouse and/or dependent

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children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- a. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). Equity interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - b. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (and/or the Investigator's spouse and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Any reimbursed or sponsored travel related to an Investigator's institutional responsibilities, including that which is paid on behalf of the investigator so that the exact monetary value may not be readily available.
 3. The term *significant financial interest* does not include the following types of financial interests:
 - a. Salary, royalties, or other remuneration paid by IIVS to the Investigator if the Investigator is currently employed or otherwise appointed by IIVS, including intellectual property rights assigned to IIVS and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
 - b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local agency located within the United States, an Institution of higher education as defined in 20 U.S.C. 1001(a) (i.e., a United States Institution of higher education), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

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- c. Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, or an Institution of higher education as defined at 20 U.S.C. 1001(a) (i.e., a United States Institution of higher education), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- d. Travel by a PHS-funded Investigator that is reimbursed or sponsored by a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

3.16 Small Business Innovation Research (SBIR) Program - the extramural research program for small businesses established by the awarding components of certain Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public law 102-564.

4.0 Policy

4.1 All IIVS Investigators (see definition) who apply for, are part of a collaborator's application, or receive PHS or NSF funding must complete a Financial Conflict of Interest in Research Disclosure Form annually and must update the disclosure under the following circumstances:

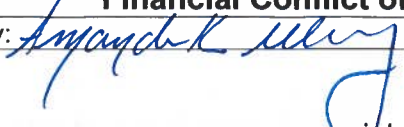
- Within 30 days of discovery or acquiring a new financial interest that relates to their institutional responsibilities
- No later than at the time of application by IIVS or collaborators for research funding.

5.0 Procedure

5.1 Investigator Responsibilities

5.1.1 Investigators are responsible for:

- Disclosing all significant financial interests including, with respect to reimbursed travel, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration
- Providing updates to disclosed information as needed
- The PI/PD must provide a list of investigators who will be

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associated with a grant or contract, as requested by IIVS collaborators

- Completing all required training and education
- Completing the annual disclosure form even if they have no financial interests to report.

5.2 Review of FCOIs

The IIVS Officer will review disclosure forms to determine whether an Investigator's disclosed significant financial interest could directly and significantly affect the design, conduct or reporting of the research, and therefore constitutes a Financial Conflict of Interest (FCOI). The Investigator may be included in making this determination.

5.3 Management of FCOIs

If a FCOI is identified for an Investigator, a Management Plan will be developed and implemented prior to the release of any sponsor or grant funds. If an Investigator discloses within the 30-day window of acquiring a new SFI, it will be reviewed by the IIVS Officer to determine whether a FCOI exists. If the SFI is determined to be a FCOI, a Management Plan, at a minimum an interim plan, will be developed and implemented within 60 days from the date of disclosure by the Investigator.

A Management Plan will include conditions and/or restrictions that have been, or will be taken, to ensure that the design, conduct or reporting of research is free from bias or the appearance of bias. A draft of the Management Plan will be provided to the Investigator for review and comment before it is finalized.

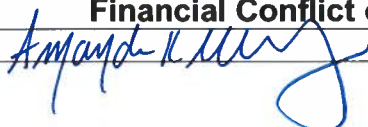
If the Institution identifies a SFI that was not disclosed or reviewed in a timely manner it will be reviewed within 60 days from the date the SFI was identified, to determine if the SFI is actually a FCOI. An interim management plan will be implemented when necessary.

5.4 Monitoring

Investigator compliance with Management Plans will be monitored by IIVS Officers. The frequency of monitoring will be dictated by sponsor/agency requirements and Management Plan provisions.

5.5 Special Considerations for Human Subject Research

Special consideration and scrutiny must be given to protect human subjects in research. Investigators with an identified financial conflict of interest or a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research shall not ordinarily participate in any research involving human subjects. This presumption against the

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participation in human subjects' research by financially interested individuals may be rebutted by compelling circumstances. Compelling justification may include factors such as unique investigator expertise, unique institutional resources, unique access to particular patient populations, nature of the science, level of risk to human subjects and the degree to which the financial conflict of interest and the research are related.

The compelling justification and the degree of risk to human subjects must be presented and reviewed by an IIVS Officer. If compelling circumstances justify a waiver of this policy, the research will be subject to the development and implementation of a management plan to ensure the safety of human subjects and the integrity of the research.

5.6 Other Special Considerations

IIVS is committed to the highest standards of integrity and objectivity in all research conducted within the system. Therefore, IIVS may request that any investigator, regardless of funding source, complete the FCOI in Research disclosure process and comply with this policy on an as needed basis.

5.7 Appeals

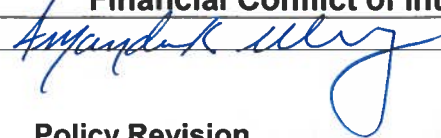
Investigators may appeal IIVS Officer decisions to the Institutional Official in writing within 15 days of receipt of the finalized Management Plan. The written appeal should include details regarding circumstances which support the request for a proposed revision to a committee decision. The Investigator may be invited to describe reasons for the appeal and to address further questions. The appeals process will take no more than 60 days from the date requested by the Investigator. The decision of the Institutional Official is final and binding.

5.8 Confidentiality

Financial information disclosed in compliance with this policy will be kept confidential and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel.

5.9 Enforcement

Failure on the part of an Investigator to comply with this policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or IIVS.

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5.10 Policy Revision

IIVS may modify this policy to conform to organizational changes and circumstances including revisions to federal or state law or regulations. When necessary, procedures will be developed or modified to implement this policy.

5.11 Additional Requirements

The following **additional** requirements also apply to all research funded by the PHS of the U.S. Department of Health and Human Services and any PHS Awarding Component including the NIH.

5.11.1 Reporting

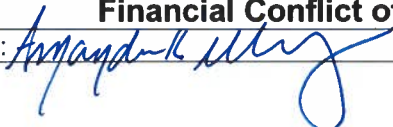
IIVS will provide to the PHS Awarding Component a FCOI report as outlined in the regulations:

Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI. This will be provided either directly to the awarding component or to our collaborators. IIVS will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. (See Attachment A for the Individual COI form to be completed by all applicable personnel.) This report will include the following information:

- Grant/Contract Number
- PD/PI
- Name of Investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
- Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
- Key elements of the Management Plan

Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

- Status of the FCOI

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- Changes to the Management Plan
- Justification if FCOI no longer exists

5.11.2 Subrecipients

For PHS-funded research that involves subcontractors, subgrantees or subawardees (collectively subrecipients) at other Institutions, IIVS will require a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements.

Subrecipient Institutions who rely on their FCOI policy must report identified financial conflicts of interests to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS Awarding component.

Subrecipients who do not have such a FCOI policy will be required to follow the IIVS FCOI in Research policy. A subrecipient's failure to promptly comply with the IIVS policy will be considered grounds for immediate termination by IIVS of any applicable subcontract or subaward. The written agreement terms required by IIVS will contain a provision that subrecipients will report to IIVS as the awardee Institution, any identified FCOI in sufficient time to allow IIVS to report and manage the FCOI to meet the reporting obligations described above.

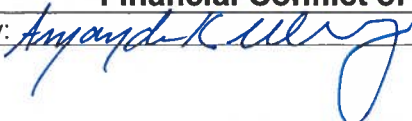
5.11.3 Travel Disclosure

PHS-funded Investigators must disclose the occurrence of reimbursable or sponsored travel related to their institutional responsibilities, **regardless of the value**. At a minimum the travel disclosure must include:

- Purpose of the trip
- Identity of the sponsor/organizer
- Destination
- Length
- Monetary value, if known

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- a federal, state, or local government agency
- an Institution of higher education as defined at 20 U.S.C. 1001(a)
- an academic teaching hospital

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- a medical center, or
- a research institute that is affiliated with an Institution of higher education

Travel disclosures will be reviewed by an IIVS Officer to determine if the travel represents a FCOI with PHS-funded research. Additional information may be requested at the time of review. Disclosure of travel must occur no more than 30 days after the last day of the trip.

5.11.4 Public Accessibility

This policy will be posted on the IIVS public website. In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestors via **an email** response within five business days from when an IIVS Officer receives the request. This information may be requested by calling **IIVS at (301-947-6523)** or through email: info@iivs.org

The written response will include:

- Senior/key personnel name
- Senior/key personnel's role in the research project
- Name of the entity in which the FCOI is held
- Nature of the FCOI
- Approximate dollar value of the FCOI or a statement that the value cannot be readily determined

This information will remain available for three years from the date the information was most recently updated.

5.11.5 Training Requirements

PHS-funded Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter. Training must also be completed *as soon as reasonably possible* under the following circumstances:

- This policy changes in a manner that affects Investigator requirements
- An Investigator is new to IIVS and will be working on PHS-funded research
- An Investigator is found to be noncompliant with this policy or their approved Management Plan

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5.11.6 Investigator/Institutional Non-Compliance

If a SFI is not disclosed or reviewed in a timely manner, IIVS will review the Investigator's financial interest, and determine if it is related to PHS-funded research; determine whether a FCOI exists, and if so:

- Implement a Management Plan for ongoing research, at a minimum implement an interim Management Plan
- Complete a retrospective review of Investigator's activities and the PHS- funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research; and
- If bias/non-compliance is found, the Institution will promptly inform the PHS Awarding Component by submitting a mitigation report

If the Department of Health and Human Services determines that a PHS-funded clinical research project 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 conflicting interest that was not managed or reported by IIVS, the Investigator must disclose the FCOI in each public presentation of the results of the research and must request an addendum to previously published presentations.

6.0 Responsibilities and Authorities

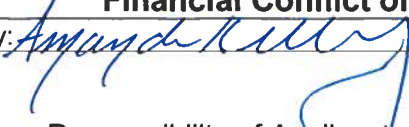
- 6.1** Investigators participating in, or planning to participate in the design, conduct, or reporting of Public Health Service (PHS) or National Science Foundation (NSF) funded research at IIVS have the authority and responsibility for the activities in this policy.

7.0 Records

- 7.1** IIVS will maintain in the electronic archives all records related to the implementation of this policy for at least three years after:
- the date of creation;
 - the date of termination or completion of a research award or contract;
 - the submission of the final expenditures report; or
 - the date of final resolution of any investigation, audit, or similar action involving the records.


8.0 References

- 8.1** Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F,

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Responsibility of Applicants for Promoting Objectivity in Research for
Which PHS Funding is Sought

- 8.2** Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors

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Attachment A

PHS/NIH SFI Disclosure Form

INITIAL Disclosure

Name: _____

Project Role: ___ PD/PI ___ Senior/Key Personnel


_____ Consultant _____ Other _____

Project lead PD/PI: _____ **Project Period:** _____

Project Title: _____

Institute for In Vitro Sciences (IIVS) Project Identification: _____

1. Do you or any member of your immediate family (spouse or partner and dependent children) have any Significant Financial Interests (SFI) in a **Publicly-Traded Entity** that might reasonably appear to be related to your Institutional Responsibilities as related to this project? (An SFI for publicly-traded entities exists if the value of any equity interest as of the date of disclosure combined with any remuneration in the past 12 months exceeds \$5,000.)
 ___ No ___ Yes If YES: Provide the following information in a sealed envelope marked **CONFIDENTIAL**: the name of the entity, the nature of the interest, its value, and any documentation.
2. Do you or any member of your immediate family (spouse or partner and dependent children) have any Significant Financial Interests (SFI) in a **Privately-Held Entity** that might reasonably appear to be related to your Institutional Responsibilities as related to this project? (An SFI for privately-held entities exists if the value of any remuneration in the past 12 months exceeds \$5,000, or when the Investigator or immediate family holds **any equity interest**.)
 ___ No ___ Yes If YES: Provide the following information in a sealed envelope marked **CONFIDENTIAL**: the name of the entity, the nature of the interest, its value, and any documentation.
3. Have you or any member of your immediate family (spouse or partner and dependent children) received **any income** related to **intellectual property** rights and interests that might reasonably appear to be related to your Institutional Responsibilities as related to this project? (Do not include any intellectual property that has been assigned to IIVS.)
 ___ No ___ Yes If YES: Provide the following information in a sealed envelope marked **CONFIDENTIAL**: the name of the entity, the nature of the interest, its value, and any documentation.
4. In the past 12 months have you undertaken any **travel** related to your Institutional Responsibilities related to this project that was either reimbursed or paid for by any individual or entity other than a Federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 ___ No ___ Yes If YES: Provide the following information in a sealed envelope marked

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CONFIDENTIAL: the purpose of the trip, the name of the sponsor/organizer, and the destination, duration, and approximate monetary value.

CERTIFICATION BY PD/PI or SENIOR/KEY PERSONNEL

- A. I have read and understand the Institute for In Vitro Sciences Financial Conflict of Interest in Research Policy.
- B. To the best of my knowledge, I have made all required financial disclosures.
- C. I agree to comply with any conditions or restrictions imposed by IIVS for the purpose of managing, reducing, or eliminating actual or potential conflicts of interest in connection with this grant. If I am unable to comply, I understand that IIVS, its partners, or collaborators may decline the grant award or terminate the PHS-funded research program.

Signature of PD/PI or Senior/Key Personnel

_____ Date _____

Check if applicable: _____

CERTIFICATION BY PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR:

The following people (or roles) meet the definition of Investigator for the above project, and I certify that they all will complete their own disclosure forms:

Signature of Investigator _____ Date _____

IF YES ABOVE, CERTIFICATION BY IIVS OFFICER

_____ No financial conflict of interest appears to exist.

_____ PROPOSALS: A financial conflict of interest may exist. The proposal may be submitted, but if the grant is awarded, research may not begin until an approved management plan is in place and our collaborators and the sponsor have been notified.

_____ UPDATES: A financial conflict of interest may exist. No research may go forward until an approved management plan is in place and our collaborators and the sponsor have been notified.

Signature of IIVS Officer

_____ Date _____

