

## APPENDIX A

### INTERNATIONAL AIDS VACCINE INITIATIVE, INC. (IAVI) RESEARCH CONFLICT OF INTEREST POLICY (FOR INVESTIGATORS INVOLVED IN PHS-FUNDED RESEARCH)

#### 1. INTRODUCTION

This Research Conflict of Interest Policy (the “*RCOI Policy*”) is designed to provide guidance for identifying and addressing potential, actual and apparent conflicts of interest of *Investigators* (as defined below) involved in Public Health Service-funded *Research* and is in compliance with Title 42 of the United States Code of Federal Regulations (CFR) Part 50, Subpart F, “Promoting Objectivity in Research.” If you have any questions regarding this *RCOI Policy* you should discuss them with the General Counsel. **Italicized terms used in this *RCOI Policy* are defined in Section 8.**

#### 2. COVERAGE AND DISCLOSURE OBLIGATION

This *RCOI Policy* applies to all *Investigators* who plan to participate in PHS-funded *Research* (except for Phase I applications under the *Small Business Innovation Research (SBIR) Program* or the *Small Business Technology Transfer (STTR) Program*).

All such *Investigators* have an obligation to make a disclosure of *Significant Financial Interests* to the General Counsel’s Office, at the following times:

- (a) prior to IAVI’s application for the relevant *PHS* award;
- (b) annually thereafter during the period of the relevant award; and
- (c) as new reportable *Significant Financial Interests* are obtained.

Disclosure questionnaires will be distributed annually as part of IAVI’s annual conflicts of interest disclosure process.

In addition, IAVI requires that its subgrantees, contractors, subcontractors and collaborators who plan to participate in such *Research* at IAVI’s request either: (a) have appropriate policies and procedures in place that comply with 42 CFR Part 50, Subpart F, in which case those policies and procedures will apply; or (b) follow this *RCOI Policy*.

#### 3. INVESTIGATOR TRAINING

Prior to the expenditures of any funds under, or engaging in *Research* related to, the relevant award, all *Investigators* are required to complete a training course on *Financial Conflict of Interest*. This training is also required every four years thereafter, or immediately under the following circumstances:

- (a) this *RCOI Policy* changes in a manner that affects *Investigator* requirements;
- (b) an *Investigator* is new to IAVI (or, in the case of a *Subawardee Investigator*, to that *Subawardee*); or
- (c) IAVI finds an *Investigator* noncompliant with this *RCOI Policy* or any plan IAVI has put in place to manage a *Financial Conflict of Interest*.

#### **4. PROCEDURES**

The General Counsel's Office will serve as the point of contact and coordinator for all conflict of interest disclosures and mitigating actions under this *RCOI Policy*. The General Counsel's Office will ensure that relevant conflicts of interest, and the procedures taken to manage those conflicts, are disclosed to the Audit & Finance Committee of the IAVI Board.

The General Counsel's Office will be responsible for evaluating and determining whether a conflict of interest exists and, if so, determining what actions should be taken by IAVI to manage such conflict of interest, except that any conflict regarding an IAVI Director or Officer will be referred to, evaluated and managed by the Audit & Finance Committee.

A conflict of interest under this *RCOI Policy* exists when the General Counsel's Office, or the Audit & Finance Committee, as applicable, reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of PHS-funded *Research*.

Disclosed relationships or transactions that constitute actual conflicts of interest that cannot be avoided or remedied may be prohibited. Each disclosure of a conflict of interest will be evaluated separately, on its merits.

If a determination is made that a disclosed relationship or transaction does not constitute a conflict of interest, no further action will be required.

Prior to IAVI's expenditure of any funds under the relevant award, IAVI will report to the *PHS Awarding Component* the existence of a conflicting interest (but not the nature of the interest or other details) found by IAVI and assure that the interest has been *Managed* in accordance with 42 CFR Part 50, Subpart F. If IAVI identifies any conflicting interest subsequent to IAVI's initial report under the relevant award, IAVI will report the conflicting interest to the *PHS Awarding Component* and will *Manage* the conflicting interest, at least on an interim basis, within 60 days of that identification.

#### **5. RECORDS OF PROCEEDINGS**

IAVI (and/or *Subawardee*, as applicable) will maintain records of all disclosures and all actions taken by IAVI with respect to each conflicting interest for at least three years from the date of submission of the relevant final expenditure report to the relevant *PHS* unit, unless any litigation, claim, financial management review or audit is started before the expiration of the three year period, in which case the records will be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken. IAVI will, upon request by *HHS*, make available to *HHS* information regarding all conflicts of interest identified by IAVI under this *RCOI Policy* and how those interests have been managed to protect the relevant research from bias.

## **6. PUBLIC ACCESSIBILITY**

Prior to the expenditure of any funds under a PHS-funded *Research* project, IAVI will ensure public accessibility, by way of a written response within five business days of a request, of information concerning any *Significant Financial Interest* disclosed to IAVI that meets all of the following criteria:

- (a) The *Significant Financial Interest* was disclosed and is still held by the *Senior/Key Personnel* for the PHS-funded *Research* project identified by IAVI (or a *Subawardee*) in the grant application, progress report, or any other required report submitted to the *PHS* unit;
- (b) IAVI determines that the *Significant Financial Interest* is related to the PHS-funded *Research*; and
- (c) IAVI determines that the *Significant Financial Interest* is a *Financial Conflict of Interest*.

The written response will note that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of IAVI's identification of a new *Financial Conflict of Interest*.

## **7. VIOLATIONS OF THE RCOI POLICY**

If an *Investigator* fails to disclose an actual or potential conflict of interest pursuant to this *RCOI Policy*, the Executive Office or the Audit & Finance Committee, as the case may be, may take appropriate disciplinary and corrective action. In addition, IAVI will, within 120 days of the determination of noncompliance with this *RCOI Policy*, complete a retrospective review of the *Investigator's* activities and the PHS-funded *Research* project to determine whether any PHS-funded *Research*, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such *Research*.

If the failure of an *Investigator* to comply with this *RCOI Policy* has biased the design, conduct, or reporting of PHS-funded *Research*, IAVI will promptly notify the *PHS Awarding Component* of the corrective action taken or to be taken.

In any case in which the *HHS* 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 disclosed or *Managed* as required by this *RCOI Policy*, the *Investigator(s)* involved must disclose the conflicting interest in each public presentation of the results of the *Research*.

## **8. DEFINITIONS**

### **Business:**

- (a) any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, limited liability company, trust or other for-profit commercial entity, whether publicly or non-publicly traded; and
- (b) any not-for-profit entity acting, directly or indirectly, as an agent for, or on behalf of, a commercial entity, or controlled by a commercial entity (i.e. where a commercial entity owns or funds 50% or more of the not-for-profit entity or otherwise controls the not-for-profit entity's activities).

**Family Member:** A spouse, domestic partner or dependent child of an *Investigator*.

**Financial Conflict of Interest:** A *Significant Financial Interest* that could directly and significantly affect the design, conduct or reporting of PHS-funded *Research*.

**HHS:** The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

**Institution:** Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, *PHS* research funding.

**Institutional Responsibilities:** An *Investigator's* professional responsibilities on behalf of the *Institution* including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**Investigator:** The project director/principal *Investigator* and any other person, regardless of title, who is responsible for the design, conduct, or reporting of research funded by *PHS*, or proposed for such funding, which may include, for example, collaborators or consultants.

**Manage:** Taking action to address a *Financial Conflict of Interest*, which can include reducing or eliminating the *Financial Conflict of Interest*, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias or the appearance of bias.

**PD/PI:** A project director or principal *Investigator* of a PHS-funded *Research* project.

**PHS:** The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

**PHS Awarding Component:** The organizational unit of the *PHS* (i.e., NIH) that funds the research that is subject to the *Regulation*.

**Regulation:** 42 CFR Part 50, Subpart F “Promoting Objectivity in Research” and any subsequent regulation that may be promulgated in its place.

**Research:** A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used herein, the term includes any such activity, study or experiment for which research funding is available from a *PHS Awarding Component* through a grant or cooperative agreement, whether authorized under the *PHS* Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

**Senior/Key Personnel:** The *PD/PI* and any other person who the *Institution* identifies as senior/key personnel in the grant application progress report, and any other report submitted to the *PHS* by the *Institution* under the *Regulation*.

**Significant Financial Interest** means:

- (a) a financial interest consisting of one or more of the following interests of the *Investigator* (and those of the *Investigator's Family Members*) that reasonably appears to be related to the *Investigator's Institutional Responsibilities*:
  - i. with regard to any publicly traded entity, a *Significant Financial Interest* exists if
    - the value of any salary or other payments for services (e.g., consulting fees, honoraria, paid authorship) received in the 12 months preceding the disclosure, and
    - the value of any equity interest in the entity (e.g., stocks, stock options or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value) as of the date of disclosure, when aggregated, exceeds USD \$5,000;
  - ii. with regard to any non-publicly traded entity, a *Significant Financial Interest* exists if
    - the value of any salary or other payments for services (e.g., consulting fees, honoraria, paid authorship) received in the 12 months preceding the disclosure, when aggregated, exceeds USD \$5,000, or
    - when the *Investigator* (or the *Investigator's Family Members*) holds any equity interest in the entity (e.g., stocks, stock options or other ownership interest); or
  - iii. any intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
- (b) the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the *Investigator* and not reimbursed to the *Investigator* so that the exact monetary value may not be readily available), related to the *Investigator's Institutional Responsibilities*. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. IAVI will determine if any further information is needed, including determination or disclosure of the monetary value, in order to determine whether the travel constitutes a *Financial Conflict of Interest*.

The term **Significant Financial Interest** does not include:

- (a) salary, royalties, or other remuneration from IAVI if the *Investigator* is currently employed or otherwise appointed by IAVI including intellectual property rights assigned to IAVI and agreements to share in royalties related to such rights;
- (b) salary, royalties, or other remuneration from a *Subawardee* if the *Investigator* is currently employed or otherwise appointed by that *Subawardee* including

- intellectual property rights assigned to that *Subawardee* and agreements to share in royalties related to such rights;
- (c) 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; or
  - (d) income from seminars, lectures, or teaching engagements sponsored by, or service on advisory committees or review panels for, or travel that is reimbursed or sponsored by, 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.

**Small Business Innovation Research (SBIR) Program:** The extramural research program for small business that is established by *PHS Awarding Components* and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this *RCOI Policy*, the term SBIR Program also includes the *Small Business Technology Transfer (STTR) Program*, which was established by Public Law 102–564.

**Small Business Technology Transfer (STTR) Program:** A research program included in the *Small Business Innovation Research (SBIR) Program*. See definition of *Small Business Innovation (SBIR) Program*.

**Subawardee** means any subgrantee, contractor, subcontractor or collaborator that is receiving PHS Funding from IAVI and is required to comply with the *Regulation*.

**Technology** means any methodology, information, software, compound, drug, device, diagnostic, medical or surgical procedure, or composition of matter intended for public use or research.