

## **HudsonAlpha Institute for Biotechnology**

Financial Conflict of Interest Policy: Dated 8/24/2012

Developed by using the FDP draft policy posted:

[http://sites.nationalacademies.org/PGA/fdp/PGA\\_061001](http://sites.nationalacademies.org/PGA/fdp/PGA_061001)

### **Introduction**

This policy governing financial conflict of interest applies to all Investigators at the institution regardless of rank. It may also apply to anyone with the reporting, design and conduct duties pertaining to the research. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other action pursuant to Institutional policy.

### **DEFINITIONS:**

**Conflict of Interest Committee** (COI Committee) means the Institution's committee that advises and reviews conflicts of interest. The committee consists of: the EVP, two HudsonAlpha Board members, the investigator compliance educational leader, the CFO, and the Director of Sponsored Programs.

**Family** means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

**Financial Interest** means anything of monetary value received or held by an Investigator or an Investigator's family, whether or not the value is readily ascertainable, including but not limited to: salary or other payments for services (eg: consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from HudsonAlpha.
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state, or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For investigators, **Financial Interest**, also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that is reasonably appears to be related to the Investigator's Institutional Responsibilities and:

- a) if with a publically traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publically traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000 or
- c) if with a non publically traded entity, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income related to intellectual property rights and interests not reimbursed through the Institution.

**Financial Conflict of Interest** means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of Institutional research.

**Institutional Official:** means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as the Executive Vice President.

**Institutional responsibilities** means the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, administration, and institutional, internal and external professional committee service.

**Investigator** means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator, or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

**Public Health Service or PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention. Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

**Research** means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The 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).

## **CONFLICT OF INTEREST**

This policy is predicated on the expectation that the Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and their Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an investigator should discuss the situation with the Institutional Official.

### **1) DISCLOSURE OF FINANCIAL INTERESTS**

All Investigators are required to disclose their outside financial interests to the Institution on an annual and ad hoc basis, as described below. The Institutional official is responsible for the distribution, receipt, processing, review and retention of disclosure forms. The Conflict of Interest committee will assist with the review of those forms and processes.

Regardless of the disclosure requirements, the Investigator, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

#### **a) Annual Disclosures**

All investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, on an annual basis.

All forms should be submitted to the Institutional Official or designee by January 1 for the previous year.

**b) Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment

Prior to entering into sponsored projects or applications for sponsored projects, where the investigator has a Significant Financial Interest, the Investigator must submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

**c) Travel**

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined about in the definition of Financial Interest. Such disclosures must include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

## **2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL AND CONFLICT OF INTEREST COMMITTEE**

If the disclosure form reveals a Significant Financial Interest, the conflict will be reviewed promptly by the Institutional Official, COI committee, or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-supported research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she

must require and approve a written management plan before any related research goes forward. The affected Investigator or the COI committee is responsible for developing and submitting a proposed management plan, in consultation with the Institutional Official.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity, to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

### **3) REPORTING TO PHS**

Should any reported conflict or non-compliance require reporting the PHS, the Institutional official will report in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awarder, such reporting will be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

### **4) INVESTIGATOR NON-COMPLIANCE**

#### **a) Disciplinary Action**

In the event of an Investigator's failure to comply with this Policy, the Institutional official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.

A Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the investigator, COI Committee, and where applicable, the IRB, and will notify the individual of the right to appeal the decision.

#### **b) Retrospective Review**

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the financial conflict of interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifically the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

## **5) TRAINING**

Each investigator must complete training on this Policy prior to engaging in research funded by PHS, and at least every four years thereafter. Investigators must also complete training within a reasonable period of time as determined by the Institutional official in the event that this policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

## **6) RECORD RETENTION**

The Institutional official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee.

## **7) CONFIDENTIALITY**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the institution may make such information available to an agency funding research of the investigator, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

## **8) SUBCONTRACT RECEIPIENTS**

Subcontractors under PHS funds will be questioned on their compliance with the FCOI policy and will be required to follow HudsonAlpha's policy unless they have an established institutional COI policy of their own.

## **9) PUBLIC ACCESSIBILITY**

Prior to the expenditure of funds, the Institution will publish on a publicly accessible website or respond to any requestor within (5) five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the Investigator.
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS policy.

## **9) Regulatory Authority**

This policy implements the requirements of 42 CFR 50 and 45 CFR94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.