

# Hearthstone Institute

## Financial Conflict of Interest (“FCOI”) Policy

### **INTRODUCTION**

This policy governing financial conflict of interest (FCOI) applies to all PHS-sponsored Investigators of The Hearthstone Institute (“HEARTHSTONE”). The Associate Director of Research for HEARTHSTONE is designated as the “Institutional Official” and is responsible for ensuring implementation of this policy, This Official may suspend all relevant research 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 administrative action pursuant to HEARTHSTONE policy.

### **DEFINITIONS**

*Clinical Trial* means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

*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 (e.g., 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 HEARTHSTONE;
  - 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; 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 as well as travel that is 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, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

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

- a) if with a publicly 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-publicly 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-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through HEARTHSTONE, or
- e) is reimbursed or sponsored travel related to their Institutional responsibilities.

*Financial Conflict of Interest* means a Significant Financial Interest (or, where Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that HEARTHSTONE reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

*Institutional Official* means the individual within HEARTHSTONE 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, Institutional Official is designated as the Associate Director of Research for HEARTHSTONE.

*Institutional responsibilities* means the Investigator's professional responsibilities associated with his or her position at HEARTHSTONE, such as research, teaching, clinical activities, administration,

and Institutional, internal and external professional committee service or in his or her service as a consultant, advisor, etc.

*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).

*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.

Investigators may be internal or subrecipients. Subrecipients are equally responsible to declare and be free of SFIs and FCOIs. Before commencement of research activities, a written agreement will be in place with any subrecipient determining whether they are to follow the current policy or the policy of their institution. In order to accept the outside institution’s FCOI policy it will have to be reviewed by HEARTHSTONE’s Institutional Official to ensure that it complies with all regulations.

**CONFLICT OF INTEREST:**

This policy is predicated on the expectation that 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 HEARTHSTONE 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 Institutional official.

## 1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests as defined above to HEARTHSTONE on an annual and on an ad hoc basis, as described below. Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

## 2) REVIEW AND DECISION OF INSTITUTIONAL OFFICIAL

All disclosure forms will be reviewed by the Institutional Official upon receipt. If the disclosure form reveals a Significant Financial Interest the Institutional Official or designee will determine whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest is found to exist, the Institutional Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. **If Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.**

The Institutional Official will periodically review the ongoing activity, 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) DISCLOSURE, REVIEW AND MONITORING

HEARTHSTONE requires each Investigator to disclose Significant Financial Interests (SFIs) including those of the Investigator’s spouse and dependent children related to the Investigator’s Institutional responsibilities. This disclosure is deemed complete when the PI returns a signed, dated copy of HEARTHSTONE Disclosure Form as directed on that form.

- This must be completed:
  - prior to the time of application for new PHS-funded research,
  - annually during the life of the award and,
  - within 30 days of discovering or acquiring a new SFI.

The Associate Director of Research for HEARTHSTONE shall be deemed the Institutional Official charged with soliciting, reviewing, and storing Disclosures.

#### **4) REPORTING TO PHS**

Institutional Official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations (42 CFR 50.604h and 42 CFR 50.605b). Such reports shall be prior to the expenditure of any funds, within 60 days of bringing in any new Investigator, within 60 days of any subsequently identified financial conflict of interest, after any retrospective review, if an Investigator fails to comply with the HEARTHSTONE's FCOI policy, if there is a lack of compliance with an FCOI management plan, if any bias is found to exist within the design, conduct, or reporting of NIH-funded research, and annually in order to fulfill reporting obligations to the PHS.

#### **5) INVESTIGATOR NON-COMPLIANCE**

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

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

An 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 Institutional official, will be described in a written explanation of the decision to the investigator and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. HEARTHSTONE will promptly notify the PHS Awarding Component of the action taken or to be taken.

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

In addition, if 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, HEARTHSTONE will complete a retrospective review of the Investigator's activities and the PHS-sponsored 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. This will be done within 120 days of the determination of non-compliance.

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.

Institutional Official will update any previously submitted report to the PHS relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, HEARTHSTONE will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, 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.

If an FCOI has been determined to exist in previously completed, or ongoing, research, the Investigator must disclose this in all public presentations of the research results. Additionally, for any prior existing results that have been reported, the Investigator must request an addendum to be published acknowledging this conflict.

## **6) TRAINING**

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

- Specifically, each Investigator (as defined earlier in this policy based on 42 CFR Part 50 Subpart F) involved with PHS-funded research and affiliated with Hearthstone Institute (“HEARTHSTONE”) shall:
  - Read the “HEARTHSTONE” FCOI Policy and disclosure forms.
  - Complete the NIH Office of Extramural Research’s online webinar entitled “FCOI ONLINE TURUORIAL” regarding the duties of PI’s receiving PHS funding and supply the Institutional Official with a Certificate of Completion for this webinar.

- This training must be completed:
  - prior to engaging in any PHS funded research,
  - every four (4) years thereafter,
  - upon the addition of a new Investigator,
  - immediately if notified that HEARTHSTONE has amended or revised its FCOI Policy in a manner that affects Investigators, and,
  - immediately if an Investigator is not in compliance with the policy or management plan.
- Sign, date and return all FCOI Policy and Disclosure Forms prior to engaging in any PHS funded research.

## **7) RECORD RETENTION**

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 as specified by 45 CFR 75.361, as applicable. Unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

## **8) CONFIDENTIALITY**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will remain confidential. However, HEARTHSTONE may be required to make such information available to the PHS Awarding Component and/or HHS, 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 HEARTHSTONE, if requested or required. If HEARTHSTONE is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

## **9) PUBLIC ACCESSIBILITY**

Prior to the expenditure of funds, and annually thereafter, HEARTHSTONE will publish this policy on a publicly-accessible website. Additionally, it will post, or respond to any requestor within five business days of the request, information concerning any FCOIs that meets the following criteria:

- The Significant Financial Interest was disclosed and is still held by the Investigator;

- A determination has been made that the Significant Financial Interest is related to the PHS-funded research; **and**
- 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 regulations. It will be updated within 60 days of any new FCOI. These items will remain accessible for a period of three years from the date of the most recent update.

### **10) REGULATORY AUTHORITY**

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

I understand and agree to abide by the above policy during the period of my involvement in PHS-funded research while working for, in conjunction with, or while acting as a consultant to, Hearthstone Institute.

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Signature

\_\_\_\_\_

Title

\_\_\_\_\_

Printed Name

\_\_\_\_\_

Date