

## Policy on Financial Conflict of Interest

### **BACKGROUND**

As a recipient of NIH-grant funding, Hawaii Biotech, Inc. (HBI) has established this Policy on Financial Conflict of Interest (Policy) to comply with the requirements of 42 CFR 50, Subpart F, "Promoting Objectivity in Research" (Regulation). HBI supports the Regulation's aim to keep the design, conduct, and reporting of funded research free from bias that could arise from a significant financial interest of an Investigator.

### **POLICIES**

- A. All Investigators (i.e., PI) shall receive FCOI training upon hire, prior to engaging in research related to any NIH-funded grant, at least every four (4) years, and immediately if the Company's policy is revised or an Investigator is not in compliance with the Policy or management plan.
- B. All Investigators (including Subrecipient Investigators) are required to disclose his/her Significant Financial Interests (SFIs) and those of the Investigator's spouse and dependent children related to the Investigator's institutional responsibilities that meet or exceed the regulatory definition of SFI<sup>1</sup>.
- C. A management plan shall be developed and executed for each FCOI. The nature and circumstances of a FCOI shall determine the conditions and/or restrictions to be imposed to manage the conflict of interest.
- D. HBI shall upload all FCOI reports, including any FCOI reports for Subrecipients, to NIH via the eRA Commons portal, as required by Regulation.
- E. FCOI reports shall be updated annually if the FCOI is ongoing or if revisions are warranted.
- F. HBI shall submit (via eRA Commons) an annual report that provides the status of any FCOI and any changes to the management plan, if applicable, until the completion of the project.
- G. NIH shall be notified promptly should bias be found with the design, conduct or reporting of NIH-funded research, an Investigator fail to comply with HBI's FCOI policy, or a FCOI management plan appears to have biased the design, conduct, or reporting of NIH-funded research.

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<sup>1</sup> As of December 1, 2020, an aggregated value exceeding \$5,000 is deemed significant.

- H. HBI shall maintain records relating to all Investigator disclosures of financial interests and HBI's review of, and response to, such disclosures (whether or not a disclosure resulted in HBI's determination of a financial conflict of interest) and all actions under HBI's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report (FER) is submitted to NIH, or where applicable from other dates specified in 45 CFR 75.361 for different situations.
- I. Failure by an Investigator to disclose a SFI that is determined by HBI to constitute a FCOI shall result in disciplinary action(s), up to and including discharge.
- J. Failure by an Investigator to comply with his/her FCOI Management Plan shall result in disciplinary action(s), up to and including discharge.
- K. HBI shall report instances of non-compliance to NIH within 120 days of discovery.
- L. Investigator shall disclose the FCOI in each public presentation of the results of research and amend previously published presentations if DHHS determines that a NIH-funded research project of clinical research 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 an FCOI that was not managed or reported by HBI as required by Regulation.
- M. HBI shall maintain a written FCOI agreement with each Subrecipient.
- N. HBI shall post its FCOI Policy on its website.
- O. HBI shall post any FCOIs held by senior/key personnel (as defined by the Regulation, not the NIH GPS), on its website prior to the expenditure of funds.

## **PROCEDURES**

1. Each HBI Investigator (i.e., PI and any other senior key person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by NIH) will submit a SFI Disclosure Statement to the CFO:
  - A. No later than at the time of application for NIH-funded research,
  - B. Each October 1st, and
  - C. Within 30-days of discovering or acquiring a new SFI.
2. CFO will review all submitted SFI Disclosure Statements and determine whether a financial conflict of interest may exist no more than 60-days following the receipt of the SFI Disclosure Statement. If necessary, the CFO will discuss the circumstances that may indicate the existence of a FCOI. If the existence of an FCOI cannot be agreed upon, the CFO will consult with the CEO to reach a decision.

3. If a FCOI exists, the CFO will prepare an appropriate management plan. This may include one or more of the following:
  - A. Public disclosure of financial conflicts of interests (when presenting or publishing the research; to staff members working on the project; to HBI's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc.)
  - B. Disclosure of financial conflicts of interest directly to participants (for research projects involving human subjects research)
  - C. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias
  - D. Modification of the research plan
  - E. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research
  - F. Reduction or elimination of the financial interest (e.g., sale of an equity interest), or
  - G. Other action that reduces or eliminates the financial conflict(s)
4. ACO will upload all FCOI reports, including any FCOI reports for Subrecipients to NIH via the eRA Commons portal at the following, prescribed times:
  - A. Prior to the expenditure of funds (i.e., initial report)
  - B. Within 60 days of identification for an Investigator who is newly participating in the project (i.e., new Investigator report)
  - C. Within 60 days for new, or newly identified, FCOIs for existing Investigators (i.e., new FCOI report)
  - D. At least annually, at the same time when HBI is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension (i.e., ongoing report).
  - E. Following a retrospective review to update a previously submitted report, if appropriate.
5. If bias is found with the design, conduct or reporting of NIH-funded research, ACO will promptly notify Human Resources, CFO and President/CEO, as well as NIH and submit a Mitigation Report.
  - A. Notification will include the: impact on the research project, extent of harm done (including any qualitative and quantitative data to support any actual or future harm) and an analysis of whether the research project is salvageable.
  - B. Mitigation Report will explain what action(s) have been or will be taken to mitigate the effects of the bias.
6. In an Investigator fails to comply with HBI's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, ACO will promptly notify Human Resources, CFO and President/CEO, as well as NIH.

7. ACO will maintain records relating to all Investigator disclosures of financial interests and HBI's review of, and response to, such disclosures (whether or not a disclosure resulted in HBI's determination of a financial conflict of interest) and all actions under HBI's policy or retrospective review, if applicable:
  - A. For at least three (3) years from the date the final expenditures report (FER) is submitted to NIH.
  - B. Or, until all litigation, claims, or audit findings involving the records have been resolved and final action taken if applicable.
8. In the event of noncompliance with this Policy, ACO will complete the FCOI Non-Compliance Management Report (see FCOI Forms) to be reviewed by Human Resources, CFO and/or President/CEO, and submitted to NIH within 120 days of discovery of noncompliance.
  - A. ACO will re-train Investigator on HBI's FCOI Policy.
  - B. Human Resources, CFO and/or President/CEO will provide a verbal and/or written reprimand to the Investigator and/or discharge the Investigator.
  - C. ACO and Accounting may restrict project funds and/or increase oversight over purchases and payments, if necessary.
  - D. If warranted, the President/CEO will require that Investigator disclose the FCOI in each public presentation of the results of research and request that s/he amend any previously published presentations.
9. ACO will obtain assurances from the Subrecipient, in writing, that they:
  - A. Already have an FCOI policy that complies with the Regulation and will apply it to the project, or if one does not exist, will agree to follow HBI's FCOI Policy,
  - B. Will report any findings of FCOI as it relates to an Investigator on the project at:
    1. Time of application,
    2. At least annually at the start of award, and
    3. Within 30 days of discovering or acquiring a new SFI.
10. ACO will take steps to ensure that the Company's FCOI Policy is posted on the Company's website.
11. ACO will take steps to make sure that any FCOIs held by senior/key personnel are posted on the Company's website prior to the expenditure of funds. Information posted will:
  - A. Include the minimum elements as provided in the Regulation
  - B. Be updated, at least annually
  - C. Be updated, within 60 days of a newly identified FCOI
  - D. Remain available for three (3) years from the date the information was most recently updated.
12. ACO will train each Investigator on the relevant portions of the HBI FCOI Policy.
  - A. Trainings will be conducted every four (4) years, and upon the:

1. Introduction of a new Investigator,
2. Revision of HBI's FCOI Policy (and in such case if the changes are negligible can be re-trained just on the changes), and
3. Occurrence of non-compliance by the Investigator.

### **Training Resources:**

Currently NIH has a training tutorial for which investigators can, in part, use toward the training requirement.

[https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)

For additional information, refer to the Definitions section that follows and a NIH FAQ page on the topic at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>.

## **Definitions:**

***Disclosure of significant financial interests*** means an Investigator's disclosure of significant financial interests to HBI.

***Financial conflict of interest (FCOI)*** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

***FCOI report*** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

***Financial interest*** means anything of monetary value, whether or not the value is readily ascertainable.

***Institutional responsibilities*** means an Investigator's professional responsibilities on behalf of HBI, and as defined by HBI's policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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

***Manage*** means 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.

***PD/PI*** means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.

***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 involved may be delegated, including the National Institutes of Health (NIH).

***Research*** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. 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). As used in this context, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement.

***Senior/key personnel*** means the PD/PI and any other person identified as senior/key personnel by HBI in the grant application, progress report, or any other report submitted to the PHS by HBI.

***Significant financial interest means:***

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) 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 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 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 interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) 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 (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose 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 their institutional responsibilities; provided, however, that this disclosure requirement does not apply to 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. HBI's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with HBI's FCOI policy, HBI official(s) will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by HBI to the Investigator if the Investigator is currently employed or otherwise appointed by HBI, including intellectual property rights assigned to HBI and agreements to share in royalties related to such rights; any ownership interest in HBI held by the Investigator, if HBI is a commercial or for-profit organization; 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; income from seminars, lectures, or teaching engagements 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; or income from service on advisory committees or review panels for 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** means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as

amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.



## FCOI ACKNOWLEDGMENT FORM

I have received a copy of HBI's Financial Conflict of Interest (FCOI) Policy. I understand that the FCOI Policy was adopted by HBI to comply with the FCOI regulation and that this Policy, as well as any other policies and guidelines which may be adopted by HBI, are subject to modification, discontinuation or change by an authorized Company officer.

By signing this form, I acknowledge the following:

1. I have read the Company's FCOI Policy and agree to comply with its requirements, including, but not limited to, my responsibility to:
  - a. submit a signed SFI Disclosure Statement at various times each year,
  - b. complete FCOI training at least once every four years, and
  - c. require each subrecipient Investigator participating in the NIH-funded research to comply with the FCOI regulation and submit a disclosure of significant financial interests at least annually.
2. I understand that violation of these policies and guidelines constitute reason for disciplinary actions up to and including discharge.

**NAME:** \_\_\_\_\_

(Print Employee's Name)

**SIGNED:** \_\_\_\_\_

(Employee's Signature)

**DATE:** \_\_\_\_\_