

## I. General Policy

Hopa Mountain requires disclosure of any actual or perceived conflict of interest in order to protect the integrity and credibility of the organization, its Board and employees, so that public trust and confidence is ensured.

An actual or perceived conflict of interest occurs when there is a divergence between one's private interests and his/her obligations to the organization such that an independent observer might reasonably question whether the individual's actions or decisions are determined by considerations of personal gain on the part of the individual (or members of his/her immediate family) that may relate to the organization's programs, research, use of facilities, or use of external or internal funds.

Any full- or part-time member of the staff, any individual conducting or cooperating on grants, research, or projects through the organization, and any employee is required to submit a written disclosure statement fully describing the situation to the Board President in a case that could present or could be perceived as presenting a conflict of interest. The disclosure statement should be submitted as soon as the situation arises. Disclosure is a key factor in protecting the organization and one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

## II. Policy Applicable to Public Health Service/National Institutes of Health Funding

### A. *PURPOSE*

The 2011 revised regulation, "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought" (<https://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>) seeks to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under Public Health Services (PHS) grants or cooperative agreements, including those awarded by the National Institutes of Health (NIH), will be free from bias resulting from an investigator's financial conflicts of interest.

This policy is designed to ensure that Hopa Mountain (hereafter, "the organization") is in full compliance with federal regulations when applying for or receiving PHS funding, as put forth in the National Institutes of Health guidelines

(see <https://grants.nih.gov/grants/policy/coi/index.htm>).

This policy applies to all Investigators (as defined by the policy) who are involved with PHS-funded research by means of a grant or cooperative agreement, including research funded by NIH.

## *B. DEFINITIONS*

As used in this policy:

***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.

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

***Institutional Official*** means the individual within the organization who has been designated to solicit and review disclosures from Investigators of significant financial interests related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official will be the Board President.

***Institutional responsibilities*** means an Investigator's professional responsibilities on behalf of the organization, and as defined by the organization in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, and professional practice.

***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.

***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, 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).

***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:
1. 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;

2. 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
3. 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. This disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this policy, the Institutional Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

***Significant financial interest*** does **NOT** include the following types of financial interests:

1. Salary, royalties, or other remuneration paid by the organization to the Investigator if the Investigator is currently employed or otherwise appointed by the organization, including intellectual property rights assigned to the organization and agreements to share in royalties related to such rights;
2. 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;
3. 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
4. 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.

### *C. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS*

All Investigators are required to disclose to the Board President the Investigator's Significant Financial Interests (and those of the Investigator's spouse and dependent children) on an annual and ad hoc basis, as described below, using the Significant Financial Interest Disclosure Form, which is available on the web site of the Office of Corporate, Foundation and Government Relations.

If a Significant Financial Interest is reported on the form, Investigators should submit the completed form together with supporting documentation in a sealed envelope marked confidential to the Board President. If no Significant Financial Interests are reported, the form should still be submitted to the Board President.

All Investigators who are participating in PHS-funded research are required to submit an updated disclosure of significant financial interests at least annually, to the Board President, during the period of the award.

In addition to the annual disclosure, Investigators must make disclosures in the following situations:

- *New applications for funding:* All Investigators who are planning to participate in the PHS-funded research must disclose to the Board President the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) before the application is submitted.
- *New significant financial interests:* All Investigators must submit an updated disclosure of significant financial interests to the Organization's Institutional Official within thirty days of acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
- *Travel:* Investigators also must disclose the occurrence of any reimbursed or sponsored travel, as defined above under the term "Significant financial interest." This disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Board President will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI.

### *D. REVIEW OF FINANCIAL DISCLOSURES*

If a Significant Financial Interest Disclosure Form reveals a Significant Financial Interest, as defined above, the Board President shall promptly review the form, together with supporting

documentation, to make a determination of whether it constitutes a FCOI. A FCOI exists when the Board President reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The organization may involve the Board's determination of whether a significant financial interest is related to the PHS-funded research.

#### *E. MANAGEMENT OF FCOI*

If the Board President determines that a FCOI exists, he or she must require the creation of and approve a written plan for the management of the FCOI before related research may proceed. The Investigator, in cooperation with the organization, shall develop and present to the Board a Conflict of Interest Management Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by the Significant Financial Interest.

Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);  
or
- Severance of relationships that create financial conflicts.

No expenditures on PHS awards will be permitted until the Investigator has complied with the disclosure and training requirements (see below) of this policy and has agreed, in writing, to comply with any plan(s) determined to be necessary for the management of the FCOI.

The Board shall monitor Investigator compliance with the FCOI management plan on an ongoing basis until the completion of the PHS-funded research project.

If the Board identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, the Board is not required to submit a FCOI report to the respective agency.

#### *F. REPORTING FINANCIAL CONFLICTS OF INTEREST*

##### *(1) Sponsoring agency.*

If the Board determines that any Significant Financial Interests is an FCOI, the Institutional Official shall provide to the PHS sponsoring agency an FCOI report regarding the FCOI and ensure that the organization has implemented a management plan in accordance with this policy. The FCOI report must be provided to the PHS sponsoring agency in accordance with its specific requirements within 60 days of the original disclosure and before any funds are expended under a PHS-funded research project, and it must include sufficient information to enable the PHS awarding agency to understand the nature and extent of the financial conflict and assess the appropriateness of the Organization's management plan.

If PHS funding for the project comes via a subaward agreement, the FCOI report shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS sponsoring agency.

##### *(2) Public request.*

As required by sponsoring agency regulations, information on Financial Conflicts of Interest will be made available to members of the public in response to inquiries to the Institutional Official within 5 business days of receipt of such requests.

#### *G. SUBRECIPIENTS*

If any part of PHS-funded research is conducted through a subrecipient (e.g., subcontractors or consortium members), the organization will take reasonable steps to ensure that any subrecipient Investigator complies with applicable federal regulations. To this end, the organization shall enter into a written agreement with each subrecipient that (1) includes a statement indicating whether the organization's or the subrecipient's institutional FCOI policy shall apply; and (2) specifies the timing for reporting of FCOIs by subrecipients to the organization to enable the timely review and reporting of such FCOIs in compliance with PHS requirements.

#### *H. TRAINING*

Investigators must complete training on this policy within a reasonable amount of time determined by the Board in any of the following circumstances:

- The Board revises its FCOI policies or procedures in a way that affects the requirements of Investigators;
- An Investigator is new to the organization;

- The organization finds that an Investigator is not in compliance with this policy or an approved FCOI management plan.

Investigators should contact the Executive Director to schedule trainings.

### *I. INVESTIGATOR NON-COMPLIANCE*

(1) **Sanctions:** The Organization requires Investigators to comply fully with this policy. Instances of deliberate breach of policy, including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms, violation of the guidelines, or failure to comply with prescribed monitoring procedures may result in sanctions being imposed upon the violating individual.

(2) **Retrospective Review:** In addition, if the Board determines that a FCOI was not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Board to constitute a FCOI; failure by the organization to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, the Board shall, within 120 days of the determination of noncompliance, 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.

The Board is required to document the retrospective review; such documentation shall include the following key elements: project number; project title; name of PI; name of the Investigator with the FCOI; name of the entity with which the Investigator has a FCOI; reason(s) for the retrospective review; detailed methodology used for the retrospective review; findings of the review; and conclusions of the review.

Based on the results of the retrospective review, if appropriate, the Board shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the Board is required to notify the PHS sponsoring agency promptly and submit a mitigation report to the PHS sponsoring agency. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Board's plan of action or actions taken to eliminate or mitigate the effect of the bias.

### *J. RECORD MAINTENANCE*

The organization 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 sponsor. Access to such records will be limited to authorized institutional officials and others who have legal right to review the records.

## *K. REGULATORY AUTHORITY*

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

### **III. Policy Applicable to National Science Foundation Funding**

In accordance with federal regulations, any employee involved with National Science Foundation (NSF) grants as an investigator, as defined below, must disclose in a particular format all significant financial interests of the investigator (including those of the investigator's spouse and dependent children): (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

#### *A. Definitions*

As used in this policy:

The term "investigator" means the PI/PD, co-PI/co-PDs, and any other person identified on the proposed project who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

The term "significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

- a. salary, royalties or other remuneration from the organization;
- b. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- c. income from service on advisory committees or review panels for public or nonprofit entities;
- d. an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
- e. salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the prior twelve-month period.

A "conflict of interest" exists when the reviewer(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.



## *B. Policy*

For NSF grant applications, any full- or part-time member of the staff, any individual conducting or cooperating on research or project grants or contracts through the organization and any Organization employee is required to submit the Significant Financial Disclosure form, together with supporting documentation in a sealed envelope marked confidential, to the Board President in a situation that could present or could be perceived as presenting a conflict of interest with respect to external grants prior to the submission of the grant application. If there are no such situations with respect to individuals associated with the grant (excluding students), the Principal Investigator(s) will so indicate on the Organization Approval Form.

The organization will be responsible for determining whether the disclosed information could directly and significantly affect the design, conduct, or reporting of grant-funded activities.

As required by the federal regulations, it is the responsibility of the individual to disclose all significant financial interests prior to the time a proposal is submitted, and any conflict of interest must be resolved prior to the expenditure of grant funds. All financial disclosures must be updated by the individual during the period of the award, either on an annual basis or earlier, as new reportable significant financial interests are obtained.

This policy also applies to situations in which the organization and its employees are involved, either as subcontractors, in grants made to another institution. Collaborators from outside the organization must either comply with this policy or provide a certification that their institutions are in compliance with federal policies regarding investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies.

Regardless of the above minimum requirements, a staff member, in his or her own best interest, may choose 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. Again, disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

## *C. Review Process*

Disclosure forms and accompanying documentation will be forwarded to Executive Director who will conduct an initial review to determine whether a conflict of interest exists. They will be guided by the following considerations:

- Assure adherence to relevant organization policies;
- Consider the nature and extent of the interest in the relationship of the individual and the funded project;

- Where appropriate, give special consideration to the terms and conditions of sponsored project agreements that may mitigate or complicate the given situation;
- Where appropriate, consult with the faculty through the FSCC;
- Consult with and obtain any additional information from the individual that may be helpful in resolving any actual or potential conflicts;
- Consult with the Board President, attorney, and/or other individuals as appropriate;
- Act in a timely manner so as not to delay unduly the conduct of activities; and,
- Reach a conclusion and communicate that, in writing, to the individual.

The Board of Directors will conclude that the organization may take one of the following actions:

- Accept the sponsored project;
- Do not accept the sponsored project; or,
- Accept the sponsored project provided certain conditions or restrictions are imposed so that the conflict will be managed, reduced, or eliminated. Examples of conditions or restrictions are:
  - public disclosure of significant financial interests
  - monitoring of research by independent reviewers
  - modification of the research plan
  - disqualification from participation in all or a portion of the research
  - divestiture of significant financial interests
  - severance of relationships that create actual or potential conflicts

If it is determined that imposing conditions or restrictions would be inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Board may recommend that, to the extent permitted by federal regulations, the research go forward without imposing such conditions or restrictions. In these cases, the Board shall make the final decision regarding resolution.

#### *D. Managing Conflicts of Interest*

The resolution shall be incorporated into a contract that details the conditions or restrictions imposed on an individual.

The Memorandum of Understanding shall be signed by the Executive Director on behalf of the Organization as appropriate. Actual or potential conflicts of interest will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines and prior to accepting any award they will be disclosed to the sponsoring agency for action.

#### *E. Notification of NSF*

The Board shall appropriately inform the NSF's Office of the General Counsel (OGC), according to applicable regulations, if the organization finds that it is unable to satisfactorily manage a conflict of interest and if the organization finds that research will proceed without the imposition of conditions or restrictions when a conflict of interest exists.

#### *F. Appeal Process*

If the individual is dissatisfied with the conclusion of the Executive Director s/he may appeal to the Board President who will consult with the individual and others as deemed necessary and appropriate to the particular circumstance. The decision of the Board President shall be final.

#### *G. Violations of Conflict of Interest Policy*

Individuals are expected to comply fully and promptly with the policy. Instances of deliberate breach of policy, including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms, violations of the guidelines, or failure to comply with prescribed monitoring procedures may result in sanctions being placed on the violating individual. The Board will review allegations of violations and resolve them accordingly.

#### *H. Record Maintenance*

Records of individual financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be maintained by the Executive Director, as the case may be, in accordance with applicable regulations, if any, for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer. Access to such records shall be at the discretion of the Executive Director, or the Board President, as the case may be, except as required by law. The sponsoring agency may have access.

#### IV. Other Funding Sources

Research by any Investigator (person responsible for the design, conduct, or reporting of research or educational activities) funded or proposed for funding by a federal agency other than NSF or the PHS shall comply with that agency's policies regarding financial conflict of interest.