

## **Financial Conflict Of Interest (FCOI) Policy for Public Health Service (PHS) Funding**

### **1. Policy Statement**

EpiVax, Inc. (EpiVax) is committed to the design, conduct, and reporting of Research in an objective manner, free from bias or undue influence due to financial conflicts of interest (FCOI). The purpose of this Policy is to promote objectivity in research for all grants, cooperative agreements, or contracts funded by any PHS agency or from any other non-PHS organization that has adopted the PHS FCOI Regulations.

This Policy is designed to comply with Public Health Service (PHS) FCOI 2011 Regulations - 42 C.F.R. Part 50 Subpart F (Grants and Cooperative Agreements) and 45 C.F.R. Part 94 (Responsible Prospective Contractors). EpiVax and each Investigator participating in any Research or Research through subgrantees, contractors, or collaborators that is funded by any PHS agency or any non-PHS organization that has adopted the PHS FCOI Regulations are required to comply with this Policy. This Policy is effective as of August 24, 2012 and will be updated annually, maintained, and made publicly accessible in compliance with most-up-to-date FCOI regulations.

### **2. Purpose**

The FCOI 2011 Regulations promote “objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.” EpiVax’s FCOI Policy establishes standards and procedures to promote and enforce the PHS Regulations to prevent financial considerations from influencing or seeming to influence an Investigator’s role in the design, conduct, or publication of PHS-funded projects. As part of its institutional responsibilities, EpiVax will promote and enforce Investigator compliance with regulations on Significant Financial Interest (SFI) disclosure, and will manage FCOIs and provide initial and ongoing FCOI reports to PHS, NIH, or other applicable organizations.

### **3. Definitions**

- A. Financial Conflict of Interest: a SFI that could direct and/or significantly affect the design, conduct, or reporting of PHS-funded Research, as determined by the IO.
- B. Financial Interest: anything of monetary value, whether or not the value is readily ascertainable.
- C. Institutional Official: the individual designated by EpiVax within the office of the CFO to be responsible for enforcing this Policy, reviewing disclosures of SFIs, determining whether disclosures constitute a Financial Conflict of Interest, and managing such conflicts.
- D. Institutional Responsibilities: an Investigator’s professional responsibilities on behalf of EpiVax, which may include: 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.
- E. Investigator: 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 PHS, or proposed for funding by PHS, which may include, for example, consultants or collaborators.
- F. PHS Awarding Component: the organizational unit within the Public Health Service that funds the research.
- G. 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. 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). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, 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.

H. Significant Financial Interest (SFI): a financial interest consisting of one or more of the following interests of the Investigator, the Investigator's spouse/domestic partner, and the Investigator's dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- (a) With regard to any publicly traded entity, a SFI 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.
- (b) With regard to any non-publicly traded entity, a SFI 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).
- (c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (d) The occurrence of any reimbursed or sponsored (i.e., paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) travel, related to their Institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation.
- (e) Note that this does not include the following: (1) salary, royalties, or other remuneration paid by EpiVax to the Investigator if the Investigator is currently employed or otherwise appointed by EpiVax; (2) Intellectual Property Rights assigned to EpiVax and agreements to share in royalties related to such rights; (3) any ownership interest in EpiVax held by the Investigator; (4) 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; (5) 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.S. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; (6) income from service on advisory committees or review panels for a federal, state, or local government agency, 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 (7) travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

#### 4. Policy Instructions and Disclosure Procedures

##### A. Responsibilities of the Institution

- (1) In compliance with PHS FCOI Regulations, the EpiVax Institutional Official (IO) will ensure that all Investigators are informed of and in compliance with this Policy regarding financial conflicts of interest, the Investigator's responsibilities of disclosing SFIs, and with PHS FCOI Regulations.
- (2) As applicable, the IO will maintain records of all Investigator disclosures of financial interests and EpiVax's review of, and response to, such disclosures under EpiVax's Policy or retrospective review, regardless of whether a disclosure resulted in the Institution's determination of FCOI:
  - (a) For at least three years following the submission date of the final expenditures report or from the date of submission of the quarterly or annual financial report; or
  - (b) From other dates stipulated by 45 C.F.R. 74.53(b) and 92.42(b).
- (3) All records of Investigator disclosures of financial interests and EpiVax's review of, and response to, such disclosures will be maintained:
  - (a) In hard copy, filed under the "Assurances" tab of the project binder specific to the PHS-funded work; and
  - (b) Electronically, filed in the "FCOI" folder in the "3 Assurances" folder of the project file tree specific to the PHS-funded work on the server.

##### B. Policy Application to Subawardees, Subcontractors, and EpiVax Affiliates

Subawardees, subcontractors, and other EpiVax affiliates collaborating on PHS-funded research will be required to confirm that they have their own FCOI policy in place that conforms to PHS FCOI 2011 Regulations prior to a grant being funded. If they do not have their own FCOI policy, they will be required to comply with this EpiVax Policy.

##### C. Mandatory Training Requirements

- (1) Per PHS FCOI Regulations, all Investigators will be required to complete FCOI training on both Federal and Institutional policies. This training must be completed prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately if any of the following circumstances apply:
  - (a) The EpiVax FCOI Policy or procedures contained within or the PHS Financial Disclosure Form are revised in any manner that affects the requirements of Investigators;
  - (b) An Investigator joins EpiVax; or
  - (c) EpiVax is made aware of an Investigator who is not in compliance with this FCOI Policy or management plan.
- (2) To fulfill the Institutional training requirement, all EpiVax personnel will be required to read through this EpiVax FCOI Policy for PHS Funding and sign to attest to the fact that they have read and understood all policies, rules, and regulations contained within this document, and that they understand their responsibilities as an Investigator to disclose any and all significant financial interests.
- (3) To fulfill the Federal training requirement, all EpiVax personnel must complete one of the following training programs:
  - (a) For personnel involved in finance, accounting, or sales: completion of the NIH Office of Extramural Research's web-based "Financial Conflict of Interest Online Tutorial" (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) is required. At the end of the tutorial, each person should fill out the Certificate of Completion and follow the instructions below for documentation.
  - (b) For all other personnel: completion of the "Biomedical Basic Course" provided through the Collaborative Institutional Training Initiative (CITI; <https://www.citiprogram.org/>) is required. Personnel must complete this

training under the affiliation of Ethical & Independent Review Services. At the end of the course, each person should obtain a Certificate of Completion and follow the instructions below for documentation.

- (c) For personnel who completed the E&I “Biomedical Basic Course” provided through CITI prior to September 23, 2011: completion of the NIH Office of Extramural Research’s web-based “Financial Conflict of Interest Online Tutorial” (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) is required, as the FCOI module of this CITI course was updated with the revised PHS FCOI 2011 Regulations at this time. Any FCOI training completed prior to this date must be supplemented by the NIH’s online tutorial to ensure familiarity with revised Federal regulations. At the end of the tutorial, each person should fill out the Certificate of Completion and follow the instructions below for documentation.
- (4) Exceptions to these training requirements will be managed on a case-by-case basis as needed.
- (5) All records of completion of training requirements will be maintained:
  - (a) In hard copy, filed under the appropriate Federal or Institutional “FCOI Training Documentation” tab of the “FCOI Compliance Documentation” binder; and
  - (b) Electronically, filed in the appropriate Federal or Institutional “FCOI Training Documentation” folder in the “Financial Conflict of Interest” folder, found under the following file path:  
\\server-sbs\corporate\Epivax\_Files\offices\locoo\public\Grants Administration\Financial Conflict of Interest

#### *D. Investigator Disclosure Requirements*

- (1) Per PHS FCOI Regulations, it is EpiVax’s Policy that any and all SFIs be disclosed to the EpiVax IO:
  - (a) At the time of application for funding by each Investigator, including sub-recipient Investigators as applicable, planning to be involved in PHS/NIH-funded research.
  - (b) Annually by each Investigator, including sub-recipient Investigators as applicable, involved with the award for the award period so as to update disclosures of SFIs.
  - (c) Within 30 days of an Investigator, including sub-recipient Investigators as applicable, discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
- (2) EpiVax will solicit and review disclosures of SFI(s) of all Investigators and their immediate family (including spouse/domestic partner and/or dependent children) related to the Investigator’s institutional responsibilities. All Investigators will utilize the “Financial Disclosure Form for Investigators in PHS Research” to either disclose SFIs or declare that there are no SFIs.

## **5. Management of Financial Conflicts of Interest**

### *A. Review of SFI disclosure*

All disclosures of SFIs will be reviewed by EpiVax’s Authorized Official(s) in a prompt manner such that within 60 days of receipt of the disclosure, the SFI can be assessed, a management plan developed, and all reviews and approvals necessary can be obtained. The Authorized Official(s) will:

- (1) Record and review all “Financial Disclosure for Investigators in PHS Research” forms from PHS-funded Investigators at EpiVax;

- (2) Assess the nature of the SFI to determine whether the Investigator working on the PHS-funded research has a FCOI;
- (3) Provide information concerning FCOIs to the expenditure of PHS funds, which will be updated at least annually and within 60 days of changes to Statement of Financial Interest Disclosure forms, whichever occurs first.

**B. Management of FCOIs**

The EpiVax Authorized Official(s) will develop a management plan based on the nature of the FCOI and will monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project. Examples of conditions or restrictions that could be established include, but are not limited, to:

- (1) Public disclosure of FCOIs;
- (2) Appointment of independent monitor(s) who will be able to prevent the FCOI from biasing the design, conduct, and reporting of PHS-funded research;
- (3) Modification of the research plan;
- (4) Change of Investigator(s) or roles/responsibilities of Investigator, or exclusion of Investigator from participating in all or a portion of research;
- (5) Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
- (6) Severance of relationships that create FCOIs.

**C. EpiVax Reporting Requirements**

- (1) Per PHS FCOI Regulations, EpiVax will submit to the NIH through the eRA Commons FCOI Module both initial and ongoing FCOI reports:
  - (a) Prior to the expenditure of funds;
  - (b) Within 60 days of identifying a new FCOI during the period of the award; and
  - (c) Annually when grantee is required to submit the annual progress report, including multi-year progress report, or at time of extension, to report on the status of FCOI and any changes in the management plan.
- (2) As per the PHS FCOI Regulations, FCOI reports will include:
  - (a) Grant number;
  - (b) PD/PI or contact PD/PI;
  - (c) Name of Investigator with FCOI;
  - (d) Name of entity with which Investigator has FCOI;
  - (e) Nature of FCOI;
  - (f) Value of the financial interest, reported as a range (\$0-4,999; \$5,000-9,999; \$10,000-19,999), in increments of \$20,000 if between \$20,000-100,000, in increments of \$50,000 if above \$100,000, or a statement that the value cannot be readily determined.
  - (g) Description of how the SFI relates to PHS-funded research and basis for EpiVax's determination that the SFI conflicts with this research; and
  - (h) Key elements of EpiVax's management plan.

**D. Public availability of FCOI disclosure**

As per the PHS FCOI Regulations, disclosure of SFIs that are still held by the Investigator for the PHS-funded research project, determined by EpiVax to be related to the PHS-funded research, and determined by EpiVax to be a FCOI disclosure of FCOIs will be made available as a written response within five business days of a request. The information made available by EpiVax in a written response will include the following information:

- (1) Name of Investigator with FCOI;
- (2) Title and role of the Investigator in the PHS-funded research project;
- (3) Name of entity with which Investigator has FCOI;
- (4) Nature of the FCOI;

- (5) Value of the financial interest, reported as a range (\$0-4,999; \$5,000-9,999; \$10,000-19,999), in increments of \$20,000 if between \$20,000-100,000, in increments of \$50,000 if above \$100,000, or a statement that the value cannot be readily determined through references to public prices or other reasonable measures of fair market value.

## **6. Enforcement of Policy and Noncompliance**

- A. All Investigators and relevant EpiVax personnel and collaborators are required to comply with this Policy in full. Violations of this policy may result in disciplinary or other appropriate action.
- B. If an FCOI is not identified or managed in a timely manner (including Investigator failure to disclose SFI(s), EpiVax failure to review or manage FCOI(s), or failure to comply with the management plan), EpiVax will within 120 days of the determination of noncompliance notify the NIH and submit a retrospective review, as per PHS FCOI Regulations. The retrospective review will include the following information:
  - (1) Grant number;
  - (2) Grant title;
  - (3) PD/PI or contact PD/PI;
  - (4) Name of Investigator with FCOI;
  - (5) Name of entity with which Investigator has FCOI;
  - (6) Reason(s) for retrospective review;
  - (7) Detailed methodology used for retrospective review (e.g., details of review process, composition of the review panel, documents reviewed);
  - (8) Findings and conclusions of the review; and
  - (9) If warranted by the retrospective review, update and revise the previously submitted FCOI report.
- C. In the case that a retrospective review finds that Investigator non-compliance with this FCOI Policy, the PHS FCOI Regulations, or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research, EpiVax will promptly submit a mitigation report to the NIH Awarding Component. The mitigation report will include:
  - (1) Key elements documented in the retrospective review;
  - (2) Description of the impact of bias on the research project; and
  - (3) Management plan(s) to eliminate or mitigate the bias on the design, conduct, or report of research.
- D. After a mitigation report is filed, FCOI reports must be submitted annually.

## **7. Acknowledgment of Understanding of the EpiVax FCOI Policy for PHS Funding**

I, \_\_\_\_\_ (print name), acknowledge that I have read and understood the policies, rules, and regulations contained above in the EpiVax FCOI Policy for PHS Funding. In signing my name, I attest that I understand my responsibilities as an Investigator, as defined by the PHS, to disclose any and all significant financial interests via the procedures detailed in this Policy.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date