Financial Conflict of Interest in Conduct of Research Policy

Property of Stem Pharm, Inc.

Policy Statement

Stem Pharm, Inc. requires Principal Investigators (PIs) and Key Personnel on federally sponsored research projects to disclose a listing of significant financial interests (and those of their spouse and dependent children) that could be reasonably expected to bias the design, conduct, or reporting of the project. All PIs, Co-Investigators and Key Personnel listed in a proposal for external funding must complete a disclosure form before expenses can be charged to an award.

The primary goal of the Financial Conflict of Interest (FCOI) regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts is free from bias resulting from Investigator financial conflicts of interest.

Institutions engaged in research funded by the PHS are required to develop an FCOI policy that is maintained and enforced and meets or exceeds the current Federal regulatory requirements. This policy applies to each Investigator, as defined by the regulation, who is planning to participate in or is participating in PHS funded research.

Definitions

1. **Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or receives NIH research funding.

2. **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 NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

3. **PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS including the NIH.

4. **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 and product development (e.g., a diagnostic test or drug).

5. **Significant Financial Interest (SFI)** is a financial interest consisting of one or more of the interests listed in Appendix A 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.

6. **Financial Conflict of Interest (FCOI)** is an SFI that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

7. **Senior/Key Personnel** means the PD/PI/Co-I and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation.

8. **Small Business Innovative Research** (SBIR) and Small Business Technology Transfer (STTR) programs and/or awards. The revised 2011 regulation does not apply to Phase I SBIR/STTR applications, but the revised 2011 regulation does apply to Phase II SBIR/STTR applications/awards.

9. **Manage** means taking action to address an FCOI, which can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

10. **Disclosure** refers to the Investigator's disclosure of Significant Financial Interests (SFI) to their Institution.

Institutional Responsibilities

Stem Pharm shall:
1. Maintain standards that provide a reasonable expectation that the design, conduct and reporting of NIH-funded research will be free from bias resulting from Investigator financial conflicts of interest.

2. Maintain an up-to-date, written, enforced policy that complies with the FCOI regulation and made available via a publicly accessible Web site.

3. Provide training to each Investigator on FCOI and require Investigators complete FCOI training and disclosure forms prior to engaging in PHS-funded research, minimally every 4 years.

4. Send initial, annual (i.e., ongoing) and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for the Institution and its subrecipients, if applicable, as required by the regulation: prior to engaging in research related to any PHS-funded grant, at least every 4 years, and immediately if FCOI policy is revised, an new Investigator is added, and Investigator if found not in compliance.

5. Notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and submit a Mitigation Report.

6. Notify NIH promptly if an Investigator fails to comply with the Stem Pharm's FCOI policy or if the FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

7. Maintain FCOI-related records for at least 3 years from the date the final expenditures report is submitted to the PHS (NIH).

8. Make Stem Pharm's FCOI Policy and identified FCOIs held by senior/key personnel publicly accessible via the company's website prior to the expenditure of funds.

Investigator Responsibility

1. Complete FCOI training
    a. Prior to beginning of PHS funded research
    b. At least every 4 years thereafter
    c. When Institution changes policy or in cases of non-compliance of the investigator

2. Complete FCOI disclosure form
    a. No later than at the time of the application for PHS-funded research
    b. At least annually during the period of an award
    c. Within 30 days of discovering or acquiring a new SFI

Non-compliance

Retrospective Review

1. Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, failure by the Institution to review or manage an FCOI, or failure to comply with the management plan, the institution shall within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research.

2. Notify NIH promptly and submit a Mitigation Report when bias is found.

3. See APPENDIX C for report formats.

Designated Official

The CEO, or a designated appointee in a Leadership Role, shall act as the Institutional Official and shall:

1. Solicit and review disclosures of SFI of the Investigators.

2. Make determinations of FCOI and implement plans to manage FCOI as needed where FCOI exists.

3. Where the CEO or designee is an Investigator on a PHS-funded research study, the President of the Company will review the FCOI disclosure and make a determination of FCOI and implement management plan.

APPENDIX A

Significant Financial Interests (SFIs)

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.

4. 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 excluded sources provided in regulation.

SFI Exclusions:

1. **Salary, royalties, or other remuneration paid by the Institution** to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;

2. **Intellectual Property Rights** assigned to the Institution and agreements to share in royalties related to such rights;

3. **Any ownership interest in the Institution** held by the Investigator, if the Institution is a commercial or for-profit organization;

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.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or

6. **Income from service on advisory committees or review panels** for a federal, state or local government agency, Institution of higher education as defied 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.

APPENDIX B

Institutional Responsibilities

1. Maintenance of Records
    a. Maintain records of all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of FCOI) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of submission of the final expenditures report

2. Application Certification - certify in each application for funding that the Institution:
    a. Has in effect an up-to-date written and enforced administrative process to identify and manage FCOIs related to all PHS research projects
    b. Shall promote and enforce Investigator compliance with the regulation pertaining to disclosure of SFI
    c. Shall manage FCOIs and provide initial and ongoing FCOI reports to PHS/NIH
    d. Agrees to make information available upon request relating to any Investigator disclosure of financial interest and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI
    e. Fully comply with the requirements of the regulation

3. Designated Institutional Official(s)
    a. Designate an Institutional Official(s) to solicit & review disclosure statements from each Investigator planning to participate in, or is participating in, PHS/NIH-funded research
    b. Provide guidelines to identify conflicting interests related to proposed or PHS/NIH-funded research
    c. Develop management plans that specify the actions that have been, and shall be, taken to manage FCOI

4. Inform Investigators
    a. Inform each Investigator of the Institution's policy and his or her "disclosure" reporting obligations, including SFIs and time frames
    b. Identifies an Institutional official(s) to determine the existence of conflicting interests and to take actions to ensure that they will be managed, reduced, or eliminated

5. Investigator Training - Institutions must require that each Investigator complete FCOI training
    a. Prior to engaging in research related to any NIH funded project
    b. At least every four years, and immediately when any of the following circumstances apply:
        i. Institution revises its policy in a manner that affects the investigator;
        ii. When an investigator is new to the institution
        iii. When the institution finds an Investigator is not in compliance with the Institution's policy or management plan

6. Investigator Disclosure of SFIs (including subrecipient Investigators)
    a. Require that each Investigator planning to participate in PHS/NIH-funded research to disclose to the designated official(s) at time of application
    b. Require each Investigator to submit an updated disclosure of SFI at least annually during the period of the award
    c. Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI

7. Management of FCOIs
    a. Take necessary actions to manage any FCOIs of its Investigators, including those of subrecipient Investigators
    b. Develop a management plan(s) and monitor compliance

c. If Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the designated official(s) shall within sixty (60) days review the SFI, determine if an FCOI exists and implement an interim management plan, if needed
d. In cases of non-compliance, complete a retrospective review and submit a Mitigation Report if bias is found

8. FCOI Reporting
   a. Provide initial and ongoing FCOI reports to NIH
      i. Prior to the expenditure of funds
      ii. During the period of award - within 60 days of identifying a new FCOI
   b. Annually
      i. Report on the status of FCOI and any changes in management plan
      ii. Due at same time as when grantee submits annual progress report, including multiyear progress report, or at time of extension
   c. All FCOI reports are submitted to NIH through the eRA Commons FCOI Module
      i. FCOI reports for NIH-funded research contracts should be sent to the NIH Office of Acquisition Management and Policy at fcoicontracts@mail.nih.gov
      ii. System allows institutions to:
         1. Initiate and send FCOI Reports to NIH electronically through the eRA Commons FCOI Module
         2. Revise or update a previously submitted FCOI report (future enhancement)
         3. Submit a Mitigation Report when bias is found (future enhancement)
         4. Search previously created records
         5. Edit a previously submitted record
         6. Respond to a request for additional information
         7. Rescind a previously submitted record
         8. View history of actions
         9. Institutional Signing Officials must assign FCOI roles to users in eRA Commons

9. Elements of an FCOI Report
   a. Grant number
   b. PD/PI or contact PD/PI
   c. Name of Investigator with the FCOI
   d. Name of the entity with which the Investigator has an FCOI
   e. Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria)
   f. Value of the financial interest $0-4,999; $5K-9,999; $10K-19,999; amts between $20K-100K by increments of $20K; amts above $100K by increments of $50K or a statement that a value cannot be readily determined
   g. A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research
   h. Key elements of the Institution's management plan

10. Subrecipient Requirements
   a. Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet SFI disclosure, if applicable, and FCOI reporting requirements
   b. Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS/NIH Awarding Component (i.e., to NIH through the eRA Commons FCOI Module) to meet FCOI reporting obligations

11. Public Accessibility of FCOIs

a. Prior to expenditure of funds, make certain information concerning FCOIs held by senior/key personnel publicly accessible via a Web site or (if no website) provide written response within five business days of a request

i. Update the website annually and within 60 days of identifying any new FCOIs when posting FCOIs to website

ii. Retain information for three years

b. Information to be made publicly available includes the following:

i. Investigator's name;

ii. Investigator's title and role with respect to the research project;

iii. Name of the entity in which the SFI is held;

iv. Nature of the SFI; and

v. Approximate dollar value of the SFI (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value

APPENDIX C

Retrospective Review Report

1. Documentation of the key elements of a retrospective review
    a. Project number;
    b. Project title;
    c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
    d. Name of the Investigator with the FCOI;
    e. Name of the entity with which the Investigator has an FCOI;
    f. Reason(s) for the retrospective review;

    g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
    h. Findings and conclusions of the review

2. If results of the retrospective review warrant, update previously submitted FCOI report

Mitigation Report

1. If bias is found through retrospective review, notify the NIH Awarding Component promptly (through the eRA Commons) and submit a Mitigation Report

2. Key Elements
    a. Key elements documented in retrospective review
    b. Description of the impact of the bias on the research project
    c. Plan of action(s) to eliminate or mitigate the effect of the bias
    d. Thereafter, submit FCOI reports annually