

Financial Conflict of Interest Policy

Covered Institution

MyExposome, Inc., “Company”, or “Institution” is covered under this policy as required by the National Institutes of Health (NIH) and applicable US regulations. It is the responsibility of the company to promote objectivity in all research performed by or for the company including all research for which Public Health Service (PHS), which includes the National Institutes of Health, funding is sought or obtained. Significant Financial Interest (SFI) include financial interests that are related to an Investigator’s institutional responsibilities. The Company is responsible for determining whether any SFI relates to NIH-funded research and if it is a Financial Conflict of Interest (FCOI).

This Policy provides the 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. The Company shall maintain an up-to-date, written, enforced policy that complies with the FCOI regulation and make available via a publicly accessible Web site. The Company and all of its employees shall comply with this Policy and applicable regulations in all research funded by NIH or other Government funded research.

Purpose

This regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. It applies to any SFI [as defined below] that could directly and significantly affect the design, conduct, or reporting of company research, including NIH-or other Government funded research. If MyExposome, Inc. determines that such an interest might reasonably appear to affect the research directly and significantly, MyExposome, Inc. will develop a mitigation plan to manage or eliminate the conflict.

Scope

These requirements are applicable to all research projects for which MyExposome submits a proposal to or receives research funding from PHS/NIH with the exception of Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) program applications or awards, where this policy does not apply.

PHS/NIH Authority

The PHS/NIH may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in NIH-funded research. The NIH and the PHS have authority that applies before, during, or after an award with regard to any Investigator

disclosure of financial interests, regardless of whether or not the disclosure resulted in the Institution's determination of an FCOI.

Applicable Regulations

- 42 CFR Part 50 Subpart F (grants and cooperative agreements)
- 45 CFR Part 94 (contracts)
- Initial Regulation effective 10-1-95 http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm
- Revised Final Rule published on 8-25-11 <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

Definitions

Company shall mean MyExposome Inc.

Institution shall mean MyExposome Inc.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, 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.

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.

Responsible Individual means the individual within the Institution 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, the *Responsible Individual* is designated as Marc Epstein.

Senior/Key Personnel means the PD/PI 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 this subpart.

Significant Financial Interest (SFI) shall be interpreted as

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 on behalf of the Company:
 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. **With regard to intellectual property rights and interests** (e.g., patents, copyrights), a SFI exists upon receipt of income of greater than \$5000 related to such rights and interests.
 4. **Third party reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse/dependent children) of greater than \$5,000 that is related to the Investigator's institutional responsibilities (i.e., administrative, teaching, research, or clinical activities) must be disclosed to the Company. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. This disclosure requirement excludes travel paid for by the Company and does not apply to travel that is reimbursed or sponsored by an U.S. federal, state, or local government agency, an U.S. 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.

The following shall be excluded from Significant Financial Interest

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 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.

Publication of FCOI Policy and Conflicts

This Policy shall be made available in the “About Us” Section of the Company’s publicly assessable web site. It shall be updated as required when changes are made or as specified in the regulation. Additionally, prior to the expenditure of any NIH/PHS funds, the Responsible Individual shall make information concerning FCOIs held by investigators via the Company’s Web site in the “About Us” Section and update such information as specified in the regulation.

Training

FCOI training is required of each Investigator:

1. Prior to engaging in research related to any NIH funded project
2. At least every four years, and
3. Immediately when any of the following circumstances apply:
 1. Institution revises its policy in a manner that affects the investigator;
 2. When an investigator is new to the institution; or
 3. When the institution finds an Investigator is not in compliance with the Institution’s policy or management plan.
4. The training must inform each Investigator of the:
 1. Regulation;
 2. Institution’s policy on FCOI; and
 3. Investigator’s responsibilities regarding disclosure of SFIs

Duties of the Investigators

- All MyExposome, Inc. employees that meet the definition of Investigator are required to complete the disclosure form annually, even if they have no financial interest to report. See next section for other disclosure requirements.
- Participate in Training and understand this Policy.
- Complete required forms in a timely manner.
- Monitor Subrecipients’ Investigators
- Take necessary actions to eliminate or mitigate FCOIs of the Investigator’s programs.
- Incorporate language as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient’s Investigators and include a time period to meet disclosure requirements, if applicable, and FCOI reporting requirements to the awardee Institution.
 - 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.

Investigator Disclosure:

The investigator shall disclose any SFI:

- **At time of Application:** Require that each Investigator, including subrecipient Investigators, if applicable, planning to participate in PHS/NIH-funded research to disclose to the designated official(s) at time of application.
- **Annually:** Require each Investigator, including subrecipient Investigator, if applicable, to submit an updated disclosure of SFI at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award.
- **Ad hoc disclosures (Within 30 days):** Require each Investigator, including subrecipient Investigator, if applicable, 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.
- 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.

Determining if a “significant financial interest” is a financial conflict of interest

An Investigator’s significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)’s determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If a conflict of interest exists, the responsible individual will determine by what means – such as the individual’s recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a

subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the COIC/designated official will be guided by the principles discussed in this Policy. The responsible individual will also take into consideration whether the Investigator’s ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification 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);
- g) Severance of relationships that create financial conflicts;
- h) For research projects involving human subjects research, use of a data and safety monitoring board;
- i) Double-blind conditions;
- j) Provisions to conduct the work simultaneously at multiple sites;
- k) Written disclosure of the conflict to all individuals working on the research project;
- l) Annual reports on the research progress to the COIC/designated official.

If the responsible individual determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The responsible individual will keep a record of the disclosure and other relevant information for at least three years. If the responsible individual prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

Duties of the Responsible Individual:

- Take necessary actions to manage FCOIs of the Company’s Investigators, including those of subrecipient Investigators
- Train Investigators and Company employees in the Policy
- Document training

- Obtain and review required documents from Investigators including disclosures at time of application, annually, and within 30 days of discovering a SFI
- Maintain Records
- Communicate SFIs and FCOIs with the President
- Communicate with the NIH/PHS as appropriate
- Monitor compliance
- Conduct an audit not less than every two years of contracts to subrecipients to for FCOI language. Document the audit findings.
- If an Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the Responsible Individual shall within sixty (60) days review the SFI in coordination with the President, determine if an FCOI exists and implement an interim management plan, if needed.
- In cases of non-compliance, complete a retrospective review and submit a Mitigation Report if bias is found.

Investigator Non-Compliance

Any FCOI or non-compliance with this Policy shall be reported to the Responsible Individual. The Responsible Individual shall determine if there was a non-compliance in coordination with the President. The Responsible Individual shall within 120 days of the Institution's determination of non-compliance, complete a retrospective review of the investigator's activities and the NIH-funded research project to determine if there was bias in the design, conduct, or reporting of such research. The Responsible Individual shall document the retrospective review.

If bias is found, a Mitigation Report shall be prepared by the Responsible Individual. The retrospective review and Mitigation Report shall include:

- Role and principal duties of the conflicted Investigator in the research project;
- How the conditions of this Management Plan and Policy were or were not followed;
- How the proposed actions are designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

Application Certification

The company shall Certify in each application for funding that the Institution:

1. Has in effect an up-to-date written, and enforced administrative process to identify and manage FCOIs related to all PHS research projects.

2. Shall promote and enforce Investigator compliance with the regulation pertaining to disclosure of SFIs.
3. Shall manage FCOIs and provide initial and ongoing FCOI reports to PHS/NIH.
4. 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.
5. Fully comply with the requirements of the regulation.

Designated Institutional Official(s); i.e.: Responsible Individual

The company shall:

1. Designate an Institutional Official(s), the Responsible Individual, to solicit & review disclosure statements from each Investigator planning to participate in, or is participating in, PHS/NIH-funded research. This Responsible Individual for the Company is the Director of Quality and Regulatory Affairs. The Responsible Individual will be made aware of any possible financial conflicts of interest by the President and/or Controller at the Company, who will both be trained on the policy.
2. Provide guidelines to identify conflicting interests related to proposed or PHS/NIH-funded research. This policy provides those guidelines.
3. Designated Institutional Official(s) develop management plans that specify the actions that have been, and shall be, taken to manage FCOI. This Policy provides that Management Plan. The person who shall update this Management Plan is the Responsible Individual.

Maintenance of Records

The Company shall 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

1. for at least three years from the date of submission of the final expenditures report or, where applicable,
2. from other dates specified in 45 CFR Part 75.361 for different situations.

Confidentiality

To the extent permitted by law, all Disclosure forms, conflict management plans, and related information will be confidential. If the Company is requested to provide Disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this Disclosure.

Reporting

The Responsible Individual will report Financial Conflicts of Interest or non-compliance to PHS/NIH in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified Financial Conflict of Interest such that the prime awardee may fulfill their reporting obligations to the PHS.

Public Accessibility of information related to FCOIs

Prior to expenditure of funds, the Company will make certain information concerning SFIs that meets the following criteria 1) the Significant Financial Interest was disclosed and is still held by the senior and Key Personnel; 2) a determination has been made that the Significant Financial Interest is related to the PHS- funded research; and 3) a determination has been made that the Significant Financial Interest is a Financial Conflict of Interest publicly accessible via a Web site or provide written response within five business days of a request.

- If the Company uses a publicly accessible Web site to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually and within 60 days of identifying any new FCOIs when posting FCOIs to website.
- If the Company responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, and within 60 days of the Company's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.
- Information concerning FCOIs will remain available for three years from the date the information was most recently updated.
- Information to be made publicly available includes the following:
 - Investigator's name;
 - Investigator's title and role with respect to the research project;
 - Name of the entity in which the SFI is held;
 - Nature of the SFI; and
 - 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.

Retrospective Review

- 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 non-compliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research.
- Notify NIH promptly and submit a Mitigation Report when bias is found.
- Documentation of the key elements of a retrospective review:
 - Project number;
 - Project title;
 - PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has an FCOI;
 - Reason(s) for the retrospective review;
 - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - Findings and conclusions of the review.

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

- If bias is found through retrospective review, notify the NIH Awarding Component promptly (through the eRA Commons) and submit a Mitigation Report.
- Mitigation Report
 - Key elements documented in retrospective review
 - Description of the impact of the bias on the research project
 - Plan of action(s) to eliminate or mitigate the effect of the bias
 - Thereafter, submit FCOI reports annually.

Enforcement

The President, with the advice and consult of the Responsible Individual, shall have the authority to enforce this Policy. Sanctions, administrative actions, and other actions up to and including termination may be taken to enforce this policy and ensure Investigator compliance.

The President may require that one or more of the following actions be taken in order to manage, reduce, or eliminate a potential Conflict of Interest:

1. Disclosure of Significant Financial Interests, including to the public, human subjects, researchers and other participants and publishers;
2. Monitoring of PHS-funded Research by independent researchers and/or reviewers, disinterested individuals or committees;
3. Disqualification from participation in all or a portion of the PHS-funded Research;

4. Requiring that Significant Financial Interests be divested, restructured, or placed in blind trust;
5. Modification or severance of relationships that create a potential Conflict of Interest;
6. Changing terms of agreement relating to the PHS-funded Research;
7. Requiring that Investigator participation in the recruitment or consent of subjects in human subjects PHS-funded Research be prohibited or restricted;
8. Requiring additional disclosures or actions with respect to matters before the Research Management Team; or
9. Requiring non-participation in any business transactions between the Company and parties to agreements involving sponsored PHS-funded Research.

Additionally, in any case in which the HHS determines that a PHS-funded 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 a financial conflict of interest that was not managed or reported by the Institution as required by this subpart, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Revision of Policies

This policy shall be reviewed upon changes to the Federal Regulation and revised as appropriate.