

## Financial Conflicts of Interest

### **Policy Statement**

As a professional research corporation, Aeon Respire is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. Aeon Respire (Company) has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest in research.

This policy has been developed to comply with specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F) for Which Public Health Service (PHS) Funding is Sought and Responsible Prospective Contractors (45 CFR part 94). These regulations do not cover Phase I Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program applications or awards but do apply to applicants and recipients under the SBIR/STTR Fast Track and Phase II Programs. These regulations were developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of research funded under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

### **Summary of Process**

For PHS-funded research, as part of the funding application or proposal and prior to performing any work on the research, all Investigators and Senior/Key Personnel participating in the research are required by regulation to complete a Significant Financial Interests (SFI) (as defined below) Disclosure Form and submit this to Aeon Respire's Company Designated Official (CDO) for review, irrespective of whether a Financial Conflict of Interest (FCOI) exists or not. It is the Principal Investigator's responsibility to ensure those with financial interests in research are identified and make the required disclosures. The Company Designated Official will be responsible for evaluating and instituting a plan for managing any disclosed financial interests, for producing institutional reports and other required reports to government agencies or external sponsors, and for administration and enforcement of this policy. Advance approval by the Chief Executive Officer (CEO) is required prior to engaging in government-sponsored research. A SFI review must be completed before any expenses are incurred under a award. Annual updates of the SFI Disclosure Form are required of all Investigators and Senior/Key Personnel participating in the research. Any Investigator who has acquired a new or increased financial interest during the course of a research project shall report it immediately to the CEO and CDO and provide an updated SFI Disclosure Form.

### **Training**

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH funded project, which includes all Investigators, consultants and employees of Aeon Respire engaged in NIH-funded research or its compliance.

The course is accessible at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. Upon completion of the training, a certificate of completion must be turned into the CDO and you should retain a copy for your records. This training is required prior to engaging in any NIH-funded research or as deemed necessary by the Company due to changes in the FCOI policy, non-compliance of the Investigator/Key Personnel or if new to the Company. At a minimum, the FCOI training shall be taken every four (4) years.

## **Key Definitions**

The following key definitions are provided as reference in understanding this FCOI policy. A complete list of official definitions can be found at 42 CFR 50.603.

**Company Designated Official (CDO)** is the individual designated by Aeon Respire to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests and ensuring training.

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

**Investigator** means the Project Director (PD) / Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of the research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

**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 NIH by the Institution under the regulation.

**Contractor** means an entity that provides property or services under contract for the direct benefit or use of the Federal Government.

**Institutional responsibilities** means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, 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.

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

**Financial conflict of interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research as determined by Aeon Respire through the CDO.

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

**PHS** means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

**PHS-funded Research** means research funded under PHS grants, cooperative agreements, or contracts.

**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). For PHS-Funded Research, 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.

**Significant financial interest** means a financial interest consisting of one or more of the following interests of the Investigator and his/her immediate family that reasonably appear to be related to the Investigator's Aeon Respire project responsibilities, including:

1. With regard to interests in any publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure and any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure, in which the value when aggregated exceeds \$5,000;
2. With regard to interests in any non-publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family 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.

Significant financial interests also include 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 the Investigator's Aeon Respire project 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.

Significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by Aeon Respire (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Aeon Respire, including that paid for intellectual property rights assigned or licensed to Aeon Respire and agreements to share in royalties related to such rights;
- Any ownership interest in Aeon Respire (or a subrecipient as applicable) held by the Investigator (e.g., Employee Stock Ownership Plan);
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education; or
- Income from service on advisory committees or review panels for a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.

## **Procedures**

A. Identification of Persons Required to Disclose a Significant Financial Interest - It shall be the responsibility of the Principal Investigator of a Research project to identify all Investigators who have a SFI requiring disclosure under this policy and to ensure that a SFI Disclosure Form is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.

B. Submission and Review of Financial Conflict of Interest Disclosure Form - Every individual having a SFI requiring disclosure under this policy shall prepare a fully-completed SFI Disclosure Form that shall be submitted to the CDO. An

initial review of the SFI Disclosure Form will be conducted by the CDO to determine whether a potential for conflict of interest exists. If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFI identified in the FCOI Disclosure Forms. A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests;
- Review of research protocols by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divesture of significant financial interests;
- Severance of relationships that create actual or potential conflicts All management plans are required to be signed by the Investigator and the CEO. Compliance of the management plan shall be monitored by the DO.

C. Annual Reporting and After-Acquired Significant Financial Interests - All Investigators shall provide annual FCOI disclosure reports or more frequently if required by the management plan. Any Investigator who acquires a new or increased SFI shall promptly submit a new FCOI Disclosure Form(s) within 30 days of discovering or acquiring the new SFI. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research project submits the required FCOI disclosure report to the CDO.

D. Violations of Conflict of Interest Policy - Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the CDO shall make recommendations to the CEO regarding the impositions of sanctions or disciplinary proceedings against the violating individual. In addition, the Company shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.

E. Record Keeping - Records of Investigator FCOI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the CDO for three (3) years from the date the final expenditure report is submitted to the NIH, or as required by 45 CFR 74.53(b) and 92.42(b) for different situations.

F. Sub-recipient Requirements - Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, *2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F)* and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. If a SFI is identified by the sub-award recipient, they are required to notify the CDO of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations.

G. Federal Reporting - The CDO is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:

- i. Initial report - prior to the Company's expenditure of any funds under a NIH-funded research project, the Company must provide to the NIH an FCOI report regarding any Investigator SFI found by the Company to be a financial conflict of interest in accordance with the regulation.
- ii. During on-going NIH-funded research projects - the Company shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, the Company shall submit a FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.
- iii. Annual FCOI report - For any FCOI previously reported to the NIH, the Company shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

**H. Point of Contact and SFI Disclosure Form**

- If you have a conflict of interest or if you have a question to discuss, contact the Company Designated Official, Dirk Smith ([smith@aeonrespire.com](mailto:smith@aeonrespire.com)).
- [Download Aeon Respire SFI Disclosure Form](#)

**For more information visit the following links:**

[42 CFR Part 50, 45 CFR Part 94](#)

[NIH FCOI](#)

[NIH FCOI Tutorial](#)

[NSF FCOI](#)