

## **Financial Conflict of Interest (FCOI) Policy**

Last Revision Date: 2/8/2021

**Purpose:** This FCOI policy was developed to:

- i) Promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research, including research funded under grants or cooperative agreements, will be free from bias resulting from investigator financial conflicts of interest;
- ii) Promote transparency in the disclosure and management of any actual or perceived FCOIs; and
- iii) Adhere to Federal and State laws and regulations relating to FCOIs, specifically 42 CFR Part 50 Subpart F.

**Scope:** This FCOI policy applies to any employee or appointee of Aeon Imaging (the “Company”) who meets the definition of an “Investigator” on a federal or state grant or cooperative agreement.

An *Investigator*, as defined in 42 CFR Part 50 Subpart F, 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 funded research, or proposed for such funding, which may include, for example, collaborators or consultants.

### **Procedures:**

A: Conflicts of Interest: Conflicts of interest occur when the private interests and Company responsibilities of an Investigator are at odds. Investigators shall not use their Company position to secure personal financial benefits for themselves or any member of their immediate family. Conflicts of interest should be avoided where possible, or otherwise disclosed and managed.

1) All Investigators shall disclose to their immediate supervisor, the CEO, or the COO any situation in which the Investigator has a real or potential significant financial interest (SFI). Disclosure must occur:

- i) No later than at the time of application for a federal or state grant or cooperative agreement;
- ii) At least annually during the period of the grant award or cooperative agreement;
- iii) Within 30 days of discovering or acquiring a new SFI.

2) The CEO is Aeon Imaging’s designated official who will solicit and review disclosures of SFIs of the Investigator (and those of the Investigator’s spouse and dependent children) related to an Investigator’s employment responsibilities within 30 days of disclosure, and prior to expenditure of related research funds. In the event that the CEO has an SFI, the COO is Aeon Imaging’s designated official who will

review the CEO's disclosure within 30 days of disclosure and prior to expenditure of related research funds.

3) The CEO (or COO, when applicable) will determine i) whether the disclosed SFI is related to performance under a federal or state grant or cooperative agreement; and ii) constitutes an FCOI based on Federal and State law, and the regulations and guidelines provided by the funding agency or organization.

An FCOI exists when the Company, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the funded research.

4) When an FCOI exists, the designated official will oversee the development and implementation of an FCOI management plan within 60 days and, if necessary, a retrospective review and a mitigation report pursuant to § 50.605(a). The designated official will further ensure:

i) That initial and ongoing FCOI reports are submitted to the funding agency or organization as required.

Initial FCOI reports are required by the NIH to be submitted: prior to the expenditure of funds; within 60 days of identification of an Investigator with an FCOI who is newly participating on a project; or within 60 days of a new or newly identified FCOI for existing Investigators. Ongoing FCOI reports are required by the NIH to be submitted: at least annually; or following a retrospective review to update a previously submitted report, if appropriate.

ii) That records are maintained relating to 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 a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the end of the grant award period or cooperative agreement, or as otherwise required by funding agency regulations or law;

iii) That adequate enforcement mechanisms are established and that provide for Investigator sanctions or other administrative actions to ensure Investigator compliance as appropriate;

iv) That the Company certifies in each request for federal or state grant funding that:

1) Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received;

2) Shall promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of significant financial interests;

3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports as required by the funding agency or applicable law;

- 4) Shall make information available, promptly upon request, to the funding agency relating to any Investigator disclosure of SFIs and the Company's review of, and response to, such disclosure, whether or not the disclosure resulted in the Company's determination of an FCOI; and
- 5) An FCOI management plan will be reviewed at least once per year to review and update the plan and ensure continued compliance by the Investigator. The FCOI management plan will remain in place until completion of the related research project.
- 6) Violations of an FCOI management plan will be reviewed by the Company's designated official. If bias is found with the design, conduct or reporting of grant-funded research, the designated official will notify the funding agency or organization within 30 days and submit a Mitigation report as required by laws or regulations.

**Significant Financial Interest Exclusions:** As provided by the NIH 2011 Revised Regulations, the term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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.

**Subrecipients:** Aeon Imaging will require all subrecipients, consultants and contractors on federal or state grant awards or cooperative agreements to adhere to all Federal and State laws and regulations relating to FCOIs. A subrecipient, consultant or contractor may follow their own internal FCOI policies and procedures provided that they agree in writing to meet or exceed the applicable regulations and requirements of the funding agency or organization.

**Policy Notification:** This FCOI policy will be provided to any employee or appointee of Aeon Imaging who meets the definition of an "Investigator" on a federal or state grant or cooperative agreement at the following times:

- 1) When the Investigator first begins employment at Aeon Imaging;

- 2) When an employee or appointee becomes an Investigator, determined by being named as a Principal Investigator or Co-Investigator on any grant award, proposal, or cooperative agreement; and
- 3) When this policy is revised.

**Training:** Each Investigator is required to complete FCOI training provided by PHS at least every four years, and immediately when any of the following circumstances apply:

- 1) The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- 2) An Investigator is new to the Company; or
- 3) The Company finds that an Investigator is not in compliance with the Company's financial conflict of interest policy or management plan.

PHS-provided FCOI training materials are currently located at: <http://grants.nih.gov/grants/policy/coi/>

Investigators are additionally required to read the Company's FCOI policy to understand their responsibilities for disclosure of FCOIs or SFIs.

**Sanctions:** Violations of this policy will be addressed with applicable Company policies and procedures, which may include disciplinary actions up to and including suspension and termination from the Company and/or criminal prosecution.

In the event that an Investigator does not disclose SFIs timely, that SFIs are not reviewed timely, or whenever an FCOI is not identified or managed in a timely manner, the Company will complete and document a retrospective review within 120 days consistent with FCOI laws and regulations of its research funding agreements.

**Clinical Research FCOIs:** In any case in which the Department of Health and Human Services determines that a PHS-funded research 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 an FCOI that was not managed or reported by the Company as required by the regulation, the Company shall require the Investigator involved to:

- 1) Disclose the FCOI in each public presentation of the results of the research, and
- 2) To request an addendum to previously published presentations.

**Public Accessibility:** As required by 42 CFR 50.604(a), the Company's FCOI policy will be made publicly accessible from its website. The Company will make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible:

- 1) prior to the expenditure of funds;
- 2) within 5 calendar days of a written request; or
- 3) within 60 days of a newly identified FCOI.

The information concerning identified FCOIs will include the minimum elements as provided by 42 CFR 50.605(a)(5)(i)-(iv), be updated at least annually, and remain available for three years from the date the information was most recently updated.