



Financial Conflict of Interest Policy

Purpose

Wearable Artificial Organs, Inc. (WAO) is committed to ensuring that the design, conduct, and reporting of its research will not be biased or appear to be biased by personal financial conflicts of interest. The following policy establishes standards and procedures in accordance with Title 42 of the Code of Federal Regulations, Part 50, Subpart F, in order to identify, evaluate, manage, reduce, or eliminate potential financial conflicts of interest in research for which National Institute of Health (NIH) funding is sought.

Scope

This policy applies to:

1. Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by the NIH, Public Health Service, or any other entity that has adopted the PHS 2011 FCOI Regulations.
2. Subrecipient institutions and Investigators.

Definitions

Disclosure - The Investigator's disclosure of Significant Financial Interests (SFIs) to their institution.

Family Member - includes the Investigator's spouse and dependent children.

Financial Conflict of Interest (FCOI) - means a Significant Financial Interest (see below) related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.

Financial Interest - means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children, regardless of whether or not the value is readily ascertainable.

Institutional Responsibilities - means an investigator's professional responsibilities on behalf of the institution, including activities such as research, teaching, clinical, or other professional practice, academic activities, scholarly events, and institutional committee memberships.

Investigator - The PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of NIH-funded research, including subgrantees, contractors, consortium participants, collaborators, or consultants.

Project - implies any externally funded activity such as basic, applied, or developmental research or other activity conducted by Company Employees on behalf of the Company.

Significant Financial Interest (SFI) – A Financial interest of the Investigator and/or the Investigator's spouse and dependent children, consisting of one or more of the interests itemized in the Disclosure section below, that reasonably appears to be related to the Investigator's Institutional responsibilities.



Financial Conflict of Interest Policy

Policy Statement

WAO will maintain, update and enforce written administrative procedures to identify and manage FCOIs, which will be made publicly available. WAO's Investigators will be trained in FCOI compliance and submit relevant financial information when required. WAO will file ongoing reports with the NIH and Provide SFI information, including related institutional review and determination to the NIH promptly upon request.

Subrecipient institutions and Investigators must have a Financial Conflict of Interest policy in effect and must assure WAO, in writing that the institution and its Investigators are compliant with all applicable federal regulations. If a subrecipient does not have such a policy in effect, the subrecipient must agree, in writing, to abide by WAO's financial conflict of interest policy and procedures.

Procedures

Training – Investigators will be trained in WAO's policies and procedures, including the reporting and filing of SFIs, and complete the NIH's online FCOI training module. Investigators will undergo training:

1. When new to WAO;
2. Prior to engaging in research related to any NIH-funded grant;
3. When WAO updates its policies and procedures;
4. When the Investigator is not in compliance with the policy or management plan; and
5. At least every 4 years if none of the above has occurred.

Disclosure – Each Investigator shall disclose foreign and domestic Significant Financial Interests (SFIs) as defined below, belonging to themselves and/or their family members, that are related to the Investigator's institutional responsibilities.

SFIs to Disclose:

1. Interest in a publicly traded entity - 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 the 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 interests 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. Interest in any non-publicly traded entity - 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 (and/or the Investigator's family members) holds any equity interest (e.g., stock, stock option, or other ownership interest).
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
4. For PHS-funded investigators, any reimbursed or sponsored travel related to an Investigator's institutional responsibilities, including that which is paid on behalf of the investigator so that the exact monetary value may not be readily available.



Financial Conflict of Interest Policy

SFIs that do NOT need to be Disclosed:

1. Salary, consulting fee, or other remuneration paid by WAO if the Investigator is currently employed or otherwise appointed by WAO.
2. Any ownership interest in WAO held by the Investigator or the Investigator's family members.
3. Income from seminars, lectures, or teaching engagements sponsored by a United States federal, state or local agency, a United States Institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education as defined at 20 USC 1001(a).
4. Income from service on advisory committees or review panels for a United States federal, state, or local government agency, an Institution of higher education as defined in 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education as defined in 20 USC 1001(a).
5. Travel by a PHS-funded Investigator that is reimbursed or sponsored by a United States federal, state, or local government agency, an Institution of higher education as defined in 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education as defined in 20 USC 1001(a).
6. Income from intellectual property rights assigned to WAO with agreements to share in royalties related to such rights.
7. 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.

Timing of Disclosure: Each Investigator will notify WAO of a disclosure in writing:

1. No later than at the time of application for NIH-funded research;
2. At least annually during the period of the award;
3. Within thirty (30) days of discovering or acquiring a new SFI.

Review and Monitoring – WAO will designate an Institutional official (Designated Official) who shall perform the Review and Monitoring steps listed below prior to WAO's expenditure of funds and periodically thereafter:

1. Develop and implement a plan to manage FCOIs, which will include adequate enforcement mechanisms and employee sanctions or other administrative actions to ensure Investigator compliance.
2. Manage and enforce subrecipients' FCOI disclosures and documentation as provided in the NIH Grants Policy Statement Section 15.2.1:
 - a. Establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient.
 - b. Obtain a certification from the subrecipient that its FCOI policy complies with the regulation.
 - c. In a written agreement, require each subrecipient to either:
 - i. Report identified FCOIs for its Investigators in a time frame that allows WAO to report identified FCOIs to the NIH as required by law; or
 - ii. To solicit and review subrecipient Investigator disclosures that enable WAO to identify, manage and report identified FCOIs to the NIH.



Financial Conflict of Interest Policy

3. Within 60 days of any SFI disclosure:
 - a. Review the disclosures to determine if the SFI is related to an Investigator's institutional responsibilities.
 - b. Determine whether an Investigator's SFI is related to PHS/NIH-funded research according to WAO's guidelines defined above. The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research.
 - c. Determine if an SFI is a FCOI by determining if it could be affected by the PHS/NIH-funded research or is in an entity whose financial interest could be affected by the research and if the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.
4. In the event that the Designated Officer finds that the SFI is a FCOI, the Designated Official will involve WAO's administration and management officers to implement the actions and conditions imposed by the management plan, including but not exclusive, of full public disclosure or appointment of an independent monitor.
5. In the event that WAO, through its Designated Official discovers that an Investigator did not disclose an SFI in a timely manner or at all; that an SFI was not reviewed in a timely manner or at all; or that an Investigator failed to comply with the FCOI management plan, the Designated Official, within 120 days of the discovery, will conduct a retrospective review of the discovery. A retrospective review shall include the following key elements:
 - a. Project Number and Project Title;
 - b. PD/PI;
 - c. Name of the Investigator with the FCOI;
 - d. Name of the entity with which the Investigator has an FCOI;
 - e. Reasons for the retrospective review;
 - f. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
 - g. Findings and conclusions of the review.
6. An Investigator whose FCOI was not reported or managed as required by law will be required to disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.

Reporting to the NIH –

1. Initial Report: Prior to expenditure of any funds under the NIH-funded research project, WAO will provide to NIH a FCOI report regarding any SFI found to be a FCOI. WAO
2. Subsequent Reports: WAO will also provide to NIH a FCOI report within 60 calendar days from the date that it identifies any SFI as an FCOI, whether filed by a newly onboarded investigator, an existing investigator disclosing a new SFI, or discovery of a prior SFI that was not disclosed or evaluated in a timely manner.
3. WAO will promptly notify the NIH of any Investigator's failure to comply with implemented FCOI management policies or if failure to comply with such policies resulted in a bias of the design, conduct or reporting of the project. In these circumstances WAO will promptly take corrective action.



Financial Conflict of Interest Policy

4. The reports will include the following information:
 - a. Grant/Contract Number
 - b. PD/PI
 - c. Name of Investigator with FCOI
 - d. Name of the entity with which the Investigator has a FCOI
 - e. Nature of FCOI
 - f. Value of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
 - g. Description of how FCOI relates to the NIH-funded research and the basis for the determination that the financial interest conflicts with such research
 - h. Key elements of the FCOI action plan as detailed in 50.605(b)(3)(viii)
5. Annual FCOI update reports will be submitted to the NIH for the duration of the research project. The annual report will relate:
 - a. The status of the FCOI; and/or
 - b. Changes to the action plan; and/or
 - c. Justification that an FCOI no longer exists

Maintenance of Records – WAO shall maintain all FCOI-related records including Investigator disclosures of financial interests, the Designated Official’s review of, and response to the disclosures, and all actions under the Institution’s policy or retrospective review, if applicable. These records will be maintained for at least three (3) years from the date that the final expenditures report is submitted. Or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

Public Accessibility - This policy, which contains the minimum elements provided by the applicable regulation, will be posted on WAO’s website www.wearableorgans.com, which is publicly accessible. Prior to the expenditure of funds WAO will make publicly available information concerning identified FCOIs held by key or senior personnel. WAO will update this information within 60 days of a newly identified FCOI. If no new FCOIs are identified, the information will be renewed annually. WAO will keep this information available for three (3) years from the date that the information is most recently updated.