

FINANCIAL CONFLICT OF INTEREST POLICY

Institutional Responsibilities

SonoVol, Inc. (“SonoVol”) is committed to ensuring its staff an open and productive environment in which to conduct business activities, research and other activities. Conflicts of interest may arise because board of directors, executives, individuals, or other individuals (“Individuals”) involved with the company may have the opportunity to influence SonoVol’s business decisions in situations where those individuals have competing interests, and/or a situation in which those individuals are in a position to derive personal benefit from actions or decisions made in their official capacity.

It is the policy of SonoVol that:

- Individuals have an obligation to avoid unacceptable ethical, legal, financial or other conflicts of interest and to ensure that their activities and interests do not materially conflict with their obligations to SonoVol or its welfare;
- Any Individual engaging in an outside activity or possessing a personal interest that could lead to a serious conflict of interest must inform SonoVol of that possibility by consulting with that individual’s supervisor or designate; and
- Relationships between individuals and outside companies or institutions must not impede or bias the generation and communication of business activities at SonoVol.

This policy is designed to comply with all necessary Federal and State Regulations. The goal at SonoVol is to ensure that the design, conduct, or reporting of research funded under Federal and State grants, cooperative agreements, or contracts will be free from bias resulting from Financial Conflicts of Interest (FCOI).

Definitions

- **Disclosure of significant financial interests** means a disclosure of significant financial interests to an Institution.
- **Financial conflict of interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of State or Federal funded research.
- **FCOI report** means an Institution’s report of a financial conflict of interest.
- **Financial interest** means anything of monetary value.
- **Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that submits a proposal, or that receives, Federal or State research funding.
- **Institutional responsibilities** means an Investigator’s professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: 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 PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- **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.

FCOI Disclosure Responsibilities

COI Coordinator

- Must review all Financial Conflict of Interest Disclosure Forms.
- Must determine whether a SonoVol investigator working on a funded research project has a FCOI.

CEO

- Ensures compliance with FCOI policy.
- In cases where the COI Coordinator determines that a potential FCOI exists, develops and coordinates implementation of FCOI Management Plan in consultation with the COI Coordinator.
- Coordinates the submission of annual reports related to the FCOI Management Plans through the COI Coordinator, as necessary.

When a conflict of interest determination is required by this policy, the employee should contact the COI Coordinator for guidance. Employees are required to cooperate fully in the review process by providing all necessary information. Requests for a conflict of interest determination will be reviewed on a case-by-case basis through the established conflict of interest review process. The employee should submit a Financial Conflict of Interest Disclosure form in a sealed envelope to the COI Coordinator.

Once a written determination has been made, it continues in effect until it is reversed, modified, or withdrawn. When changed circumstances or new developments occur, the employee is responsible for informing the COI Coordinator. Upon review, the previous decision may be reversed, modified, or withdrawn. Records of conflict of interest reviews will be retained by the COI Coordinator and a copy will be provided to the employee. An employee may appeal a conflict of interest review determination.

Enforcement and Sanctions

Employees who violate company standards of conduct including the Financial Conflict of Interest Policy will be subject to disciplinary action. Such action may include suspension or termination of employment or reimbursement to SonoVol for financial losses suffered. Violations may also result in civil or criminal penalties.

Financial Conflict of Interest Disclosure Form Guidelines

The requested financial disclosure attempts to balance SonoVol's needs for information with the individual's reasonable expectation of privacy in his or her personal affairs. There are materiality guidelines to assist individuals with disclosures (see below). Should you need further guidance in preparing your form, please contact the COI Coordinator.

Significant Financial Interest (SFI) is defined by regulation 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:

- With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 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 payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock options, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when

the Investigator (or the Investigator's spouse or dependent children) hold any equity interest (e.g., stock, stock options, or other ownership interest); or

- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) 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 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. The Investigator's disclosure will include the identity of the sponsor/organizer, the destination, and the duration. The SonoVol COI Coordinator can request additional information from the Investigator in order to determine whether the travel constitutes an FCOI.

(3) The term SFI does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by the Institution (i.e., Investigator's employer) to the Investigator if the Investigator is currently employed 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.