EVERMORE

Evermore's Financial Conflict of Interest (FCOI) Policy Submission for NIH Grant

November 2023

Overview

Evermore recognizes the importance of collaborations with industry, government, academia and others, and seeks to encourage such relationships. However, it is important that the financial incentives that may accompany such relationships do not create financial conflicts of interest that might undermine the validity of the research or the safety of human research subjects. Such conflicts of interest have the potential to create real or apparent bias in research and may reduce public confidence in the research enterprise.

For these reasons, Evermore has established the following Investigator Financial Conflicts of Interest Policy for Research. The purpose of this policy is to uphold the highest ethical standards of objectivity in research by identifying and evaluating financial conflicts of interest ("FCOI") that may affect research decisions, transactions and operations at Evermore and managing them so that important collaborations can be undertaken without compromising integrity. This policy is intended to comply with the requirements of the federal regulations set forth in 42 CFR Part 50 and 45 CFR Part 94 for research funded through the Public Health Service (PHS). This policy shall be construed in accordance with such regulations and shall be deemed to include any requirements set forth in such regulations that are not expressly set forth below.

Covered Parties

This policy applies to all individuals, regardless of title or position, responsible for the design, conduct or reporting of PHS-Funded and Non-PHS Research at or under the auspices of Evermore.

Applicability to PHS-Funded Subrecipients

For PHS-Funded Research that involves a subrecipient (i.e., subcontractor, subgrantee or subawardee) at other Institutions, Evermore requires a written agreement from the subrecipient that establishes whether Evermore's policy or the subrecipient's policy shall

apply to the subrecipient's Investigators. In all cases, Evermore must report to the PHS-Funding agency any subrecipient FCOI (as defined below) prior to the execution of the subcontract or within 60 days of identification of a new FCOI that arises during the term of the subcontract.

If the subrecipient's policy is used, the subrecipient must certify that its FCOI policy is compliant with 42 CFR Part 50 and 45 CFR Part 94 and that they will be responsible for ensuring that the subrecipient Institution and its Investigators comply with the federal regulations. Subrecipients must report to Evermore, as the awardee Institution, any identified FCOI within 10 business days of the management plan agreement with the subrecipient's Investigator, but no later than 45 days after identification of the FCOI by the subrecipient. The details of the FCOI will be reported to the funding agency as required under applicable regulations or policies.

If Evermore's policy is used, the subrecipient must ensure that its Investigators disclose to Evermore all Significant Financial Interests ("SFI") as defined below) that are directly related to the subrecipient's work for Evermore at the time of submission of the application by Evermore or at the time the subrecipient signs an institutional letter of support if during an ongoing award grant or contract.

Definitions
The following definitions are provided as a reference for the purpose of understanding this policy. A complete list of official definitions which apply to this policy can be found at 42 CFR 50.603.

- **Disclosure of significant financial interests** means an Investigator's 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 PHS-funded research.
- **FCOI report** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- **Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.
- **HHS** means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- **Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS 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.
- **PD/PI** means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.
- **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** means:
  (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:
    (i) 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;
    (ii) With regard to any non-publicly traded entity, 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
    (iii) 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 related to their institutional responsibilities according to federal guidelines.

  (3) 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.

Responsibilities

The Designated Official (or designee) shall be responsible for the following:

• Informing SPI Investigators of their obligations under this policy and any related regulations;

• Reviewing disclosures of significant financial interest with heads of department to determine whether they are related to the subject research and, if so, whether they constitute financial conflicts of interest;

• Screening and managing potential financial conflicts of interest;

• Maintaining all records relating to disclosures of financial interests, and any related actions under this policy;

• Ensuring inclusion of any required certifications in applications for funding or contract proposals; and

• Reporting and disclosure as required under this policy and applicable regulations.

For PHS/NIH-funded research, the Designated Official shall also have the following responsibility:

Taking reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subcontractors, or collaborators) fully comply with this policy or provide SPI with sufficient assurances to enable SPI's compliance with all applicable laws or regulations. To this end, the written agreement between SPI and the subrecipient will specify whether SPI's or the subrecipient's financial conflicts of interest policy will apply to the subrecipient's Investigators and, if the subrecipient's policy will apply, the Designated Official will:

- Obtain certification from the subrecipient that its policy complies with SPI's policy and the applicable regulations (absent such certification, SPI's policy will apply to the subrecipient's Investigators), and
- Establish time periods for subrecipient reporting of financial conflicts of interest to SPI that enable SPI to report such conflicts in a timely manner, as required under its policy and the applicable regulations.

If SPI's policy applies to the subrecipient Investigators, SPI will be responsible for meeting the requirements of this policy and the reporting obligations reflected in the applicable regulations.

Training

The NIH Financial Conflict of Interest tutorial was designed by the NIH to provide education training on what constitutes financial conflict of interest. This course is required for Investigators involved with an PHS/NIH-funded project. FCOI training will be completed by Investigators (at minimum):

- Prior to engaging in research related to any PHS/NIH-funded grant
- At least every four (4) years
- Immediately, if:
    - SPI revises its FCOI policy in any manner that affects requirements of Investigators
    - An Investigator is new to SPI
    - An Investigator is not in compliance with the policy or management plan

The NIH course is accessible at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.

Upon completion of the training, a certificate of completion must be turned into the Designated Official and will be stored on the SPI internal server with other staff training qualifications. The Investigator should also retain a copy of the certificate for their records.

Disclosure, Review, and Monitoring

Disclosure of Significant Financial Interests (SFI) shall be via the Investigator Financial Interests and Disclosure Statement Form (Exhibit 1), which is completed by an Investigator prior to engaging in research related to any PHS/NIH-funded grant, and when an SFI arises during the course of research.

At minimum, disclosure of SFI must occur:

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

When an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, the Designated Official shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.

The Designated Official shall determine whether an Investigator's SFI is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If SPI determines that a financial conflict of interest exists, a financial conflicts of interest management plan will be implemented and monitored on an ongoing basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest; or
- Severance of relationships that create actual or potential conflicts.

In addition to the conditions or restrictions described above, SPI may require the management of conflicting financial interests in other ways as it deems appropriate.

Reporting

The Designated Official will be report 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.

The Designated Official will notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation. The Designated Official will notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research. The Designated Official and Investigator will develop and undergo a corrective action plan for noncompliance with the SPI FCOI policy or the management plan.

Reporting to NIH will include reporting elements (e.g., entity name, name of the investigator with the FCOI, nature of SFI(s), value of the SFI(s), etc.) as required by the regulation.

Documentation of any retrospective reviews shall include at a minimum the following key elements: Project Number; Project Title; PD/PI or contact PD/PI if multiple PD/PI model is used; Name of the Investigator with the FCOI; Name of the entity with which the Investigator has an FCOI; Reasons for the retrospective review; Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed); Findings of the review; and Conclusions of the review.

Investigator Noncompliance

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), SPI may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. Per federal regulations, SPI will conduct a retrospective review within 120 days of the SPI's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a significant financial interest that is determined by SPI to constitute a financial conflict of interest;
- Failure by SPI to review or manage such a financial conflict of interest;
- Failure by the Investigator to comply with the financial conflict of interest management plan;

For PHS/NIH-funded research, failure to comply with this policy or the applicable regulations shall result in the following:

- If the Investigator's failure to comply with this policy or a financial conflicts of interest management plan has biased the design, conduct, or reporting of the PHS/NIH -funded research, SPI shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;
- SPI will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts; and

- If HHS determines that a clinical PHS-funded research project 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 neither disclosed nor managed, SPI shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

Retention of Records

The Designated Official will retain financial conflicts of interest disclosure forms and other supporting information including actions taken to manage actual or potential conflicts of interest. For PHS/NIH-funded research, these records shall be retained for at least 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.

Disclosure

SPI will make the following information publicly available:

- This FCOI policy
- Any information concerning identified FCOIs held by senior/key personnel (as defined by federal regulations) participating in PHS/NIH-funded research. The publicly accessible information will:
    - Be made available prior to the expenditure of funds
    - Include the minimum elements as provided in the regulation
    - Be made available within five (5) business days of a written request to SPI
    - Be updated, at least annually and/or within sixty (60) days of a newly identified FCOI
    - Remain available for three (3) years from the date the information was most recently updated

Exhibit 1

Investigator Financial Interests and Disclosure Statement Form

In compliance with the U.S. Code of Federal Regulations 21CFR54, clinical Investigators are required to disclose to the Study Sponsor their financial interests for the period of time he or she participated in the study and for one year following the end of his or her participation in the study.

Protocol Title:			
Protocol Number:		**Study Sponsor:**	Sound Pharmaceuticals, Inc.
Study Site No.: *(if unknown leave blank)*		**Other Study Sponsor/Co-Development Partner:**	**N/A**
Principal Investigator Name:			
Address:			
This Financial Disclosure form is submitted for:	☐ **Principal Investigator as listed above OR** ☐ **Sub-Investigator (**please print) _____		
Information collected at study time-point:	☐ **Initial Disclosure**	**Updates, if applicable:**	☐ **Interim time point** ☐ **End of participation in study** ☐ **One Year Post Study Participation**

TO BE COMPLETED AND SIGNED BY EACH PARTICIPATING INVESTIGATOR AND SUB-INVESTIGATOR (AS LISTED ON FORM FDA 1572)

- **Complete all the information below, retain a copy in your records and provide the original to the Study Sponsor**
- **Investigators who join the study after the site initiation date, complete and sign this form before performing study-related activities**

Please indicate by marking *YES* or *NO* below if any of the financial interests or arrangements applies to you, your spouse, dependent children, or any combination.

1.	Are you, your spouse or any of your dependent children an employee of the Study Sponsor(s)**?**	☐ **YES** ☐ **NO**
2.	Have you, your spouse or any of your dependent children entered into a **financial arrangement with the Study Sponsor(s) whereby the value of the compensation could be influenced by the outcome** of the trial, such as a bonus, royalty or other financial incentive (i.e., compensation that could be higher for a favourable outcome than for and unfavourable outcome)? *This could be compensation that is explicitly greater for a favourable result, compensation in the form of an equity interest in Study Sponsor(s) or compensation tied to sales of the product, such as a royalty interest.*	☐ **YES** ☐ **NO**
3.	Do you, your spouse or any of your dependent children have a **proprietary interest** in the tested product, including, but not limited to, a patent, trademark, copyright or licensing agreement? *Proprietary interest would include, but not be limited to, a patent, trademark, copyright or licensing agreement.*	☐ **YES** ☐ **NO**
4.	Do you, your spouse, any of your dependent children, or any combination hold any significant **equity interest** in Study Sponsor(s) (stock, stock options, or other financial interest) that exceeds $50,000.00 U.S. dollars? *Equity interest includes any options, puts, calls, straddles and other privileges in addition to an equity ownership position in Study Sponsor(s). This does not include ownership interest, stock options or other financial interest over which you have no direct control or input as to the quantities or amounts, e.g., a 401k, IRA, Mutual Fund.*	☐ **YES** ☐ **NO**
5.	Have you, your spouse, any of your dependent children, or any combination received significant payments of other sorts (SPOOS) having total value in excess of $25,000.00 from Study Sponsor(s) other than payments for conducting on this clinical study or other clinical studies. Examples of such significant payment, include, but are not limited to, grants or funding for ongoing research, compensation in the form of equipment, retains for ongoing consultation or honoraria that are (A) paid directly to me or the institution with which I am affiliated, and (B) paid in support of my activities (i.e., payment paid directly or indirectly to me by Study Sponsor(s)?	☐ **YES** ☐ **NO**

For each **YES** response above, please provide detailed information disclosing the nature of the financial arrangement, including total value amounts, (If additional space is needed, please attach to this document. Indicate the number of attached pages _____)

By signing this form:

1. I confirm/declare that the information provided on this form is, to the best of my knowledge and belief, true, complete, and correct.
2. I also confirm that to the extent I have provided any information about other individuals, I have appropriate permission to provide the financial information on their behalf to Sound Pharmaceuticals, Inc.
3. I consent to the disclosure, collection, and further use of the relevant financial information outside of my country/region to employees, agents and contractors of Study Sponsor(s), its representatives, and business partners, for submission to the United States Food and Drug Administration (US FDA) regulation as required by Title 21 of the Code of Federal Regulations Part 54, Financial Disclosure by Clinical Investigators. I further understand and agree that such recipients may be based in countries whose laws do not provide equivalent protection for personal data to those in the country in which I reside.
4. I agree to promptly **update the above information if my legal name or financial interests and arrangements, or those of my spouse and dependent children, changes from the information provided above during the clinical study or within 1 year after its completion.**

Signature:		**Date:**	