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## **Trace-Ability, Inc. Company Policy – Financial Conflict of Interest (FCOI) Policy, November 23rd, 2020**

Objective research is of paramount importance to Trace-Ability and our subgrantees and defined vendors herein, to ensure public trust and meet scientific, program and ethical goals of our National Institutes Health (NIH) grant efforts. Trace-Ability believes we have fully addressed the requirements (including those of our defined sub-level vendors) of this ruling although we will continue to update this policy as needed, particularly related to any changes in personnel FCOI issues or upon further DHHS guidance.

Effective November 23, 2020, Trace-Ability, Inc.'s policy requires that each investigator, subrecipient, subgrantee and collaborator affiliated with Trace-Ability, by NIH or any other applicable grant or contract, be in compliance with 42 CFR Part 50, Subpart F for PHS grants and cooperative agreements (and 45 CFR Part 94 for contracts). In addition, this legislation spells out NIH's commitment to preserving the public's trust that the research supported by them is conducted without bias and with the highest scientific and ethical standards. Trace-Ability, Inc. intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

The following are key term definitions and Trace-Ability, Inc.'s policy guidance for principal or program investigators, subrecipients, subgrantees and collaborators affiliated with Trace-Ability. Upon written request, this policy will be made available within 5 calendar days.

### **Definition of Terms of FCOI Policy:**

**Designated Official(s):** means a person designated by Trace-Ability, Inc. to determine whether an Investigator's Significant Financial Interest is related to PHS-funded research, and if related, whether the Significant Financial Interest is a Financial Conflict of Interest.

**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.

**Financial Interest:** means any interest of economic value in or relationship with an entity, whether private or public, including, but not limited to, ownership of stocks, bonds, stock options, partnership or other equity interests, rights to patent or royalty payments, receipt of consulting fees, speaking fees, salary, loans, gifts, lectureship fees, compensation for serving on boards of directors, scientific and other advisory boards, reimbursed or sponsored travel expenses related to Investigator's Company Responsibilities, or other remuneration.

**Significant Financial Interest (SFI):** Significant Financial Interest is defined by the regulations 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 for the PHS-funded project:
  - 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. For the 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 interest in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;
  - With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remunerations 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 interests (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, medical center, or research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.
- 3) The term significant financial interest does not include the following types of financial interests: salaries, 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 retirements 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, 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.

**Immediate Family or Dependents:** means a (i) spouse; (ii) child; or (iii) any other person residing in the same household as the Investigator who is a dependent of the Investigator or of whom the Investigator is a dependent.

**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 under PHS grants, cooperative agreements, or contracts, including Investigators working for subrecipients.

**Management Plan:** means a written plan for the management, reduction or elimination of a FCOI relating to PHS-funded Research.

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

**PHS Awarding Component:** The PHS awarding component is any sub-agency of the Public Health Service or Department of Health and Human Services.

**Research:** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development. This term includes any such activity for which research funding is available from a PHS Awarding Component through a contract, grant, or cooperative agreement.

**Senior or Key Personnel:** means the Project Director or Principal Investigator and any other person identified as Senior or Key Personnel in Trace-Ability, Inc. grant application, grant proposal, progress report, contract proposal, contract, or other report submitted to the PHS.

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

**Subrecipient:** means an individual or entity receiving federal funds that have come from or through Trace-Ability, Inc. to conduct a substantive portion of the PHS-funded research and is accountable to Trace-Ability, Inc. for programmatic outcomes and compliance matters.

## **Training Requirement**

Trace-Ability and all defined sub-level vendors are required to complete training related to Financial Conflict of Interest (FCOI). If any conflicts of interest are found or known, they must be disclosed. The training must be updated no-less than every four years or as designated based on grant or role circumstances. Information and other resources developed by NIH can be accessed through the NIH Web site. (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>).

Training must take place if

- Trace-Ability, Inc. revises its Financial Conflict of Interest policy in a manner that affects Investigator disclosure or compliance requirements.
- An Investigator is new to Trace-Ability, Inc.
- An Investigator is found to be not in compliance with the Trace-Ability, Inc.'s FCOI policy or Management Plan

## **Disclosure of Investigator's Financial Interests**

It is each Investigator's responsibility to disclose all of his or her (including those of the Investigator's spouse and dependent children) Financial Interests as set forth herein. All such Significant Financial Interests shall be submitted on Trace-Ability, Inc. FCOI Disclosure form.

### **1) Prior to Making a Research Submission**

Prior to the submission of an application or proposal for PHS-funded Research, each Investigator must submit any Significant Financial Interest over the previous twelve-month period as well as immediate spouse and dependent children, that reasonably appear to be related to the Investigator's institutional responsibilities. Such Significant Financial Interest may include remuneration from any publicly traded or non-publicly traded company, and any reimbursed or sponsored travel in the preceding twelve (12) months. Trace-Ability, Inc. will not expend any funds under a PHS-funded research project in the event an Investigator reports a Significant Financial Interest, without first providing a FCOI report to the PHS Awarding Component outlining Trace-Ability, Inc.'s implementation of a Management Plan for the Investigator with a Significant Financial Interest. However, if Trace-Ability, Inc. eliminates the conflict of interest prior to the expenditure of PHS-awarded funds, a FCOI report will not be submitted.

- 2) Annually during the period of the award Each Investigator shall submit an annual Trace-Ability, Inc. Disclosure Form during the period of the applicable PHS-funded Research program. Annual reporting shall include submission of any new significant financial interests. These reports shall be submitted to Trace-Ability, Inc.'s Designated Official via email as instructed on the form.
- 3) Within 30 days of discovering or acquiring a new SFI Each Investigator shall submit a Trace-Ability, Inc. Disclosure Form identifying any new or increased Significant Financial Interest within thirty (30) days of acquiring such Financial Interest. These reports shall be submitted to Trace-Ability, Inc.'s Designated Official in accordance with the reporting instructions as instructed on the form.

## **Guidelines for Identifying Conflict of Interest**

All SFI disclosures, including those submitted by a new Investigator who joins an ongoing PHS-funded project will be reviewed by the Trace-Ability, Inc. Designated Official. The review will determine whether an SFI is related to the PHS-funded research and therefore an FCOI. A conflict of interest exists when the Designated Official reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the proposed or funded research activities. Trace-Ability, Inc.'s Designated Official will work with appropriate support to design a COI Management Plan, if needed, and make appropriate disclosures to the Federal Government as required by TITLE 42 CODE OF FEDERAL REGULATIONS (CFR) PART 50 SUBPART F pertaining to grants and cooperative agreements and TITLE 45 CFR PART 94. When an SFI that was not disclosed by a PHS-funded Investigator in a timely manner is identified, the Designated Official will determine if FCOI exists, develop and implement a management plan within sixty (60) days after the identification of the SFI. In addition, the Designated Official will conduct a retrospective review of SFIs for the PHS-funded Investigator within one hundred twenty (120) days.

## **Standards for Approval for Financial Disclosures**

Proposed Research will only be approved if the Designated Official determines that 1) no FCOI exists or that 2) an adequate Management Plan can be implemented to manage or eliminate a Financial Conflict of Interest.

## **Management Plan for Financial Conflicts of Interest**

The Designated Official shall determine the terms, conditions and restrictions, if any, that are required as part of a Management Plan. The Designated Official will convey the Management Plan in writing to the persons deemed appropriate. The Management Plan will address, at a minimum:

- The role and principal duties of the conflicted Investigator in the research project
- Conditions of the Management Plan
- How the Management Plan is designed to safeguard objectivity in the research project.
- Confirmation of the Investigator's agreement to the Management Plan.

## **Monitoring compliance with the Management Plan**

The Management Plan may require that one or more of the following actions are taken in order to manage, reduce, or eliminate a potential FCOI that was not managed or prior disclosed by the Trace-Ability, Inc.:

- Disclosure of the Financial Conflict of Interest, in each public presentation of the results of the Research and to request an addendum to previously published presentations;
- Monitoring of PHS-funded Research by independent researchers and/or reviewers, disinterested individuals or committees;
- Disqualification from participation in all or a portion of the PHS-funded Research; Requiring that Significant Financial Interests be divested, restructured, or placed in blind trust;

- Modification or severance of relationships that create a potential FCOI;
- Changing terms of agreement relating to the PHS-funded Research;
- Requiring additional disclosures or actions; or
- Requiring non-participation in any business transactions between Trace-Ability, Inc. and parties to agreements involving sponsored PHS-funded Research.

### **Summary Disposition Procedures**

The Designated Official may implement procedures for the disposition of matters involving compliance with this policy that it deems reasonable and appropriate. These procedures may include written approvals for annual reports, renewals, and no-cost extensions where the Designated Official reasonably determines that the facts and circumstances pertaining to the matter being approved have not materially changed since the date of the original review and approval. All such summary approvals shall be in writing. Enforcement and Remedies for Noncompliance Whenever an Investigator has violated this policy, including failure to make a required disclosure of Significant Financial Interests or failure to comply with the requirements of any Management Plan, the Designated Official shall be responsible for enforcing this policy, and shall take reasonable steps to respond appropriately to violations, including, but not limited to:

- 1) Implementing a mitigation plan
- 2) suspending expenditures on applicable Research account;
- 3) administratively suspending approval;
- 4) instituting disciplinary measures to include suspension or termination of such Investigator.

### **Retrospective Review**

When Trace-Ability, Inc. identifies a Significant Financial Interest that was not timely disclosed by an Investigator or otherwise was not previously reviewed during a PHS-funded Research project, the Designated Official will review the Financial Interest and determine whether it is related to the PHS funded Research, and whether it is a Significant Financial Interest within sixty (60) days. The Designated Official will implement a Management Plan specifying actions that have been or will be taken to manage the Significant Financial Interest. In addition, the Designated Official will conduct and document retrospective review of the Investigator's activities within one hundred and twenty (120) days of the Designated Official's determination of such non-compliance. If bias is identified as a result of the retrospective review, Trace-Ability, Inc. will promptly notify the PHS Awarding Component and submit a mitigation report documenting the retrospective review, describing the impact of the bias on the Research project, and Trace-Ability, Inc.'s plan of action to eliminate or mitigate the effect of the bias in accordance with 42 CFR 50.605(b)(3). Companywide, Trace-Ability, Inc. will disclose the Investigator's FCOI in each public presentation with research results if it was not reported up front and request an addendum to previously published presentations.

## **Subrecipient Requirements**

Trace-Ability, Inc. takes reasonable steps to confirm that all Investigators who are Subrecipients participating in PHS-funded Research are in compliance with the FCOI regulation. Such reasonable steps include:

- 1) a written agreement stating which organization's (prime awardee or subrecipient) FCOI policy will be followed
- 2) if the Subrecipient Investigator is to comply with Subrecipient's FCOI policy, the Subrecipient shall certify that such policy complies with Trace-Ability, Inc.'s FCOI policy, or if certification cannot be obtained, the written agreement must state the Subrecipient Investigators are subject to disclosing significant financial interests that are directly related to the subrecipient's work for Trace-Ability, Inc.;
- 3) Subrecipient's Investigators must comply with the Subrecipient's FCOI policy and the agreement shall specify time period(s) for the Subrecipient to report all identified financial conflicts of interest to Trace-Ability, Inc. so that Trace-Ability, Inc. can provide timely FCOI reports, as necessary, to the PHS, or alternatively, Subrecipient's Investigators must comply with Trace-Ability, Inc.'s FCOI policy and the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to Trace-Ability, Inc. so that Trace-Ability, Inc. can comply timely with its review, management, and reporting obligations; and Trace-Ability, Inc. providing FCOI reports to the PHS Awarding component regarding all financial conflicts of interest of all Subrecipient Investigators prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

## **Maintenance of Record**

Records of and related to Significant Financial Interest disclosures shall be retained by Trace-Ability, Inc. for no less than three (3) years after the termination or completion of the PHS-funded Research to which they relate or from the date the final expenditure report is submitted to the PHS Awarding Component, whichever is later.

## **Reporting Requirement**

Trace-Ability, Inc. shall be responsible for reporting to the applicable PHS Awarding Component all Significant Financial Interests in accordance with federal requirements. Trace-Ability, Inc. will promptly notify the applicable PHS Awarding Component in accordance with federal regulations if bias is found with the design, conduct, or reporting of any Research. This report will address the impact of the bias of the Research and the actions Trace-Ability, Inc. has taken, or will take, to eliminate or mitigate the bias. Trace-Ability, Inc.'s designated official will review all "disclosure" and evaluate whether they contain any FCOI. If no FCOI is found, the "disclosure forms" will be filed in the SFI binder. If a FCOI is identified it will be put on the FCOI report through the eRA Commons FCOI module prior to expending any funds. The initial FCOI report will be submitted prior to the expenditure of funds under the Notice of Award. If any interests are identified as conflicting subsequent to the initial report, they must be reported to Trace-Ability, Inc. within 30 days. Trace-Ability, Inc. will then report it to the PHS awarding component that has issued the award within 60 days. Annual FCOI reports (or revised reports as a result of retrospective reviews) will also be submitted and will include the status of any FCOI, whether the FCOI is still being managed or explains why the FCO no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

**Public Disclosure for FCOIs**

The Trace-Ability, Inc. FCOI Policy will be posted on its public web site to ensure public accessibility of information. Identified FCOIs held by a senior or key personnel related to PHS-funded research will be made available on Trace-Ability, Inc.'s website to ensure public accessibility of information concerning any identified FCOI related to the PHS-funded research. FCOI will be updated at least annually and within 60 days of a newly identified FCOI. Such FCOI will remain disclosed on Trace-Ability, Inc.'s website for three (3) years from the date the information was most recently updated.