
POLICY: Financial Conflict of Interest (FCOI)

INTRODUCTION AND PURPOSE

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of research conducted by Cove Technology Consulting, LLC ('Cove Technology', or 'Company') and to comply with federal regulations.

This policy has been developed to address and comply with the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F). This regulation was developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of research funded under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. An electronic version of the regulation is found at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.

DEFINITIONS

The following definitions are provided as a reference. A complete list of definitions can be found in 42 CFR 50.603.

Company official – means a designated institutional official for the Research project, such as the CEO or Signing Official.

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 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.

Investigator – means the project director or principal investigator and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the NIH, which may include, for example, collaborators or consultants.

Institutional Responsibilities – means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, 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.

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 42 CFR part 50 subpart F.

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 (NIH).

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Research – means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in 42 CFR part 50 subpart F, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

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 NIH by the Institution under the regulation.

Significant Financial Interest (SFI) – 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. 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 interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-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, 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 (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 excluded sources provided in regulation. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination and duration. The Company is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes a FCI with NIH-funded research.

(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.

POLICY AND PROCEDURES

A. Identification of Persons Required to Disclose a Significant Financial Interest

It shall be the responsibility of the Principal Investigator of a Research project to identify all Investigators who have a SFI requiring disclosure under this policy and to ensure that a SFI Disclosure Form is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.

B. Training

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education on what constitutes FCOI. This course is required for all Investigators involved with an NIH funded project. The course is accessible at <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>. Upon completion of the training, a certificate of completion must be turned into the Company Official.

This training is required prior to engaging in research relating to any NIH-funded grant or as deemed necessary by the Company due to changes in the FCOI policy, non-compliance of the Investigator/Key Personnel or new to the Company. At a minimum, the FCOI training shall be taken every four (4) years.

C. Submission and Review of Significant Financial Interest Disclosure Form

Every individual having a SFI requiring disclosure under this policy shall prepare a fully-completed SFI Disclosure Form (Appendix 1) that shall be submitted to the Company Official. An initial review of the SFI Disclosure Form will be conducted by the Company Official to determine whether a potential for conflict of interest exists. If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFI identified in the SFI Disclosure Form. A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests;
- Review of research protocols by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflicts

All management plans are required to be signed by the Investigator and the Company Official. Compliance of the management plan shall be monitored by the Company Official.

D. Annual Reporting and After-Acquired Significant Financial Interests

All Investigators shall provide annual SFI Disclosure reports or more frequently if required by the management plan. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFI Disclosure Form within 30 days of discovering or acquiring the new SFI. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research project submits the required SFI report to the Company Official.

E. Investigator Non-Compliance

Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the Principal Investigator shall make recommendations to the Company Official regarding the impositions of sanctions or disciplinary proceedings against the violating individual. In addition, the Company shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.

F. Records Management

Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Company for three (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.

G. Sub-Recipients Requirements

Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F) and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. If a SFI is identified by the sub-award recipient, they are required to notify the Company Official of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations.

H. Federal Reporting

The Company Official is responsible for the reporting 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.

I. Regulatory Authority

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

J. Confidentiality

The Company will, to the extent possible, protect the confidentiality of disclosures. In every instance, the Company will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to Company staff only on a need-to-know basis and will not be disclosed outside of the Company unless necessary to comply with contractual, legal, or regulatory requirements.

APPENDIX 1: Significant Financial Interest Disclosure Form

This Disclosure Form is to be completed by each Investigator pursuant to the Cove Technology Consulting, LLC (Company) Financial Conflict of Interest Policy. Please refer to that Policy for detailed requirements and definitions. All Investigators must complete this form and submit it to the Company Official.

For all Investigators, please sign below:

I have **received and reviewed** the Company's Financial Conflict of Interest Policy.

Signature of Investigator

Date

Part I. Project Title:

Part II. Principal Investigator:

Part III. Name of Investigator making this report about his/her financial interest(s):

Part IV.

Check for which of the following you are submitting:

- A. _____ Initial Disclosure Form: Pre-award application for a Sponsored Project
- B. _____ Update Disclosure Form: Within 30 days discovering or acquiring a new Significant Financial Interest during a Sponsored Project award
- C. _____ For Public Health Services-funded research only: Annual update of Significant Financial Interest

Part V.

Indicate whether you, the Investigator, have any Significant Financial Interests related to the work to be conducted under the Sponsored Project(s):

- A. _____ I have no Significant Financial Interest as that term is defined in the Policy (stop here; submit the Disclosure Form)
- B. _____ I do have Significant Financial Interest(s) to report (continue to Part VI and complete the rest of this

Disclosure Form)

Part VI. Complete for each Significant Financial Interest (use additional pages if necessary):

A. Provide the name of each entity in which the Investigator has a Significant Financial Interest:

B. Provide the nature of the financial interest (for example, equity, consulting fee, travel reimbursement, or honorarium):

C. Indicate the value (dollar amount) of the Significant Financial Interest:

D. For Reimbursed or Sponsored Travel required to be reported by the Policy, indicate all of the following:

1. The purpose of the trip:
2. The identity of the sponsor/organizer:
3. The destination:
4. The duration:

E. Describe how the Significant Financial Interest relates to the Sponsored Project:

F. Do you believe that the sponsored project(s) for which you are an Investigator could directly and significantly affect the Significant Financial Interest(s) you are reporting?

Signature of Investigator

Date