

Procedure Details

Title: **1.41.2 Public Health Service, Department of Energy, and NASA Financial Conflicts of Interest Requirements**

Current Revision
Effective Date: 02/06/2026

Original Effective Date: 11/13/2024

Parent Policy: 1.41 Client Conflicts of Interest

Contact: Ethics Office

Procedure Statement(s)

This procedure is designed to comply with Public Health Service (PHS) regulations (42 CFR Part 50 Subpart F, Financial Conflicts of Interest [FCOI] for Grants/Cooperative Agreements, 45 CFR Part 94, Responsible Prospective Contractors), the Department of Energy (DOE) Conflict of Interest Policy, and the National Aeronautics and Space Administration (NASA) Conflicts of Interest Policy. These standards and procedures are intended to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or research contracts and DOE or NASA grants and cooperative agreements (together Applicable Agreements) will be free from bias resulting from Investigator FCOIs. RTI's Conflict of Interest Policy 1.4 and this procedure implement the requirements of these federal regulations.

Compliance with this procedure is a condition of employment and/or participation for all applicable Investigators. Investigators who fail to comply with these requirements are subject to discipline, including letters of reprimand, restriction on the use of funds, discipline, up to and including termination of employment, or disqualification from further participation in any funded research, as deemed appropriate.

For questions related to this procedure, contact Ethics@rti.org.

Definitions

For the purposes of this procedure the following definitions apply:

Applicable Agreement refers to RTI's research contract, cooperative agreement, or grant for a PHS research project or RTI's grant or cooperative agreement with DOE or NASA.

FCOI Client Report means the RTI disclosures (initial and annual) to the applicable agency of an FCOI with respect to a particular Applicable Agreement. This report must be provided in advance of spending funds from the Applicable Agreement.

FCOI Management Plan means the RTI actions addressing an FCOI, which can include reducing or eliminating the FCOI, to ensure that the design, conduct, and reporting of the Applicable Agreement will be free from bias.

FCOI Public Disclosure Form means the document used to make information related to FCOIs publicly available upon request. The completed form must be available for release in advance of spending funds from the Applicable Agreement.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the Applicable Agreement as determined by the RTI Ethics Office.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable, including remuneration, salary, other payments for services (e.g., consulting fees, paid authorship or honoraria), equity interests (e.g., stocks, stock options, or other ownership interest), intellectual property rights (e.g., patents, copyrights, and royalties from such rights), and reimbursed or sponsored travel unless the sponsored travel is paid for by a federal, state, or local government agency located in the United States or a United States institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with a United States institution of higher education.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of RTI or "the Institute", which includes activities such as research, research consultation, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards, and any other work conducted as a representative of or on behalf of the RTI.

Investigator means the project director or principal investigator, project manager, or other person, regardless of title or position, who is responsible for the design, conduct, or reporting of an Applicable Agreement, or is proposed for such funding, which may include persons who are subrecipients, collaborators, or consultants.

Project Scope and Roster Form means the form available through RTI systems used in conjunction with the SFI Disclosure Form to determine if an FCOI exists in the context of a particular Applicable Agreement. 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

SFI Disclosure Form is the document used to identify and transmit SFIs to the RTI Ethics Office.

Significant Financial Interest (SFI) is defined as one or more Financial Interests of Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears related to the Investigator's Institutional Responsibilities and

(1) with regard to any publicly traded entity, the value of any remuneration 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 or, **with regard to any NSF assistance agreement, but not including PHS research assistance agreements or contracts**, 5% ownership interest in a single entity. 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;

(2) with regard to any non-publicly traded entity, the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or any equity interest;

(3) venture or other capital financing;

(4) travel reimbursed or sponsored (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) by an entity other than RTI or for work on behalf of RTI which, when aggregated for each entity, exceeds \$5,000, unless reimbursed or sponsored by a Federal, state, or local government agency located in the United States or a United States institution of higher education, academic teaching hospital, medical center, or research institute affiliated with a United States institution of higher education; or

(5) intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests greater than \$5,000 received over the preceding months. For purposes of this definition, remuneration includes salary from an institution other than RTI 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.

For avoidance of doubt, SFI does *not* include: (1) salary, royalties, or other remuneration from RTI, including intellectual property rights assigned to RTI and agreements to share royalties related to such rights, (2) income from seminars, lectures, or teaching engagements, service on advisory committees or review panels sponsored by federal, state or local government agencies located in the United States or a United States institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with a United States institution of higher education, or (3) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control such fund's or account's investment decisions.

NOTE: Exclusions above do not apply to foreign financial interests. Investigators must disclose all foreign financial interests (including income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

Subrecipient means any party that has entered into an agreement with RTI as a subgrantee, subcontractor, collaborator, contractor, or consultant.

Disclosure Requirements

Before submitting an application for PHS-funded research or for DOE or NASA financial assistance and before a resulting awarded project is officially authorized for charging, all Investigators/project directors requesting applicable funding—whether grant, cooperative agreement, or, in the case of PHS, research contract—are required to have submitted to the Ethics Office a SFI Disclosure Form. These completed forms either indicate that the Investigator/project director has no **SFIs** or includes a listing of known SFIs as defined below, including those of the spouse and dependent children).

The SFI Disclosure Form must be updated by all Investigators/project directors on an annual basis during the award period and/or within thirty (30) days of discovering or acquiring new reportable SFIs, whichever occurs first.

Responsibilities

Investigators

- Must complete FCOI training concerning RTI’s policy, the Investigator’s responsibilities regarding disclosure of SFIs, and the FCOI regulations prior to engaging in an Applicable Agreement and every 4 years thereafter. Training is also required immediately when any of the following circumstances apply:
 - RTI revises its FCOI policies or procedures in any manner that affects the requirements of Investigators;
 - An Investigator is new to RTI; or
 - RTI finds that an Investigator is not in compliance with RTI’s FCOI policy or management plan.
- Must complete and submit to the RTI Ethics Office a SFI Disclosure Form, including a signature on the certification statement, no later than at the time of application for an Applicable Agreement and, when an SFI Disclosure Form has not been submitted with the last year or requires updates, prior to participating in a project.
- Must update the SFI Disclosure Form annually or within 30 days of discovering or acquiring a new SFI, whichever occurs first.
- The RTI project manager/principal investigator must complete and submit to the RTI Ethics Office a Project Scope and Roster Form, describing the project scope and the names of all other Investigators.

RTI Ethics Office

- Ensures compliance with RTI’s FCOI policy and procedures.
- Maintains RTI’s FCOI policy and procedures on RTI’s external website.
- Prior to the expenditure of funds from an Applicable Agreement, records and reviews all SFI Disclosure Forms submitted for Applicable Agreements at RTI, determines whether an

RTI Investigator working on, or proposed to work on, an Applicable Agreement has an FCOI, and, if so, develops and implements an FCOI Management Plan.

- Prior to allowing an Investigator for whom an SFI Disclosure Form was not submitted to work on an Applicable Agreement, records and reviews an SFI Disclosure Form to determine whether the Investigator has an FCOI and, if so, develops and implements an FCOI Management Plan.
- When assessing an SFI for an FCOI, determines whether an Investigator's SFI is related to an Applicable Agreement and, if so related, whether the SFI is an FCOI. An Investigator's SFI is related to an Applicable Agreement when the Ethics Office reasonably determines the SFI: (1) could be affected by the Applicable Agreement or (2) is in an entity whose financial interest could be affected by the research. An FCOI exists when RTI's Ethics Office reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Applicable Agreement.
- In cases where the Ethics Office determines that a potential FCOI exists, develops and coordinates implementation of an FCOI Management Plan in consultation with the RTI project manager. The FCOI Management Plan will include conditions and/or strategies to manage the FCOI, examples include, but are not limited to, public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the Institution's Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.); for research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document; appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI; modification of the research plan; change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; reduction or elimination of the financial interest (e.g., sale of an equity interest); and severance of relationships that create the FCOI.
- In advance of RTI expending funds on an Applicable Agreement, the FCOI Management Plan must be completed and approved by the Ethics Office, and, if applicable for the funding agency, the Ethics Office must, with assistance from the RTI Contracts Representative for the Applicable Agreement, provide required information to the applicable agency concerning FCOIs on Applicable Agreements, including a summary of the management plan in the FCOI Client Report, with updates provided to the applicable agency at least annually, at the same time as when the Research Performance Progress Report or multi-year progress report is due and at the time of grant extension, and within 60 days of changes to or identification of new SFIs, whichever occurs first. All FCOI Client Reports must include the following information:
 - Project number;
 - PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has an FCOI;
 - Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - Value of the financial interest (using the ranges of \$0-\$4,999; \$5,000- \$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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;
- A description of how the financial interest relates to the Applicable Agreement and why the Institution determined that the financial interest conflicts with such research;
 - A description of the key elements of the FCOI Management Plan, including:
 - 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;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.
- Whenever an SFI is identified that was not disclosed timely, or for whatever reason was not previously reviewed, within 60 days, review the SFI and determine if it is an FCOI. If the SFI is an FCOI, implement an FCOI Management Plan, provide the applicable agency with an FCOI Client Report, and, within 120 days of the Ethics Office's determination of noncompliance, complete a retrospective review of the Investigator's activities on the Applicable Agreement to determine whether any research, or portion thereof, conducted during the time of noncompliance, was biased in the design, conduct, or reporting of such research.
 - Whenever an FCOI Management Plan is implemented, monitors Investigator compliance with the FCOI Management Plan on an ongoing basis until completion of the Applicable Agreement.
 - If the Investigator fails to comply with an FCOI Management Plan, if RTI fails to review or manage an FCOI, or the Investigator fails to disclose an SFI, within 120 days of the Ethics Office's determination of noncompliance, complete a retrospective review of the Investigator's activities and the Applicable Agreement to determine whether any research, or portion thereof, conducted during the time of noncompliance, was biased in the design, conduct, or reporting of such research. All retrospective reviews will be documented and will include at least the following key elements:
 - Project number;
 - Project title;
 - PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has an FCOI;
 - Reason(s) for the retrospective review;
 - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
 - Findings of the review; and
 - Conclusions of the review.
 - Following any retrospective review, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, promptly notify the applicable agency and submit a mitigation report.

- In any case in which the HHS, or other applicable federal agency, determines that an Applicable Agreement funding clinical research 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 an FCOI that was not managed or reported by RTI as required the applicable FCOI regulations, the Investigator involved will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.
- Prior to the expenditure of any funds on an Applicable Agreement, and for three years from the date the information was most recently updated, ensure public accessibility of information concerning any SFI disclosed to RTI by Senior/key Personnel by written response within five (5) business days of a request if it meets the following criteria:
 - The SFI was disclosed and is still held by the Senior/key Personnel for the Applicable Agreement;
 - The Ethics Office determines the SFI is related to the Applicable Agreement;
 - The Ethics Office determines that the SFI is an FCOI
- Where required to make information publicly accessible via written response, prepare the Financial Conflict of Interest Public Disclosure Form, including the following information:
 - Investigator's name;
 - Investigator's title and role with respect to the research project;
 - Name of the entity in which the relevant SFI is held;
 - Nature of the relevant SFI (e.g., equity, consulting fees, travel reimbursement, honoraria); and
 - Approximate dollar value of the relevant SFI (dollar ranges are permissible: \$5,000-\$9,999; \$10,000-\$19,999; etc.).
- Must maintain for 3 years from the date of the final expenditures report submitted to the Applicable Agency records of all SFI Disclosure Forms and FCOI Management Plans.

RTI Contracting Officers

When applicable, certifies in all proposals for Applicable Agreements that RTI (1) has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all Applicable Agreements; (2) shall promote and enforce Investigator compliance with FCOI requirements, including those pertaining to disclosure of an SFI; (3) shall manage FCOIs and, as necessary, provide initial and ongoing FCOI Client Reports to the applicable agency; (4) agrees to make information available, promptly upon request, to the applicable agency relating to any Investigator disclosure of financial interests and RTI's review of, and response to, such disclosure; and (5) shall fully comply with the FCOI requirements contained in the referenced regulations in the context of Applicable Agreements.

Proposal Managers

Coordinates with RTI proposal leaders to ensure that RTI staff members expected to work as Investigators on Applicable Agreements complete and submit the SFI Disclosure Form sufficiently in advance of the proposal due date and, as necessary, prior to project award.

Sourcing/Subcontracts Specialists

If the Applicable Agreement involves Investigators from subrecipients, RTI is responsible to ensure that such subrecipients comply with the FCOI requirements contained in the referenced regulations. This may be accomplished through one of the following methods:

- Review the list of organizations maintained by the Federal Demonstration Partnership that have a compliant process. This list is located at https://thefdp-archive.org/pages/fcoi_list.cfm .
- Obtain written confirmation that the subrecipient has an FCOI policy that complies with the FCOI requirements contained in the referenced regulations and will ensure it will be followed; or
- Require subrecipient to comply with RTI's FCOI policy including submission of the SFI Disclosure Form by the subrecipient Investigators.