

ETR Associates Financial Conflict of Interest (FCOI) Policy

What is the purpose of this policy?

This policy promotes objectivity in research. ETR has established standards, aligned with federal regulation, that provides a reasonable expectation that the design, conduct, and reporting of research performed under grants, contracts, or cooperative agreements will be free from bias resulting from financial conflicts of interest. This policy is commonly referred to as the **Financial Conflict of Interest (FCOI) Policy** and conforms to the following requirements:

- Complies with the standards (see below for source of standards);
- Informs staff/external parties of ETR's policy;
- Informs staff/external parties of reporting responsibilities; and
- Provides adequate guidelines for enforcement mechanisms and sanctions where appropriate.

What standards are being used for the policy?

The standards used for this policy are in the Federal regulations regarding Financial Conflict of Interest (FCOI), Title [42 CFR Part 50, subpart F](#): Promoting Objectivity in Research.

Who is covered by this policy?

This policy applies to all ETR staff that apply for, or receive, external funding through a grant, contract, or cooperative agreement and to contracted external parties that don't have their own FCOI policy. (Note: This regulation does not apply to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) program applications or awards.)

What is the essence of the policy?

Under this policy, ETR will take all reasonable steps to ensure that Investigators comply by providing funders with appropriate assurances. Specifically, Investigators must report identified FCOIs as specified in this policy statement. Depending on the funder terms, ETR may need to report the existence of any conflicting interests and assure that the interest has been managed, reduced, or eliminated as provided for in this policy statement.

Who is considered an "Investigator" for this purpose?

An "Investigator" is defined as the staff/external party and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by external sources or proposed for such funding, which may include, for example, collaborators or consultants. Except as prescribed by Grantor terms, ETR shall consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of staff/external party is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk that an unidentified FCOI may compromise the research enterprise increases.

The staff/external party spouse/domestic partner and dependent children are referenced in the definition of "Significant Financial Interest" (SFI) because staff must also disclose SFIs of their spouse/domestic partner and dependent children.

What financial interests are covered by the policy?

A "Significant Financial Interest" is defined as anything of monetary value, **including** but not limited to:

- payments for services (e.g., consulting fees);
- equity interests (e.g., stocks, stock options, mutual funds, retirement funds, or other ownership interests);
- intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

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The term does **not** include:

- salary, royalties, or other remuneration from ETR;
- any ownership interests in ETR, if ETR is an applicant under the SBIR and STTR programs;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- honorarium types of income from service on advisory committees or review panels for public or nonprofit entities;
- an equity interest that, when aggregated for staff and the staff's spouse/domestic partner and dependent children, does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity;
- salary, royalties, or other payments that, when aggregated for the staff and the staff's spouse/domestic partner and dependent children over the next twelve months, are not expected to exceed \$5,000.

Who at ETR will implement and maintain this policy?

Wendi Gephart, Grants and Contracts Manager, is responsible for implementing and maintaining this policy. She has been designated by the Leadership Team as the "Institutional Official" whose responsibility is to review financial disclosure statements from each staff/external party planning to participate in the research. The Grants and Contracts Manager will determine whether a financial conflict of interest exists; and, if so, determine what actions should be taken to manage, reduce, or eliminate such conflict of interest.

What information must be obtained from Staff/External Party and when should it be collected?

- a. **ETR Staff:** During the early stages of proposal development, ETR staff designated as Key Personnel planning to participate in the research must submit an [ETR FCOI Disclosure of Financial Interests](#) to the Grants and Contracts Manager. This form calls for the staff to affirm whether they have any financial interest(s): 1) that would reasonably appear to be impacted by the research for which funding is sought, 2) that would influence how research is performed, and 2) in entities whose financial interests would reasonably appear to be impacted by the research. If the answer is in the affirmative, the staff must arrange a meeting with the Grants and Contracts Manager to discuss the situation.
- b. **Subrecipients, contractors, or collaborators:** Every agreement sent to subgrantees, contractors, or collaborators who will participate in research projects shall require that they also complete, sign and return the [ETR FCOI Disclosure of Financial Interests](#), along with the signed contract. Subrecipient organizations may use their own FCOI policy after certifying that is aligned with ETR standards. The agreement also will require that, if the subgrantees, contractors, or collaborators respond that they have a potential financial interest, they must arrange a meeting with the Grants and Contracts Manager to discuss the situation.

What about interests incurred during the award period subsequent to the initial expenditure of funds?

All financial disclosures (both internal and external) must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

What about enforcement mechanisms and /or sanctions?

When a Significant Financial Interest is identified, ETR's enforcement mechanisms and sanctions include, but are not limited to:

- public disclosure of Significant Financial Interests;
- addendum request to previously published presentations;

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- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification from participation in all or a portion of the research;
- divestiture of Significant Financial Interests;
- severance of relationships that create actual or potential conflicts; or
- suspension or termination of employment.

Required ETR Training

NIH has developed an [online training](#) which reviews the requirements of, and the Institutional and Staff/External Party responsibilities for, compliance with the standards. ETR requires that all ETR staff/external parties, as defined above, complete this training and quiz. Training must be completed prior to initiating work on a federally-funded project and renewed every four years.

Upon completion of the training, the Grants and Contracts Manager shall save a completion certificate as a PDF and forward it to the Institutional and Staff/External Party. The Grants and Contracts Manager maintains all FCOI documentation.

Where can staff find additional information?

More information on the standards, and the application thereof, is available on the Conflict of Interest Page of the Grants Policy and Guidance section of the NIH Office of Extramural Research home page: (<http://grants.nih.gov/grants/policy/coi/index.htm>).

Outline of Required Action

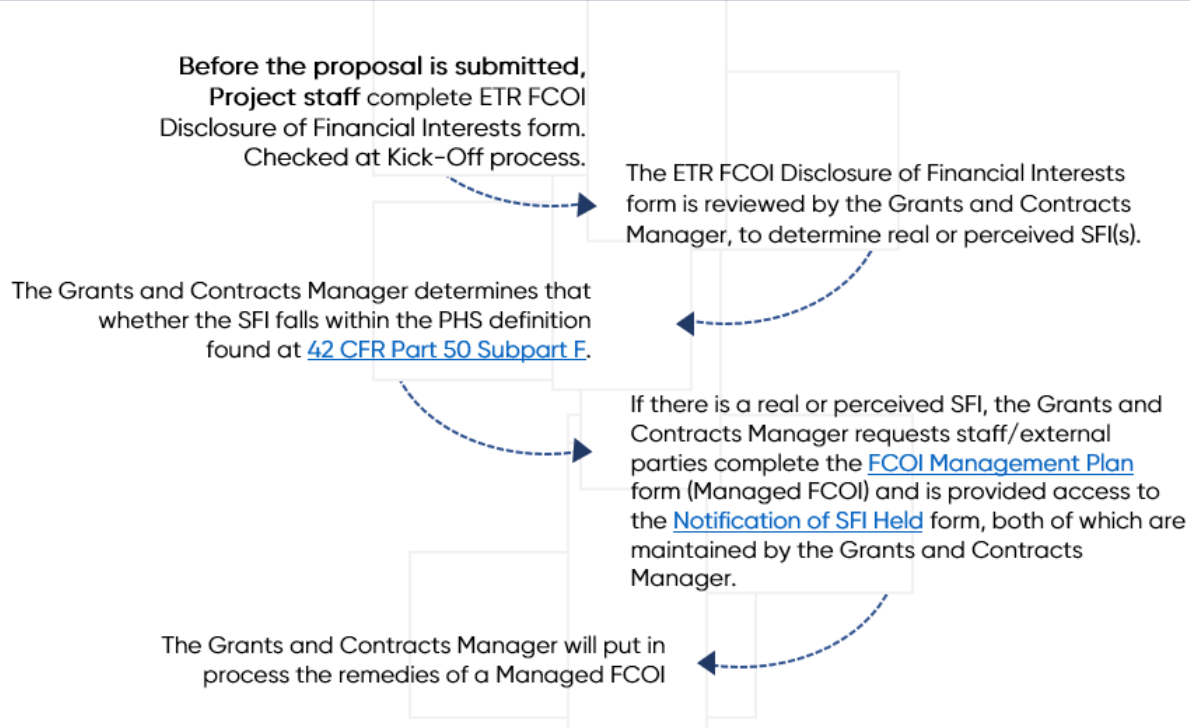
(modified from ETR Associates Research Misconduct Policy Outline of Required Action)

- Step 1:** Prior to submitting a proposal, ETR project staff will complete the [ETR FCOI Disclosure of Financial Interests](#) form, to be updated on no less than an annual basis. New staff/external parties to federally-funded projects will complete the [ETR FCOI Disclosure of Financial Interests](#) form within 60 days of working on federally-funded awards.
- Step 2:** The ETR FCOI Disclosure of Financial Interests form is reviewed by the Grants and Contracts Manager to determine real or perceived SFI(s).
- Step 3:** The Grants and Contracts Manager determines: 1) whether the Significant Financial Interest falls within the PHS definition found at [42 CFR Part 50 Subpart F](#).
- Step 4:** If there is a real or perceived SFI, the Grants and Contracts Manager requests staff/external parties complete the [FCOI Management Plan](#) form (Managed FCOI) and is provided access to the [Notification of SFI Held](#) form, both of which are maintained by the Grants and Contracts Manager.
- Step 5:** The Grants and Contracts Manager will initiate processing the remedies of a Managed FCOI, which may include, but are not limited to:
- Managed FCOIs made available upon request to the public, including the following information:
 - Date disclosed
 - Staff/External Party with FCOI
 - Title
 - Funder Award (number and title of agreement)
 - Role on research project
 - Name of entity in which SFI is held

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- Nature of the SFI
- Approximate dollar value of the SFI;
- Disclosure of Staff/External Party SFI in any abstracts, presentations, press releases, or publications and any proposals or applications for research related to the SFI; and/or
- Notification of others engaged in the research project of Staff/External Party SFI.

OVERVIEW of ETR PROCEDURE: ETR FCOI Disclosure of Financial Interests



In Case of Undisclosed FCOI Identification:

The following process will be followed when an undisclosed Significant Financial Interest of staff or parties is identified.

- Step 1:** The Grants and Contracts Manager routes the [ETR FCOI Disclosure of Financial Interests](#) form to the FCOI Inquiry Committee Chair (VP of Finance or designee).
- Step 2:** The FCOI Inquiry Committee Chair (VP of Finance or designee) recruits at least two additional members of the FCOI Inquiry Committee (at least one of which will be part of the Services Team). FCOI Inquiry Committee members will be individuals who do not have actual or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the Staff/External Party SFI.
- Step 3:** The FCOI Inquiry Committee Chair (VP of Finance or designee) will notify the Grants and Contracts Manager and Staff/External Party in writing that the review process has been initiated.

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- Step 4:** Within 14 days, the Grants and Contracts Manager will provide the Staff/External Party with a copy of the draft inquiry report for comment and rebuttal and will provide the Staff/External Party with portions of the draft report.
- Step 5:** Within seven calendar days of their receipt of the draft report, the Staff/External Party will provide their comments, if any, to the FCOI Inquiry Committee.
- Step 6:** The FCOI Inquiry Committee will transmit the final report and any comments to the Grants and Contracts Manager and Deciding Official (CEO or designee). The Deciding Official will determine whether findings from the inquiry provide sufficient evidence of possible SFI to justify notifying the funder and the public.
- Step 7:** The inquiry is completed when the Deciding Official makes this determination, which will be made within 14 days of the FCOI Inquiry Committee meeting.
- Step 8:** The Grants and Contracts Manager will notify the Staff/External Party Spouse/Domestic Partner in writing of the Deciding Official's decision and the determined remedy. Remedies of a "Managed FCOI" may include, but are not limited to:
- Publication of the "Managed FCOI" posted on a public website, including the following information:
 - Date disclosed
 - Staff/External Party with FCOI
 - Title
 - Funder Award (number and title of grant)
 - Role on research project
 - Name of entity in which SFI is held
 - Nature of the SFI
 - Approximate dollar value of the SFI;
 - Disclosure of Staff/External Party's SFI in any abstracts, presentations, press releases, or publications and any proposals or applications for research related to the SFI; and/or
 - Notification of others engaged in the research project of Staff/External Party's SFI.

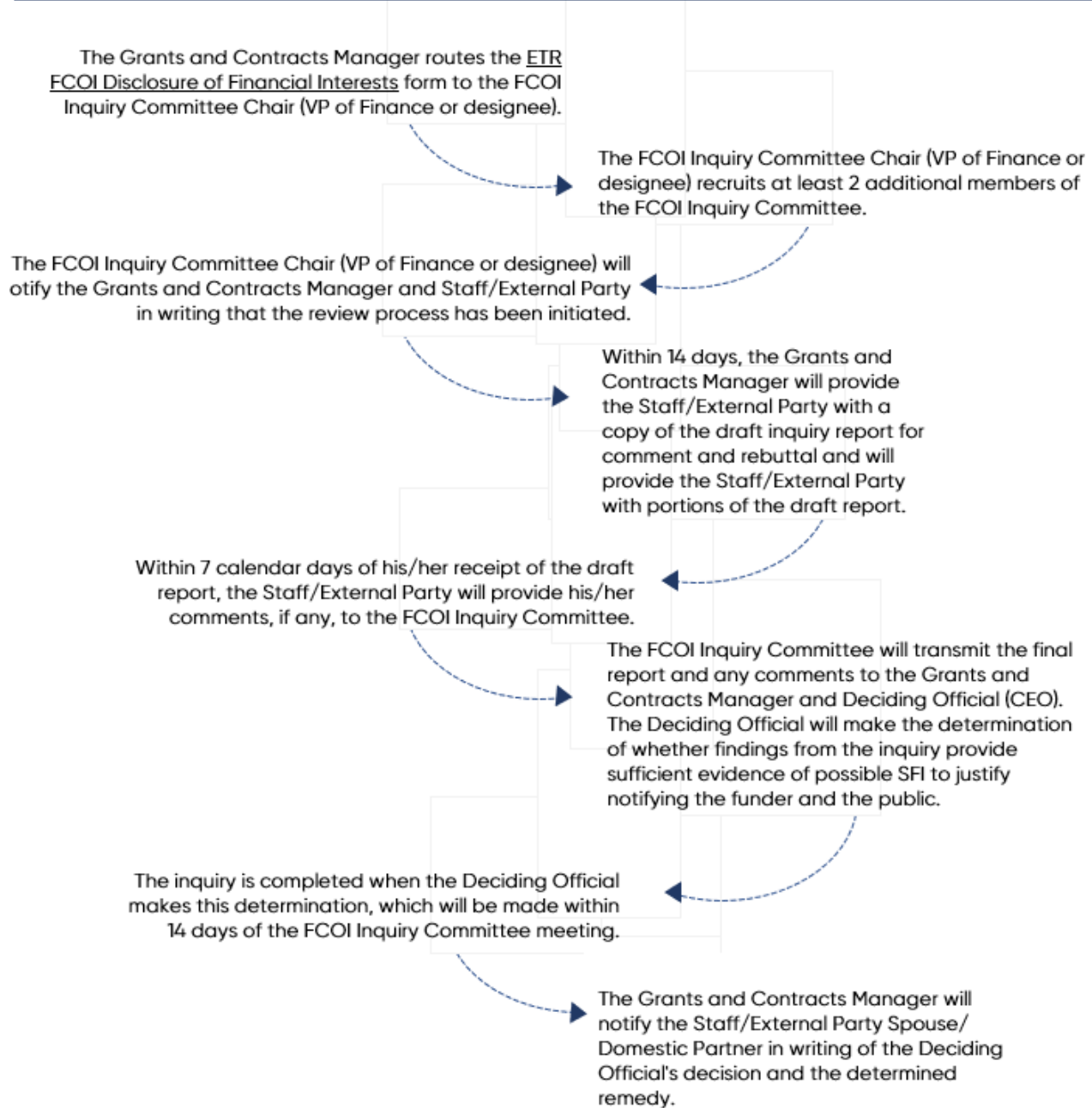
Process:

1. Staff complete the general Conflict of Interest upon hire
2. Staff working on federally-funded projects complete the [ETR FCOI Disclosure of Financial Interests](#)
 - a. In the case of actual or perceived FCOI, Staff with SFI Complete the [FCOI Management Plan](#)
 - b. If Staff with SFI disputes the Management Plan, Grants and Contracts Manager forwards documentation to FCOI Inquiry Committee Chair for resolution as described above
 - c. When appropriate, staff complete the [Notification of SFI Held](#)
3. Grants and Contracts Manager maintains all FCOI documentation.

See next Page

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ETR PROCEDURE: In Case of FCOI Dispute



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Glossary

Financial Conflict of Interest = FCOI

Significant Financial Interest = SFI

External Party = Subawardee, Contractor, Vendor – anyone/thing that is not a part of ETR

Key Personnel = Key personnel have substantial involvement and whose positions are essential to the successful implementation of an award.

FAQs

Question: Does this policy apply to all federally funded agreements?

Answer: Almost all – the Grants and Contracts Manager will contact the Project Lead to inform of the necessity of FCOI reporting.