

CHECKLIST FOR POLICY DEVELOPMENT RELATED TO THE 2011 FINANCIAL CONFLICT OF INTEREST (FCOI) REGULATION, PROMOTING OBJECTIVITY IN RESEARCH ([42 CFR Part 50 Subpart F](#))

The purpose of this document is to provide an overview of the requirements of the 2011 revised FCOI regulation to serve as a checklist resource when developing, revising or reviewing an Institution’s FCOI policy to assure compliance with all regulatory requirements.

Institutions are required to develop an FCOI Policy or revise an existing policy that addresses [Investigator](#) FCOIs. The policy must be maintained, enforced and meet the regulatory requirements¹, and apply to:

- all National Institutes of Health (NIH) grants and cooperative agreements, excluding the Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) applications and awards.
- each [Investigator](#), as defined by the regulation, who is planning to participate in or is participating in) NIH-funded research.

Institutions must be able to certify in each application for funding that the Institution:

- Has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI.
- Shall post their FCOI policy on their publicly accessible Web site and submit a copy to the NIH via the eRA Commons [Institution Profile Module](#).
- Shall promote and enforce Investigator compliance with the regulation.
- Shall manage FCOI and provide initial and ongoing FCOI reports to the NIH via [FCOI Module](#).
- Agrees to make FCOI and SFI information (including related institutional reviews and determinations) available to the NIH promptly, upon request.
- Shall fully comply with the regulation’s requirements

To promote compliance with the FCOI regulation, the FCOI policy and/or procedures must include all of the regulatory requirements outlined below. Institutions must establish a process to ensure compliance with these requirements:

Training Requirements	Regulatory Citation
<input type="checkbox"/> Inform each Investigator of the:	42 CFR 50.604(b)
<input type="checkbox"/> Institution’s policy	
<input type="checkbox"/> Investigator’s disclosure responsibilities of all foreign and domestic significant financial interests (SFI) per the SFI definition and NIH’s FAQs E.9. and E.20. or the institution’s disclosure requirements if more restrictive.	
<input type="checkbox"/> Federal regulation (See NIH’s FAQ L.1. , “FCOI Training” tutorial and other training resources on NIH’s FCOI Training website)	
<input type="checkbox"/> Require each NIH-supported Investigator to complete FCOI training:	42 CFR 50.604(b)
<input type="checkbox"/> Prior to engaging in research related to any NIH-funded grant	
<input type="checkbox"/> At least every four (4) years	
<input type="checkbox"/> Immediately, if:	
<input type="checkbox"/> Institution revises its FCOI policy that affects requirements of Investigators	
<input type="checkbox"/> An Investigator is new to an Institution	

¹ If an Institution’s FCOI policy includes standards that are more stringent than the regulation (e.g., that require a more extensive disclosure of financial interests), the Institution must adhere to its policy and must provide FCOI reports regarding identified FCOIs to NIH in accordance with the Institution’s own standards and within the timeframe prescribed by the regulation.

<input type="checkbox"/> An Investigator is not in compliance with the policy or management plan	
Institutions are encouraged to utilize resources available on NIH's FCOI Training Webpage at FCOI Training grants.nih.gov to satisfy the training requirements related to the Federal regulation.	

Disclosure, Review and Monitoring Requirements	Regulatory Citation
<input type="checkbox"/> Require each Investigator to disclose their foreign and domestic Significant Financial Interests (SFIs) (see FAQs D.8. and E.26) (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities ² (e.g., research, research consultation, teaching, professional practice, etc.) that meet the regulatory definition of SFI:	42 CFR 50.603 42 CFR 50.604(e)(1)-(3)
<input type="checkbox"/> No later than at the time of application for NIH-funded research (see FAQ D.35)	
<input type="checkbox"/> At least annually during the period of the award	
<input type="checkbox"/> Within thirty (30) days of discovering or acquiring a new SFI	
<input type="checkbox"/> Designate an Institutional official(s) to:	42 CFR 50.604(d)
<input type="checkbox"/> Solicit and review Investigator SFI disclosures (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities for a determination of FCOI.	
<input type="checkbox"/> Provide adequate guidelines consistent with the regulation for the designated institutional official(s) to determine whether an Investigator's SFI is related to PHS/NIH-funded research and, if so related, whether the SFI is an FCOI. NOTE: An SFI is related to PHS/NIH-funded research when the Institution through its designated official(s), reasonably determines that the SFI: <ul style="list-style-type: none"> • could be affected by the PHS/NIH-funded research; or • is in an entity whose financial interest could be affected by the research. <p>The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research.</p> <p>An FCOI exists when the Institution, through its designated official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.</p>	42 CFR 50.604(f)
<input type="checkbox"/> Include the examples of conditions or restrictions that might be imposed to manage conflicts of interest (e.g., full public disclosure, appointment of an independent monitor, modification of the research plan, etc.). See regulation and NIH's FAQ F.1. for more information on how to manage an FCOI). Adding additional conditions to manage an FCOI is at the institution's discretion.	42 CFR 50.605(a)(1)
<input type="checkbox"/> Require the designated official(s), prior to Institution's expenditure of funds, to:	42 CFR 50.605(a)(1)
<input type="checkbox"/> Review all Investigator SFI disclosures	
<input type="checkbox"/> Determine if any SFIs relate to the Investigator's NIH-funded research	
<input type="checkbox"/> Determine if an FCOI exists (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research)	
<input type="checkbox"/> Develop and implement a management plan to manage the FCOI(s)	

² An Investigator's institutional responsibilities are those professional responsibilities on behalf of the Institution, and as defined by the Institution in its FCOI policy,

<input type="checkbox"/> Require when an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, the institution's designated official(s) will review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's 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 the FCOI.	42 CFR 50.605(a)(2)
<input type="checkbox"/> Require whenever an Institution identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) will review within sixty (60) days disclosures of SFIs, determine whether the SFI is related to the Investigator's NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage the FCOI going forward.	42 CFR 50.605(a)(3)(i)-(iii)
<input type="checkbox"/> Take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.	42 CFR 50.604 (g) 42 CFR 50.605(a)(4)

Reporting Requirements to NIH

Regulatory Citation

<input type="checkbox"/> Send initial, annual (i.e., ongoing) and revised FCOI reports for the Institution's Investigators and those of its subrecipients, if applicable, including all required information defined in the regulation and in NIH's FAQ H.5 , to the NIH via the eRA Commons FCOI Module, as required by the regulation and as stated below:	42 CFR 50.604(h) 42 CFR 50.605(b)
<input type="checkbox"/> Prior to the expenditure of funds	
<input type="checkbox"/> Within sixty (60) days of identification for an Investigator who is newly participating in the project	
<input type="checkbox"/> Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators	
<input type="checkbox"/> At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.	
<input type="checkbox"/> After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.	42 CFR 50.605(a)(3)(iii)
<input type="checkbox"/> Based on the results of a retrospective review, notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and submit the required Mitigation Report. The Mitigation report includes the key elements of the Retrospective review plus information to explain what action(s) have been or will be taken to mitigate the effects of the bias (i.e., a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.	42 CFR 50.605(a)(3)(iii)
<input type="checkbox"/> To ensure compliance with retrospective review and bias mitigation reporting requirements, the policy and/or procedures should include all of the key elements documented in the retrospective review as well as the elements of a mitigation report that must be submitted to NIH.	
<input type="checkbox"/> Notify NIH promptly if an Investigator (or subrecipient Investigator) fails to comply with the Institution's FCOI policy or noncompliance with a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.	42 CFR 50.606(a)
<input type="checkbox"/> Notify NIH promptly and take corrective action for noncompliance with the	

Institution's policy or the management plan.	
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Maintenance of Records	Regulatory Citation
<input type="checkbox"/> Maintain all FCOI-related records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable,:	42 CFR 50.604(i)
<input type="checkbox"/> For at least three (3) years from the date the final expenditures report (Final Federal Financial Report) is submitted.	
<input type="checkbox"/> Or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.	

Enforcement Mechanisms and Remedies and Noncompliance	Regulatory Citation
<input type="checkbox"/> Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance (e.g., letters of reprimand, restriction on the use of funds, etc.).	42 CFR 50.604(j)
<input type="checkbox"/> Complete a retrospective review (see FAQs in Section I) within 120 days of the Institution'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:	42 CFR 50.605(a)(3)(ii)(A)
<input type="checkbox"/> Failure by the Investigator to disclose an SFI that is determined by the Institution to constitute a financial conflict of interest;	
<input type="checkbox"/> Failure by the Institution to review or manage such a financial conflict of interest;	
<input type="checkbox"/> Failure by the Investigator to comply with the financial conflict of interest management plan;	
<input type="checkbox"/> Document the retrospective review which shall include at a minimum the following key elements:	42 CFR 50.605(a)(3)(ii)(B)
<input type="checkbox"/> Project Number <input type="checkbox"/> Project Title <input type="checkbox"/> PD/PI or contact PD/PI if multiple PD/PI model is used; <input type="checkbox"/> Name of the Investigator with the FCOI; <input type="checkbox"/> Name of the entity with which the Investigator has an FCOI; <input type="checkbox"/> Reasons for the retrospective review; <input type="checkbox"/> Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed); <input type="checkbox"/> Findings of the review; and <input type="checkbox"/> Conclusions of the review	
<input type="checkbox"/> Ensure that in any case in which the Department of Health and Human Services determines that an NIH-funded research project of 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 the Institution as required by the regulation, the Institution shall require the Investigator involved to:	42 CFR 50.606(c)
<input type="checkbox"/> Disclose the FCOI in each public presentation of the results of the research, and	
<input type="checkbox"/> Request an addendum to previously published presentations.	

Subrecipient Requirements	Regulatory Citation
<input type="checkbox"/> Address FCOI subrecipient requirements (See FAQ K.1) including compliance with NIH subaward/consortium written agreement requirements provided in the NIH Grants Policy Statement Section 15.2.1.	42 CFR 50.604(c) (also see NIH Grants Policy Statement 15.2.1)
<input type="checkbox"/> Establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient.	42 CFR 50.604(c)(1)(i)-(iii)
<input type="checkbox"/> Obtain a certification from the subrecipient that its FCOI policy complies with the regulation.	
<input type="checkbox"/> Include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee Institution to report identified FCOIs to the NIH as required by the regulation.	
<input type="checkbox"/> Alternatively, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage and report identified FCOIs to the NIH.	

Public Accessibility Requirements	Regulatory Citation
<input type="checkbox"/> Make the Institution's FCOI policy publicly accessible:	42 CFR 50.604(a) (also see NIH GPS 4.1.10)
<input type="checkbox"/> Post the FCOI policy on the Institution's public Web site	
<input type="checkbox"/> Make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation ³ , not the NIH Grants Policy Statement), publicly accessible prior to the expenditure of funds. See FAQs in Section G.1 .	42 CFR 50.605(a)(5)(i)-(iv)
The publicly accessible information will:	
<input type="checkbox"/> Include the minimum elements as provided in the regulation	
<input type="checkbox"/> Be posted on a Public Website or made available within five (5) business days of a written request (Determine which option will apply).	
<input type="checkbox"/> Be updated, at least annually (Web site only but any response to a written request should include the updated information)	
<input type="checkbox"/> Be updated, within sixty (60) days of a newly identified FCOI (Web site only but any response to a written request should include the updated information)	
<input type="checkbox"/> Remain available for three (3) years from the date the information was most recently updated.	

A "SIGNIFICANT FINANCIAL INTEREST" (SFI) DISCLOSURE FORM Recommendations

Although not required, many institutions have chosen to develop a financial disclosure form for use in FCOI disclosure requirements. The financial disclosure form is used by "Investigators" to disclose their SFIs (i.e., domestic and foreign) to the Institution's designated official(s) typically to determine if the SFI is related to an

³ 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 NIH by the Institution under this regulation.

Investigator's NIH-funded research and if there is an FCOI, for example. The following includes our recommendation for the information such forms should include as well as some helpful implementation notes:

- Investigator's name
- Entity name in which the Investigator (and spouse and dependent children) has an SFI
- Disclosure requirement that is consistent with the institution's definition of SFI
- Disclosure of financial interests in the 12 months preceding the disclosure and value of each equity interest as of the date of disclosure
- Disclosure of intellectual property (IP) rights and interests (e.g., patents, copyrights), upon the receipt of income related to such rights and interests. Institutions should note that they may impose a \$5,000 threshold in the SFI definition for IP rights and interests as described in the [Final Rule](#) on page 53265). If the institution utilizes the narrative from the regulatory definition of SFI as stated in 42 CFR 50.603, the threshold for disclosure related to such interests is \$0.
- Disclosure of reimbursed or sponsored travel may include a threshold for disclosure as provided in NIH's FAQs [E.9.](#) and [E.24.](#) If the institution does not include a threshold for disclosure, the threshold is \$0. The policy must specify the details of such disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- Clarify that disclosure is required for all financial interests received from foreign institutions of higher education or the government of another country when such income meets the threshold for disclosure (e.g., income in excess of \$5,000) (see FAQs [E.9.](#), [E.21.](#), [E.24.](#), [E.36.](#) and [E.37.](#)) Note the 20 U.S.C. Code 1001(a) citation within the SFI definition, refers to institutions of higher education located in the United States or a federal, state, or local government agency within the United States.
- The value of the SFI.
- Indicate whether the SFI is from a publicly traded or non-publicly traded entity. Also note that disclosure requirements for equity interest differ for each.
- Describe the nature of the SFI (e.g., salary, royalties, consulting fees, honoraria, paid authorship, reimbursed or sponsored travel).
- Indicate whether the SFI is related to any NIH application or NIH-funded project and an explanation for the relatedness to assist with the institution's designated official(s) review. Some information to consider:
 - The institution's designated official(s) makes the determination whether the SFI is an FCOI (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research).
 - Per the preamble in the [Final Rule](#) (page 53261), "significantly" means "...the financial interest would have a 'material effect on the research'..."

USEFUL FCOI AND NIH RESOURCES

Subscribe to the NIH Guide to Grants and Contracts at [NIH Guide LISTSERV: Subscribe to Weekly TOC E-Mail with New NIH Guide Postings and Funding Opportunities](#)

[NIH Guide Notices Related to Financial Conflict of Interest | grants.nih.gov](#) are posted at this NIH website.

FCOI Regulation 42 CFR Part 50 Subpart F at [eCFR :: 42 CFR Part 50 Subpart F -- Promoting Objectivity in Research](#)

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FCOI Webpage at [Financial Conflict of Interest | grants.nih.gov](https://grants.nih.gov/financial-conflict-of-interest)

FCOI Training Webpage at [FCOI Training | grants.nih.gov](https://grants.nih.gov/foi-training)

FCOI FAQs at [Frequently Asked Questions \(FAQs\) | grants.nih.gov](https://grants.nih.gov/foi-faq)

Foreign Grant webpage at [Information For Foreign Grants | grants.nih.gov](https://grants.nih.gov/information-for-foreign-grants) and [Important Highlights of FCOI Regulatory Requirements for Foreign Institutions | grants.nih.gov](https://grants.nih.gov/important-highlights-of-foi-regulatory-requirements)

NIH's Welcome Wagon letter at [NIH "WELCOME WAGON" LETTER Information for New Recipient Organizations | grants.nih.gov](https://grants.nih.gov/foi-welcome-wagon) and FCOI information at <https://grants.nih.gov/grants/funding/welcomewagon.htm#foi>