Checklist for Policy Development
Related to the 2011 Revised 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 determine compliance with all regulatory requirements.

Institutions are required to develop an FCOI Policy or revise an existing policy that will be maintained and enforced, and that meets or exceeds the regulatory requirements. The policy must apply to each Investigator, as defined by the regulation, who is planning to participate in or is participating in Public Health Service (PHS) 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 promote and enforce Investigator compliance with the regulation.
- Shall manage FCOI and provide initial and ongoing FCOI reports.
- Agrees to make FCOI and SFI information (including related Institutional reviews and determinations) available to HHS, promptly, upon request.
- Shall fully comply with the regulation's requirements

The Institution's FCOI policy and/or procedures should address the following requirements:

Training Requirements	**Regulatory Citation**
☐ Establish a process to inform each Investigator of the:	42 CFR 50.604(b)
☐ Institution's policy	
☐ Investigator's disclosure responsibilities	
☐ Federal regulation	
☐ Establish a process to require each PHS-supported Investigator to complete FCOI training:	42 CFR 50.604(b)
☐ Prior to engaging in research related to any PHS-funded grant	
☐ At least every 4 years	
☐ Immediately, if:	
☐ Institution revises its FCOI policy that affects requirements of Investigators	
☐ An Investigator is new to an Institution	
☐ An Investigator is not in compliance with the policy or management plan	

Disclosure, Review and Monitoring Requirements	**Regulatory Citation**
☐ Establish a process to require each Investigator to disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definition of SFI:	42 CFR 50.603 42 CFR 50.604(e)(1)-(3)
☐ No later than at the time of application for PHS-funded research	
☐ At least annually during the period of the award	
☐ Within 30 days of discovering or acquiring a new SFI	
☐ Designate an Institutional official(s) to:	42 CFR 50.604(d)

☐ Solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities.	
☐ Provide adequate guidelines consistent with the regulation for the designated institutional official(s) to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI.	42 CFR 50.604(f)
☐ Establish a process to require the designated official(s), prior to Institution's expenditure of funds, to:	42 CFR 50.605(a)(1)
☐ Review all Investigator SFI disclosures	
☐ Determine if any SFIs relate to PHS-funded research	
☐ Determine if an FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research)	
☐ Develop and implement management plans, as needed to manage FCOIs	
☐ Establish a process to review disclosures of SFIs, make determination of FCOIs, and implement a management plan when required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI.	42 CFR 50.605(a)(2)
☐ Establish a process to review disclosures of SFIs, make determination of FCOIs, and implement a management plan within sixty days whenever an Institution identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution.	42 CFR 50.605(a)(3) and (i) – (iii)
☐ Establish a process to 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**
☐ Establish a process to send initial, annual (i.e., ongoing) and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for the Institution and its subrecipients, if applicable, as required by the regulation:	42 CFR 50.604(h) 42 CFR 50.605(b)
☐ Prior to the expenditure of funds	
☐ Within 60 days of identification for an Investigator who is newly participating in the project	
☐ Within 60 days for new, or newly identified, FCOIs for existing Investigators	
☐ 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) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.	
☐ Following a retrospective review to update a previously submitted report, if appropriate.	42 CFR 50.605(a)(3)(iii)
☐ Establish a policy and procedure to notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with the regulation.	42 CFR 50.605(a)(3)(iii)
☐ The policy and/or procedures includes all reporting elements as required by the regulation.	
☐ Establish a policy and procedure to notify NIH promptly if an Investigator fails	42 CFR 50.606(a)

to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.	
☐ The policy addresses the Institution's requirement to notify NIH promptly and take corrective action for noncompliance with the Institution's policy or the management plan.	

Maintenance of Records	**Regulatory Citation**
☐ Establish a policy and procedure to maintain all FCOI-related records that meets or exceeds the regulatory requirements:	42 CFR 50.604(i)
☐ For at least 3 years from the date the final expenditures report is submitted to the PHS (NIH).	
☐ From other dates specified in 45 CFR 75.361, where applicable.	

Enforcement Mechanisms and Remedies and Noncompliance	**Regulatory Citation**
☐ Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance.	42 CFR 50.604(j)
☐ Establish a policy requirement to complete and document retrospective reviews within 120 days of the Institution's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation.	42 CFR 50.605(a)(3)
☐ Establish a policy and procedure to ensure that in any case in which the Department of Health and Human Services determines that a PHS-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)
☐ Disclose the FCOI in each public presentation of the results of the research, and	
☐ To request an addendum to previously published presentations.	

Subrecipient Requirements	**Regulatory Citation**
☐ Establish a policy and procedure to address subrecipient requirements.	42 CFR 50.604(c) (also see NIH Grants Policy Statement 15.2.1)
☐ Where applicable, 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)
☐ If applicable, obtain a certification from the subrecipient that its FCOI policy complies with the regulation.	
☐ If applicable, 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.	

☐ Alternatively, if applicable, 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**
☐ Make the Institution's FCOI policy publicly accessible:	42 CFR 50.604(a) (also see NIH GPS 4.1.10)
☐ Post the FCOI policy on the Institution's public Web site	
☐ Establish a process to make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible prior to the expenditure of funds. The information will:	42 CFR 50.605(a)(5)(i)-(iv)
☐ Include the minimum elements as provided in the regulation	
☐ Be posted on a Public Website or made available within 5 calendar days of a written request	
☐ Be updated, at least annually (Web site only but any response to a written request should include the updated information)	
☐ Be updated, within 60 days of a newly identified FCOI (Web site only but any response to a written request should include the updated information)	
☐ Remain available for three years from the date the information was most recently updated.	

Revised 4/21/2020 (Maintenance of Records and Public Accessibility Requirements sections. Also added links to regulation and NIH GPS)