

Timing of FCOI Reporting

- Applicability – Applies to each grant or cooperative agreement with an issue date that is subsequent to the compliance date, no later than August 24th or immediately upon making the Financial Conflict of Interest policy publicly available. Institutions may choose to implement the regulation on a single date for all PHS funded awards
 - How many applications have been submitted with proposed start date >Aug 23rd
 - When do we need to start reviewing SFI's?
 - Only if fundable scores?
 - Is that enough time?

Investigator SFI Disclosure and Institutional FCOI Reporting Requirements

(From NIH webinar)

<p>Investigator Discloses known SFI(s) to the Institution</p>	<p>Institution Reports identified FCOI(s) to the NIH (Designated official(s) review the disclosures to make determinations of FCOIs and report any FCOIs to NIH.)</p>
<p>At time of Application</p>	<p>Prior to the Expenditure of Funds</p>
<p>Within 30 days of acquiring or discovering SFI</p>	<p>Within 60 days of identification</p>
<p>Annually at the time period prescribed by the Institution during the award period</p>	<p>Annually: At the same time as when the grantee submits the annual progress report or the extension of project. Annual FCOI report is submitted through eRA Commons FCOI Module.</p>

**REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH
THROUGH eRA COMMONS FCOI MODULE
(From NIH Webinar)**

Report	Content	Required when?
Initial FCOI Report	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	(1) Prior to expenditure of funds (2) Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI and Changes to Management Plan	Annual report due at same time as when submitting annual progress report or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward.	After completion of retrospective review, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	When bias is found as a result of a retrospective review.

Initial Reports

- At time of application, all SFI's related to institutional responsibility are to be disclosed
- Institution must review and determine if the SFI is a FCOI related to the funded research.
 - If so, **prior to the expenditure of any funds** :
 - Institution must report through the eRA Commons
 - Institution shall ensure public accessibility , via a publicly accessible Web site
 - or written response **within 5 business** days of a request, of information concerning
 - *Must report if the Investigator does not timely disclose a SFI or whenever the institution does not review a disclosed SFI and the Institution then determines that a FCOI exists*
 - *NIH FAQ's H.2*

Initial reports

- If an FCOI is eliminated prior to the expenditure of funds NO report is required
- Questions:
 - If disclosure was not made timely, but all review was completed prior to the expenditure of funds, does the report include the fact of the late disclosure?

Submission of reports during an on-going project

- When a new Investigator or an existing Investigator discloses a SFI, the Institution must review the SFI, determine its relatedness and if a FCOI exists implement a management plan within **60 days of disclosure**
- For any SFI that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded project, the Institution shall provide the PHS awarding component **within 60 days**, an FCOI report

FAQ's

- E.4 Financial Interests acquired or discovered subsequent to the submission of the initial report
- *The Institution's designated official(s) will have sixty (60) days to review the Significant Financial Interest disclosure, determine whether the Significant Financial Interest is related to NIH-funded research, determine whether a Financial Conflict of Interest exists, and if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage the Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institution must submit an FCOI report to the NIH within this same 60-day period*

FAQ's

- H.2.a

Submission of Initial FCOI reports during an Ongoing NIH-funded Research Project:

- *The Institution must submit an FCOI report **within sixty (60) days after its determination that an FCOI exists** for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to the Institution during the period of award.*

Submission of reports during an on-going project

- Whenever an Investigator does not disclose timely a previously existing SFI or if the institution fails to review a previously existing SFI during an ongoing project, the institution's designated official(s) shall review the SFI, determine its relatedness and determine if a FCOI exists. If an FCOI exists, the institution must implement, on at least an interim basis, a management plans and submit an FCOI report to the NIH within sixty (60) days.

Non-Compliance Reporting

- In addition to the FCOI report, the Institution must within **120 days** of the Institution's determination of non-compliance:
 - Complete a retrospective review of the Investigators research activities and the NIH funded project to determine whether any of the NIH funded research or portion thereof conducted during the time of non compliance was biased in the design, conduct or reporting of such research
 - If bias is found notify the NIH **promptly** and submit a mitigation report
 - Based on the results of the retrospective review, the Institution may need to update a previously submitted reports

Subrecipients

- Agreements must specify time periods for disclosure and review that allow for the timely reporting by the Prime to the NIH, as necessary
 - Communication will need to begin with the proposal process
 - Are subrecipient reports tied into the Prime's ability to expend funds?

Annual Reports

- For any FCOI previously reported by the Institution, the institution shall provide to the PHS awarding component an annual report
 - *Annual FCOI reports must be submitted through the Commons at the same time when the institution submits the annual progress report or at the time of the extension*
 - *Submission of extension notification or prior approval request NIH FAQ H.2*