

FCOI Management

How can an Institution manage conflicting financial interests? (Institution and Investigator)

How an Institution manages an Investigator's conflicting financial interest is left to the Institution's policies and procedures. Examples of conditions or restrictions that might be imposed to manage an Investigator's Financial Conflict of Interest include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc;
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications 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); or
- Severance of relationships that create financial conflicts

What must the FCOI report include? (Institution)

All FCOI reports must include sufficient information to enable the NIH to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the Institution's management plan. The regulation provides key elements that must be included in the FCOI report to NIH. These include but are not necessarily limited to the following:

- i. Project number;
- ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- iii. Name of the Investigator with the Financial Conflict of Interest;
- iv. Name of the entity with which the Investigator has a Financial Conflict of Interest;
- v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- vi. Value of the financial interest (dollar ranges are permissible: \$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;
- vii. A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research;

A description of the key elements of the Institution's management plan, including:
(A) Role and principal duties of the conflicted Investigator in the research project;

- (B) Conditions of the management plan
- (C) How the management plan is designed to safeguard objectivity in the research project;
- (D) Confirmation of the Investigator's agreement to the management plan;
- (E) How the management plan will be monitored to ensure Investigator compliance; and
- (F) Other information as needed.

See the "Management" section for the questions for guidance on the minimum requirements for the management plan.

NIH grant and cooperative agreement award recipients should continue to submit FCOI reports using the electronic Research Administration (eRA) Commons FCOI Module. Once the institution is required to be in full compliance with the regulatory requirements, the additional reporting requirements must be met. Therefore, if the eRA Commons FCOI Module is not updated by the time this occurs, the FCOI report should include an attachment that addresses the minimum elements of the FCOI report as stated above and provided in 42 CFR 50.605(b)(3)

Retrospective Review and Mitigation Report

What is a retrospective review and when is it required? (Institution)

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
- Failure by the Institution to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

What are the key elements for documenting the retrospective review? (Institution)

The Institution shall document the retrospective review which must include at least the following key elements:

- D. Project number;
- E. Project title;
- F. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- G. Name of the Investigator with the FCOI;
- H. Name of the entity with which the Investigator has a financial conflict of interest
- I. Reason(s) for the retrospective review;

- J. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- K. Findings of the review; and
- L. Conclusions of the review.

What should the Institution do if bias is found during the retrospective review? Is a mitigation report required? (Institution)

If bias is found, the Institution must notify NIH promptly and submit a mitigation report. If the FCOI was previously reported to the NIH, the mitigation report is submitted as a "Revised FCOI Report." (see FAQ H.2.). The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and 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 (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation.

Is a grantee required to notify NIH following the completion of a Retrospective Review when bias is not found? (Institution)

No. When bias is not found following the completion of a Retrospective Review, the grantee should not submit a "Revised" FCOI report to notify NIH that either the Retrospective Review has been completed or that bias is not found. See FAQ H.22. for more information about when it is appropriate to submit a "Revised" FCOI report following the completion of a Retrospective Review.