

EXHIBIT 3
FCOI REPORT TEMPLATE

This template outlines the information to be provided when submitting an FCOI report to PHS in accordance with the terms of the Policy. This template is only intended to serve as a guide to the reporting process. The actual reporting must be completed through the eRA Commons FCOI Module, or as otherwise directed by PHS.

INITIAL FCOI REPORT

As indicated in the Policy, an FCOI Report shall be submitted 1) prior to the expenditure of any funds under a PHS-funded Research project and 2) within sixty (60) days of any subsequently-identified Financial Conflict of Interest.

An initial FCOI Report must include, at a minimum, the following elements:

1. The project number;
2. PD/PI(or Contact PD/PI if a multiple PD/PI model is used);
3. Name of the Investigator with the Financial Conflict of Interest;
4. Name of the entity with which the Investigator has a Financial Conflict of Interest;
5. Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. 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 Financial Interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
7. A description of how the Financial Interest relates to the PHS–funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
8. 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.

ANNUAL FCOI REPORT

After an FCOI Report has been filed for a particular Financial Conflict of Interest, the Institution shall provide annual updates to PHS regarding that Financial Conflict of Interest. These annual updates must continue for the duration of the PHS-funded Research project.

An annual FCOI Report must include, at a minimum, the following elements:

1. Status of the Financial Conflict of Interest (if the Financial Conflict of Interest has been eliminated, explain how); and
2. Any changes to the management plan.

MITIGATION REPORT

When conducting a retrospective review, if the Institution determines that the Financial Conflict of Interest created bias, the Institution shall file a mitigation report to PHS.

A mitigation report must include, at a minimum, the following elements:

1. The project number;
2. Project title;
3. PD/PI(or Contact PD/PI if a multiple PD/PI model is used);
4. Name of Investigator with the Financial Conflict of Interest;
5. Name of the entity with which the Investigator has the Financial Conflict of Interest
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review;
8. Findings of the review;
9. Conclusions of the review;
10. A description of the impact of the bias on the Research project; and
11. The plan of action to eliminate or mitigate the effect of the bias.