

At. 3

Public reporting burden for this collection of information is estimated to average 2 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0417). Do not return the completed form to this address.

45 CFR 50.605(b)(1) and (b)(3) for grants and cooperative agreements

(b) Reporting of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

(3) Any FCOI report required under [paragraphs \(b\)\(1\)](#) or [\(b\)\(2\)](#) of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall 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 PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- (viii) 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.

SCREEN SHOTS OF eRA COMMONS FCOI MODULE INCLUDES THE INTITIAL OR ORIGINAL REPORT AND THE "SUBSEQUENT REPORTS" OR THE MITIGATION REPORT (42 CFR 50.605[a][3][iii] and [b][2]) for grants and cooperative agreements from awardees.

Financial Conflict of Interest - Initiate New Report ?

Required fields are marked with an *

Application Information

Grant Number

Type

Activity

IC *

Serial # *

Year *

1

R01

CA

123456

1

PD/PI or Contact PD/PI

Suffix

ex.A1

Name of Investigator with Conflict

Last Name *

Toth

First Name *

Teresa

Middle Name

Project Title

Subrecipient Report *

☐ No ☒ Yes

Subrecipient Institution Name

Project Period Start & End Dates

Budget Period Start & End Dates

Cancel

Validate

Save

Save And Submit

FCOI Information

Section 1.

Entity Name *

Please use the full name of the Entity as it appears on the Entity's publicly accessible website or type in the full name as it is known. Enter the name of the entity that the Investigator has a financial interest.

Nature of SFI(s)

Annual Value of the SFI Within These Dollar Ranges

Add New SFI

Add as many SFIs (Significant Financial Interest) as needed within one FCOI report for the same entity.

Nature of SFI(s)	Value
------------------	-------

Section 2.

For each Significant Financial Interest include a description of how the financial interests relates to the funded research identified above and the basis for the Institution's determination that the financial interest conflicts with such research.

Enter required information below or upload an attachment. *

2000 remaining.

Drop file or browse to attach 1 PDF file, not exceeding 6MB.

File Name	Date Created	Status
No documents provided		

Section 3.

Include a description of the key elements of the Institutions 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.

Enter required information below or upload an attachment. *

2000 remaining.

Drop file or browse to attach 1 PDF file, not exceeding 6MB.

File Name	Date Created	Status
No documents provided		

Section 4.

Does this FCOI report include a failure to comply with the regulation? * ☐ No ☐ Yes

Upload PDF Documents

The section below is used for submitting additional information if requested by the PHS Awarding Component or to upload additional attachments which are optional.

Description:

30 remaining.

Drop file or browse to attach 10 total PDF files, not exceeding 6MB.

File Name	Description	Date Created
No documents provided		

Cancel

View FCOI History

Save

Save And Submit

Section 4.

Does this FCOI report include a failure to comply with the regulation? * ☐ No ☒ Yes

Description of Noncompliance with the FCOI regulation:

An FCOI report represents noncompliance when an FCOI is not identified or managed in a timely manner, including: failure by the Investigator to disclose a Significant Financial Interest; failure by the Institution to review or manage a financial conflict of interest; or failure by the Investigator to comply with the management plan.

Describe the situation of noncompliance in the text box below.



2000 remaining.

Section 5.

Retrospective Review Completed? * ☐ No ☐ Yes

If there is noncompliance associated with this FCOI report, a retrospective review must be completed within 120 days of the Institution's determination of noncompliance. In addition, a mitigation report must be submitted if bias is found.

Section 5.

Retrospective Review Completed? * ☐ No ☒ Yes

If there is noncompliance associated with this FCOI report, a retrospective review must be completed within 120 days of the Institution's determination of noncompliance. In addition, a mitigation report must be submitted if bias is found.

Section 6.

Mitigation Report Required? * ☐ No ☒ Yes bias found

If bias is found, the regulation requires the institution to:

- notify the NIH Awarding Component promptly;
- update previously submitted FCOI report if applicable; and
- submit a mitigation report to the PHS Awarding Component that shall address the following:
 - Impact of the bias on the research project and
 - the Institution's plan of action or actions taken to eliminate or mitigate the effects of the bias.

If appropriate, a revised FCOI report is required to update a previously submitted FCOI report to the specific action that will be taken to manage the FCOI going forward. Thereafter, the Institution shall submit FCOI reports annually, in accordance with the regulation. Depending on the nature of the financial conflict of interest, an institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the Financial Conflict of Interest is identified or the Investigator's noncompliance is determined and the completion of the Institution's independent retrospective review, in accordance with 42 CFR 50.60(a)(3) and 42 CFR 50.605(b)(3).

Provide mitigation report per 42 CFR 50.605(a)(3)(iii)

2000 remaining.

Drop file or browse to attach 1 PDF file, not exceeding 6MB.

File Name	Date Created	Status
No documents provided		

45 CFR 94.5(b)(1) and (b)(3) for research contracts

(b) Reporting of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this part. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

(3) Any FCOI report required under [paragraphs \(b\)\(1\)](#) or [\(b\)\(2\)](#) of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

(i) Project/Contract 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 PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and

(viii) 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.