



# Financial Conflict of Interest

## Reporting Requirements and a Demonstration of the eRA Commons FCOI Module



August 14, 2012

Office of Extramural Research  
National Institutes of Health, HHS

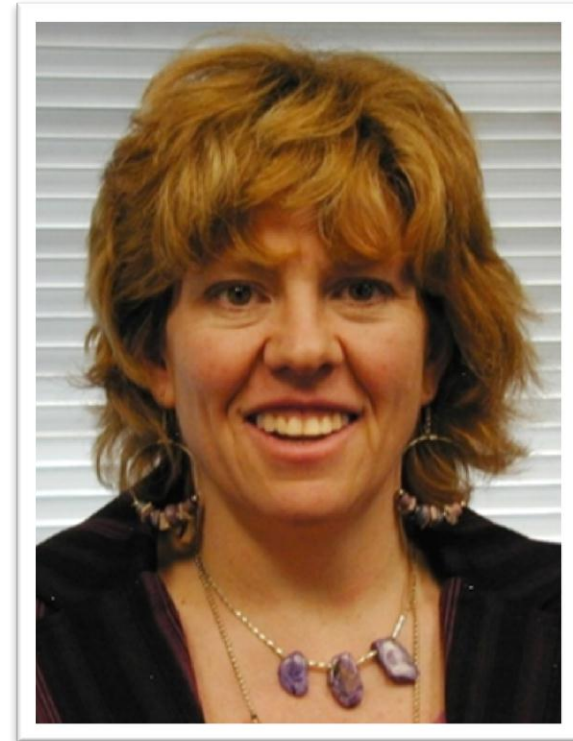
**Scarlett Gibb**, Customer Relationship Manager, eRA Commons  
**Kathy Hancock**, Assistant Grants Compliance Officer



# Presenters



**Kathy Hancock**  
NIH Assistant Grants  
Compliance Officer



**Scarlett Gibb**  
NIH Customer Relationship  
Manager, eRA Commons

# Summary of Topics

- **What to report?**
- **How to report?**
- **Changes to the eRA Commons FCOI Module**
- **Types of Reports & Other Actions to be taken related to FCOI**
- **Live Demonstration of the FCOI Module**

# Financial Conflict of Interest (FCOI) Regulations

- **42 CFR Part 50 Subpart F (grants and cooperative agreements)**
- **45 CFR Part 94 (contracts)**

## **Revised Final Rule published on 8-25-11**

- <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

## **Regulation for 42 CFR Part 50 Subpart F**

- <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=f67ea01984581d3934103b5074c05500&rgn=div5&view=text&node=42:1.0.1.4.22&idno=42#42:1.0.1.4.22.6>

# 2011 Revised FCOI Regulation

- **Implementation by August 24, 2012**
- **Applies to each Notice of Award (NoA) that is issued on or after 8/24/2012**
  - **Not retroactive**
  - **Important in considering compliance with the regulation**
- **Example:**

**On going awards or FY 2012 awards issued PRIOR to 8/24/2012 are subject to 1995 regulation.**

**Awards issued ON or AFTER 8/24/2012 are subject to the 2011 revised regulation, regardless of the budget period start date. This excludes any awards extended without funds that were previously subject to 1995 regulation.**

# What do Institution's Report to NIH?

## **Institutions report Identified FCOIs for its**

- **Investigators and**
- **Subrecipient Investigators, if applicable**

# What is an FCOI?

**A Significant Financial Interest (SFI) that an Investigator or subrecipient Investigator has (including their spouse and dependent children) that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.**

# How are FCOI Reports submitted to NIH?

**Electronic Research Administration (eRA) Commons FCOI Module – FCOI Reporting Tool**

**FCOI Module accessed via [eRA Commons](#)**



# What are the features of the FCOI Module?

**The FCOI Module allows Institutions to:**

- **Electronically submit FCOI reports and supporting documentation**
- **Submit a New (initiate 2011 FCOI report), Annual, and Revised FCOI reports and a Mitigation report**
- **Search and view FCOI reports and associated data previously submitted through Commons**
- **Receive an email confirmation that NIH received the report.**
- **Submit additional information when requested by NIH.**
- **Receive email reminders when an annual FCOI report is due.**

# How to get access to the FCOI Module?

- **Institutional Signing Officials assign FCOI roles to users in eRA Commons.**
  - **FCOI Role**
  - **FCOI ASST**
  - **FCOI View only role**
- **More information on the FCOI Module can be found at**  
**[http://era.nih.gov/services\\_for\\_applicants/other/fcoi.cfm](http://era.nih.gov/services_for_applicants/other/fcoi.cfm)**

# What additional information is required in a 2011 FCOI Report?

**FCOI Module is designed to collect the following additional information per the regulation:**

- **The name of the entity with which the Investigator has an FCOI;**
  - **Entity name is entered in a text box.**
- **Nature of the Significant Financial Interest (SFI);**
  - **The SFI information will be selected from a drop down menu.**

# What additional information is required under a 2011 FCOI Report?

- **Value of the SFI;**
  - **The Value of SFI will be selected from a drop down menu.**
- **Description via text box or uploaded PDF of how the financial interest relates to NIH-funded research and why the Institution determined that the financial interest conflicts with such research; and**

# What additional information is required under a 2011 FCOI Report?

- **Description of the key elements of the Institution's management plan, including other required information.**
  - **Information submitted via text box or uploaded PDF file**

# What are the Key Elements of a Management Plan?

- **Key Elements of a Management Plan include:**
  - **Role and principal duties of the conflicted Investigator in the research project;**
  - **Conditions of the management plan;**
  - **How the management plan is designed to safeguard objectivity in the research project;**
  - **Confirmation of the Investigator's agreement to the management plan;**
  - **How the management plan will be monitored to ensure Investigator compliance; and**
  - **Other information as needed.**

# What additional information is required under a 2011 FCOI Report?

- **Verification that the Institution is submitting an FCOI report that is in compliance with the 2011 revised regulation.**
  - **Does this FCOI report include a failure to comply with the FCOI regulation?**

# How is “noncompliance with regulation” defined?

**An FCOI is not identified or managed in a timely manner, for any of the following reasons:**

- **failure by the Investigator to disclose an SFI,**
- **failure by the Institution to review or manage an FCOI, or**
- **failure to comply with the management plan**



# What happens when the Institution submits an FCOI report that includes noncompliance?

**In situations of noncompliance, the FCOI Module will allow the Institution to:**

- **Address whether the Retrospective Review was completed;**
- **Submit a Mitigation Report when bias is found following the completion of the Retrospective Review; and**
- **Submit a Revised FCOI Report, if needed, to update the previously submitted FCOI information or specify the actions that will be taken to manage the FCOI going forward.**

# REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE

<b>Report</b>	<b>Content</b>	<b>Required when?</b>
New FCOI Report (Initial submission)	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 (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year 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 or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for	When bias is found as a result of a retrospective review.

# How to Get Started?

## **Initiate 2011 FCOI Report**

# How to Submit an FCOI Report for the first time?

## **Choose - Initiate 2011 FCOI Report**

- **Used for reporting FCOIs for the first time under a competing or noncompeting award**
- **Provides the details of the FCOI report as required under 2011 revised regulation**
- **FCOI reports submitted thereafter are “Annual” reports for any future year within the same competitive segment.**

# When to Submit an FCOI Report? (Reporting Requirements)

## Provide initial and ongoing FCOI reports to NIH:

- **Prior to the expenditure of funds under a NIH-funded research project**
- **During the period of award**
  - **Within 60 days of identifying a new FCOI**
- **Annually**

# When NOT to submit an FCOI report?

**FCOI report is not required if the conflicting interest is eliminated prior to the expenditure of NIH awarded funds.**



# **ANNUAL FCOI REPORT**

# When to Submit an Annual FCOI Report? (Reporting Requirements)

## **The Annual FCOI Report is due**

- **At the same time as when the Institution is required to submit the annual progress report, including multi-year progress report, or at time of extension.**



# When are Annual Reports submitted?

- **Annual Reports are submitted following the submission of a fully detailed FCOI Report (Initiate 2011 FCOI Report)**
- **FCOIs previously reported under the 1995 regulation that no longer exist by the FCOI report due date do not require an annual report.**
- **NIH staff may request information on previously submitted FCOIs through the eRA Commons.**

# What information is required in an Annual FCOI Report?

**After submitting an Initial 2011 FCOI Report, an Annual Report will address the status of the FCOI during the current competitive segment.**

## **FCOI Module Question:**

**“Does the FCOI still exist?”**

- If “No”, provide an explanation in a text box or upload a PDF attachment.**
- If “No”, FCOI report is removed from future reporting requirements.**

# What information is required in an Annual FCOI Report?

**After submitting an Initial 2011 FCOI Report, an Annual Report will address the status of the FCOI during the current competitive segment.**

## **FCOI Module Question:**

**“Does the FCOI still exist?”**

- If “Yes” – “Are there any changes to the management plan?”**
  - If yes, provide information in a text box or upload a PDF attachment.**

# Mitigation Report

# What is a Mitigation Report?

- **Only required when bias is found in the design, conduct or reporting of NIH-funded research following a Retrospective Review.**
- **Describes the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.**

# What to include in a Mitigation Report?

**Mitigation Report must include the following information:**

- **Key elements documented in the Retrospective Review.**
- **Description of the impact of the bias on the research project**
- **Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias**

# How to Submit a Mitigation Report?

**FCOI Module allows the Mitigation Report to be submitted as follows:**

- **Via a text box or PDF upload**
- **With Initial FCOI Report if the Retrospective Review is complete or**
- **Through a “Revised” FCOI Report upon completion of the Retrospective Review**

# Revised FCOI Report



# When is a Revised FCOI Report required?

**A Revised Report is used to:**

- **To submit a Mitigation Report when bias is found**

# When is a Revised FCOI Report required?

## A Revised Report is used:

- **When the Institution discovers new information following the Retrospective Review that changes a previously submitted FCOI report. For example:**
  - **An increase in value of a previously reported SFI**
  - **To report a change to the management of the FCOI from what was previously reported under the previously submitted FCOI report.**

# Summary of FCOI Noncompliance and FCOI Reporting

## FCOI REPORT (within 60 days)

- Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.

## RETROSPECTIVE REVIEW (to determine bias)

- If an FCOI exists, complete and document a retrospective review within 120 days of the Institution's determination of noncompliance. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.

## UPDATE/REVISE FCOI REPORT (following retrospective review)

- If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report.

## MITIGATION REPORT (promptly after retrospective review)

- If bias is found, notify NIH promptly
- Submit mitigation report through FCOI Module

## ANNUAL FCOI REPORT

- Submit annual FCOI report thereafter through FCOI Module

# **“Rescind” a Previously Submitted FCOI Report**

# Rescinded FCOI Reports

**FCOI Reports submitted in error may be “rescinded”. Examples include:**

- **Submission of a duplicate report**
  - **Incorrect name of the Investigator with FCOI**
  - **Incorrect name of the entity**
- **NIH will use the “rescind” feature when an incomplete report is submitted**

# What to do when the Institution needs to Rescind an FCOI Report?

## FCOI report submitted in error?

- **Contact the Grants Management Specialist (GMS) noted on the most recent Notice of Award (NoA)**
- **Request the IC to rescind the report, and**
- **Provide an explanation why the report should be rescinded.**

# Information/Resources

- **NIH Office of Extramural Research FCOI Web Site**
  - <http://grants.nih.gov/grants/policy/coi/>

## Some Resources include:

- **A tutorial, webinar, PowerPoint presentations**
- **FAQs are periodically updated and will be updated soon.**
  - <http://grants.nih.gov/grants/policy/coifaq.htm>



**LIVE DEMONSTRATION**  
**eRA COMMONS**  
**FCOI MODULE**



# Receipt of FCOI Report by the NIH (New)

From: era-notify-test@mail.nih.gov  
To: eRA Test (NIH/OD); eRA Test (NIH/OD)  
Cc:  
Subject: Receipt of a New FCOI report 3261 for grant number: 5R03DA031663-02

Sent: Thu 8/9/2012 1:4

A New Financial Conflict of Interest (FCOI) ID # 3261 report has been successfully received through the eRA Commons for the above referenced grant. The information provided will be evaluated by professional and scientific staff to determine whether an Institutions actions are sufficient to manage the identified FCOI. The awarding component will follow-up when additional information is needed to complete the review and/or address specific questions, if necessary. If additional information is required, the status of the FCOI record will change to a Work in Progress (WIP), which will allow the Institution to submit the additional information.

Please remember that for any FCOI previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

Additional information on the FCOI reporting Requirements can be found in Section "H. Reporting Requirements" of the Frequently Asked Question document posted on the Office of Extramural Research - Financial Conflict of Interest webpage found at [here](#).

\* Note - FCOI ID will be FCOI Family ID for 2011 reg. FCOIs

For any further questions about this email, please contact the eRA Help Desk at our preferred method of contact <http://ithelpdesk.nih.gov/eRA/> or call 1-866-504-9552 (tty: 301-451-5939) or [commons@od.nih.gov](mailto:commons@od.nih.gov).

Please access the NIH Commons at <https://commons.test.era.nih.gov/commons/>

# Receipt of FCOI Report by the NIH (Revised)

From: era-notify-test@mail.nih.gov  
To: eRA Test (NIH/OD); eRA Test (NIH/OD)  
Cc:  
Subject: Receipt of a Revised FCOI report 3261 for grant number: 5R03DA031663-02

Sent: Thu 8/9/2012 1:5

A Revised Financial Conflict of Interest (FCOI) ID # 3261 report has been successfully received through the eRA Commons for the above referenced grant. The information provided will be evaluated by professional and scientific staff to determine whether an Institutions actions are sufficient to manage the identified FCOI. The awarding component will follow-up when additional information is needed to complete the review and/or address specific questions, if necessary. If additional information is required, the status of the FCOI record will change to a Work in Progress (WIP), which will allow the Institution to submit the additional information.

Please remember that for any FCOI previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

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Please access the NIH Commons at <https://commons.test.era.nih.gov/commons/>

# Receipt of FCOI Report by the NIH (Annual)

From: era-notify-test@mail.nih.gov  
To: Oliver, Lakeysha (NIH/OD) [C]; McKinney, Mark (NIH/OD) [C]  
Cc:  
Subject: Receipt of an Annual FCOI report 3258 for grant number: 5R01DC009823-03

Sent: Thu 8/9/2012 1:28

An Annual Financial Conflict of Interest (FCOI) ID # 3258 report has been successfully received through the eRA Commons for the above referenced grant. The information provided will be evaluated by professional and scientific staff to determine whether an Institutions actions are sufficient to manage the identified FCOI. The awarding component will follow-up when additional information is needed to complete the review and/or address specific questions, if necessary. If additional information is required, the status of the FCOI record will change to a Work in Progress (WIP), which will allow the Institution to submit the additional information.

Please remember that for any FCOI previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

Additional information on the FCOI reporting Requirements can be found in Section "H. Reporting Requirements" of the Frequently Asked Question document posted on the Office of Extramural Research - Financial Conflict of Interest webpage found at [here](#).

\* Note - FCOI ID will be FCOI Family ID for 2011 reg. FCOIs

For any further questions about this email, please contact the eRA Help Desk at our preferred method of contact <http://ithelpdesk.nih.gov/eRA/> or call 1-866-504-9552 (tty: 301-451-5939) or [commons@od.nih.gov](mailto:commons@od.nih.gov).

Please access the NIH Commons at <https://commons.test.era.nih.gov/commons/>

# Receipt of Report by the NIH (Mitigation)

From: era-notify-test@mail.nih.gov  
To: eRA Test (NIH/OD); eRA Test (NIH/OD)  
Cc:  
Subject: Receipt of a Mitigation Report in FCOIID 3261 for grant number: 5R03DA031663-02

Sent: Thu 8/9/2012 1:4

A mitigation report has been successfully submitted for the above referenced grant. The information provided will be evaluated by professional and scientific staff to determine whether the mitigation report is complete and that appropriate action has been or will be taken to eliminate or appropriately mitigate the effect of the bias.

Please remember the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists.

Additional information on the FCOI reporting Requirements can be found in Sections "H. Reporting Requirements" and "I. Retrospective Review and Mitigation Report" of the Frequently Asked Question document posted on the Office of Extramural Research - Financial Conflict of Interest webpage found at [here](#).

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Please access the NIH Commons at <https://commons.test.era.nih.gov/commons/>

# Q&A Panel



**Kathy Hancock**  
NIH Assistant  
Grants Compliance  
Officer



**Scarlett Gibb**  
NIH Customer  
Relationship Manager,  
eRA Commons

# Questions?

For questions regarding the FCOI regulation, please contact:

**Kathy Hancock**

**Assistant Grants Compliance Officer**

**Division of Grants Compliance and Oversight, OPERA, OER**

**301-435-1962**

**[kathy.hancock@nih.gov](mailto:kathy.hancock@nih.gov)**

**General FCOI Inquiries: [FCOICompliance@mail.nih.gov](mailto:FCOICompliance@mail.nih.gov)**

For questions regarding FCOI Module contact:

**eRA Commons Help Desk**

**Web: [grants.nih.gov/support](http://grants.nih.gov/support) (Preferred method of contact)**

**Toll-free: 1-866-504-9552**

**Phone: 301-402-7469**

**Hours: Mon.-Fri., 7a.m. to 8 p.m. Eastern Standard Time**