# Job Aid - PHS & Other Federal Implementing Agencies FCOI Training Verification Review

## Purpose

To define how to verify the completion of required Financial Conflict of Interest (FCOI) training for Investigators on ASU awards that are subject to or have adopted the Public Health Service (PHS) regulations and/or other non-PHS federal implementing agencies that have adopted similar FCOI requirements.  PHS falls under the Department of Health & Human Services (DHHS).  Other federal agencies, i.e. currently the U.S. Department of Energy, have implemented similar FCOI training requirements.  All Investigators designated as being responsible for the design, conduct, or reporting of research must complete COI training (online) prior to spending PHS (and other implementing federal agency) funds on an ASU award.

Verification of completed COI training for Investigators on ASU awards that are subject to or have adopted the PHS FCOI regulations and/or other federal implementing agencies that have adopted similar Financial Conflict of Interest (FCOI) requirements may be completed by Award Management Team (AMT)  or Office of Research Integrity and Assurance (ORIA) personnel with this job aid as the guide for that activity.

This job aid also defines the Contract Negotiation Team process to verify subawards issued by ASU on awards subject to the PHS and other federal implementing agencies FCOI regulations. Subaward FCOI Verification is required regardless of whether the sub-awardee is impacted by the current award activation or not.

## Resources

- ORIA COI Website – https://researchintegrity.asu.edu/coi
- PHS FCOI & Other Implementing Agencies ORIA Dashboard - https://researchintegrity.asu.edu/trained
- ERA COI Module – https://era.oked.asu.edu (select COI)
- PHS FCOI FDP Institutional Clearinghouse - https://thefdp.org/default/fcoi-clearinghouse/
- PHS FCOI Certification Letters – PNT SharePoint Site > Reference Documents > SUBAWARDS > PHS FCOI Certification Letters
- DOE Interim Financial Conflicts of Interest Policy: https://www.energy.gov/sites/default/files/2021-12/Interim%20COI%20Policy%20FAL2022-02%20to%20SPEs.pdf

## Verifying FCOI Compliance for ASU Investigators

ERA has been designed to identify which sponsors are subject to PHS and other implementing agencies FCOI regulations. If the award is funded by one of these sponsors, Smart Form (SF) 7.0 Special Review will require an "Update" to the FCOI training status for each project personnel subject to a COI review.

**EXAMPLE:** For a sponsor subject to PHS and other implementing agencies FCOI regulations, "Update" will display.

# Job Aid - PHS & Other Federal Implementing Agencies FCOI Training Verification Review



For a sponsor not subject to PHS and other implementing agencies FCOI regulations, "Update" will not display.

In the event a notice of award states PHS and other implementing agencies FCOI regulations apply, but the "Update" option does not display for the sponsor as expected, notify ORIA via "Additional Information Requested – Notification" activity (selecting ORIA as recipient) from the award workspace, requesting the sponsor be added to the list with a copy of the award.

If "Update" is available, verification that **each** Investigator, listed under the COI Certification List, has completed the FCOI training is required.

## STEP 1: Accessing the FCOI ORIA Training Dashboard

There are 3 ways to access the FCOI ORIA Training Dashboard:

### Option 1:

Access the dashboard directly from SF 7.0 by selecting link, "To check the PHS COI, click here."

### Option 2:

Navigate directly to https://researchintegrity.asu.edu/trained

### Option3:

Access the Research Integrity Website at https://researchintegrity.asu.edu/, select the Conflicts of Interest menu item and click "COI training data." **Please note:** If an "Access Denied" message appears, make sure you are signed in under your ASUrite ID and password.

## STEP 2: Searching the Training Dashboard

Once you have successfully accessed the FCOI ORIA Training Dashboard, the training records will be displayed.

### STEP 2.a: Access Search Bar

To search the records, press "CTRL+F" to access the browser search bar. The search bar will display either in the upper left portion of the window or on the bottom, depending on the browser being used. **PLEASE NOTE:** The search function does not work on first and last name together.

### STEP 2.b: Verify COI training status for each Investigator

Verify training status for **all** Investigators listed under the COI Certification List at: https://researchintegrity.asu.edu/trained.  Note:  Investigators may have multiple training time stamps.

# Job Aid - PHS & Other Federal Implementing Agencies FCOI Training Verification Review

**The regulations require that training must have been completed in the last four years.**

-If the verification result returns a COI training record with a timestamp that is current (within the last four years), the investigator has completed the training.

-If the time stamp is more than four years old, the training is expired, and the investigator is required to complete training before funds can be spent on the award.

- If the verification indicates "No Matches Found," the Investigator hasn't completed the training.

In cases of expired training or "No Matches Found," mark COI training in the ERA award record per STEP 3 below as "No" and reach out to the Investigator to complete training. Email the Investigator, indicating that training is required before the award can be activated. Provide a due date to complete training (usually 2-3 days from the date of the email prompt.)

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Email example:

Email Subject Line: Conflict of Interest Training Required: DUE XXX

Dear Dr. XXX,

The (Sponsor Name) requires investigators funded by them to complete Conflict of Interest (COI) training at least every four years. You are currently listed as (role of investigator) on an incoming award from Sponsor Name) (ASU Award #AWDXXX). The award is titled "XXX," and COI training is required. The training can be accessed using the link below and will take 15 – 20 minutes to finish.

Please complete the training by XXX. Funds cannot be spent on the award until training is completed.

https://researchintegrity.asu.edu/coi/go-training

Please let me know if you have any questions.

Thanks,

XXX

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If the Investigator has not completed training by the due date, send a follow-up email to remind them that training is required, and the award activation will continue to hold pending completion of required training.

Once you have verified the status of each Investigator, return to ERA and update per STEP 3.

## STEP 3: Update the ERA award record

Update each Investigator record on the COI Certification List as appropriate.
Select the "Update" button, which will bring up a pop-up window for the COI

training status, then select "Yes" or "No."

**STEP 4: Review COI items that may impact successful activation of the award**

- If a required item record is not properly updated, an error message will populate, preventing completion of the "Activate" activity.

- The following COI statuses indicate the COI certification process is completed and no further action is required:
  - No Review Required
  - Review Complete
  - Withdrawn
  - Under Management/Mitigation Plan
  - Management/Mitigation Plan Satisfied

- COI statuses other than that above indicate the COI certification process is still outstanding, and ORIA action will be required. Review COI Section 7.0 of the award for comments from ORIA, indicating COI issues. If no comments are there and/or an update is needed, contact ORIA for information.

**STEP 5: Understanding the impact COI issues have on the "Activate" activity in ERA**

- If an investigator has not completed the required COI training, or if there is a COI certification outstanding, ERA will prevent the award from being activated. When the "Activate" activity is run, the award will be placed in an "Activation Hold" state. Awards in an "Activation Hold" state for COI will automatically show in a report for ORIA that is reviewed daily. It is no longer necessary to notify ORIA directly of these held awards. ORIA will review reported awards, process the COI certifications, verify training completion (if needed), and run the "Update Compliance Information" activity, which should remove the award activation hold unless there are other 7.0 special review items pending.

- For awards that have met all COI requirements, but have other special review items pending, ORIA also receives reports and acts daily on these items. Notifying ORIA of the non-COI pending special review items is not necessary except in cases of URGENT/RUSH activations. If the status of a special review item(s) is unclear by reviewing 7.0, please contact ORIA.

- Once all 7.0 special review item holds have been resolved, the "Activate" activity will activate the Award and associated accounts.

**AMT PROCESS**: In certain instances, ORIA will notify AMT that an Investigator must be removed from the proposal/award. AMT is not authorized to remove an Investigator from a project without approval via an ERA Award Change Request from the unit. Therefore, the activation can continue to be processed (if cleared), however, the unit should be notified to initiate the process in removing the Investigator. The below template can be used for this notification.

# Job Aid - PHS & Other Federal Implementing Agencies FCOI Training Verification Review

*Dear <RA NAME>,*

*During award setup, our office received notification from Dr. <Investigator's Full Name>, stating <HE/SHE> is no longer affiliated with the project under Award <ERA AWARD NUMBER>. I have attached documentation confirming this correspondence.*

*To remove Dr. <INVESTIGATOR'S LAST NAME> as an investigator on the project, please submit an Award Change Request in ERA. Please note that Dr. <INVESTIGATOR'S LAST NAME> will receive an Annual COI Disclosure notice until <HE/SHE> is either removed from the project or terminated as an active ASU employee. If approved, and investigator allocations will be impacted, please also submit an Award Change Request (IAC Modification Type).*

*Thank you for your attention to this request, and please feel free to contact me if you have any questions.*

# Job Aid - PHS & Other Federal Implementing Agencies FCOI Training Verification Review

## Verifying PHS and Other Implementing Agencies FCOI Compliance with ASU-Issued Subawards (Subaward Negotiation Team Process)

**STEP 1: Verify subaward institution compliance using the FDP Institutional Clearinghouse**

- Access the FDP Institutional Clearinghouse at: https://thefdp.org/default/fcoi-clearinghouse/
- Follow the link to the List Institutions and Entities that have demonstrated compliance.
- Search by the institution's name or primary DUNS Number.
- For awards that have <u>met</u> this requirement, proceed with the activation. If the institution does not appear on this list, continue with the next review step.

**STEP 2: Verify subaward institution compliance using ASU SharePoint**

- Verify the subaward institution has a PHS FCOI Certification Letter on file with ASU.
- Letters can be found in 2007 SharePoint ORSPA > Proposals and Negotiations > Reference Documents > SUBAWARDS > PHS FCOI Certification Letters.
- For subaward institutions that have <u>met</u> this requirement, proceed with the subaward process. If the institution does not appear on this list, continue with the next review step.

**STEP 3: Resolving subaward institutions with no documentation of compliance**

- If the subaward institution compliance cannot be verified, the subawards group will send a notification the subaward institution to implement a PHS FCOI compliant policy and either register with the FDP Institutional Clearinghouse: Institutional Certification of Compliance with PHS FCOI Regulations **or** complete, sign and return on institutional letterhead the PHS Certification Letter.

   - If the subaward institution provides the PHS Certification Letter, upload the letter to 2007 SharePoint ORSPA > Proposals and Negotiations > Reference Documents > SUBAWARDS > PHS FCOI Certification Letters.

   Once subaward institution provides documentation of compliance, the subaward group will proceed with the subaward process.

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