

# FCOI FAQs

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## General

### **Am I subject to the COI requirements?**

Before RSP receives a notice of award, the controlling document with regard to who is considered key personnel, and consequently who is subject to the COI requirements, is the funding proposal and corresponding WISPER record. Anyone listed as PI, co-I and key personnel are subject to COI requirements. Once a notice of award is received, that NOA becomes the controlling document with regard to determining who is considered key personnel and, consequently, is subject to the COI requirements.

If an individual is listed on the award notice from NIH, then she or he is considered key personnel and is required to complete the COI requirements. All individuals who are on the award notice from NIH will be listed on the award set-up worklist. If he or she does not appear, then s/he does not need to complete COI requirements because NIH has determined s/he is not considered key personnel.

## Travel

### **Who must comply with the travel disclosure requirement?**

The travel disclosure requirement applies only to Public Health Services (PHS)-funded investigators or investigators funded by one of the few non-PHS organizations that have adopted the PHS regulations.

PHS agencies include the following:

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Substance Abuse and Mental Health Services Administration

Non-PHS organizations that have adopted the PHS regulations include the following:

- Alliance for Lupus Research
- Lupus Foundation of America
- Juvenile Diabetes Research Foundation
- American Cancer Society
- American Heart Association
- Arthritis Foundation
- Susan G. Komen for the Cure

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If an investigator is funded by any of the above federal agencies or non-PHS organizations that have adopted the PHS regs, that investigator is subject to the travel disclosure requirement.

## **What does an investigator have to do?**

PHS-funded investigators are required to disclose any reimbursed or sponsored travel related to their institutional responsibilities within 30 days of the start of the travel event.

## **When the disclosure requirement does NOT apply**

This disclosure requirement does not apply to travel that is reimbursed or sponsored by a U.S. Federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, U.S. a medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.

## **What does "reimbursed" or "sponsored" mean?**

In this context, "reimbursed" means payments made by an outside entity to cover expenses paid by a PHS-funded investigator as part of the travel event; "sponsored" means expenditures made by the entity without transfer of funds to the PHS-funded investigator.

## **What to disclose**

The information to be disclosed includes

- Purpose of the trip,
- Identity of the sponsor/organizer,
- Destination, and
- Duration of travel.

In summary, any PHS-funded investigator must update their OAR every time they have a reportable travel event within 30 days of the start of that travel event, as required under the federal regulations. Please note that, if a PHS-funded investigator knows in advance they will have reportable travel events coming up in a reporting year, they may log in and update their OAR to report all of their known travel events at one time for that year.

## **How do I disclose travel?**

Please go to <http://www.grad.wisc.edu/coi/disclose.html>. You will see a section in the upper left corner of the page that says "To access your 20XX OAR:" clicking the "Start Here" button will allow you to log in to update your OAR form with your travel event.

1. Answer the basic questions in the beginning of the OAR, being sure to answer "yes" to Basic Question #6 related to travel.

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2. If you have not done so already, enter information about the reimbursing or sponsoring entity by selecting "add a new entity."
3. Then answer the travel-specific questions, providing the following: \*name of entity; \*purpose of travel; \*duration of travel; \*destination of travel. Please note that you do not have to disclose the \$\$ value of your travel sponsorship / reimbursement. The federal regulations require investigators to only provide the 4 pieces of information I mentioned.

Please submit your revised report when you have finished making changes by using the "Submit My Completed Report" button on the Main Menu page of the reporting program.

## **What about travel reimbursed or sponsored by the National Research Commission or the related National Academies?**

Travel reimbursed or sponsored by the National Research Commission or the related National Academies does NOT need to be disclosed. The National Academies only fall under an exception to the travel disclosure requirement and are not an exception to any other part of the new federal policy.

## **COI Review**

### **What does "Office Review" and "Investigator Follow-up" mean in FAST?**

The Office Review column in the FAST tool indicates that the COI Office is in the process of reviewing an individual's OAR.

The Investigator Follow-up column in FAST indicates the COI Office has completed its review and is waiting for the individual to respond to an assigned management plan by either accepting or appealing that management plan. Instructions are provided to the individual to whom a management plan is assigned for how they may log in and accept or appeal a management plan. Once an individual accepts his or her management plan, then the COI office can affirm his or her acceptance, and the Office Review column in FAST will change to "complete." RSP then receives information from the COI office via an automated process so that RSP may complete an FCOI report that the UW is federally required to submit to the funding agency.

## **Communication**

### **Why am I receiving this email when I haven't even received an award yet?**

The email you received is automatically generated and sent to anyone listed as PI, co-Investigator and/or Senior / Key Personnel on a proposal to a Public Health Service (PHS) agency. The email is meant to inform investigators listed on PHS proposals that, in the event their proposal gets awarded, they will be asked to complete COI Training and update their OAR.

At this point, if you have not already completed the COI training, you may go ahead and do so by logging into Learn@UW, registering for the course, and completing the

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training. Instructions for accessing and completing the training can be found at [www.grad.wisc.edu/research/policyrp/coi/COITraining.html](http://www.grad.wisc.edu/research/policyrp/coi/COITraining.html).

If you are unsure if you have completed the training, please read the email you received. That email indicates whether you have completed the COI Training. If you have \*\* after your name, then you have NOT completed the COI Training. Any individuals who do not have \*\* after their name have already completed the COI Training and do not have to complete training again for four years.

If you have already completed the COI Training, no action is required at this point.

Upon receiving a notice of award (NOA) email from the Research and Sponsored Programs Office (RSP), you won't have to complete the training (training only has to be repeated once every 4 years), but you *may* need to file an updated OAR, provided that you haven't already done so within 30 days of receiving that NOA email from RSP. Our electronic system looks back in time 30 days to see if you've updated your OAR. If you and any other investigators on the NOA have already updated your OARs and the date on which you filed your OAR is within 30 days of receiving the NOA email notification, then you do not need to update your OARs again. If you haven't in the past 30 days, then upon receiving the NOA email from RSP, you will have 30 days to update your OAR.

## **I just updated my OAR not long ago. Why do I have to do this again?**

The federal regulations require investigators to verify that their disclosure of their outside financial interests is up to date for each notice of award (NOA) and to complete training.

In the circumstance that multiple grants get awarded in a thirty-day period, our electronic system will know when the OAR update occurs and will automatically mark that person's OAR update complete for all other awards that arrive in that time period. Our electronic system looks back in time 30 days to see if an investigator has updated their OAR. If they and any other investigators on the NOA have already updated their OARs and the date on which they filed their OAR is within 30 days of receiving the NOA email notification, then they do not need to update their OARs again. If they haven't in the past 30 days, then upon receiving the NOA email from RSP, they will have 30 days to update their OAR.

## **Why am I getting so many emails?**

All investigators (PIs, co-Is, and key personnel listed on a proposal or on an award) will receive this automated email each time a PHS proposal is submitted (if FCOI training is not completed) and each time RSP receives a PHS notice of award. These automated emails are intended to remind individuals of federal financial conflict of interest regulatory requirements and are sent to all investigators regardless of whether they completed their COI requirements or not. If an investigator(s) have completed everything, then they do not need to respond. They, or an administrator,

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can simply check FAST (RSP's look-up tool for COI requirements: <https://my.gradsch.wisc.edu/coi-rsp/setupListView.pl>) and verify they are all set.

## Subrecipients

### What are the new subrecipient requirements?

A **sub-recipient** relationship is established when federal funds flow from or through the UW-Madison to another individual or **entity** and the **sub-recipient** will be conducting a portion of the PHS-funded research project and is accountable to the UW-Madison for programmatic outcomes and compliance matters. Accordingly, as a recipient of federal funds from an awardee **institution**, the **financial conflict of interest** regulation applies to **sub-recipients**. See 42 CFR 50.604 (c).

If an **investigator** on a PHS-funded grant has or will have a **sub-recipient** (e.g., subcontractors or consortium members) on the funded project, the UW-Madison, as the awardee **institution**, must take reasonable steps to ensure that any **sub-recipient investigator** complies with the federal FCOI regulations by incorporating as part of a written agreement with the **sub-recipient** terms that establish whether the UW-Madison's COI policy or that of the **sub-recipient** will apply to the **sub-recipient's investigators**.

Two classes of **sub-recipients** are identified: **sub-recipients** that certify their own **entities'** COI Policy complies with federal FCOI regulations and **sub-recipients** that do not have policies that comply with federal FCOI regulations, and so will comply with UW-Madison COI Policy.

### Sub-recipient Investigators Comply with Sub-recipient Entity's COI Policy

If the **sub-recipient's investigators** comply with the **sub-recipient's** COI policy, the **sub-recipient** shall certify as part of the subaward agreement with the UW-Madison that its policy complies with the federal FCOI regulations. The agreement will also specify time periods for the **sub-recipient** to report identified **financial conflicts of interest** to the UW-Madison so that the UW-Madison has sufficient time to provide FCOI reports as necessary to the PHS funding agency. Sub-recipients that are recognized to have policies and procedures that comply with federal FCOI regulations can be found at the following website: [http://sites.nationalacademies.org/PGA/fdp/PGA\\_070596](http://sites.nationalacademies.org/PGA/fdp/PGA_070596)

### Sub-recipient Investigators Comply with UW-Madison COI Policy

If the **sub-recipient** does not have a COI policy or its policy does not comply with the federal regulations, the **sub-recipient** must certify as part of the subaward agreement that it will comply with the UW-Madison COI policy. The agreement will also specify time periods for the **sub-recipient** to submit all **investigator** disclosures of outside financial interests to the UW-Madison to allow the UW-Madison to review, potentially manage, and report to PHS about these outside interests.

**Sub-recipient investigators** who must comply with the UW-Madison COI Policy are required to fulfill specific requirements at two different times: before a proposal for funding is submitted to a PHS agency, and before any funds on a PHS award may be expended.

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*At Proposal Submission*—Before a proposal to a PHS agency may be submitted for funding, all **investigators**, including **sub-recipient investigators**, must have disclosed their outside financial interests. If the **sub-recipient** does not have a COI policy and certifies it will comply with the UW-Madison COI policy, all **sub-recipient investigators** on the proposal must disclose their outside financial interests to the UW-Madison.

*At Award Set-up*—Before **investigators** on a PHS-funded project may expend PHS funds, all **investigators** must update their Outside Activities Report (regardless of whether **investigators** have new or changed outside interests to disclose) and complete COI training. **Sub-recipient investigators** who do not have a UW-Madison NetID must apply for one online at <http://www.grad.wisc.edu/research/policyrp/coi/COITraining.html#subnetid>.

Link to RSP Subrecipient page, with instructions for at proposal submission:  
<https://www.rsp.wisc.edu/subfcoi/index.html>  
Contact: Nick Novak

For Subrecipient requirements at award set up, contact: David Ngo

Subrecipient instructions for getting NetID:  
<http://www.grad.wisc.edu/research/policyrp/coi/COITraining.html#subnetid>

## **I am a subrecipient investigator. What do I do after I receive a UW NetID?**

Once you have activated your UW-NetID, please use your NetID to log in and complete steps 1 and 2 below:

1) Complete UW-Madison COI Training--The UW-Madison COI policy requires all investigators complete COI Training. This training is available at Learn@UW, a UW-Madison training program. The UW COI Training should take only 10-15 minutes to complete.

PLEASE NOTE: there is a 24-hour period following your UW NetID activation during which you will be unable to access Learn@UW. The Learn@UW system does not recognize a new NetID until 24 hours after it has been activated.

Please click on the following url to complete your UW COI Training.

<http://www.grad.wisc.edu/research/policyrp/coi/COITraining.html>

2) File a UW-Madison Outside Activities Report—The UW-Madison COI policy also requires all investigators to file an Outside Activities Report within 30 days of the start of spending on PHS awards. This electronic form will ask you a series of questions required by federal regulations about your outside financial interests. Please use your UW NetID to log in to the

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Outside Activities Report database and fill out and complete your Outside Activities Report.

PLEASE NOTE: there is no 24-hour delay period using your UW NetID for filing an OAR like there is with Learn@UW. You may log in to the OAR system and file your OAR at anytime after you activate your NetID.

Please click on the following url to file your UW Outside Activities Report.

<http://www.grad.wisc.edu/coi/disclose.html>

Please complete these requirements at your earliest convenience. Once you have filed your Outside Activities Report and completed the COI Training, the UW-Madison COI Office and RSP will work to complete the award set-up process and authorize the expenditure of your funds. As a reminder, failure to complete required training and/or file your Outside Activities Report in a timely manner will delay your ability to expend award funds.

If you have questions, please contact us [atcoiprogram@grad.wisc.edu](mailto:atcoiprogram@grad.wisc.edu).

## **I am a subrecipient investigator and I received a UW NetID. Why can't I access the Learn@UW training?**

Once an a subrecipient investigator activates their UW NetID, they may immediately log into the OAR system and file an updated OAR. However, the subrecipient investigator cannot access the COI Training until 24 hours *after* their NetID has been activated. The Learn@UW system will not recognize this NetID until 24 hours after the ID has been activated.

## **Will the UW-Madison review a subrecipient entity's COI Policy to determine if the policy complies with the new federal regulations?**

No, the UW-Madison will not review a subrecipient entity's COI Policy to determine if the policy complies with the new federal regulations. If a subrecipient entity reports to the UW-Madison through a properly completed subrecipient agreement form that it has a COI policy that complies with the new federal regulations, then the UW-Madison accepts that assertion.

## **Where can I check the status of subrecipient investigators in terms of COI compliance?**

For those sub-awardees who do not have a COI policy at the sub-recipient institution and instead are following the UW-Madison COI Policy, campus personnel can track these individuals through a web-based tool developed by RSP. RSP has created an excellent one-stop web page for all subrecipient-related requirements, instructions, and forms: <https://www.rsp.wisc.edu/subfcoi/index.html>. On this page, toward the bottom, are two links under the sub-heading "Electronic Lookup Tools." The first link is to the FCOI Award Setup Tool, or "FAST"

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(<https://my.gradsch.wisc.edu/coi-rsp/setupListView.pl>). If you know the PI of the project or the MSN # for that award, you just click on the MSN Number (first column) and you'll see the COI status of all individuals listed on that award. These individuals include UW investigators as well as sub-recipient investigators who are complying with UW-Madison COI policy.

## Training

### How do I access and complete COI Training?

Effective August 24, 2012, the University of Wisconsin-Madison Conflict of Interest Policy requires all investigators engaged in federally funded and/or human subjects research to receive training in financial conflict of interest. The conflict of interest training must be completed every four years. The training is offered through Learn@UW (<https://learnuw.wisc.edu>).

#### *Training Access: Instructions for self-registration*

1. Login to Learn@UW using your UW NetID.
2. Click on the Self Registration link in the upper right corner beneath the picture.
3. Select course offering code cit\_000\_ongoing and click on course offering name: [INFO Course: Conflict of Interest Training](#).
4. When the next screen appears, click register.
5. After registering, you will see the Registration Form. Please fill out the form and click submit.
6. On the registration confirmation page, click on the Finish button.

The registration summary will take you directly to the course or you may click on the link to the COI course.

#### *Training Completion: Instructions for navigating and completing the training*

1. Click on the Content Browser link, then click on Module 1: COI Overview to begin.
2. Use the Next button in the upper right corner of the first page to advance the training.
3. Use the Next button to read through all five modules of the course until you get to the module page: Conflict of Interest Training: QUIZ.
4. Click on start quiz at the bottom of the page and answer the single quiz question (there is only one question in the quiz).
5. Complete the quiz and click Save, then click Submit.

The course is also viewable from the Learn@UW homepage.

If you have any questions or concerns, please email [coiprogram@grad.wisc.edu](mailto:coiprogram@grad.wisc.edu) or call (608) 890-4603 or (608) 890-4460.

### How can I check whether an individual has completed COI Training?

1. For college/school research administrators - the COI Training Status Lookup Tool: <https://my.gradsch.wisc.edu/coi-rsp/trainingStatus.pl>

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A user can look up the training status for an individual -- or enter a UDDS code and view a list of who, from that department/college/unit, has taken the training. This is now in production, with production data. It requires a NetID login, just so that we are not making our training status info available to every journalist who wants to browse it. To see a list of all UW-Madison personnel who have completed the training so far, enter an "A" in the UDDS field. (This uses appointment info from the campus directory -- *NOT* appointment info entered on the OAR form.)

2. For investigators as well as college / school research administrators – Training Certification Database:

<https://my.gradsch.wisc.edu/lookups/citi/trainingStatus.html>

Look up by last name, first name. Shows UW NetID for that person too (email).

## **There's only one question in the quiz and I can't advance to the next question.**

The quiz only consists of one (1) question. The single question is only meant to confirm that the trainee has read through all modules and has completed the training. The trainee who has read through all the training modules clicks "True" that they have completed the training, and then "submit" and they are done.

## **I completed the COI Training, but the training completion is not appearing in the look-up tools. Why?**

COI Training data, as well as completion data for other compliance training programs, is updated once daily at 10am. DOIT takes a "snapshot" of training completion data at 8am each morning. This information is uploaded to campus look-up tools by 10am each morning. Therefore, if an individual completed training before 8am, their training completion would appear after 10am that same day. However, if that individual completed training at 8:05am, their training completion would not appear on campus look-up tools until 10am the following business day.

## **Award Setup**

### **Do Fellows now have to complete an OAR?**

Yes. Fellows are listed as the PI on PHS grants and therefore must complete an OAR and have a full FCOI compliance check.

### **This is not an NIH award, so why am I being asked to do this?**

The FCOI policy applies to all PHS agencies, including but not limited to NIH. An updated list of all agencies that the FCOI policy applies to can be found here:

[http://sites.nationalacademies.org/PGA/fdp/PGA\\_070596](http://sites.nationalacademies.org/PGA/fdp/PGA_070596)

### **Is the OAR process at award setup the same as the annual process?**

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The process at award setup time is similar to the annual process. At award setup time investigators will need to update their OAR with any new or changed outside interests. If no changes have occurred, then the investigator can simply mark no changes.

## **How are Significant Financial Conflicts (SFI) reported?**

Most SFIs are reported via NIH Commons. Other PHS agencies are starting to use commons along with NIH. In instances in which an agency does not use Commons, the Award Setup Team Member will work with the Grants Management Specialist to find the preferred way SFIs need to be reported.

## **How long does the COI Office Review take?**

The time it takes will vary by each situation. Investigators with multiple SFIs will take longer than those with no SFIs. In addition, awards with multiple key personnel will take long than those with just the PI.

## **What is FAST?**

FAST is a Dashboard tool that was developed to inform users where their award setup is in the FCOI process. The tool provides information to users as to what actions have been completed, who needs to still complete certain actions, and whom to call with questions. It can be accessed via this link:

<https://www.rsp.wisc.edu/subfcoi/index.html>

Towards the bottom of the page there will be a link to the FCOI Award Setup Tool, or FAST.

## **Why is there an additional COI approval in WISPER along with the Setup Project Approval?**

The COI approval was added to provide information to campus that the award needs to comply with the FCOI regulations, provide information to campus on what that entails, as well as a tracking tool to see how long the FCOI review takes for each award. Please carefully read the instructions in the approval for additional information.

## **Why does RSP need to know when the Key Personnel are added and accurate in the Project Details of WISPER?**

This is important so that everyone that is considered Key Personnel will be checked under the FCOI review. When the WISPER record is added to FAST by the Award Setup team member, the Key Personnel must be accurate in the Project Details. If anyone is added who is not Key, that person will then be checked in the FCOI review unnecessarily. If someone is not added that should be, that person will not be checked and the UW would not be in compliance with the FCOI regulations. If it is determined that a person was added incorrectly or was not added, the department must then create a new WISPER record and all FCOI review must start over for everyone listed as Key, therefore it is important that the Key Personnel are listed correctly when RSP is notified the Project Details are complete.