October Webinar

Question & Answer

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1. **What are the drawbacks of utilizing the conflict of interest (COI) module versus the paper forms that are currently used?**

   The COI module utilizes a defined process that cannot be modified. If that process does not align with the existing process utilized at a particular site, then it would be up to that site to determine the value of using the module. For this reason, the adoption of the COI module is optional at this time.

2. **If a principal investigator (PI) is listed on multiple projects, can they search for a particular project when they create a new COI disclosure or will they have to scroll through the drop-down menu?**

   The PI will need to scroll through the drop-down menu. Currently, there is no search capability within the drop-down menu.

3. **How is the COI smart form signed?**

   The COI smart form is signed with an individuals' IRBNet credentials.

4. **If paper financial conflict of interest (fCOI) forms are being used, can they be uploaded into IRBNet?**

   Yes, paper forms can be uploaded within the COI module workspace.

5. **When would someone share a COI with a researcher?**

   The COI package is not shared with other researchers. However, the related project may be shared with researchers within a study team to allow those researchers to complete and submit a COI package for the project.

6. **Do COIs need to be manually linked, or will they automatically show up in Project Team Tracking?**

   If a study team member is shared on a project, they will automatically appear in Project Team Tracking, just as they do with training information. The only difference is that there is a new column for the status of the COI review.

7. **Can a COI disclosure be linked to multiple projects or does a new one need to be filled out for each project?**

   No. A COI disclosure cannot be linked to multiple projects. Each COI disclosure is distinct to an individual project.

8. **Does each investigator have to create a new package or is it one package for all investigators for a given submission?**

   As it relates to creating the COI disclosure, each investigator will need to create a new package in their own account. However, when the package is submitted for review, all of the individual COI disclosures will be linked to that one package.

9. **If a PI submits a disclosure and the local COI administrator wants to submit it to the Office of General Counsel (OGC) for review, can that be done through IRBNet?**

   Yes, there is a workspace for the OGC Ethics Specialty Team within IRBNet. The COI administrator at each facility will know how to submit to the OGC once they have completed the COI administrator training. COI administrators may contact VAIRRS@va.gov or IRBNet Support at govsupport@IRBNet.org to coordinate training.

10. **Who reviews COI submissions?**

    The designated COI administrator at a particular site reviews COI submissions.

11. **How is an investigator's signature recorded on the COI smart form?**

    The COI smart form prompts the user to enter their initials, as well as their name, email and other credentials, all of which are populated in the PDF form.

12. **Is there an option to receive a COI determination letter that can be used for IRB submissions?**

    The committee can access or view the status of the COI review in the Project Team Tracking section. The Office of Research Protections, Policy, & Education (ORPP&E) does not currently have any letter templates in the workspace. If that is something a site believes they need, they

can reach out to ORPP&E, who can start discussions around the development of a determination letter template.

13. **Is the COI Module used for VA Central IRB (CIRB) and local IRB? Does the COI Module replace uploading COIs for initial VA CIRB studies?**

    The VA CIRB has access to the COI module. They will communicate their requirements as it relates to whether or not they will continue their current processes or use the module to confirm COI review.

14. **When the COI directive is published, will the use of the module within the VA Innovation and Research Review System (VAIRRS) be mandated?**

    In 2022, the research fCOI policy was placed into pre-concurrence. Part of that pre-concurrence is the use of an electronic module to ensure consistency. As such, it is anticipated that the Office of Research and Development (ORD) will mandate the use of this module as part of the research fCOI policy.

15. **Does IRBNet track when an fCOI is required (i.e., who is an investigator)?**

    No. IRBNet does not distinguish between investigator and non-investigator study team members. It is up to the individual study teams to track that information.

16. **Does the COI module remove the necessity for a concurrence form?**

    Currently, there is no concurrence requirement that goes along with the COI module. Whether a concurrence form would still be required depends on local processes, procedures, SOPs, etc. at a particular site.

17. **Once a COI package is submitted, how is the study documents package submitted?**

    The COI package is separate from the study documents package. An individual may need to upload the study protocol or other supporting documents within the COI package. However, when the individual submits the project to the research administration workspace, it will be as a separate package. For example, the COI package would be package-1 and would go to the COI administrator. The project submitted to the research administration workspace for review would be package-2.

18. **Can a site have more than one COI administrator?**

    Functionally, more than one COI administrator can access the module. However, whether a site allows for more than one COI administrator is defined by local processes and procedures.

19. **Do projects that are submitted requesting non-research determination also require an fCOI form?**

    No. If the project is determined non-research, then it is not research and there are no VA investigators. Only VA investigators are required to submit the fCOI OGE 450 Alt VA form that is linked to a specific research project.

    However, if there is a non-investigator who thinks they may have a conflict, they can simply send a description of the potential conflict to the OGC Ethics Specialty Team. They do not need to fill out the OGE 450 Alt VA form.

20. **Can local sites require the use of the COI module?**

    That is a local decision. If a site decides to use the COI module, they can communicate to their investigator community about the new procedure for submitting a COI disclosure.

21. **If a site decides to use the COI module, does everyone affiliated with the site automatically get access to the *My COI* tab?**

    Yes. Any user affiliated with a site that decides to use the COI module would have access to the *My COI* button and their COI administrator(s) would have access to the review module.

22. **How can sites enroll in the COI module?**

    If a site is interested in accessing the COI module, they can reach out to IRBNet Support at govsupport@irbnet.org or contact the VAIRRS Support Team at VAIRRS@va.gov, who can connect them with IRBNet Support.

23. **Does IRBNet require all staff tied to the project to complete an fCOI disclosure?**

    IRBNet is not a governing body. IRBNet is the vendor of a software product that ORPP&E uses to facilitate and support processes at VA. However, VA investigators are required to submit an fCOI disclosure using the OGE 450 Alt VA form.

    If there are non-investigatory study staff who think they have a conflict, a description of the potential conflict can be sent directly to the OGC Ethics Specialty Team for review, instead of filling out the OGE 450 Alt VA form.

24. **Can 208 waivers be uploaded if they exist and relate to a project?**

    Yes. If an individual has a waiver they think applies to the study, they can upload it along with other supporting documents.

25. **Does the system require all users shared on a project to complete COI forms?**

    No. The system does not place requirements. The system only supports local procedures required by a particular site. Therefore, determinations for whether users shared on a project must complete COI forms depend on the local processes and procedures defined at the site level. Users that are shared on the project will appear in Project Team Tracking. The icons will appear gray if that user has not submitted a COI disclosure.

26. **How will the information that is being collected in the smart form be used?**

    The information collected in the smart form is used by COI administrators to perform their review. There is no other use for the data collected in the referenced smart form. That information is protected. ORPP&E does not receive reports related to the COI module.

27. **Will there be a published list of VA sites that have chosen to use the COI module? This would be a helpful resource for multisite projects so the principal investigator/study chair (PISC) or Cooperative Studies Program Coordinating Centers (CSPCCs) can know how the COIs will be routed/processed.**

    Currently, ORPP&E has not considered publishing a list of sites that use the COI module. However, this is a future possibility that can be discussed among the relevant parties involved.

28. **Can sites try the COI module out in the training environment before deciding whether to adopt?**

    Yes. The COI module is available in the IRBNet sandbox training environment. There is a specific login to act in the role of the COI administrator. To obtain that login information, sites should have their local IRBNet administrator contact IRBNet Support (govsupport@irbnet.org), letting them know the site would like to test the module in the sandbox. IRBNet Support will provide the necessary credentials.

29. **Is the smart form downloadable in case sites are required to request an ethics review because of a potential fCOI?**

    The PDF version of the COI smart form is downloadable. However, if a site needs to send the COI to the OGC Ethics Specialty Team, they can do so directly within IRBNet. The COI administrator can provide the instructions.

30. **Are study staff able to submit signed COIs on behalf of investigators with this new system?**

    No. The only user who has access to the COI smart form is the individual user that owns the account.

31. **How does the reviewer determine whether a particular study team member needs to submit a COI form?**

    The system itself does not distinguish between investigator and non-investigator study team members. All individuals shared on the project will be included in the Project Team Tracking section. It is up to the study team, local research office and COI administrator to determine investigator vs. non-investigator study team members. All VA investigators must complete the OGE 450 Alt VA form. If there are non-investigator study team members with a potential conflict, a description of that conflict can be provided to the OGC Ethics Specialty Team for review instead of filling out the OGE 450 Alt VA form.

32. **How do COI administrators create determinations if there is a management plan that needs to be communicated to the investigator?**

    COI administrators have access to a separate tool set that was not reviewed during this webinar (VAIRRS Webinar October 2022) but is reviewed within the COI administrator training session. As a part of the tool set, COI administrators can add remarks to their review results and upload documents.

33. **On the fCOI form, it requires the "reviewing official" signature. How would one get that signed if the PI is submitting the form?**

    COI administrators have access to a separate tool set within the COI module, which provides them with the capability of "signing" in the reviewing official section.

34. **What types of disclosures should be escalated to OGC for review?**

    OGC is working on guidance that will be distributed to fCOI administrators regarding what to look for, how to review and what can be handled at the local level versus what should be escalated to OGC.

    It is recommended that COI administrators understand the potential conflict the investigator is reporting. If the potential conflict is not clear, the COI administrator should seek clarification or additional information from the investigator in question.

    OGC will distribute additional guidance delineating what can be handled at the local level by the COI administrator versus what should be escalated to OGC.

35. **Does the COI module replace the VA CIRB 115C supplement?**

    No. Until the CIRB issues instructions on the replacement of any form or change to their procedures, everything continues as it has. However, the CIRB will be issuing instructions in the near term.

36. Can a study coordinator place the fCOI for the PI (i.e., the PI signs their initials, and the study coordinator checks for changes and submits the form)?

No. The only user with access to an individual's COI smart form is the owner of the account. Even if a study coordinator is shared on the project, that study coordinator does not have access to the PI's COI module.

37. How does the process differ when the person completing the COI module for the project is renewing their COI?

There is no difference in the process. The individual would create their COI submission, create a new package in their project, link the COI submission in question to that project and submit it to the COI administrator.

38. Is it necessary to keep electronic copies and hard copies of fCOI forms when using the COI module?

There is no need to maintain a hard copy of the OGE 450 Alt VA form when it is completed using the fCOI module in IRBNet.

39. Will the directive mandating the use of the VAIRRS fCOI module be published prior to the re-write of VHA Directive 1200.12?

The revision of VHA Handbook 1200.12 is not connected with the proposed directive for financial conflicts of interest. Ideally, the proposed directive for research financial conflict of interest will be published before the VHA Handbook 1200.12 is revised.

40. What is an interim fCOI form?

An interim fCOI refers to a scenario described at the beginning of the OGE 450 Alt VA form when there is a change in relevant information that requires an individual to change an answer on Section I of the statement to "yes" or that changes the reasoning behind a "yes" answer.

41. Are study team members able to view the submitted COI? Can fCOI forms be shared with the entire study team? Can a project manager view an investigator's completed COI to ensure there are no errors before moving forward with a submission?

The only individuals that may access a COI package are the IRBNet account owner and the COI administrator. Individuals with access to the project may view the status of COI review (i.e., "complete," "pending" or "not submitted") in the Project Team Tracking section.

42. Does an fCOI have to be submitted in a separate package than the rest of the initial review documents?

Yes. The COI package is submitted separately from a study action.

43. Does the COI module prompt investigators to submit their COI packages annually?

No. The COI module does not send annual reminders.

44. Is it accurate to say that COIs should not be linked to packages with initial or continuing review documents going to IRB or Research and Development Committee (R&DC) workspaces, and should instead be submitted in their own packages?

Yes. The COI package is submitted separately from a study action.

45. If fCOI disclosures are not fully reviewed before the submission is ready to be forwarded to the R&DC, does the packet get forwarded as well or does the IRB coordinator wait for the completed review before forwarding?

The system does not prevent the COI administrator from forwarding a study action package based on the status of the COI review.

46. Do investigators have the option of completing the document wizard or uploading a signed OGE 450 Alt VA form PDF form to the COI Committee space?

The intent of the COI module is to complete the online OGE 450 Alt VA smart form. If necessary, supporting documents may also be uploaded to the COI package.

47. How can an individual view the status of COI review within the committee review workspace?

The COI indicator icons reflect the status of COI review (i.e., “complete,” “pending” or “not submitted”).

48. For annual renewals, if nothing has changed, does the investigator need to re-enter all of the data or can they just re-sign the current information?

The OGE 450 Alt VA smart form will need to be completed for annual renewals. The individual would create their COI submission, create a new package in their project, link the COI submission to that project and submit it to the COI administrator.

49. If paper COIs are uploaded to the COI module, will the COI administrator get an alert that a form has been uploaded?

Yes. The COI administrator will receive a notification upon submission of the COI package.

50. What type of access needs to be granted for a co-investigator to be able to complete the COI form?

The co-investigator will require full access to the IRBNet project.

51. Should the fCOI for CIRB studies be handled centrally?

The CIRB has access to the COI module and they will communicate their requirements as it relates to whether they will continue their current processes or use the module to confirm COI review.

52. Are there plans to develop a scope of practice module?

Currently, ORPP&E has not considered a scope of practice module. However, this is a future possibility that can be discussed among the appropriate parties.

53. If there are multiple PIs on a project that need to submit a COI, does each PI have to "link" their COI to that specific project?

Yes. Each investigator will need to link their COI submission to the related project.

54. The CIRB requires that a separate attestation from the local COI administrator, stating that the fCOI form was submitted, reviewed and has no unresolved conflicts, be submitted with continuations. This is an extra form to be signed by the COI administrator. Can IRBNet automatically produce a letter stating that such a review has been completed?

The CIRB has access to the COI module, and they will communicate their requirements as it relates to whether they will continue their current processes or use the module to confirm COI review.

55. Is there a way to disable the gray COI icon for study team members shared on a project who are non-investigators?

There is no capability to disable the COI icon. However, we will forward this suggestion to IRBNet Support.

56. What other portions of the IRBNet package, if any, will the fCOI administrator have access to (e.g., the abstract, funding information, etc.)?

The COI administrator can access all documents submitted as part of the COI package.

57. When is the COI directive expected to be published?

In 2022, the research fCOI policy was placed into pre-concurrence. There is no expected publication date.

58. Can sites set up annual reminders within the COI workspace that produce automated emails when COIs are due?

There is no capability to set up local reminders at this time. However, ORPP&E will forward this suggestion to IRBNet Support.

59. Since COIs were not allowed to be uploaded in IRBNet, many sites uploaded "concurrence" or "COI Admin Review" letters to document that COIs were done. Does the COI module satisfy the COI documentation so that those letters won't be needed anymore?

Yes. Use of the COI module alleviates the need of separate COI documentation.

60. Can OGC provide some examples of mitigation strategies they suggest when, for example, an investigator has been a consultant for a company that makes the drug that is part of a study?

When an investigator is, or was in the past year, a consultant for a drug company—and that company's drug is being studied—OGC first seeks to determine whether there is a criminal conflict under 18 U.S.C. § 208, which would exist if the investigator's work on the VA study would affect the company's willingness to pay consulting fees to the investigator. If there is a 208 issue, the investigator cannot work on the VA study, because OGC would not support a 208 waiver in that scenario. If there is no 208 issue, OGC looks at the impartiality regulation, 5 C.F.R. § 2635.502. Under 502, if the investigator has a current consultant relationship or one that existed in the past year, the investigator should not work on the study unless their leadership grants them a 502 authorization. Whether OGC supports the granting of a 502 authorization is fact-dependent, but historically they have not supported 502 authorizations when the investigator continues to consult for the company. In summary, if an investigator is currently consulting for a drug company, they are unlikely to be permitted to work on a study examining the company's drug. The possibility of the investigator being permitted to work on the study increases if they end their consultant position.

61. Please describe which disclosure purpose to select and when to select each disclosure. For example, if this is the first time using the COI wizard for an existing expedited/exempt project's annual report, is it appropriate to select "Annual," "Initial" or "Interim" for the disclosure option?

"Initial" should be chosen for the first COI submission. "Annual" should be chosen for annual renewals. "Interim" is appropriate for disclosures that are required outside of the initial or annual reporting cycle. In the given example, "Annual" should be chosen since the submission is part of the annual report.

62. What are some examples of how to manage an existing COI?

The primary method for resolving a conflict is recusal (i.e., not participating in the matter). Another method is divestiture of the conflicting interest (e.g., selling stock or leaving an outside position). Other methods are 208 waivers (for potential violations of 18 U.S.C. § 208) and 502 authorizations (for potential violations of 5 C.F.R. § 2635.502), but waivers and authorizations are granted only in limited circumstances. It is important to note that the federal government does not "manage" conflicts of interest in the same way that the private sector does. In the private sector, a conflict is often managed by disclosing the interest or by placing safeguards around the investigator. Those options are not available under government ethics laws.

63. If a protocol makes it to the R&DC for review with a missing fCOI, will IRBNet flag the missing fCOI?

The system does not flag study actions when a COI review is overdue.

64. Is there an email or phone number to contact someone with questions while using the COI module?

Please send questions regarding the COI module to the VAIRRS Support Team at VAIRRS@va.gov or IRBNet Support at govsupport@irbnet.org.