August Webinar

Question & Answer

August 23, 2022

1. **Within the context of the workflow presented in this webinar, are co-principal investigators (co-PIs) and co-investigators considered to be the same?**

   No, within the context of this workflow, the co-PIs and co-investigators represent two distinct types of personnel. Co-PIs share the same oversight responsibility for the project overall, but a co-investigator would be underneath the co-PI.

2. **How are local site investigators (LSIs) involved in the workflow presented in this webinar?**

   The process presented during this webinar is specific to multiple principal investigator/study chair (PISC) workflows. The process to submit an LSI application to the Central IRB will not deviate from the current practice.

3. **Once a principal investigator/study chair (PISC) application is approved, does each co-investigator site send the PISC application to their respective research administration/Research and Development Committee (R&DC) for review? Or is it just the co-investigator's submission that is sent to the local R&DC for review?**

   After the PISC application is approved, each of the co-PIs (lead and non-lead) will submit the PISC application to their local research administration or R&DC for review.

4. **What is the difference between a co-PI submission and an LSI submission?**

   The workflow presented during this webinar described a PISC project with multiple co-PIs located at different VA facilities. Regardless of whether a PISC project has multiple co-PIs, the process to submit an LSI application to the Central IRB will not deviate from the current practice.

5. **Since the PISC Project Cover Sheet (PCS) lists the co-PIs at other sites, should it also list the other co-investigators or study personnel at other sites?**

   The PISC PCS should list all co-PIs, including those at other facilities. However, the PCS should *not* list study personnel from the LSI applications. Personnel from the LSI should only be listed on the LSI project's PCS.

6. **Can you confirm whether co-PI and/or LSI local VA Project Cover Sheets (PCS) should only list local site personnel?**

According to the process described in this webinar, the PISC VA PCS will list all co-PIs, including those at other facilities. Personnel from the local site should only be listed on the LSI project's PCS.

7. **Can administrative staff working with co-PIs also receive notifications in IRBNet?**

   Yes. Any personnel that have been granted full access to a project within IRBNet will receive all IRBNet notifications. Access will be delegated by the PI, but any individual on the project can be granted full access.

8. **In the future, will IRBNet include the capability to add co-PIs and co-investigators?**

   The Office of Research Protections, Policy, and Education (ORPP&E) cannot mandate this capability to be added, but they are providing feedback and recommendations to IRBNet, so that those options can be added in the future. However, due to the nature of the contract, ORPP&E cannot make that request now.

9. **Are there any specific considerations or guidance that would differ for exempt projects with multiple co-PIs?**

   No, the VA Central IRB has adapted the PISC model to exempt multi-site studies to allow Research and Development Committees to understand what they are reviewing. While the PISC is responsible for running the study overall, LSIs are responsible for the reliable discharge of the protocol at their specific location.

10. **A study with co-PIs was recently reviewed by the Central IRB and received approval dependent on certain conditions. It was only reviewed by the lead co-PI research administration and forwarded to the Central IRB. Is it acceptable to have the non-lead co-PI research administration/ R&DC review the project after CIRB full approval? The 102 Local ACOS/R&D Review Supplement form for the non-lead co-PI was submitted with the initial package.**

    Email the Central IRB Manager responsible for this project and copy VA Central IRB Administrator Jessica Kroll (Jessica.kroll@va.gov). She will work with the manager to come up with a solution.

11. **Can IRBNet add "LSI" to their dropdown list of roles, instead of only including a principal investigator (PI) option?**

    ORPP&E cannot mandate this capability be added, but they are providing feedback and recommendations to IRBNet, so that those options can be added in the future. However, due to the nature of the contract, ORPP&E cannot make that request now.

12. **Does the LSI submit two packages in IRBNet – one to the local R&DC with the Central IRB LSI submission for the R&DC to forward to the Central IRB and a separate second package to the local R&DC for the local R&DC to review, with the R&DC submission documents?**

The VA Central IRB workflows allow two pathways for initial submissions. Of note, this question asks about the local R&DC, which is not involved until after Central IRB approval is given. The VA Central IRB requires new submissions to go through the local research office, which is not the same as the R&DC. The workflow allows the original package to be forwarded by the research office to the Central IRB, or for the research officer to inform the investigator to submit the second package to the Central IRB.

13. **Will written instructions describing all of the processes for co-PI study submissions to the VA Central IRB be made available to everyone?**

    Yes, the resources mentioned in this webinar will be available on the Central IRB website and in the IRBNet Forms and Templates Library.

14. **Does the PISC submission have to be approved by the Central IRB and locally for co-PIs before LSI applications are submitted for co-investigators?**

    Yes, the LSI application should begin *after* the PISC has received final approval from the Central IRB and the local R&DC. The Central IRB stages the process for approving the PISC first in case there are any revisions or changes to the documents. With this approach, when it comes time to submit the LSI application, sites will be working with the PISC-approved documents.

15. **In the 5th step of the process outlined in this webinar, it states that once the local research administration review is complete, the lead co-PI submits the project to the Central IRB. How is the local research administration notifying the lead co-PI? Once Central IRB approves the PISC, does the LSI package follow the same process?**

    It is difficult to answer how lead co-PIs will be notified because all local research administrations have their own practices. The Central IRB recommends that individuals reach out to their local office or local site liaison for guidance.

    Also, once the Central IRB approves the PISC, the LSI package *does* follow the same process. Once the Central IRB approves the PISC, and the PISC receives local R&DC approval, then an LSI package can be submitted.

16. **Which institution is responsible for financial conflict of interest (FCOI) review of a co-PI: the site of the lead PISC or each co-PI's local institution?**

    FCOI is the responsibility of each of the co-PIs' local institutions and occurs at the step where all co-PIs simultaneously submit to their local sites for review.

17. **How do the co-investigator sites get a copy of the protocol for local reviews?**

After the package for a new project is compiled, and all of the documents are submitted into IRBNet, each co-PI) can submit the same package to each of their local research administrations for review. That package will contain the protocol, which all local sites will be able to access.

18. **Does the local site always use their own local privacy and information security reviews? Is it necessary for a main site privacy officer-information system security officer (PO-ISSO) review to occur?**

    The Central IRB conducts a central PO and ISSO review. As such, there is no need for a local privacy or information system security review to occur for any research that is being reviewed by the Central IRB.

19. **Should the PISC have separate local R&DC approval before the local site investigator (LSI) R&DC approval?**

    Yes, the PISC review process should occur first. Once that review is complete through the Central IRB and the submission receives R&DC approval, the LSI can begin the submission process. Sites can find a workflow describing this process in the Central IRB IRBNet Forms and Templates Library and on the Central IRB website.

20. **How does the local site obtain privacy and information system security reviews?**

    The signed central PO and ISSO checklists can be found in the Board Documents section of the reviewed package. The local site will have access to the checklists in IRBNet.

21. **Does the local privacy officer (PO) need to review a 10-250 form?**

    No, not for the Central IRB. The 10-250 VHA Research Protocol Privacy Review Checklist form is required for local site IRB applications, but not for the VA Central IRB Panels #1 and #2. The form is not applicable for multi-site studies. Additionally, there is no local PO review for the VA Central IRB. So, for research to be submitted to the local IRB, affiliate IRB or Commercial IRB, the local PO would need to review a 10-250 form. But again, for the VA Central IRB, there is no local PO review and no 10-250 form.

22. **PO reviews are required for regulatory audits, and if these are internal to the VA Central IRB, how are these audits supposed to occur?**

    Central PO reviews occur and are documented during the VA Central IRB review process. Like all of the VA Central IRB regulatory documents, they are available in IRBNet under Board Documents for any regulatory audits.

23. **If the local research administration only receives a lead co-PI principal investigator/study chair (PISC) submission after Central IRB approval, how and when should a local feasibility assessment**

be done? What if that Central IRB-approved study is not feasible at one of the non-lead co-PI facilities?

In that instance, it would be assumed that the facility did not provide a signed 102 Local ACOS/R&D Review Supplement form, which is the document that requires approval of the ACOS. If the Central IRB did not receive that document, that would halt the review process, which would be evaluated at that time.

24. **Is it standard for the information system security officer (ISSO) to have to review and sign the local Enterprise Research Data Security Plan (ERDSP) form for a co-PI submission to Central IRB?**

    No, the memorandum of understanding (MOU) between VA facilities and the VA Central IRB stipulates that the PO and ISSO review are all conducted centrally. Local ISSO involvement should only occur if the Central ISSO requests site-specific information from the local ISSO. The MOU is clear that local review is not to occur unless there is a question from Central ISSO.

25. **Is the R&DC required (by policy) to review and provide an Associate Chief of Staff (ACOS)/R&DC approval letter for PISC applications, or is it just recommended best practice?**

    This question is out of scope for this presentation. It is recommended that individuals consult the policies related to RDC responsibilities. You may review related R&DC policy guidance on the FAQs Portal of the ORPP&E website.

26. **For special subject populations (e.g., enrollment of non-Veterans), which R&DC should approve enrollment of these populations, the main site or each local R&DC for their own local site?**

    Each site that is planning to enroll non-Veterans in research is required to have local R&DC approval.

27. **Does the Central IRB consider the lead PISC or any of the co-PIs responsible for reporting unanticipated problems involving risks to subjects or others (UPIRTSOs) or potential non-compliance for a PISC protocol?**

    The Central IRB plans to release guidance relating to reporting requirements when there are multiple co-PIs. This guidance will be included on the instructions document for multiple co-PIs at different VA facilities. This will be available in the IRBNet Forms and Templates library, as well as on the Central IRB website.

28. **If the principal investigator (PI) provides the 102 Local ACOS/R&D Review Supplement form with the top filled out and then ACOS approval is secured, sites can only upload to board documents. Should the PI then download and upload to the package to send to the Central IRB for review?**

    There shouldn't be any barriers to uploading a signed 102 form into a package, however sites can reach out to the Central IRB manager responsible for the project if an issue is encountered.

29. **Is it correct to say that the PISC submission process occurs first by the lead co-PI, and then essentially gets repeated by the same individual "wearing the LSI hat" afterwards?**

    Yes, that is correct.

30. **When did the process featured in this webinar go into effect? What if a site had a recent multi-site PI study, but only reviewed the LSI application? The PISC approval letter was included, but the PISC packaged was not reviewed. How can this be corrected?**

    This process outlined in this webinar is new and went into effect on August 23, 2022. For anything that was processed prior to this date, contact the Central IRB manager responsible for the project and they can help to resolve any issues.