February Webinar

Question & Answer

February 22, 2022

1. **How do we know which studies will require continuing review versus just the annual report?**

   Your initial approval letter will state whether continuing review is required. Your initial approval letter will note that continuing review is unnecessary if the study is minimal risk, adheres to the 2018 Common Rule, and meets all other criteria. It will only require an Annual Status Report. The approval letter will be specific and provide you with the form number: Form 130 Annual Status Report. Some studies are minimal risk and typically do not require continuing review; however, should the Central IRB reviewer or the Central IRB want to see that study, it will be stated in the initial approval letter and continuing review approval letter if an additional continuing review is needed. This is true even if only for one cycle of continuing review.

2. **Is there a flow chart for continuing review on IRBNet?**

   Currently, there is no flow chart documenting the continuing review process. The process is as follows:

   Step 1: The package is submitted/uploaded to IRBNet.
   Step 2: The CIRB Administrator gatekeeper reviews the package and then sends it to Central IRB Manager (or whoever is handling the continuing review).
   Step 3: It is added to this individuals' Admin agenda, and she will conduct an administrative review.
   Step 4: At this point, they will identify any errors, deficiencies, needed revisions or additions.
   Step 5: Next, they will open the package and contact the study team with a list of required revisions.
   Step 6: The study team will make necessary revisions.
   Step 7: The individual handling the continuing review will forward the submission to panel 1 or 2 for the reviewer and/or the convened board action.
   Step 8: Once the board or the reviewer, in the case of expedited review, completes their review and approves, the individual handling the continuing review will create and publish a continuing review approval letter.

3. **Will the old CIRB number ever be needed?**

   Yes, section 1 of the 115a and 115b asks for the VA Central IRB number. Both numbers are recorded – the IRBNet number assigned and the VA Central IRB number. Enter the old CIRB number in the space provided for a four-digit number.

4. **Where do we get the VA Central IRB study number (the 4-digit number)?**

The number (two-digit year-sequency number) is assigned by the VA CIRB office and is added to IRBNet once it is assigned. The number is inserted as the "Ref #" next to the submission date on your Submission Manager page.

5. **Do you want only the project ID or also the package ID after the hyphen?**

   Only the project ID number is required. A package will not be returned if it includes the package ID, but the IRBNet project number is all that is needed in section 1.

6. **Where do we get the VA Central IRB study number (the 4-digit number)?**

   The number (two-digit year-sequency number) is assigned by the VA CIRB office and is added to IRBNet once it is assigned. The number is inserted as the "Reference #" next to the submission date on your Submission Manager page.

7. **Can you clarify if the local review of fCOI is required annually for all investigators?**

   The Office of General Counsel requires an annual review of the fCOI. Your local research office determines the process or policy for accomplishing that. The Central IRB only requires documentation that the annual review has occurred and must be informed if there is a management plan that would be of relevance to the IRB.

8. **For the PISC site, does the 115c include all PISC investigators at all sites, just the PISC investigators at the PISC site, or all investigators at the PISC site regardless of whether they are designated as PISC investigators?**

   For all the investigators at the PISC site – if the COI administrator or designee has reviewed all the fCOI forms for investigators listed in the PISC 115a, then no further action is required. They must also be covered in the 115c form signed by the fCOI Administrator or designee. Each site must have the COI Administrator or designee complete and upload form 115c for investigators listed in the 115b at that site as well.

9. **Can we put a note in assuring that the training will not lapse if it is due to expire in the 60-days prior to study expiration?**

   No. Unfortunately, it must remain current throughout the process and up to continuing review approval.

10. **Why does the Collaborative Institutional Training Initiative (CITI) not allow updated certificates if completed more than 30 days prior to expiration?**

    Per CITI Customer Service, Human Subject Training can be taken up to 90 days in advance of expiration. If you are having a problem accessing the training, you need to contact your local CITI administrator, who can manually show the training as expired, allowing immediate access to the applicable training.

11. **How do we update if staff leave the project?**

You can list staff that have left the study in 115 section II. Section II has various areas in the 115a PISC Continuing Review Application and the 115b Local Site Investigator (LSI) Continuing Review Application to list staff that have left the study.

12. **If we have a staff member (sub-investigator) who is not on ICF/recruitment material and we intend to add the staff member to the continuing review, how do we do so?**

    The 115a and 115b state that you can add non-investigator staff at continuing review. Those staff members can be added as long as no study documents require revisions, such as a consent form or recruitment materials. Investigators have not been allowed to be added at continuing review for at least several years. They always require an amendment, even if the materials don't need to be revised.

13. **Do local, non-investigator staff need to be approved locally before adding them at continuing review?**

    This is something you must check with the local site about. Generally, the R&D Office has its own established policy, and it is not for the Central IRB to determine. Central IRB can approve non-investigator staff added at continuing review, even if the local site hasn't approved them.

14. **What was the amendment number supposed to be? The number of the amendment within the study or the project package ID?**

    You can put the amendment number within the study. There was some confusion initially as to how amendments are numbered. If there is an amendment number that has been made explicitly for the given protocol, please include that. If there's not, please put the package number that houses the final determination of that amendment.

15. **Will the information from the February webinar be pulled together into a cheat sheet of some sort that can be provided to study teams upon initial approval, so the first continuing review is done right?**

    The webinar slides are available and encouraged to be shared. If desired, you can contact Mary Eckart at Mary.Eckart@va.gov to schedule a one-on-one meeting to cover specific, unique matters and clarification on points of confusion. The forms are templates; they can't possibly cover every scenario and every type of study. Please reach out, for personal, direct guidance.

16. **Can you clarify when a separate amendment is needed? And when investigators can be added at continuing review?**

    No investigator in any role can be added at continuing review. The addition of an investigator always requires an amendment, which is always handled separately from continuing review. No amendments are accepted at continuing review. As such, you cannot revise a consent form or recruitment materials at continuing review. Amendments are always handled separately from the continuing review.

17. **Section III should be the dates for the study as a whole or the specific site on the 11b?**

    For the PISC 115a, Section III should be the status of the overall study. For the local sites, Section III should be specific to their site. There are cases where some local sites are closed to enrollment, but other sites are still enrolling, so Section III should be the current status at your local site.

18. **Besides CITI and credentialing, are there any other trainings that CIRB checks as part of the continuing review process?**

    Training, credentialing, and privileging are all dictated locally through the R&D Office. The Central IRB does not explicitly dictate the training. The Central IRB confirms that the listed staff has completed the local requirements from the local R&D Office.

19. **If a local R&D requests an abstract on their review, how should this be handled locally?**

    If the local R&D wants to see the abstract provided by the PISC site, all local sites can see the abstract that the PISC has uploaded for continuing review. They can make that abstract available to their local R&D site.

20. **Should we be including the closed sites in that last section tally?**

    Suppose this question is regarding Section 9, which lists all the local sites participating. In that case, the very last column asks for the total number of participants enrolled or charts reviewed at that local site, so the total number would not change from year to year once the site is closed. Please provide that total number. The column before the "total" column asks for number of enrollment or charts reviewed since the last continuing review. Those numbers would be included if the site closed during the continuing review look-back period. If the local site has been closed for several years, there would only be a number in the last column.

21. **If a site was part of the PISC application and has an IRBNet project number as part of the multi-study but never completed an LSI application, are they considered closed (i.e., need to be listed in the PI SC CR Form 115a)?**

    If a site never received CIRB approval, it is not considered open and active and should not be listed in the 115a PISC CR application.

22. **For the "*Current Project Status*" question on form 115b, why does the CIRB need to know these three dates: (1) date closed to enrollment, (2) date participant intervention ended, and (3) date follow-up ended?**
    These are milestones in the life of a research project, and they inform the VA CIRB and RDC about the current status of the project as it comes back for continuing review or study closure/termination.

23. **Is the continuing review due 60 days or 30 days ahead of its expiration date?**

The continuing review is due in IRBNet 60 days ahead of its expiration date.

24. **If staff changes are reported as part of continuing review, does the project cover sheet need to be updated to reflect that change?**

    Yes, please.

25. **Will there be a separate presentation for non-significant risk studies?**

    No. As noted in the initial approval letter, for studies not requiring continuing review, Form 130 Annual Status Report is due from the PISC site 30 days before its due date, as specified in the reminder notice.

26. **If some currently approved documents are not available on IRBNet (i.e., study began pre-IRBNet) and these documents were previously submitted with the PI/SC CR application (specifically, the ICF/HIPAA waivers), should they be submitted with the PI/SC CR app?**

    There is no need to upload currently approved documents, such as a consent form, HIPAA authorization, etc. to the continuing review package, if they are currently in IRBNet. This is one of the benefits of our electronic system. Please contact the manager of your study well in advance of the continuing review to assist in assuring that you have all the currently approved documents in IRBNet.

27. **Can a site member check "*No*" for obtaining consent, but then change it to "*Yes*" at the following continuing review if no changes are made to the process in the protocol (i.e., they have been obtaining consent since the study's approval)?**

    It is acceptable if all training is current, and the staff member is qualified to obtain informed consent.

28. **What type of AEs would be included in the continuing review?**

    Events that are anticipated and/or unrelated to the research. Please see Table of Reporting Requirements to the CIRB, found on the website: Table of Reporting Requirements to the VA Central IRB**.**

29. **If a PD/AE was previously reported to CIRB, do we report/state/share anything at continuing review?**

    No. Only report the events that occurred since the last continuing review or initial approval that have NOT been previously reported to the CIRB.

30. **Why are there two columns for IV (i.e., initial vs. last continuing review)? All the other questions ask either/or.**

    One column is for total participants enrolled since initial approval (overall total), and the other column is for total enrolled since the last continuing review.

31. **Within IRBNet, some CIRB studies have an expiration date, but no report due date; some have a report date, but no expiration date; and some have neither of those dates. Can you explain why this is and what it means for each project?**

    An expiration date indicates that continuing review is required. Reminder notices will go out at 90, 60, and 30 days prior to the expiration date. The continuing review is due into IRBNet 60 days before the expiration date. Report due date only means that an Annual Status Report is due from the PISC Study Team. The Annual Status Report is due 30 days before the due date. No dates would indicate that a local site does not require continuing review and that the PISC Study Team will upload the Annual Status Report for all sites.

32. **If it is a new study in IRBNet, is there still a 4-digit number?**

    Yes, the study will be assigned a 4-digit VA CIRB study number.

33. **Has this guidance been shared yet with the study teams who will be completing the continuing review submission? If not, will that be sent by VA CIRB?**

    Continuing review applications are completed by PISC or designee, such as national coordinator, program manager or another staff member deemed qualified by the PISC. LSI continuing review applications are completed by LSI or designee, such as local site coordinator or another staff member deemed qualified by LSI. The process for creating the CR package and uploading the documents for each site into IRBNet is strictly up to the PISC and Study Team. With proper access, any study team member can create the package and upload documents. The PISC and Study Team coordinate the submission process for all sites.

34. **Is the determination letter completed at the initial review for fCOIs under one-year-old acceptable to submit for continuing review?**

    Yes, if the date of review and signature of the COI Administrator is on the letter.

35. **SRS form has an "*Add*" or "*Remove*" personnel section. How is this handled if the PI or co-PI cannot be added at continuing review?**

    An amendment must be submitted to add PISC, co-PISC, or any investigator. This amendment is handled separately from the continuing review.