June Webinar

Question & Answer

June 28, 2022

1. **Have Millennium user roles been assigned to VA staff? Is it acceptable to select "Unsure" for this question in the Project Cover Sheet Wizard and then update at a later time?**

   As sites begin to transition to the Cerner Millennium, the new electronic health record (EHR), it is mandatory that sites have this information to ensure users have access to the EHR for research purposes. All sites that have already transitioned, or are in the process of transitioning, will be assigned Millennium user roles using this data. Responses to the EHR/Cerner Millennium-related questions are only for duties related to the specific research project. If a user is unsure of whether or not they already have a role in Cerner Millennium, then select "Unsure."

2. **Do sites need to re-do Project Cover Sheets using the new version released on June 27, 2022?**

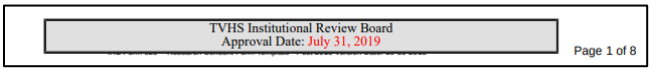
   No. Project Cover Sheets only need to be updated when there is a change to the study or if their VAMC is converting to Cerner in the near future.

3. **How is the HIPAA Authorization form stamped without IRBNet actually placing a stamp on the document? Does that have to be configured with IRBNet Support?**

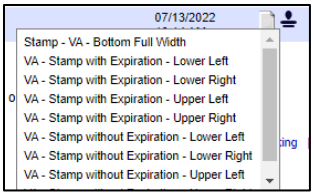
   When VA Tennessee Valley Healthcare System stamps consent forms, IRBNet puts a stamp at the bottom that says, "*IRB approved this consent form on [month, date, year]*." When the HIPPAA Authorization form is stamped, nothing physically happens. It just moves the HIPAA Authorization to the board documents. It will include "stamped" in the title of the document, but it won't physically stamp the document, like it does with the consent forms. Please contact IRBNet Support, at govsupport@irbnet.org, for site-level configuration of the stamps.

4. **What is the difference between stamped and non-stamped documents?**

   Stamping a document puts an IRB approval "stamp" in the footer of the document to indicate that the document has been officially approved (as seen below).

   The screenshot below is from the Submission Detail page and shows the different stamping options.



5. **Does the pencil icon only work for packages that are unlocked? When starting a new package, does one need to start a new document as well?**

   The pencil icon only works for packages that are unlocked. When creating a new package, a new document does not need to be started. Instead, a previously submitted document can be updated.

6. **Are users required to revise a continuing review form rather than starting a new form?**

   No. Users have the option to create a new continuing review form or revise an existing continuing review form. IRBNet gives users the option to revise a previous continuing review form because it makes it easier to track version history, but it is not a requirement.

7. **Are principal investigators (PIs) the only users that can see the document history?**

   Committee administrators and study team members can also access the version history if the pencil icon  was used to update the document.

8. **Do research coordinators have the ability to see documents associated with a project?**

   If a project is shared with a user, the user should have “read access” to all documents associated with that project. Read access allows the user to view the documents associated with a project. However, the user will not be able to modify documents or submit a package.

9. **If PIs have not been using the pencil function, who can re-organize things within IRBNet? Can the study team organize all of the consents or is it only the IRB administrator that has that capability?**

   If the user created and submitted a package without using the pencil function to create version histories, those version histories cannot be generated after the fact. Users can only utilize the pencil function going forward.

   The IRB administrators do not have access to the organization function. Once the package is submitted to the workspace, the user can no longer stack documents and create those version histories. Stacking documents and creating version histories must be done by a PI and their staff as the package is being created. At VA Tennessee Valley Healthcare System, staff are told that if they have a previous version, be sure to use the pencil icon and stack the documents so they have that version history.

10. **Is the Submission Manager only available to IRB administrators?**

    The Submission Manager is available to administrators and reviewers. It is not available to study coordinators or study PIs. If a facility does not have a Submission Manager and thinks they should, please reach out to the IRBNet Support contact at your facility or email govsupport@irbnet.org.

11. **Can a user revise an old continuing review form if there was a new version issued since the last continuing review?**

    The most recent version should always be used when completing a continuing review submission.

12. **Is it true that once a user is in a package, the user can also click "Project History" on the navigation pane to quickly go back to previous packages?**

    Yes, that is true. During this webinar, Daniel Edwards demonstrated the "Jump" function, where a user can go to a package and then jump quickly to the package histories, but the user can also use the navigation pane to access the project history.

13. **Should research and development committee (R&DC) members have access to the board documents section?**

    Committee members can access the board documents section for all studies in which they have been assigned as a reviewer.

14. **Where is the "Search All" option for a package?**

    The "Search All" function is located on the Submission Manager page.

15. **For a Central IRB study, how does a PI submit a package or project only for local review (not for the lead site or other sites to review)?**

    A PI would just submit directly to the research committee at their particular site instead of to VA Central IRB Administration.

16. **Do project coordinators have access to tags, as a tool?**

    Project coordinators can assign individual tags to their projects by going to the Submission Manager page and clicking on the  icon to the right of the project title. The user is the only person who can see the individual tags they generate. If the user creates global tags for a project, then everyone that is shared on that project will be able to see the global tags.

17. **If a user adds a tag to a project, is it visible to their entire team or only to the user?**

If the user is in the research service administration, IRB administration or one of the subcommittees or workgroup administrations, the tags are created for the workspace. At VA Tennessee Valley Healthcare System, there is an R&D committee, a research safety committee, and IRB. Each workspace has their own tagging system, which are not visible to the other workspaces, unless a user goes to that specific workspace and looks at projects from that workspace. For administration, everyone would be able to see the tags. However, from the perspective of the PI and/or research team, the user can create tags and has the ability to make them personal (only visible to that user) or global (visible to the entire team on the project).

18. **How does one access the tag nomenclature reviewed during this webinar?**

    A PDF document of the tag nomenclature deployed by VA Tennessee Valley Healthcare System is available for download here in the ORPP&E Webinar Archive.

19. **Who has access to the RCO audits within VAIRRS?**

    Individuals with access to an RCO audit depends on whether the audit is published internally or externally. When published internally, the audit is only available to the individual that published it and other auditors. When published externally, the audit is available to the study teams and review committees. Publishing externally triggers an email notification to the study team and review committee. Sites can reference the IRBNet Notes – Enterprise Audit Tools document located on the VAIRRS SharePoint to address any other questions surrounding publishing.

20. **Does each user have to set up their own tags and tag colors?**

    PIs have their own tags. Administrators can set up global tags, which will be applied to all submissions for that project to the specific committee.

21. **Is the Submission Manager tab only provided to the research office staff and/or to the PIs? Can anyone request access?**

    Only the research office can access the Submission Manager.

22. **Where is the IRBNet Training Energizer?**

    The IRBNet Training Energizer is available for download here in the ORPP&E Webinar Archive.

23. **How does one access the Training Tracker Guidance document VA Tennessee Valley Healthcare System generated to help PIs track staff training?**

    The Training Tracker Guidance document is available for download here in the ORPP&E Webinar Archive.

24. **If a PI creates a training tracker, will they get expiration reminders from IRBNet for all team members?**

    As long as trainings have not been linked or unlinked, then a PI should not get team member reminders from IRBNet. The training tracker only puts team members on a single project so users can view the associated trainings in one place.

25. **How does one access the user guides utilized at VA Tennessee Valley Healthcare System?**

    The user guides utilized by VA Tennessee Valley Healthcare System are available for download here in the ORPP&E Webinar Archive.

26. **Can any team member access the track training tool or just the PI?**

    The track training tool is only available to the research administration and the coordinators for each of the workspaces. The track training tool is not available to the PI. VA Tennessee Valley Healthcare System encourages PIs to create a track training project so they can see when personnel trainings are expiring.

27. **Which of the tools discussed during this webinar are available to research staff?**

    All of the functions reviewed during this webinar are available to the research office. Staff can work with IRBNet Support to determine what tools are available to their facility, if they are not already turned on.

28. **Does VA Tennessee Valley Healthcare System require all study team members to have access to relevant projects in VAIRRS?**

    Yes. If a person is on the study, they must be shared on the project. This allows the site to have access to all of their trainings and their user profiles.

29. **At VA Tennessee Valley Healthcare system, do the study teams upload Without Compensation (WOC) letters or are they obtained from HR for upload?**

    WOC letters are obtained from HR and then uploaded by the Research Service or the study team.

30. **Can administrators submit training certifications, curricula vitae, and/or appointment letters for other users?**

    Yes. For WOC appointment letters, VA Tennessee Valley Healthcare System recommends that research staff upload the WOC letters directly, instead of sending them to the PI to upload, so they can set expiration dates in the system and so the reports that are conducted would be accurate.

31. **Does VA Tennessee Valley Healthcare System upload RCO audits to their agenda or do they place them in the RCO option under "Project Overview"?**

    RCO audits are uploaded to the IRB agenda.

32. **Does VA Tennessee Valley Healthcare System forward all packages to the R&DC workspace? If so, why?**

    Yes. All continuing review packages are forwarded to the R&D committee workspace once the IRB or Safety Committee gives it a determination. At VA Tennessee Valley Healthcare System, all projects require initial R&D committee approval, with the exception of quality improvement projects that have been determined "not research."

33. **When setting up studies in IRBNet, should all study team members be listed?**

    Yes. All study team members should have access to ensure their training records are linked.

34. **Can a user filter projects by tags in IRBNet?**

    Yes.

35. **How can a user request IRB reports to be generated and delivered monthly?**

    Sites can request monthly IRB reports by emailing govsupport@irbnet.org.