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Enterprise Research Data Security Plan (ERDSP) Wizard Training

**Presenter, Branden Lathan, Cybersecurity Analyst,
Office of Research Reviews (ORR)
Office of Information Security (OIS)
August 28, 2024**

LIVE DEMONSTRATION

Questions?

1. Will studies be required to resubmit ERDSP with wizard?

2. When entering wizard for the first time for existing studies, do we select NEW or AMENDMENT?

3. For animal research only - if work is being conducted at the affiliate, do you select that it is a multi-site study, or no?

4. For Multi site study question, what happen with sponsored studies ?

5. Currently the ERDSP for commercial IRB's is completed and routed to the ISSO for the pre-review outside of IRBNet via YourIT. How will the wizard be routed to the ISSO for the pre-review for commercial IRBs?

6. Some projects will use both Sensitive *AND* Non-Sensitive data. Can both be selected?

7. Would suggest labeling Cerner Milleninium as "Cerner Milleninium (CPRS)" if that is correct. If not, what is Cerner Milleninium?

8. Are studies expected to immediately start using this IRBNet Wizard effective 09/03? Will studies that are currently under review at CIRB that already submitted a PDF ERDSP be asked to update their packages?

9. Does "electronic questionnaire" refer to patients entering information directly into e-questionnaire, or any use of electronic data capture?

10. The list of data sources is a bit confusing as there seem to be platforms included in the list.

11. Who will be a point of contact in case a study team have questions about completing the wizard?

12. Why is the Recipient Name listed at the end of the Information Sharing Recipient information list?

13. If using Teams, why is that not an option for transfer?

14. Does the wizard allow for skipping around to complete sections and more than one person may need to add to the wizard to get it to completion.

15. Suggestion - put an asterisk or parenthetical after DaVINCI reminding folks the difference from VINCI because they'll see vinci and stop thinking.

16. A VINCI study mart would not be considered VA Network? You would expect that to be entered as Other?

17. Will the function use for human studies be the same for animal studies going to the IACUC for review.

18. With regard to VA Network, we do not receive a study folder until the study has R&DC approval

    - *If your facility has a standard naming convention for research folders they might be able to tell you what the folder name and path will be once the study is approved.*

19. If using Teams, why is that not an option for transfer?

20. I understand for remote Monitor visits, screensharing of CPRS is permitted using WebEx. Will this be info need to be noted on this form? If so, where?

21. Why is Teams missing from cloud-based software? Is approved for PII/PHI.

22. Just an FYI - ISSO's do sign the authority to transport forms.   6500 Rules of Behavior state that VA Sensitive information cannot be transported out of VA controlled spaces without the approval of their supervisor.

23. Could an aside be added to the owner to maybe include the really common websites and whether they are VA or non-VA owned? I can see study teams assuming the VA owns "VA Redcap" or "VA Qualtrics" and checking the wrong box.

24. Will this wizard still be reviewed by local ISSOs or will this be reviewed centrally? ORR Response: All local IRB studies will continue to be reviewed by local ISSOs

25. Could "CRADA" be added to the Contracts section as oftentimes a CRADA will include the language that would otherwise be covered by a DUA ORR Response: CRADA was not mentioned intentionally because ISSOs do not review CRADAs

26. For Contracts & Agreements section, can the option become homogenous with the listing in the Project Cover Sheet wizard? ORR Response: we will look into this change

27. Can you let us know what research sites tested this form so we can reach out with questions on real-time use? ORR Response: Boston HCS was the pilot site for this Wizard

28. Why is HIPAA, HIPAA/ICF, and HIPAA waiver on this form, shouldn't it be the PO? ORR Response: Because ISSOs often need to verify data ownership and these documents are used to do so.

29. Are local ISSOs required to use IRBNet to review....or can they refuse? ORR Response: Please speak to OIS leadership regarding this. IRBNet is required to be used at all research sites by ORD.

30. Will this wizard still be reviewed by local ISSOs or will this be reviewed centrally? ORR Response: All local IRB studies will continue to be reviewed by local ISSOs

31. How does the ISSO complete their review? The ISSO wrote comments on the current ERDSP. The wizard does not allow that. ORR Response: ISSOs should utilize IRBNet for communications of necessary changes to the study team. If desired, Local ISSOs can draft memos to list changes similar to what is done by ORR.

32. So the original and all the amendments will be visible in one output report? ORR Response: Yes, an amendment ERDSP will contain previously approved information along with amended information

33. Could you please confirm that the output PDF has the SAME language as is in the wizard, i.e., not rephrased/reworded? ORR Response: Yes

34. Can we combine all the forms to one wizard super smart form and use branching rules. ORR Response: This is being discussed as a part of the DARRS Workgroup

35. Does the ISSO approve within the Reviewer section of IRBNet? ORR Response: Yes

36. How can you tell that the ISSO review has been completed? ORR Response: ISSOs will use IRBNet to mark reviews as complete

38. Will this wizard still be reviewed by local ISSOs or will this be reviewed centrally? ORR Response: This question has already been answered

39. Have ISSOs already had training on this and the IRBNet requirement to publish? ORR Response: Yes

40. Will the ISSO be notified by IRBNet to log in and review the form? ORR Response: IRBNet can be configured to send notifications when studies are ready for ISSO review

41. Please clarify again how the ISSO approval occurs, does the IRBNet administrator still need to Share the project for the review, how will the review be documented by ISSO indicating approval? ORR Response: IRB Admins will add ISSOs to projects. When an ISSO is done with their review, they will mark it as complete in IRBNet.

42. The ISSO has to publish the ERDSP or add the ERDSP to his/her reviewer comments? ORR Response: This is not necessary as the ERDSP will be in the package as a document already.

43. Can completed ERDSP be saved as PDF? ORR Response: Yes, a completed ERDSP Smart Form is exported as a PDF.

44. If ISSO requires additional information, can you remind the field how to do that (and use the pencil function update and replace the old version)? ORR Response: This can be accomplished through the use of the internal messaging system in IRBNet, or you can publish a memo or other document in VAIRRS outlining any changes you have for the study team.

45. Very helpful, Branden! What is CRG? and KBA?? ORR Response: A CGR is a Cybersecurity Guidance Request (SNOW Ticket), and a KBA is a Knowledge Based Article. KBAs are written and maintained by ORR here

46. Are ISSO's still going to put a review/approval comment in IRBNet so R&D can verify the ERDSP was reviewed by the ISSO? If not how does R&D know it was reviewed/approved by the ISSO? ORR Response: Yes

47. How will i know who completed the form? ORR Response: IRBNet will display that information in the ERDSP

48. For multisite projects will it be possible to submit one ERDSP for an entire multisite study? ORR Response: The Prime site in a Multi-site project should create an ERDSP that is then shared with all LSI sites using the share feature in IRBNet so that they are all using the same template.

49. For CIRB exempt projects, who would review an amended ERDSP? Does that move to local review? ORR Response: CIRB Exempt projects are still reviewed

51. Don't RCO looks for ERDSP approval? ORR Response: If an RCO is looking for ERDSP approval they will be able to find it in IRBNet.

52. If we have an ammendment, will we need to transfer to the wizard?
ORR Response: If the amendment affects something on the ERDSP form then yes you will need to complete an ERDSP amendment using the wizard.

53. Will notification be sent to the ISSO when a ERDSP has been completed, or will a SNOW ticket still be required to notify the ISSO?
ORR Response: There is no SNOW ticket requirement from ORR. This may be a local process. ISSOs can be notified of studies awaiting their review within IRBNet. You will need to work with your local IRB admin to figure this out.

54. For project transfers, should the PI submit a new or amended ERDSP? ORR Response: We are not familiar with a project transfer. Suggest asking this question to your local IRB admin.

55. How does the ISSO get notify to review? ORR Response: IRBNet can be configured to notify ISSOs when a project is assigned to them for review.

56. To clarify, as of November 1st will all currently submitted and approved ERDSPs need to be resubmitted with the wizard? ORR Response: Yes

58. We've recently been informed that ERDSP forms for studies under external IRBS are not to be reviewed by our local ISSO, but are instead to be reviewed by ORR. How do we facilitate that ORR review via IRBNet? ORR Response: ORR only reviews External IRB studies that are managed by the Central IRB. If your local IRB is managing the study, then the Local ISSO should review.

59. Is TBD acceptable for VA EE tag number? For VA studies, approval often comes before funds, which comes before the portable drive to be used by the study. ORR Response: This is an acceptable process as long as the study team is aware they may need to submit an amendment when they update the EE tag.

60. VINCI is not a data source. ORR Response: VINCI can be used as a data source depending on there is a data repository housed within VINCI.

61. Suggest making the data sources list consistent with the data sources included on the HIPAA waiver. ORR Response: This has been proposed and it is under consideration.

62. Does this change only apply to VA CIRB studies? The VAIRRS newsletter says that the wizard "should be used for obtaining centralized information security review from ORR" which is related to VA CIRB protocol applications. But now it sounds like all studies will have to use this new wizard. Can you please clarify? ORR Response: Yes this applies to all studies not just CIRB studies.

63. Can this Q&A be turned into an FAQ?

64. How does the ERDSP get routed to the ISSO review in IRBNet? ORR Response: ISSOs are added as reviewers to the study package.

65. Have ISSOs had a separate training on the ERDSP Wizard? If our ISSO has not yet, how can they acquire the training now? ORR Response: Yes they have been provided training and information has gone out on where training resources are located in the latest ESO bulletin.

66. Will ERDSPs have admin review acknowledgment for amendments that for example devices have been upgraded replaced or is that be a full protocol amendment review? ORR Response: This is a question better suited for your IRB Admin.

67. The Contracts section doesn't have an "other" option. ORR Response: The list of contracts is inclusive to everything ISSOs should be concerned with.

68. RCOs have to audit the date the ISSOs sign the ERDSP. Can you repeat how will an RCO know if an ISSO reviewed an ERDSP if they no longer are required to sign? Thank you. Great presentation. ORR Response: The date will be listed when the ISSO signs off on the package within IRBNet.

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Documents Available
- VA Directives & Handbooks *
- VHA Directives & Handbooks *
- ORD Program Guides *
- ORD Guidance Documents **
- ORD FAQs
- ORR KBAs

* Documents automatically validated daily
** Some documents automatically validated daily

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