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Office for Research Protections, Policy, and Education (ORPP&E) Update

Topic: Revision in Endorsement Letters for Submitting Any VA Study to an ORD-Approved Commercial IRB: Verification of Preliminary Privacy and Information System Security Reviews

Date: September 11, 2020

For questions on the content of this update, please send questions to IRBRelianceandSIRBExceptions@va.gov.

This ORPP&E update to the VA research community is being issued in collaboration with the VHA Privacy Office, VHA Privacy Compliance Assurance, and the VA Office of Information Security (OIS) to inform the VA research community of an immediate revision in the endorsement letters required for submission for any VA study using a commercial IRB. This revision is made to facilitate the completion of required privacy and information security reviews prior to commercial IRB approval.

ORD has received multiple reports of VA studies requiring a second commercial IRB review following IRB approval because the commercial IRB applications were submitted by VA Investigators prior to the completion of preliminary privacy and information security reviews. VA Facility Privacy Officers and Information System Security Officers (ISSO) are being sent materials for their preliminary reviews after commercial IRB approval.

1. VHA Directive 1605.03 requires that a preliminary research privacy review is completed prior to IRB approval. As stated in VHA Directive 1605.03, Appendix D, Paragraph 1.k.(5) states that the VA Facility Privacy Officer must

> ". . . Conduct the preliminary research privacy review. The preliminary research privacy review is required for any human subjects study submitted for approval prior to approval being granted, in order to address any privacy concerns before the review. If the human subjects study requires IRB review, including a limited IRB review for the applicable exempt human subject research study as described in VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research, dated January 7, 2019, the review is conducted prior to IRB review. If the exempt human subjects research study does not require a limited IRB review, the review is conducted prior to VA Research and Development Committee review . . ."

2. VHA Directive 1200.05 does not specifically state a preliminary ISSO review is required prior to IRB approval, however, VA Handbook 6500, Paragraph 4.b.(15)(s), require the ISSOs to:

> ". . . Participate in the Institutional Review Board (IRB) protocol review and approval process, evaluating the study's data usage, and making recommendations to ensure implementation of reasonable safeguards for the data."

In order for the ISSO to comply with this requirement, the ISSO must complete a preliminary review prior to IRB approval.

3. Many VA Investigators submitting studies to the commercial IRBs are informed by the sponsor that the study application is time sensitive. However, all VA Investigators must follow all applicable federal regulations and VA/VHA policies applicable to that research study. It is not an option for any VA Investigator or VA Facility to choose which VA regulations or policies will apply to a VA study using time sensitivity as the rationale or reason for circumventing compliance with the VA regulation or policy. The commercial IRBs are required to apply VA regulations and policies to any VA study it approves. The ORD-approved commercial IRBs have been given the VA requirements, but the commercial IRBs do not interpret VA regulations and policies. When the preliminary privacy reviews and ISSO reviews are not being conducted, many of the commercial IRB approved studies are being returned to the commercial IRB for a second review and approval, resulting in a time delay for initiating the study.

4. As of the date of this update, the endorsement letter required for a VA study's submission to an ORD-approved commercial IRB has been modified to include a statement requiring the signatory to verify the preliminary reviews by the Privacy Officer and the ISSO have been completed. This endorsement letter must be signed by the ACOS/R&D, the AO/R&D, or a designee within the research office; it cannot be signed by the VA Investigator. The commercial IRB will not review a VA study unless the signed endorsement letter has been received. A copy of this endorsement letter is attached with this update and will also be posted at https://www.research.va.gov/programs/orppe/single_irb.cfm.

5. The purpose of the preliminary privacy and ISSO review is to identify issues directly impacting the ability of the research to be conducted. The VA Facility Privacy Officers and ISSOs must receive sufficient documentation to conduct the preliminary reviews. At a minimum, the documents that must be available to the VA Facility Privacy Officer and ISSO for the preliminary privacy review are as follows as applicable:

(a) Application for HIPAA Waiver of Authorization

(b) Research Protocol

(c) Informed Consent Form (ICF)

(d) HIPAA Authorization Language if combined with the ICF or the completed VA Form 10-0493

(e) IRB Application Materials

6. The following options recommended by ORD and verified with the commercial IRBs can be used to ensure that the VA Facility Privacy Officers and ISSOs have access to the application materials for VA studies to be submitted to a commercial IRB prior to the VA Investigator submitting the materials. Other processes may also be developed that are not included in this list. Information on how to set up accounts for each commercial IRB approved by ORD will be placed on ORD's commercial IRB webpage at https://www.research.va.gov/programs/orppe/single_irb.cfm.

a. Option #1: Adding the VA Facility Privacy Officer and ISSO as a contact for the study within the electronic platform used by the commercial IRB.

With this option, the VA Facility Privacy Officer and ISSO can be added as a contact on the submission and will be able to access all documents completed by the VA investigator prior to the VA Investigator submitting the IRB application packet to the commercial IRB.

The VA Facility Privacy Officer and ISSO must set up an account with each commercial IRB when using this option.

Advarra IRB: To set up an account with Advarra to use CIRBI, please follow the CIRBI Quick Steps instructions attached as a supplemental document to this update. For additional assistance contact the Advarra CIRBI helpdesk between 8am – 8am ET send an email to CIRBI@advarra.com or call 1-866-99CIRBI (1-866-992-4724).

WIRB IRB: To set up an account with WIRB, please follow the instructions located on the VAIRRS Share Point site: https://dvagov.sharepoint.com/sites/VHAORPPE/VAIRRS/Shared%20Documents/Forms/AllItems.aspx?id=%2Fsites%2FVHAORPPE%2FVAIRRS%2FShared%20Documents%2FTraining%20Energizers%2F%5FSubmission%20to%20WIRB&viewid=fe3edab7%2D7515%2D45bf%2D9ef0%2D68cfd7777f46. Review the IRBNet GovCloud Training Energizer – Submitting to WIRB as WIRB uses IRBNet. If the VA facility is live on VAIRRS

(IRBNet), the VA Facility Privacy Officer and ISSO may already have an account. The VA investigator or study team member with full access to the project should be able to "share" the project with the VA Facility Privacy Officer and ISSO. For additional assistance contact WIRB at VAreliance@wirb.com.

ORD will be announcing shortly after the release of this update training opportunities on the electronic submission platforms used by Advarra IRB and WIRB IRB for VA Facility Privacy Officers and ISSOs.

b. Option #2: Sending the VA Facility Privacy Officer and ISSO a PDF of the application materials prior to submission to the commercial IRB.

The investigator can complete the application materials and either print or save the files as a PDF.

7. Communication between the Principal Investigator (PI), VA Facility Privacy Officer, and the ISSO is vital to ensure the timely completion of required reviews. This communication should originate from the PI in a proactive manner for all time-sensitive projects including those projects reviewed by a commercial IRB. The VA Facility Privacy Officer and ISSO should communicate promptly with the PI to identify any issues that require resolution prior to IRB review and approval.

8. Please inform ORD and the VHA Privacy and Privacy Compliance Assurance Offices of any delays in the conduct of preliminary privacy reviews that may result in the VA Facility being removed from the study as a study site by emailing: VHAPrivIssues@va.gov,VHAPCS@va.gov and IRBRelianceandSIRBExceptions@va.gov. Please identify and contact the facility Information System Security Manager (ISSM) Point of Contact (POC) available on the ISSO PO Locator if delays are occurring in the conduct of local facility ISSO reviews that may result in the VA Facility being removed from the study as a study site. For any research related information security protocol review questions/concerns, please contact the OIS-Research Support Division (RSD) by emailing: OISISPSSSSRSDInformationSecuritySupport@va.gov.