Spring Research Town Hall
Frequently Asked Questions (FAQs)

These FAQs were generated from questions submitted during the Spring Research Town Hall webinar that was hosted by the Office of Research and Development (ORD); the Office of Research Oversight (ORO); VHA Privacy Office; and the Research Support Division (RSD) in the Office of Information Security on May 4, 2020.

1. **ORD: Non-Veteran Enrollment in the Mayo Clinic Expanded Access to Convalescent Plasma Protocol**

   Question: Can non-Veterans treated in VHA Facilities under VA's 4th mission be enrolled as VA subjects in the Mayo Clinic Expanded Access Program (EAP) to Convalescent Plasma for the treatment of COVID-19 protocol?

   Answer: Yes, non-Veterans who are admitted to VHA facilities under VA's 4th mission can be enrolled as VA subjects in the Mayo Clinic EAP when the VA facility is a participating site   As with the enrollment of non-Veterans in any VA approved research, the R&D Committee must approve the enrollment of non-Veterans. VHA facilities will not be responsible for covering costs related to research-related injuries incurred by non-Veterans enrolled in the Mayo Clinic EAP if any occur.

   Release Date: 06-18-2020

2. **ORD: Accessing Remdesivir for the Treatment of Severe COVID-19**

   Question: How can VA facilities gain access to Remdesivir for the treatment of severe COVID-19 now that it has been granted Emergency Use Authorization (EUA) by the FDA?

   Answer: Pharmacy Benefits Management (PBM) coordinates the acquisition of Remdesivir from Health and Human Services (HHS) for use under the EUA. ORD is not involved in the clinical use of Remdesivir. Use of Remdesivir in accordance with the criteria and requirements of the EUA for clinical treatment of VA patients with COVID-19 does not constitute human subjects research; it does not

require IRB and R&D Committee approval or reporting to either committee following its use.

For any patients identified as appropriate Remdesivir candidates, clinical staff will work with their local pharmacy department to complete and submit electronically the Remdesivir Order Form to VA's Pharmacy Benefits Management Services (PBM) office for processing https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/COVID/Lists/ROF/Item/newifs.aspx. Jennifer Martin (jennifer.zacher@va.gov) in PBM can be contacted for questions pertaining to obtaining Remdesivir under the EUA for clinical care.

Limited access to Remdesivir remains available outside the EUA as a research use requiring an approved Investigational New Drug Application (IND) through expanded access protocols, emergency INDs for pregnant women and children, and a number of Gilead Science sponsored randomized controlled trials.

Source: https://www.fda.gov/media/137574/download

Release Date: 06-18-2020

3. **ORD: Rollout Schedule for the VA Innovation Research Review System (VAIRRS)**

Question: Where can VA research offices or VA research staff and Investigators find the most recent schedule for the rollout of the VA Innovation Research Review System (VAIRRS) to VA facilities?

Answer: Each VA facility and the VA Central IRB has been assigned to one of three tiers that will be transitioning to VAIRRS according to the following schedule, subject to operations returning to normal in the Fall:
- Tier 1 sites will complete transition by July 2020.
- Tier 2 sites will begin training in August 2020 and will transition in late September thru October 2020.
- Tier 3 sites will begin training in November 2020 and will transition in late December 2020 thru January 2021.

A list of tier assignments can be found on ORPP&E's webpage here: https://www.research.va.gov/programs/orppe/vairrs/VAIRRS_Tiers.pdf

Release Date: 06-18-2020

4. ORD: VA Central IRB Review of COVID-19 Research

Question: Does the VA Central IRB have a streamlined process for reviewing COVID-19 research studies submitted for review?

Answer: Yes. The VA Central IRB (CIRB) is prioritizing COVID-19 studies that have been cleared by the ORD COVID-19 Steering Committee, have been funded by ORD, or COVID-19 amendments added to currently approved studies overseen by the CIRB. For those COVID-19 studies requiring review by the convened IRB, ad hoc meetings are held to ensure as timely a review as possible. Otherwise, the submission and review process are the same as for non-COVID-19 studies. All other VA CIRB business is conducted at the regularly scheduled meetings.

Release Date: 06-18-2020

5. ORO: RCO Audit of Exempt Research

Question: What level of RCO audit, if any, is required for human subjects research that is exempt from the Common Rule?

Answer: Research Compliance Officers (RCOs) may be required to audit exempt research; audit requirements differ depending on when the study was determined to be exempt.

Annual Informed Consent Audit: While exempt studies do not have IRB approved informed consent forms, RCOs are required to conduct an annual informed consent audit of ALL exempt studies. The audit requirement for exempt human research is fulfilled by completing or re-confirming the administrative data section of the ORO informed consent audit tool (or locally-modified equivalent). The box for "exempt" should be checked, and the auditor should confirm that the R&D Committee has performed initial and/or continuing reviews as required by VA policy for any active study that is not followed by any other research oversight committee (see section 2.b. of the RCO Audit Guidance).

Regulatory Audit: Only exempt studies that are subject to the 2018 Common Rule are required to undergo RCO regulatory audits, i.e. studies determined to be exempt on or after January 21, 2019 or exempt human subjects research activities approved by an R&DC prior to January 21, 2019 for which a VA facility has documented that the research has transitioned to the 2018 Requirements (see section 3.b. of the RCO Audit Guidance). Exempt studies that are subject to the 2018

Common Rule require a one-time completion of the administrative portion of the HRPP regulatory audit tool, as well as the "STUDY STAFF QUALIFICATIONS AND TRAINING" portion of the tool.

If a study was approved by expedited review under the pre-2018 Common Rule and after January 21, 2019 was transitioned to the 2018 rule and is determined to be exempt, the following apply to fulfill the regulatory audit requirement of this now-exempt study:

- If the study had a full HRPP regulatory audit prior to its transition to the 2018 Common Rule, the study only needs to have a one-time limited/exempt HRPP audit after transition.

- If the study did not have a full HRPP regulatory audit prior to transition, the study needs to have a one-time full HRPP regulatory audit (look-back to study initiation) after transition.

Release Date: 06-18-2020

6. Privacy: VA Form 10-250, VHA Research Protocol Privacy Review Checklist

Question: Is completion of a VA Form 10-250, VHA Research Protocol Privacy Review Checklist, required for all VA research?

Answer: No. VHA Directive 1605.03, Appendix A, Paragraph k.(1) requires VHA Privacy Officers to conduct a privacy review of all VA **human** subject research protocols. Completion of the applicable sections of VA Form 10-250 is required for all VA research involving human subjects or data from humans, including exempt research and research involving de-identified data from humans. Basic laboratory research not involving data from humans and animal research does not require completion of a VA Form 10-250. ORO has agreed to exercise enforcement discretion of the policy requirement in VHA Directive 1200.01 requiring Privacy Officer review of all VA research.

As noted in the current exception under review by ORD, "Memorandum from the DEAN-DUSH: Delay in Implementation of VHA Directive 1200.01", ORO will continue to exercise its enforcement discretion of the following policy requirement until July 31, 2020:

Paragraphs 5.h.(6), 5.j, and 5.k – Completion of Information System Security Officer (ISSO) and Privacy Officer (PO) review before any VA study is given final approval. ORD is working with the Office of Information Security and VHA Privacy to resolve issues and revise policy language. NOTE: All VA human subjects' studies (including

exact research) must continue to have an ISSO and PO review prior to the study receiving final R&D Committee approval, and such reviews must be documented. This requirement will continue to be enforced by ORO.

Release Date: 06-18-2020

Revised Date: 06-30-2020

7. **Privacy: Combined ICF/HIPAA Authorization and Banking**

   Question: Can a combined ICF/HIPAA be used if a study involves banking (mandatory or optional)?

   Answer: No. ORD is working with VHA Privacy on formal guidance on use of a combined ICF/HIPAA for VA research studies involving mandatory banking or optional banking of identifiable data and biospecimens. At the present time, a combined ICF/HIPAA Authorization may not be used for any VA study involving optional banking of identifiable data and/or identifiable biospecimens.

   Release Date: 06-18-2020

8. **Privacy: Combined ICF/HIPAA Authorization and Banking**

   Question: When a study includes storing of VA data or VA specimen banking as an optional component in a VA research database or VA biospecimen repository, must the subject sign the HIPAA authorization form (VA Form 10-0493) using their full signature or are the subject's initials acceptable?

   Answer: Subject initials are acceptable. The HIPAA Authorization Form, VA Form 10-0493 page 5, must be used when banking of identifiable data or identifiable biospecimens is optional. It includes a separate signature line for subjects to agree to the optional banking component of the study. However, it is acceptable for the subject to use his/her initials as their signature when signing the form, as any mark can legally be considered a signature if the subject's intent was to sign the form.

   Release Date: 06-18-2020

9. Privacy: Waiver of HIPAA Authorization

Question: If an IRB or Privacy Board has approved a waiver of HIPAA authorization for subjects that do not have personal representatives (PRs), must subjects sign a written HIPAA authorization once they regain capacity?

Answer: No. While there is no privacy prohibition to subjects signing a HIPAA authorization when they regain capacity, it is not required by the HIPAA Privacy Rule unless the IRB/Privacy Board-approved waiver of HIPAA Authorization specifies such limitation. It is a best practice to have the subject sign once he/she regains capacity.

Release Date: 06-18-2020

10. Privacy: Waiver of HIPAA Authorization and Disclosure of Data

Question: Can data containing PHI/PII be disclosed outside the VA for research purposes under an IRB/Privacy Board approved waiver of HIPAA authorization?

Answer: No. A waiver of HIPAA Authorization only provides legal authority to disclose PII/PHI under the HIPAA Privacy Rule. You still need authority to make the disclosure under the Privacy Act and if applicable, 38 U.S.C. 5701 and 7332. Legal authority under these other federal privacy laws may exist to permit the disclosure without the subject's signed, written authorization but that determination must be made on a case by case basis in consultation with your local Privacy Officer.

Release Date: 06-18-2020

11. RSD: Enterprise Research Data Security Plan (ERDSP)

Question: When will use of the Enterprise Research Data Security Plan (ERDSP) be required?

Answer: The Enterprise Research Data Security Plan is currently undergoing field testing. The soft pilot and testing of the tool is currently aligned with the implementation of the VA Innovation and Research Review System (VAIRRS) platform.

ERDSP will be required at the Phase 4 of the ERDSP Implementation Plan when it is in full operational capability on May 10, 2021. Approximately 30

research facilities participated in an initial ERDSP soft pilot release from March 22, 2021 to April 19, 2021, to support the IRB/Research & Development (R&D) Committee study/protocol review processes and procedures within VAIRRS. Below is the implementation plan for the ERDSP rollout:

• Phase 1: Pilot & Soft Launch - 30 VA research facilities will begin using the new ERDSP toolset to support the IRB/R&D committee protocol review processes and procedures (3/22/21 – 4/19/21)
• Phase 2: Collect and incorporate feedback (4/19/21 – 4/26/21)
• Phase 3: Training to the field (4/26/21 – 5/7/21)
• Phase 4: Full Operational Capability (5/10/21)

‒ VA Research Principal Investigators are required to submit an ERDSP for each human, animal, and basic laboratory protocol/amendment submission detailing the proposed study's/protocol's plan for implementing reasonable safeguards to protect research data.

Release Date: 06-18-2020

Revised Date: 03-31-2021

12. RSD: ISSO Review

Question: Is ISSO review required for all VA research?

Answer: ISSO review is required for all VA research involving human subjects, to include research that is exempt from the Common Rule.

(a) If the proposed new/amended research protocol meets any of the high-risk conditions, sections selected for an amendment, or certain questions are answered within the ERDSP template, then an ISSO review maybe required:

e.g. High Risk Conditions:

‒ Will any VA Sensitive Information (VASI) be accessed, stored, generated or transmitted during the research study?

‒ Will the research study use any VA Mobile Devices or Mobile Applications?

‒ Will any research study/protocol data be transmitted or transferred to an external entity?

‒ Will the research study use any external information systems or devices?

(b) If the Research protocol amendment changes any of the ERDSP questions related to the research study conditions, an ISSO review is required. The ERDSP will display an "ISSO Review Required" banner above the PI signature block if an ISSO review is required.

Best Practice: The ISSO should review the proposed research study protocol and verify the information contained in the ERDSP is correct. At a minimum, the ISSO will review the following documents:

• ERDSP

• Protocol

• Informed Consent Application

• HIPAA authorization

• IRB Application

• Local site developed forms that may contain information relevant to the security of the research study data.

NOTE: All VA human subjects' studies (including exempt research) must continue to have an ISSO and PO review prior to the study receiving final R&D Committee approval, and such reviews must be documented. This requirement will continue to be enforced by ORO.

For more information, locate the ERDSP Toolset and supporting User Guide within the following web portals:

    i. ORD Toolkit: [Research Information Security & Cybersecurity](#)

    ii. OIS Research Support Division [Public Documents](#)

Release Date: 06-18-2020

Revised Date: 03-31-2021

13. RSD: ISSO Review

Question: Is it possible to obtain central ISSO review of VA multisite research studies submitted to commercial IRBs, similar to how the VA Central IRB ISSO performs a central ISSO review of studies submitted to the VA Central IRB?

Answer: Yes. For VA facilities who are participating in research protocols that are submitted through the VA Central Office (VACO) Central IRB (CIRB), an OIS-Research Support Division Enterprise ISSO will provide a

standardized ISSO review. We are currently coordinating with both ORPP&E and the Cooperative Studies Program (CSP) to develop a process to facilitate an enterprise level ISSO security review process for facilities who are participating within either multi-site Clinical Trials, or research protocols that are submitted through a commercial IRB.

Release Date: 06-18-2020

14. RSD: ISSO Review

Question: How can a Principal Investigator obtain additional assistance and guidance on information security issues impacting their research?

Answer: The Research Support Division encourages Principal Investigators to work with their local Facility ISSO who serves as a primary point of contact for research related information security questions/concerns. However, if the local Research Program/Facility PI is experiencing protocol review/assessment delays, we recommended the PI engage the ISSO's Information System Security Manager (ISSM) or Team Lead for resolution. If the PI, or the Facility ISSOs are seeking additional guidance, a request can be submitted to Research Support Division to provide guidance/assessment on the specific Research Information Security issue by emailing the **OITITOPSSOESOResearchSupportDivision@va.gov** distribution list. Research Support Division will work collaboratively with both the PI and the local facility ISSO to provide guidance, direction, and support to resolve your questions/concerns.

Release Date: 06-18-2020

15. RSD: RedCap

Question: Is RedCap approved for use in VA research?

Answer: Yes. The VA approved REDCap instance hosted behind the VA Firewall is the only instance of REDCap approved to store, process, and transit VA Data that is not protected health information. The System Owner is Dr. Breeling. The RSD is working on an Authority to Operate to be able to store, process and transmit PHI/PII, but it is not in place at this time. Additional information on the use of VA REDCap is available on [VIRECs REDCap portal](#).

Other External (Affiliate, Sponsor, etc.) provided Instances of REDCap require review by the Facility ISSO during the Institutional Review Board (IRB) and Research & Development Committee protocol review process.

Release Date: 06-18-2020

16. RSD: RedCap

Question: Can VA REDCap be used to collect Protected Health Information (PHI) or Personally Identifiable Information (PII) from research subjects?

Answer: No. VA REDCap instance has not been approved for the storage, processing or transmission of data containing PHI/PII. VA REDCap is currently being recategorized through the Assessment & Authorization (A&A) process for inclusion of PHI/PII which requires both System Owner and OI&T Authorizing Official (AO) approval.   RSD will continue supporting the System Owner through this recategorization process. Continued updates of REDCap's status can be reviewed both on VIREC's REDCap portal and RSD's Application Information System Tracker.

Release Date: 06-18-2020

17. RSD: Scanning Documents Containing PHI/PII

Question: Is it permissible to scan subject signed informed consent forms and HIPAA authorizations containing PHI/PII using scanner/copy machines available in each Service for the purpose of auditing electronic documents?

Answer: There have been no published restrictions on scanning signed informed consent forms and signed HIPAA Authorization using the facility's approved secure Multi-Functional Device (MFD) Printer. OIS-Research Support Division recommends PIs and the Research Service coordinate with their Facility ISSO and/or Area Manager/IT Support to ensure MFD Printers have been configured and approved for scanning documents containing sensitive information. The Facility ISSO and/or Area Manager/IT Support are responsible for ensuring the Multi-Functional Device adheres to the VA Security Policy and the approved Printer and Multifunction Device Secure Configuration Baseline.

Release Date: 06-18-2020

18. RSD: Transferring Data Outside the VA

Question: What are the approved methods for transferring data externally/outside the VA?

Answer: The following methods are approved for transferring data externally/outside the VA:

Sensitive Data:

1. VA Issued, Encrypted (FIPS 140-2 Validated) Thumb Drive
2. VA Issued, Encrypted (FIPS 140-2 Validated) External Hard Drive
3. Encrypted (FIPS 140-2 Validated) CD/DVD
4. Azure RMS (The Affiliate can include sensitive information in a reply to an VA originated Azure RMS email)
5. Research Study Sponsor eCRF (For Data Owned by the Sponsor, sensitive data must be encrypted in transmission with FIPS 140-2 validated encryption).

Non-Sensitive Data

Non-Sensitive data can be transferred using the methods above and can also be sent using unencrypted email.

Guidance is provided here for reviewing the approved whitelist of approved portable storage devices. RMS Azure email transfer is approved and guidance is available from both ORD's "FAQs: IRB and R&D Committee Considerations for Use of Azure RMS in VA Research" and OI&T's "User Guide for External Azure RMS Recipients" published guidance. Additionally, guidance for the eCRF review process is detailed within ESO Bulletin 364, "Release of VA Research Data to Non-VA Entities and External Web Portal Reviews".

Release Date: 06-18-2020

19. RSD: ISSO Training

Question: Are Information System Security Officers (ISSOs) required to complete Collaborative Institutional Training Initiative (CITI) training in ethical principles governing human subjects research?

Answer: No. There is no requirement from ORD, Enterprise Security

Operations (ESO), or Office of Information Security (OIS) for ISSOs to complete Collaborative Institutional Training Initiative (CITI) training. Facility ISSOs are required to review the [ESO Research Information Security Compliance Standard Operating Procedures (SOP)](#) and are recommended to take the following OIS-Research Support Division ITWD developed courses:

1. [VA Research Overview for Information System Security Officers and Managers (ISSOs/ISSMs)](#)
2. [Research Institutional Review Board ISSO Protocol Review](#)
3. [Research Electronic Case Report Form (eCRF)/Web Portal Security Review for ISSOs](#)

Release Date: 06-18-2020