**January Webinar**

## Question & Answer

January 31, 2022

1. **Is it acceptable if a site considers feasibility and scientific merit, but lacks a formalized Feasibility Alignment and Scientific Review (FA+SR) process?**

The use of the Feasibility, Alignment (FA), and Scientific Review (SR) checklists are encouraged but not required if the facility has an established process in place. This process was established to help sites with no existing FA+SR process. FA+SR is designed to determine whether the project has the appropriate resources and expertise to complete the study, whether the nature of the research is appropriate to be conducted at a given institution, and whether the project is sufficiently meritorious to proceed. The goal of FA+SR is to determine these factors at the beginning of the regulatory review process.

1. **Is the burden of FA+SR shifted from the IRB to the R&DC? The workload of the R&DC has increased substantially and seems unsustainable.**

FA+SR is an institutional responsibility and does not necessarily fall within the IRB’s purview. The goal of FA+SR is not to increase the workload of the R&DC. The VA Electronic Determination Aid (VAEDA) will be available to all facilities in the Fall of 2022. VAEDA is intended to relieve the R&DC and IRB from reviewing projects that are not research, thereby reducing the burden on both committees. The initial FA Review can be conducted by an R&DC member and is intended to keep projects that are not feasible from ever reaching the R&DC. Like the Enterprise Research Data Security Plan (ERDSP), if proposed technology has little to no chance of being acquired or approved within the VA environment, hopefully, the R&DC will not have to review the project. The goal of FA+SR is to determine these factors at the beginning of the regulatory review process.

1. **What is the purpose of the Project Cover Sheet (PCS) Wizard?**

The Project Cover Sheet Wizard is what drives a majority of the metrics needed for the research enterprise dashboards. The data collected in the Wizard feeds the local and ORD dashboards. The Chief Research and Development Officer (CRADO) currently utilizes the ORD-level dashboard to view research activity at a national level. The facilities participating in the Dashboard Focus Group may access their dashboard to view research activity at their facility. Dashboards for all medical centers will be deployed in May 2022. The ORD dashboard is a decision-making tool that allows ORD to identify gaps in the national research program. Prior to VAIRRS, ORD did not have a central data collection tool that included data on ORD-sponsored, externally funded and locally funded projects. VAIRRS now provides a complete picture of research activity across the VHA research enterprise. Numerous groups within the Central Office are partnering with ORD to use the data provided by VAIRRS to decrease the burden on research offices as it relates to reporting. The end goal is to no longer need to conduct data calls out to the field.

1. **Is it recommended to add the Feasibility, Alignment, and Scientific Reviewer checklists to IRBNet/VAIRRS?**

The FA+SR checklists are currently located on the VAIRRS SharePoint within the VAIRRS Toolkit. The checklists are titled “1.0R Feasibility and Alignment Reviewer Checklist” and “1.1R Science Reviewer Checklist.”

1. **Are service chiefs still required to sign off or acknowledge the Project Cover Sheets prior to review?**

The VAIRRS Program Office does not require service chiefs to sign off or acknowledge the Project Cover Sheets.

1. **When did the VA research community learn about the purpose of integrated Feasibility Review?**

The FA+SR was initially introduced at the Tier briefings during the VAIRRS onboarding phase. The “[VAIRRS Routing Overview New Protocol Submission Process Map”](https://www.research.va.gov/programs/orppe/education/webinars/orppe-013122.pptx) (slide 7) outlined in this webinar is the same diagram used for the Tier briefings, and FA+SR has always been included. If a facility needs support implementing the FA+SR process, contact the VAIRRS Support Team at VAIRRS@va.gov. The VAIRRS program is willing to engage with leadership teams to further explain the FA+SR process and its importance.

1. **Is it possible to add the local board reference number to system-generated emails?**

The VAIRRS Administrator at the facility may contact IRBNet Support at govsupport@irbnet.org to discuss the configuration of the system-generated emails.

1. **Is VAEDA ready for use?**

The VA Electronic Determination Aid (VAEDA) will be available to all facilities in the Fall of 2022.

1. **If a facility has an existing scientific review committee, should the committee leverage the questions from the Scientific Reviewer Checklist?**

The reviewing official should complete the 1.1R Science Reviewer Checklist. Instead of recreating the checklist, the Scientific Review Committee can use the checklist as a guide when conducting Scientific reviews.

1. **Who is responsible for completing the VA Feasibility and Alignment forms?**

The reviewing official should complete the 1.0R Feasibility and Alignment Reviewer Checklist and 1.1R Science Reviewer Checklist. It is recommended that a member of the R&DC serve as the reviewing official. If an R&DC member conducts the FA+SR Review at the beginning of the review process, it is expected that the R&DC would have familiarity with the study once it reaches the R&DC for final review.

1. **Does the ERDSP form get submitted to the CIRB or just locally?**

Refer to the VA Central IRB Submissions page at [https://www.research.va.gov/programs/‌orppe/vacentralirb/irb\_submissions.cfm](https://www.research.va.gov/programs/orppe/vacentralirb/irb_submissions.cfm) for CIRB submission instructions and required forms.

1. **According to 1200.01, the R&DC or a subcommittee of the R&DC must determine the scientific merit of a proposal. What is the process for creating this type of subcommittee and the protocol for membership requirements?**

It is recommended that a member of the R&DC serve as the FA+SR reviewing official. The R&DC is responsible for conducting the final review, including determining the scientific merit of proposals that did not undergo peer review. The FA+SR process does not create the need to form a new subcommittee or revise 1200.01.

1. **Do studies submitted to the CIRB for review require FA+SR?**

Questions related to the VA Central IRB (CIRB) review process may be directed to the CIRB’s general intake box at VACentralIRB@va.gov, or you may email the VA Central IRB Manager responsible for the project.

1. **Regarding an amendment, if the ERDSP form states that ISSO review is not required, does the ISSO need to acknowledge this in IRBNet via a reviewer comment?**

For questions related to the ERDSP review process, refer to the ERDSP FAQ Sheet located on the Research Support Division’s SharePoint portal at [ERDSP Template and User Guide - All Documents (sharepoint.com)](https://dvagov.sharepoint.com/sites/OITRSDResearchCybersecurity/RSD%20Documents/Forms/AllItems.aspx?RootFolder=%2Fsites%2FOITRSDResearchCybersecurity%2FRSD%20Documents%2FEnterprise%20Research%20Data%20Security%20Plan%20%28ERDSP%29%2FERDSP%20Template%20and%20User%20Guide&FolderCTID=0x012000A71201A05A749545A370DB74151D69D6&View=%7B49F2E741%2D4B47%2D429F%2DA7AC%2D91D187041478%7D).

1. **In addition to the R&DC, some facilities have seen the burden increase substantially on the gatekeeper role in Research Administration. The gatekeeper and the R&D Coordinator can be the same people at some facilities. In these cases, the Feasibility, Alignment, Scientific, ISSO, and PO reviews all happen in the Research Administration workspace, managed by the gatekeeper. One person responsible for handling all “pre-IRB” reviews for every submission can bog down the process at the front end and over-burden the R&DC Coordinator.**

The gatekeeper role is a critical component in the IRBNet workflow. Several tools are provided in the Research Administration workspace to help manage and organize the workspace. Tags, Reviewer Designations, Reviewer Reminders, and Alert Settings can help the administrator keep track of the pending review projects and send notifications when reviews are complete.

1. **It was suggested that the R&DC should not review the ethics and scientific merit of submitted applications. If that is true, what exactly is the R&DC responsible for as it relates to the FA+SR process?**

The FA+SR process is a preliminary review of the study and does not replace the R&DC’s overall responsibility.The initial FA Review is intended to identify projects that are not feasible and prevent them from ever reaching the R&DC. Like the Enterprise Research Data Security Plan (ERDSP), if proposed technology has little to no chance of being acquired or approved within the VA environment, hopefully, the R&DC will not have to review the project. The goal of FA+SR is to determine these factors at the beginning of the regulatory review process.

1. **There was an email sent to VAIRRS administrators regarding Project Cover Sheet tracking. Was this email sent to the listserv or just IRB administrators? Are exempt Project Cover Sheets tracked on the IRB or R&DC Project Cover Sheet dashboard?**

The email requesting validation of active projects was sent to all committee administrators currently registered in IRBNet for each medical center. Project Cover Sheet submissions are tracked for all active and exempt projects recorded in a subcommittee or R&DC workspace.

1. **A facility completed Project Cover Sheets for existing approved projects. The Project Cover Sheet indicated that a 10-250 form must be completed. Does the 10-250 form need to be completed, even if the PO has already reviewed it during the initial approval using an internal pre-10-250 checklist?**

The instructions provided at the end of the Project Cover Sheet Wizard are intended for study actions (initial review, amendments, etc.). If the existing approved project is only submitting the Project Cover Sheet to comply with ORD’s request, the instructions regarding the 10-250 form may be disregarded.

1. **If a researcher submits a Project Cover Sheet Wizard and information is found to be incorrect, can the research team go back to the Wizard and correct the information? How can this be accomplished without having to generate a new Wizard?**

Two mechanisms allow you to do so. First, if the Project Cover Sheet Wizard is already submitted and the package is locked, the researcher can clone a previously completed Wizard and jump to the section that needs to be revised. The second scenario is if the package is unlocked, and the researcher was instructed to revise it. There is a pencil icon next to the Wizard on the Designer page for the package to allow them to edit the Wizard for resubmission.

1. **In this scenario, a VAEDA form is completed first outside of VAIRRS. Suppose the study is determined to be research (in VAEDA). In that case, the PI enters a new project into VAIRRS, where they would follow the flowchart and complete the Feasibility and Scientific Reviews within VAIRRS while in the administration workspace. Please confirm that this process is correct.**

The steps, as outlined in the scenario, are correct. Ultimately, VAEDA will be included within VAIRRS as a Wizard (iVAEDA). For this example, VAEDA will generate a preliminary determination of “research” or “not research.” The PI would then upload the VAEDA determination to the administrative workspace to support FA+SR Review.