For all active projects, use the newly migrated CIRB project shell for future IRB Information Sheet: Page if registered in IRBNet.

The CIRB and IRBNet are developing an SOP to reconcile records where the local copy has been marked as No Exempt or Exempt in the local submission. The SOP is expected to be released in the next few months. The SOP will also include guidance on how to correct any discrepancies that may have occurred on projects that have already been submitted prior to the release of the SOP. The SOP will be updated regularly to reflect any changes made to the CIRB project shell.

The PI/LSI must grant access to the Study Coordinator, PM, and MDC using the sharing function in order for the study team to have access and work on submissions.

For regulatory compliance, verify all active projects, use the newly migrated CIRB project shell for future use.

If registered in IRBNet, the PI/LSI should have access to their project shell.

The PI/LSI must grant access to the Study Coordinator, PM, and MDC using the sharing function in order for the study team to have access and work on submissions.

The team will be addressing the issue on a site-by-site basis as this is a complex process. Please contact the IRB manager responsible for your project at va@irbnet.org to discuss reconciling your duplicate project records.

LEARNING CENTER VAIRRS Library Updates

The following library updates are posted to the VAIRRS Sharepoint portal for review.

- Local requirements section added to the IRBNet Checklist.
- Two new field added to the IRBNet Checklist.
- Updated guidance on signing off on SOP documents where the local copy has been marked as completed reviews which involves:
  - withdrawing the CIRB record with the no history
  - submitting the record with the local copy to the CIRB
  - loading the record into the study site

The VAIRRS program is forming a focus group to discuss the impact of developing an enterprise IRB system. The focus group will meet monthly to discuss regulatory and operational issues. The focus group is open to all stakeholders and will meet to discuss regulatory and operational issues, strategies for addressing the needs of stakeholders, and opportunities for improving the enterprise IRB system.

The VAIRRS program is transitioning all VA medical centers in the United States to the IRBNet platform. The transition will be completed in 2020, and all VA medical centers will be live on IRBNet by the end of the year. The transition will include updating all forms and letter templates. The program will also be forming a focus group to discuss the impact of developing an enterprise IRB system. The focus group will meet monthly to discuss regulatory and operational issues. The focus group is open to all stakeholders and will meet to discuss regulatory and operational issues, strategies for addressing the needs of stakeholders, and opportunities for improving the enterprise IRB system.
IRBNet provides the ability for the administration to analyze all inputs provided by local sites' project documents. When inputted correctly, the data allow synchronization of project findings, reveal trends, and allow end-users to examine a variety of fields. When pieces of information are omitted from study documentation submissions, the administration is unable to conclusively conduct findings and the final dashboards have incomplete elements. To facilitate proper implementation of all data fields on submissions, we provide the following guidance.

**Data Definitions**

Three data fields are most omitted from project document submissions: project status, initial approval date, and project risk level. To aid in the input of these data, the following definitions are provided below. Additional definitions are provided in the VAIRRS Data Dictionary.

- **Project Status** – Status of the project at the time of the recorded board action. See Data Dictionary for the definitions of each project status option.

- **Initial Approval Date** – Date the project received its initial approval from the board where the action is being recorded.

- **Project Risk Level** – Amount of risk the project has based on characteristics of each study involved. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Greater than minimal risk means that the research procedures may include risk beyond what is ordinarily encountered by subjects (e.g. maximal exercise testing, experimental drugs, invasive procedures, biologics or medical devices, stressful psychological testing, use of special populations).

**How to Input Data Correctly**

Step 1. Log into IRBNet and access your project submission(s) by clicking on its title.
Step 2. On the Submission Detail page, scroll down to Review Details.
Step 3. Click on “Edit Review Details and Minutes”

![Submission Details
- Title: [1612533-2] CSP 2016, National Adaptive Trial for PTSD-related Insomnia (NAP)
- Local Principal Investigator: Juergens, Timothy
- Local Board Reference Number: Other

Step 4. Enter the Submission Details per the submission requirements with attention to project status, initial approval date, and project risk level.

![Submission Details
- Project Status: 
- Project Expiration Date: 
- Next Report Due: 
- Initial Approval Date: 
- Project Risk Level: 
- Votes For: 
- Votes Opposed: 
- Abstained: 

Points to Remember
- The more accurately you input your data, the more meaningful all reports will be.
- When you are submitting your package, ensure all questions are answered completely and that all fields have a set response inputted. Should you have any questions about a particular data field, please contact your local IRB Manager.