

GUIDANCE – CEDE REVIEW REQUEST

Before a research site may participate in a study being reviewed by an external IRB, Prisma Health IRB will conduct an initial assessment to facilitate compliance with federal regulation and institutional policy. This review will be conducted within IRBNet.

This pre-review is required prior to submission to any external IRB for the validation of an existing reliance agreement and to assess the need for other internal reviews. To facilitate the pre-review, please create a new project in IRBNet as an “OTHER” submission type and attach the following to the Designer page:

1. Current protocol and sponsor template informed consent documents
2. Completed Cede Request Cover Sheet (note: items a-c may require additional reviews, approvals, and consent revisions):
 - a. Identify if the study presents additional radiation risks in the cover sheet. This should be assessed by the site PI prior to submitting the cede request.
 - b. Identify if the study requires additional hardware, software installations, or a direct connection to the Prisma Health network or EMR in the cover sheet.
 - c. Identify any potential conflicts of interest of the local study team in the Cover Sheet.

To submit this Cede Request to Prisma Health IRB:

1. Navigate to IRBNet.org
2. In IRBNet, “Create a New Project” and complete the requested information.
3. Attach the above listed items.
4. No PI signature or IRB application is required for submission of a Cede Request.
5. When ready to submit, choose the applicable IRB Board and submit as an “OTHER” submission type.
6. Once the cede request has been approved, you will receive the Cede Request Approval Letter in the “OTHER” package submission (package #1) under Board Documents.
7. Following cede request approval, when ready to submit the new study submission, navigate to the same project in IRBNet, create a new *package* (should be package #2), and proceed with IRB submission as normal.

Most external IRBs will request documentation that the submitting organization has approval from the institution’s HRPP or IRB prior to proceeding with their IRB review.