**Office of Human Research Protection**
**Institutional Review Board**
**701 Grove Rd**
**ESC158**
**Greenville, SC 29605**

**External Review - Local Acknowledgment Submissions Guidance**

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All studies requiring review by an external IRB require submission of a "Request to Cede" application and an acknowledgement of that request by the Prisma Health IRB Reliance Administrator or designee. Studies reviewed by external IRBs require the Prisma Health study team to submit the initial site and site update approval requests directly to the identified external IRB via their protocol management system. Once the external IRB has granted approval the study team submits the approval documents for acknowledgment to Prisma Health within IRBNet.

**A. New Project Submissions:**

- To begin the submission, choose "create new project" and enter basic information about the study.
- Click "next" to be taken to the designer page. In the designer page start the wizard to complete the Prisma Health IRB application and attach Prisma Health required attachments.

The submission includes but is not limited to the following:

1. Completed IRB application (in the beginning of the application please mark external review and choose the appropriate Prisma Health committee and in section "VI. Review Information" select "external" for review type and enter "External IRB name").
2. The following attachments:
   a. External IRB Site specific approval letter (lists local PI or references the site on the letter).
   b. Documents listed on the approval letter (approved consents, protocol, Investigator Brochure, Instructions for Use, participant facing materials, etc.).
   c. Study wide approval letters for any study documents not specifically listed on the site-specific approval letter that will be utilized locally.
   d. Request to CEDE approval letter.
   e. Documentation of additional local reviews as necessary (COI management plans, Radiation Safety Review, Data Agreements, etc...).
   f. Application checklist items Not required for external review: 1572, Device FDA letters, device risk assessment, non-patient facing forms, and package inserts for approved drugs/biologics.
3. Share the project with each study team member listed on the IRB application and assign them Read Access unless they need to edit or prepare submissions. Read access study sharing with non-study personnel is allowed if those individuals are responsible for the oversight of the

study team but not directly involved in study conduct (i.e., Research Director or Research Manager).

4. Linked CITI biomedical training and credentials, CRC Assurance for Coordinators and Investigator Assurance and CV's for investigators.
5. Academic Vice Chair (AVC) signature on the package.
6. Local Principal Investigator signature on submission.
7. Submit project. This process is considered complete once the submissions is acknowledged by the Prisma Health IRB.

**B. Amendments / Modifications, Continuing Review, and Reportable Events.**

These actions are submitted directly to the External IRB. Once approval has been issued, the approval letter and all approved study documents listed on that approval letter are submitted in IRBNet for acknowledgement by Prisma Health IRB.

1. Additional documents and actions included with the IRBNet submission of Amendments and Modifications.
   a. Clean and tracked change versions of revised consent forms and protocols.
   b. Update IRB application if the amendment impacts any of the previously submitted information.
   c. External review cover sheet to add staff as applicable.
   d. Training and credentials for added staff.
   e. Each amendment submission package signed by the local PI.
2. Continuing Review Submissions
   a. Reviewing IRB continuing review determination letter
   b. Any other relevant documentation i.e., DSMB report, summary reports of adverse events of reports of non-compliance or deviations from protocol, and study related publications.
   c. Each continuing review submission package is signed by the local PI.
   d. External review cover sheet to change study status as applicable.
   e. The local IRB will review and provide acknowledgement. Expiration date will be noted in IRBNet as determined by the reviewing IRB.

3. Local reportable events *that meet External IRB Reporting criteria*:
    a. Forms and supporting documentation required by the reviewing IRB.
    b. Findings of the Reviewing IRB.
    c. Any additional documents required by the reviewing IRB.
    d. Significant serious, unanticipated issues and issues of local non-compliance determined to be serious and / or continuing will be reported to the local IRB for information and determination if any action is required by the Prisma Health IRB or if the issue requires reporting to appropriate Prisma Health leadership.
    e. Each reportable event submission package is signed by the local PI.