PRISMA HEALTH®

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All IRB submissions are to be submitted for review through IRBNet. This includes all requests for modifications (amendments), continuing reviews, status changes, and any interim reports to include SAEs, Deviations, and other study related materials. If you are just getting started in research, or if you are needing some reminders on how to get going with a new research project, we have a wealth of information readily available for you on our website:

General Pre-Submission Requirements:
- All investigators must complete the Prisma Health Compliance Conflicts of Interest Disclosure. This must be completed annually and will be checked during all initial and continuing review submissions.

- If you are a faculty member, staff, or a student from an institution outside of Prisma Health, you must complete the Clearance Process on the Researcher Access Page in order to participate in research at Prisma Health.

- Every member of a study team must register for an IRBNet User Profile, instructions for which can be located under the Access to IRBNet section on our IRBNet Help page. There is also an IRBNet Training Energizer with step-by-step instructions for registering.
  - Please note that no matter which organization or institution your primary affiliation is with, if you are conducting research at Prisma, you should affiliate with Prisma Health, Greenville SC - not your institution.
  - Please also note that you should never create multiple IRBNet accounts. If you had an IRBNet account with a previous institution, please see the our FAQ page under the question "I was registered for IRBNet at a previous institution but now work at Prisma Health. What do I do?" for information on how to handle this.

- All study team members have required trainings and credentials that must be uploaded to their individual IRBNet User profiles:
  - All users should either link or upload their current CITI training. If your CITI was completed through Prisma, it can be linked by following these instructions. However, if your CITI was completed at another institution, please upload them into the Trainings & Credentials Section of your User Profile.
  - All investigators on a project must upload and *submit* a signed and dated Curriculum Vitae (CV) into the Trainings & Credentials Section of their User Profile.
  - All investigators on a project must complete, upload, and *submit* the Investigator Assurance (IA) form located on our Forms and Templates page.
  - All clinical research coordinators (CRC) must complete, upload, and *submit* the CRC Assurance form, also located on our Forms and Templates page.

Study Specific Pre-Submission Requirements:
- If your project involves a chart review, whether the review will be carried out manually or through an EPIC data pull request, the Prisma Health Data Support Core (DSC) must review all of these projects prior to IRBNet submission.
  - Please note that the DSC review is separate from the IRB review, but the approval letter received after DSC review is a required document for all projects, as applicable. Please

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see the DSC website for instructions on submitting your protocol for the Data Consultation and Approval Request Intake Form.

- If your project will be sending study data outside of the Prisma Health network, a Data Agreement or Clinical Trial Agreement may be required. Please visit the Clinical Research Management Office (CRMO) website for information and the link for the CRMO Proposed Research Agreement Review process.
    - o Please note that for this review process, you must submit BOTH your project protocol and DSC approval letter (if applicable).
    - o Please also note that this step may be taken in conjunction with IRB review, but the IRB must be explicitly notified that an agreement is in process.

- If you are an investigator whose primary affiliation is with an organization or institution other than Prisma Health, a reliance agreement may be necessary for you to participate in research at Prisma. Please be sure to reach out to both the Prisma IRB and your local institution's IRB. If your institution does not have an IRB, please inform the Prisma IRB. Reliance agreements are study-specific, meaning that an agreement may be necessary for each study you are involved with at Prisma Health. (This currently *excludes* USC investigators.)

- IRB Fees only apply to studies that are both full board reviewed and industry sponsored. Investigators do not need to submit a Fee Waiver application for projects that are not subject to IRB Fees. Please see IRB Fee information on the IRB Fees webpage.

- For projects that will be specifically targeting vulnerable populations, specifically children, pregnant mothers, or neonates, the investigator must complete the Vulnerable Population Assessment form located on the IRBNet Forms and Templates Library.

Submitting a Project in IRBNet for IRB Review
- *Before beginning a new project submission, you must ensure that all the pre-submission requirements outlined above are complete.*

- Please utilize the resources on the website for determining study type and reviewing committee.

- For help creating a new project submissions, please visit the Submission Requirements page. This page contains information related to protocol development along with templates, information regarding the IRB Application form, as well as information about Subsequent Submissions. Informed Consent Templates are available on our Forms and Templates page.

- All submissions are to be made in IRBNet. For specific IRBNet resources, please visit our IRBNet Help page. If you are looking for a step-by-step guide on how to upload documents and build your project in IRBNet, please use the Submission Help Sheet or any of the applicable IRBNet Training Energizers located on the IRBNet Help page.

- ❖ **How to make a new project submission:**
    1. Log into your IRBNet Account and click on "create new project".
    2. Complete the project information and click "continue".

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3. On the Designer page under Step 1, you will select the Prisma Health Committee that you will submit your project to for review. This allows you to view all the documents in the Forms and Templates Library.
4. Before uploading documents, you should complete the Prisma Health IRB Application Form via the "Start a Wizard" button on the Designer page. At the end of the application, a list of required documents will be supplied to you.
5. Once you know which documents your project requires, you may begin uploading all applicable documents on the Designer page.
6. Prior to linking trainings and credentials on the Designer page, you must first "Share this Project" with all study team members. Once this is completed, you'll be able to click the "Link/Unlink Training Records" button on the Designer page and choose all applicable training and credentials. Each individual listed on the IRB application must be shared to the project and have trainings and credentials linked to the New Project package.
7. The Academic Vice Chair (AVC) for the department that the research will be conducted in must be shared on the project so that they can review the protocol and sign the package. The current list of AVCs are available on the Research Leadership webpage. *Please note that once an AVC has signed the package, they should be unshared from the project.*
8. Before submitting the package for IRB review, all investigators and CRCs must sign the package. The signature on the package is what validates the assurance form, which is uploaded into the individual user profiles.
9. Once all of this is complete, you may submit the project for IRB review via the "Submit this Package" button. You will select the appropriate reviewing IRB, and the package will be locked. Once the IRB review has been conducted, you will receive a notification via email as to if revisions are required or if the study has been approved.

❖ **How to handle revisions required (When your package is unlocked by the IRB):**
   1. You will receive an email notification if revisions are required. Within that email you will have a list of items that must be revised.
   2. Log into your IRBNet account and click on the project (it will have a red unlocked icon), which means you are able to edit.
   3. Make all changes as required by the IRB by updating documents via the pencil icon, adding new documents, or editing the application form.
   4. Once completed, please scroll to the top of the project page and click "revisions complete – lock package". This will notify the IRB.

❖ **How to handle subsequent submissions (Amendments, Continuing Reviews, Status Changes, Reportable Events):**
   1. Step-by-step instructions on submitting a subsequent submission are located on our Submission Requirements page under the Subsequent Package Submissions section of the IRB website.
   2. For each subsequent submission, you must complete the appropriate coversheet, all of which are located in the Forms and Templates Library within IRBNet.
   3. All relevant documents should be uploaded along with the coversheet. In order to make revisions to existing documents, please utilize the pencil icon located to the right of the current document in the Designer page.

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4. The Principal Investigator must sign the package prior to submission to the IRB for review.
5. If submitting an amendment to add new study investigators or clinical research coordinators, the new staff must also sign the package prior to submission to the IRB.
6. All applicable trainings and credentials should be linked to the package via the "link/unlink trainings and credentials" button in the Designer page.

- Communication between you and the committee will take place within IRBNet. All study staff with full access to the project will be notified by an automatically generated email when the IRB takes action on a project. The email notification will instruct you to login to IRBNet to view the information regarding the action.

- Our FAQs page has many of the "frequently asked questions" that researchers might have. If you have a question, the IRB FAQs page should be your first stop.

- All of our Forms and Templates can be found in both the Forms and Templates page of our website as well as the Forms and Templates Library within IRBNet.

- All of our Policies and Guidance Documents can be found on the Policies and Guidance page. These contain a wealth of information regarding review types, requirements, and IRB expectations for conducting research at Prisma Health.