How do I submit to the Prisma Health IRB?

Each person doing research at Prisma Health will need to (1) register *themselves* for IRBNet and (2) upload trainings and credentials to their own User Profile in order to make a project submission. To do that, go to www.irbnet.org and click New User Registration and complete the requested information. **Be sure to select Prisma health, Greenville SC – for both Midlands and Upstate research!** Greenville SC is the address of the corporate office therefore that is our IRB location.

If you are affiliated with another institution (UofSC, Clemson, etc) but are conducting research at Prisma Health, **you must affiliate with Prisma Health, Greenville SC.** You can also affiliate with your home institution*, but if you do not affiliate with Prisma Health, Greenville, SC you will not be able to submit to any of our committees or see our IRB application.*

~ Oops! I didn't affiliate correctly! ~ From within your User Profile click "Add an Additional Affiliation" and add Prisma Health, Greenville SC.

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Once you have registered for an account, upload your trainings and credentials in your **User Profile**:

- Each **research team member** is required to complete *Biomedical* CITI training (not GCP, not IS).
- Each **investigator** is required to upload a **signed** and **dated** CV, and an Investigator Assurance form.
- Each **coordinator** is required to upload a CRC Assurance Form.
- Each **student** researcher should be listed as such in the application and have completed CITI training.

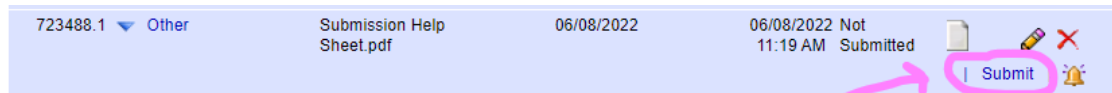To upload trainings, navigate to the User Profile (see above image)

To upload a CV or Assurance form, click "Add a New Training & Credentials Record"

Training & Credentials

IRBNet allows you to track and share your training records, certifications, resumes and other personal credentials. Once added to your profile, your training and credentials can be easily linked to your projects from the Designer, are accessible by your project teams and can be quickly accessed and tracked by the boards that review your projects. Some boards also permit you to directly submit your training and credentials without requiring you to link these records to specific projects.

▸ Add a New Training & Credentials Record

Once you upload, be sure to click "submit" and submit it for review to your most used IRB board.

| 723488.1 ▼ Other | Submission Help Sheet.pdf | 06/08/2022 | 06/08/2022 11:19 AM Not Submitted | | Submit |

To import CITI training, click "Add an External Account" where you will then be prompted to input your CITI ID number. If you conducted CITI training via Prisma Health, your CITI trainings will import automatically via this external account 24 hours after you verified the email that is generated upon adding the CITI account.

External Accounts

You can add your accounts from other organizations such as CITI to your IRBNet profile. Once you add an external account to your IRBNet profile, then external information such as training records can be automatically available to you in IRBNet.
| Learn More |

▸ Add an External Account

If you completed CITI training outside of Prisma Health, upload your CITI certificate via the "Add a New Training and Credentials Record" button.

*this completes the User Registration aspect of IRBNet. Please recall that each study team member will need to complete this step as the project will need to be *shared* with them and trainings linked to new project submissions.

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To submit a project, click "Create new Project" and begin to complete the application.

Fill in the information to create an IRB record for the project. Click Continue. This automatically takes you to the Designer page. The Designer page is your "homebase" for creating your project submission where you will complete the IRB application and upload your study documents.

To navigate to the designer page – click "My projects" – navigate to the project in question from the My Projects page – then click "Designer" in the left-hand side menu

Within the designer, you will complete the Prisma Health IRB Application and upload all study documents.

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To complete the IRB Application, click "Start a Wizard". You will then select "Prisma health IRB Application" and answer all the questions that follow. This smartform generates the IRB application part of your submission. At the end, there will be a list of documents you should submit under step 2. This always includes a protocol (yes, even for NHSR, case reports, or QI projects), and will also include any other relevant documentation.

To upload study documents (protocol, consent forms, surveys, DSC approval, advertisements, handouts, etc.). Click "Attach New Document". Once you upload the documents you'll need to "type" them by clicking the down arrow and selecting the most relevant type of document you just uploaded.

To edit your application (or any document for that matter), click on the pencil icon! Do not start multiple wizards. To delete, click the red "X"

How do I submit to the Prisma Health IRB?

Once the IRB application is complete and all of your documents are uploaded, you're ready to share the project with *each study team member*, link trainings, and have investigators sign the package.

To share the project, click "Share this Project" from the left-hand side menu.
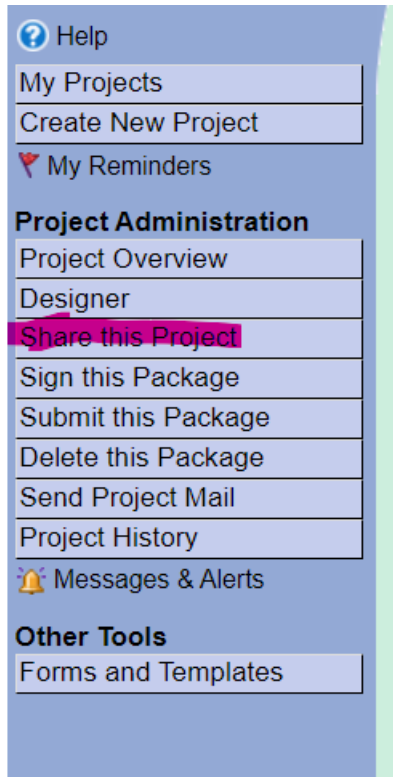
Click "Share"

Choose Prisma Health, Greenville SC

And select your study team members from the list.

Grant them read, write, or full access depending on their roles.

Academic Vice Chairs should be granted READ access and then asked to sign the package. Each AVC knows how to sign a package. This signature represents academic review of the project.

For nursing projects, be sure to upload your proposal approved by Veronica Deas (this satisfies the AVC requirement).

Now, you can link trainings. *For new study submissions, CITI trainings should be linked for each study team member, Assurance forms should be linked for each investigator/CRC and CVs should be linked for each investigator.*

To link, click "Link/Un-link Training Records" and select your study team members documents. *You will only see documents for study team members who have been shared to the project.*

Step 2:
Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. | Learn more |

Documents in this Package:

Document Type	Description	Last Modified	
▼ Protocol	Protocol.docx	06/07/2022 04:20 PM	📄 🗐 ✏ ✕

There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |
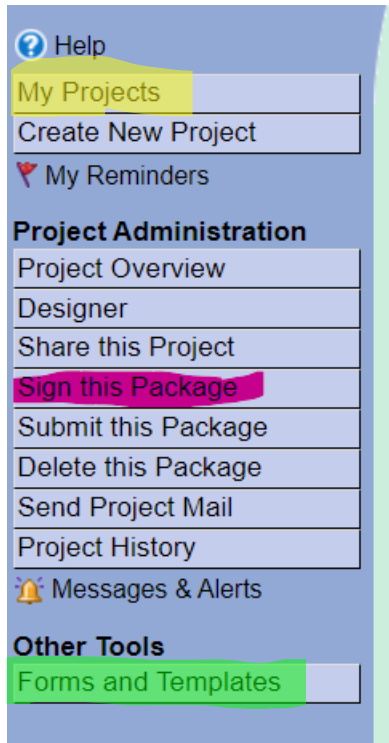
Start a Wizard   OR   Attach New Document   (When should I do this?)

How do I submit to the Prisma Health IRB?

Finally, for new project submissions each investigator must sign the package. Each investigator will need to log into IRBNet and navigate to the submission via their "My Projects" page (see in yellow). Once in the project, they should click "Sign this package"

Select the appropriate role from the drop-down menu.

Click sign.

Input username and password to validate the electronic signature.

~ For each subsequent submission going forward (amendment, CR, reportable event) only the PI's signature is required.

~ For amendments adding additional study staff, each study team member will need to add their signature to the amendment package adding them. Their trainings will also need to be linked to the amendment package adding them.

When all this is done, you're ready to submit! To submit the project, from the left-hand side menu, click Submit this Package. Submit your project to the appropriate board:

- Committee A – Upstate non-oncology projects
- Midlands Committee – Midlands non-oncology projects
- Committee C – Oncology projects

The IRB staff will do an administrative pre-review of your submission prior to protocol review. Application issues and missing elements are required to be resolved prior to protocol review.

All projects submitted that require changes should address those changes within 60 days of submission. Projects that sit in an "unlocked" state for more than 60 days will be processed with a Modifications Required determination and will require resubmission for review.

For templates and additional guidance documents, reference "Forms and Templates" from the left-hand side menu (highlighted green above). Please visit the IRB website for additional resources https://academics.prismahealth.org/research-and-innovation-institute/administration/office-of-human-research-protection