IRBNet Frequently Asked Questions

Updated January 26, 2022

I only see "Prisma Health, Greenville, SC" listed on the organization listing in IRBNet. What do I choose if I am located the Midlands?

There is only one listing for Prisma Health in IRBNet. The organization is required to list a city and state, and the corporate office for Prisma Health is located in Greenville so that was chosen as the location. These is no differentiation in the system. You will be able to choose the Institutional Review Board (IRB) of record for specific studies.

Why does is say "unverified" when I add CITI training to the user profile?

IRBNet requires verification to link your CITI credentials to your profile. An email with a verification link will be sent to the email in your CITI Prisma Health Institutional Profile. If you previously had a palmettohealth.org or ghs.org email, please check that your Prisma Health Institutional Profile email address to assure that your prismahealth.org or other active email is listed. Be aware that your preferred email within your Member Profile may be different than your Prisma Health Institutional email address: you must update your Prisma Health Institutional email address as this is the address that is used during IRBNet verification. If you experience difficulties in updating your email address, please contact Rebecca Marigliano, PhD, Director of Research Policy and Education.

Do I need to use my Prisma Health network credentials to create an account in IRBNet?

IRBNet is a web-based application, and Prisma Health network credentials are not required for user registration. If you are not a Prisma Health employee, you will be asked to identify your affiliation. However, it will not prevent you from registering as a user in the system.

Are all investigators, sub-investigators, and study staff required to have user accounts in IRBNet?

Yes, anyone listed on a submission is required to register. The IRB validates credentials and training through this process.

Will existing, approved studies be merged to the new system by the IRB staff or will individual study teams be responsible?

The IRB staff has provided a conversion file to IRBNet which was used to generate "study shells" that contain study demographic information to include type of review, last reviewed action, last date reviewed, initial approval date, expiration date, and study sponsor. The IRB coordinators will share these study shells with a designated individual listed on the study. Once received, the study team will be responsible for generating a new "package" for the study, completing the new submission document that is available as a "wizard" document on the designer page of the submission, and attaching currently approved documents. These "packages" should not be submitted to the IRB for review until the next required

action on that study. For further information, review the File Conversion Guidance, which is also available in IRBNet -> *Other Tools* (left sidebar) -> *Forms and Templates -> Conversion File - Guidance*.

What types of notification reminders does the system provide, and what are the increments?

IRBNet will provide notifications at 60 days prior to expiration, 30 days prior to expiration, and the day of expiration for studies. These notifications will be emailed to the Principal Investigator (PI) and the Research Coordinator if there is one listed on the application.

Is it necessary to attach an Investigator Assurance to each submission?

Each Investigator, regardless of their role on any particular study, will complete a Investigator Assurance Form that may be downloaded within IRBNet (*Other Tools* on the left sidebar -> *Forms and Templates -> Investigator Assurance Form*). The completed form must be uploaded to the Investigator's "User Profile" under the "Training & Credentials" section by clicking the link "Add a New Training & Credentials Record". The form will only need to be completed and uploaded once. In individual study applications, the completed form along with CITI training and current CVs are linked to that particular study.

How do I see studies in IRBNet that I am involved in?

When the study shell file is completed, the Research Coordinator or PI completing the application will share that submission with everyone listed on the study. You will receive an email notification from IRBNet notifying you that a study has been shared with you. When you log into IRBNet and click on the "My Projects" button near the top of the left sidebar, the studies that have been shared with you will show on the page.

Can you provide written directions for IRBNet registration so that those investigators who were unable to attend a training session may easily register?

Detailed directions for user registration are available on the IRBNet Resources webpage. There is a document entitled, IRBNet Training Energizer: New Registration Tips, that provides step-by-step instructions regarding the registration process. Also, a recording of one of the training sessions conducted prior to the holidays is available on the same webpage.

How are exempt studies being handled?

Exempt studies that were previously reviewed in the eIRB system have not been transferred to the IRBNet system. These studies do not require further review. Changes to exempt studies, such as adding or deleting study staff or minor changes to the protocol, do not require IRB review. If, however, proposed changes affect the risk level of the study and require IRB review, a new submission must be submitted in IRBNet.

How do you submit an amendment or continuing review in IRBNet?

First a review of some basic IRBNet terminology. When a new study is submitted in IRBNet, it is called a "project". At the time of a submission, a project number is assigned to the project. This number can be found at the top left corner of the site page titled "Submission

Detail" and is formatted to appear as [xxxxxxx-1]. The "1" indicates this is the initial submission. Subsequent submissions will be numbered sequentially. For example, the second submission will be assigned the project number, [xxxxxxx-2].

It is recommended that you review the documents provided in the **Forms and Template** button found on the left toolbar of your home page in IRBNet. Among those documents, you will find various Cover Sheets to be attached to subsequent submissions – there is a unique Cover Sheet for each type of submission, such as a cover sheet for continuing reviews, amendments, and reportable events. Once completed, the cover sheet document is attached to the "package" from the **Designer** page of the study record. Any additional documents related to the specific submission are added in the same manner. If there are change(s) to the information provided in the initial Prisma Health IRB Application, open this document, make the required changes and save. This will create a new version of that document and automatically attach it to the package.

This is a much different process than the previous workflows in eIRB. However, once you have completed the process a few times, you will likely find it to be a much more efficient.

More detailed information on submitting subsequent submissions can be found here.

When can the system accept new studies or amendments?
IRBNet was fully activated on January 3, 2022. All new submissions and actions on previously approved studies should be submitted through IRBNet. Please be mindful that in order to submit new actions to an existing study, you will need to complete the associated study file. This requires that all individuals that are listed on the project to have completed their user registration in IRBNet, uploaded their credentials, and linked their CITI training.

Will IRBNet provide electronic reminders for continuing reviews?
Yes, IRBNet will provide renewal notifications of expiring studies, credentials, and CITI training at 60 days prior to expiration, 30 days prior to expiration, and the day of expiration for studies.

How do I unlock a package if I forgot to attach something or left out some relevant information?
You are not able to unlock a package once submitted to the IRB. Contact the appropriate IRB Coordinator, and they will be able to unlock it and send it back so that the additional information may be provided.

Package signing: who, when, and where?

Initial "new project" submissions in IRBNet must be signed by the Principal Investigator, each Sub-Investigator listed on the project, and the Academic Vice Chair (AVC) or approved delegate.

Additional packages such as continuing reviews, reportable events, and amendments require only the Principal Investigator's signature except in the instance of amendments to add additional investigators, which must be signed by those investigators being added within the amendment. These signatures serve as the signature for the Investigator Assurance form, which must be linked to the project.

For the first package when transferring a study from eIRB to IRBNet, the signature requirement is determined by the nature of the submission as outlined above for additional packages. Should the first package submitted be an amendment adding additional Sub-Investigator(s), only the Principal Investigator and the added Sub-Investigator(s) sign the package prior to submission. Each Sub-Investigator is not required to sign the first package in IRBNet for projects transferred from eIRB except in the above noted circumstance.

Packages may be signed by the Investigators and/or AVCs by logging into IRBNet, navigating to the package needing signature, and clicking "Sign this Package" on the left side bar.

### What role should an Academic Vice Chair select when they sign an initial project submission?
Academic Vice Chairs should select "Scientific Reviewer" in the drop down box after clicking "Sign this Package" as indicated in the above question.

What do I need to link and when should I link it?
An **initial "new project" submission** requires the following items to be linked to the package:

- Principal Investigator and Sub-Investigator(s) CVs
- Investigator Assurance forms for each Investigator listed on the project to include both Principal Investigator and Sub-Investigator(s)
- CRC Assurance forms for each Clinical Research Coordinator listed on the project
- CITI human subjects protection training for all study personnel listed on the project.

Additional packages such as continuing reviews, reportable events, and amendments do not require the linkage of CVs, assurances, or CITI trainings <u>unless</u> the
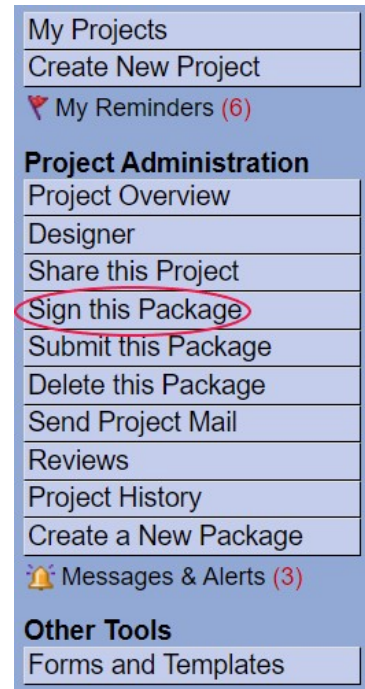
amendment in question is adding additional investigators/study personnel. If so, the applicable CVs, assurances, and/or CITI trainings should be linked in the package for the new individual(s).

For projects that were transferred from eIRB to IRBNet, follow the above linking requirements relative to the requirements for an initial "new project" submission in IRBNet. **Reminder!** For transferred projects, the first submission must contain all core documents for the project (i.e., protocol, informed consent documents, advertisements, surveys, patient materials, etc.) as well as a completed "Prisma Health - IRB application", which is generated by clicking "Start a Wizard" on the Designer page of a project.

The linking of items occurs within a project package on the Designer page. Under the table that lists the "Documents in this Package", there is a sentence referring to Training & Credentials records. Click on "Link/Un-Link Training Records" to select the appropriate records to attach to the package and then click "Save". Please note that to view available training and credential records, the project must be shared to the appropriate individual by clicking "Share this Project" and performing the necessary steps to share the project with the individual.