How do I create an account in IRBNet?

Go to www.IRBNet.org.

Click New user registration.

Create an account using firstname.lastname (this is the recommended format) as your user ID, password, and enter your email address using the aah.org email, if you have one.

Registration is not complete until you click on the link that is sent to the email address you provided to register with IRBNet.

Where can I find the RSPP forms?

Located in the menu on the left of your screen in your project is a tab for “Forms and Template”. Here you will find the library of forms you will need to complete your submission package.

How do I create my first electronic project?

When you log onto IRBNet, there will be a button to Create a New Project. Follow the instructions to create a shell with basic project information and upload documents that are saved on your computer.

You will upload documents on the Designer page by Starting a Wizard or attaching/uploading a document that is saved to your computer. See below “How can I access the IRBNet Smart forms” for information on Starting a Wizard.

You will need to select a document type using the drop box menu when you attach/upload a document.

How do I provide the RSPP with research preauthorization?

Prior to submitting a new human subject research application to the IRB, you must receive preauthorization from Research (RAPR or GME). Instructions on the research preauthorization process can be found here or by contacting the RAPR office. Once you have received research preauthorization you must upload the authorization document along with your submission to the IRB. Submissions without research authorization will not be accepted for review by the RSPP office and returned to the submitter for further action.

How do I share a project with a team member?

The team member must have an IRBNet account to share the project with them in IRBNet.

Located in the menu on the left of your screen in your project is a “Share this Project” tab. You will be asked to select the organization of the team member and then you will see a drop box menu of names. Select the team member from the drop box and provide their level of access.
There are 4 levels of access:

- **Signature Only (Read):** Users whose only role is to sign off on project documentation should be granted “Read” access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.

- **Read:** Users that are granted “Read” access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.

- **Write:** Users that are granted “Write” access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.

- **Full:** Users that are granted “Full” access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only project owners with day-to-day responsibility for the project should be granted Full access. Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the project owners. Principal Investigators and project owners (regulatory specialists) should have full access.

**Should the PI continue to have Full access in IRBNet for the life of the study for as long as he/she is the PI?**

YES, as the PI is ultimately responsible for the conduct of the study, he/she should be aware of all events related to the study. This means he/she should be aware of all Changes, Continuing Reviews, Significant New Information, Unanticipated Problem Reports, and incidents of Noncompliance being reported in the study. The IRB will communicate outcome of IRB actions using IRB Net only, and therefore the PI will only be made aware of the outcomes via IRB Net. It is expected that the PI retain their status as a ‘full’ user for the life of the study at AAH.

**How do I send project mail to team members?**

Located in the menu on the left of your screen is a tab for “Send Project Mail”. It will bring you to a screen of team members who have access to the project. Select the name of the team member and draft your message in the message box.

Messages sent from this page become part of the project record and can be viewed by the project team and other users who have been granted access to the project.

**How do I sign?**
Located in the menu on the left of your screen in your project is a tab for “Sign this Package”. You will be asked to select your project role from the drop-down menu and enter your password to confirm your identity.

**Who can sign?**

Principal Investigators (PI) are required to sign the initial package for the project. The study coordinator or regulatory specialist may sign on subsequent packages unless a PI signature is requested by the RSPP/IRB.

**How can I access the IRBNet Smart forms?**

There are two IRBNet Smart forms: The Project Summary and Delegation Log. These forms can be accessed on the Designer page. Located in the menu on the left of your screen in your project is a tab for “Designer”. Click on the button “Start a Wizard”. You may clone an existing wizard which is helpful when you are submitting a revised delegation log with a modification.

The **Project Summary** is required for every new submission application, including HSR determinations.

A **Personnel Delegation** is required for all new submission application except HSR determinations. It is also required to be updated with personnel changes.

**What forms will I need to submit?**

Each submission type requires different forms. Please review the forms themselves and/or specific guidance document for the type of documents you will need for your application.

**How do I submit my package for review?**

Located in the menu on the left of your screen in your project is a tab for “Submit this Package”. You will be asked to select the IRB from a drop box menu and select the submission type (e.g., new project, continuing review, closure, etc.).

The package will be locked upon submission. This means that you cannot make changes to it unless unlocked by the RSPP office. If you have forgotten to add or delete a document, or need to revise a document, you will need to contact the RSPP office to unlock.

Also, please note that after a package has been submitted, it cannot be deleted from IRBNet. You will need to contact the RSPP office so it can be marked as withdrawn.

**How do I manage unlocked packages?**

If the RSPP/IRB requires changes to your package, the package will be unlocked so you can modify. When it is unlocked, it will have a RED open padlock. You will receive an IRBNet email message when this occurs. After you complete the requested revisions, you need to mark revisions complete and lock the package. To indicate revisions are complete and relock the package, go to the top of the Designer page and click Mark Revisions Complete, above the red Unlocked symbol. Otherwise, the RSPP office will not know to go back to the package, and it will remain stagnant in IRBNet.

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Your “My Projects” workspace will have the projects you have created and projects that have been shared with you. On the right-hand side, you will see padlocks: unlocked in red will symbolize that revisions are required by the RSPP/IRB and locked in green means that you have completed the revisions requested and waiting for the RSPP/IRB to review your changes. The grayed out locked padlock means that you submitted it to IRBNet and the RSPP office has either not yet looked at the package for triaging, or it has been triaged and now waiting for RSPP/IRB review – nothing is needed on your end with this padlock.

**How can I find previous packages in a project?**

Located in the menu on the left of your screen is a tab for “Project History”. This will show you all the packages that have been submitted for the project and all document versions for each document type within the project.

**May I submit to multiple IRBs who use IRBNet?**

WCG IRB also uses IRBNet so you may submit to them using IRBNet after receiving authorization from the AAH RSPP to cede the research to WCG IRB. You will need to select WCG in the drop box menu.

You do not need to use Connexus anymore.

In addition, you may submit the same package to multiple IRBs. You will need to submit the package to each IRB separately as you cannot select more than one IRB in the drop box menu.

**My project has been approved, but the email from IRBNet did not include an attachment. How do I access review decisions and documentation?**

Notifications from IRBNet will not include any attachments. You will need to log onto IRBNet to download your approval document. You will find your approval documents under the tab “Reviews”, located in the menu on the left of your screen.

At the top of you will see all the packages that have been submitted under the project and the bottom shows the documents that have been published by the RSPP/IRB corresponding with each package that was submitted.

**My project is approved. How do I submit a post-approval application such as a modification or continuing review?**

Located in the menu on the left of your screen in your project is a tab to create a new package.

Do **not** start a new project each time you want to add something to the original project. All subsequent submissions should have the same 7-digit IRBNet ID that was assigned in the beginning project with the suffix increasing numerically with each package. (-1; -2; and so on).

The documents you will need to complete can be found in the library. You will need to download, complete, and save documents to your computer before you can upload to IRBNet.

**What kind of notifications will I receive from IRBNet?**

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**Project expiration** - IRBNet will send project expiration notices at 60-, 30-, 15-days prior to expiration and day of. Only users shared with Full researcher access to a project will receive Project Expiration alerts for that project. Individuals with Write or Read access can view the alert message by navigating to the Messages & Alerts page for that project, but they won't receive an email or any notifications regarding the expiration within the system.

This will be your only notification of the need for continuing review (CR). It is up to the study team to access and complete the continuing review application found in the IRB Net Forms Library. The study team is responsible for returning the completed CR application, and all necessary supplemental documents to the RSPP office in sufficient time so that the RSPP office as well as the IRB have time to review the project prior to expiration. At a minimum, you should plan on returning the CR application no less than 4 weeks prior to the last AAH IRB meeting before study expiration. If there is insufficient time for IRB review prior to study expiration, all research activities will need to be halted on the date of expiration and remain so until AAH IRB review can occur.

**Package Unlocked** - You will also receive notifications when the package is unlocked, when a message is sent using Project mail, when a determination has been entered, and when there are published documents to view.

**Training expiration** – Once your CITI program training certification is linked with IRB Net, you will receive notifications from IRBNet at 60 and 30 days prior to training expiration, as well as on the day of expiration. IRBNet will send emails to the individual named on the CITI/IRB Net account. No others will be contacted by email although notices of training expiration will appear in IRB Net for authorized study members to see. The RSPP Office will also be notified when training certification expires so that action per RSPP SOP 11 may commence.

**How do I access my projects?**

Go to the “My Projects” tab located in the menu on the left of your screen. This will show all the projects you have created and projects that have been shared with you by other users. You can use Reminders, Tags, and Archiving to help organize your workspace.

Please note that the search feature at the top allows you to search by project tags, as well as fields such as PI, key words, and the AAH IRB#.

**Can I link my CITI training to the project?**

Yes, when you are on the Designer page, you can link your training records by clicking on the button at the bottom. However, the user must first enable the linking feature to their account by updating their user profile.

**How do I change PI or study title in IRB Net?**

When a package is unlocked the study team can change the protocol details in IRBNet, including the PI name or Study Title. If you are making this type of change, revise the information in IRBNet at the time the Modification is submitted for approval.
Go to the Project Overview section. CLICK on EDIT, and then insert the correct/new information. (Example below)

Do I need to provide the PI’s CV with the application?

YES, the PI’s CV must be uploaded into IRB Net in the Designer section, step 2 section where you assemble your document package.

Request for Stand Alone Prep to Research submission-

If you are planning on submitting a standalone Prep to Research form, you will need to complete the Study Summary Wizard form. (You will NOT need to complete the Personnel Delegation Log Wizard form.) The PI will need to Sign the submission in IRBNet. (This is because there is no longer a place for the PI to sign on the 502.1 form itself, so the PI signing off on the Submission, gives us the documentation that we need.)