How-To Guide

For Researchers

VA IACUC Functions in VAIRRS

Office of the CVMO

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Contents

1. Researcher: Access IRBNet

Anyone may self-register an account -- "Researcher" access is assigned by default

{There is no vetting of Researcher accounts

Researcher account can only access projects created by this account or that have been "shared" with the account

Researcher account can submit a package to a board – the board Administrator is responsible for ensuring that the submission is legitimate before processing it}

To log in, go to https://gov.irbnet.org => IRBNet logon page

To register for a new account, click on the "Register Now" link => "Welcome to IRBNet GovCloud" page, with fields to enter:

First name: [free text field]
Last name: [free text field]
Email address: [free text field]
> *{IRBNet uses this email address as the unique identifier for each account and will not allow more than one account to be associated with a single email address. This is the address to which IRBNet sends all communications related to the account as a whole, including security (multifactor authentication, login) and recovery messages. Choose an email address that you can access even if you are not logged into the institutional network.*
> *Packages and projects are specific to institutions, and messages about them go to the email address specified separately for the affiliated institution, in the account profile.}*

Verify email address by entering again: [free text field]
Phone number: [free text field]
> *{IRBNet currently does not use this phone number, but recommends choosing a number that can receive text messages for communications about the account as a whole}*

Research institution: [select from drop-down menu – menu is specific to gov.irbnet.org]
> *{See Excel spreadsheet of station names ("VAIRRS Station Identifiers") for the names used in IRBNet for each VA city name/station number}*
> If the station you are looking for does not have a VAIRRS identifier shown, use the "add a new organization" link below the drop-down menu *{IRBNet Support monitors for duplicates and removes/merges them as necessary}*

Username: [free text field]
Password: [free text field]
> *{Hover over the blue circle with a "?" in it to see the requirements for the password}*

Verify Password by entering again: [free text field]

To activate the new account, use the link that IRBNet sends to the account email address

{If a person winds up with multiple accounts (each with a different email address), these can be merged on request from a local Administrator to IRBNet Support}

2. Researcher: Edit Account Profile

Click "USER PROFILE" in banner at the top of any page => "User Profile" page

<u>Account Information and Password</u> -- to edit, click on "Update" link => page showing all the profile fields, for editing

"Recovery Email" is grayed out – to edit, click on "Update" link => confirmation window
{The Recovery Email address is for the account as a whole}

Click "Cancel" in the confirmation window to avoid removing the existing Recovery Email address

To remove the existing Recovery Email address, click "Continue" *{This removes the existing Recovery Email address}* => a window with fields to enter and confirm a new Recovery Email address
{The previous Recovery Email address has been removed by the time this window appears, so clicking "Cancel" in this window only logs the account out; it does NOT restore the previous Recovery Email address – subsequent attempts to log onto the account return to the window for entering and confirming a new Recovery Email address}

<u>Affiliations</u>

To add a Researcher affiliation to another station, click the "Add an Additional Affiliation" link in the "Affiliations" section of the "User Profile" page => "Add Affiliation" page
Select from the dropdown menu of stations
{See Excel spreadsheet of station names ("VAIRRS Station Identifiers") for the names used in IRBNet for each VA city name/station number}
If the station you are looking for does not have a VAIRRS identifier shown, use the "add a new organization" link below the drop-down menu *{IRBNet Support monitors for duplicates and removes/merges them as necessary}*
To activate the new affiliation, respond to the email sent to the Recovery Email address

To edit the contact information for an existing affiliation, click the "(Edit)" link for that affiliation => the "Contact Information" for that affiliation
Telephone Number: [free text field *{any characters, any format}*]
Fax Number: [optional free text field]
Email: [free text field] *{This is the address to which messages specific to this affiliation are sent. The same email address may be provided for more than one affiliation. This address is maintained separately from the Recovery Email address.]*

To deactivate a particular affiliation, click the "(Deactivate)" link

{This immediately deactivates (without any confirmation window), so the account can no longer access anything at that affiliation. The institution is still displayed, and the "(Edit)" link remains active}

To re-activate an affiliation that has been de-activated, click the "Send me an activation email" link => an email is sent to the Recovery email address for the account

Respond to the email to re-activate the affiliation

<u>External Accounts</u> *{this is for external training accounts}*

Click the "Add an External Account" link in the "External Accounts" section of the "User Profile" page => "Add External Account" window

Account Type: [select from menu]

{CITI Training Program is currently the only external account available for linking in IRBNet}

CITI Member ID: [field accepts 5-8 digits]

{this is the number under the learner's name, at top of the CIITI home page}

Follow validation instructions sent to the Recovery email to address associated with the CITI account to make "Status" of external account change from "un-verified" to "verified"

External account is displayed in table

<u>Training & Credentials</u> *{this is for manually adding individual documents designated as "training and credentials records" to the account}*

To add training records manually to the profile, click the "Add a New Training & Credentials Record" link in the "Training & Credentials" section of the "User Profile" page

{IACUC Administrator can edit all Researcher entries and correct as necessary}

If any record has already been added, the option is provided for the new record to be added as an updated version of a previously added record

For any training record, enter the following information

Document Type: [select from menu]

{Menu for a Researcher includes all options that a board administrator has granted Researcher access to, for any board at any station with which the Researcher is affiliated.}

IRBNet Standard Types *{None are required for VA IACUCs, so all IACUC Standard Types have been set to "inactive" by default}*

Other *{Options provided by IRBNet, cannot be inactivated}*

Custom *{Options customized for the institution – this is where "Types" for CITI courses and ALL courses appear}*

{Choose the Document Type that seems most appropriate – Researchers cannot add new Types, but the IACUC Administrator can add new Custom types and change the "type" for a document later, if necessary}

Description: [optional free text description]

Credits/Credit Hours (if applicable): [optional free text number of up to 5 digits, with up to two decimal places]

Effective Date: [select from calendar]

Expiration Date: [optional, select from calendar]

File: [select from browser]

Training records that have been added to the account are displayed in table below the "Add a New Training & Credentials Record"

To view a training record, click the Document Type link OR the "sheet of paper" icon for that record

The Status column reflects the processing of each record

"not submitted" *{record has not been made available to any board yet}*

To make the record available to a board for board tracking purposes, do one of the following:

Click "submit" => "Submit training & Credentials" page *{displays each board to which record has already been submitted}*

Select a board [drop-down menu]

Click the "Continue" button

OR link the record to a package and submit the package to a board

After a record is submitted to at least one board

To see the board that a Status refers to, hover over the Status link for the record *{the board is displayed only if the record has been submitted}*

To see history of board actions on a training record, click the "Status" link for the record => "Training & Credentials: Board Status"

"pending review" *{record has been submitted to a board, but no board administrator has acted on it yet}*

{By default, if a training record is submitted to more than one board, its "Status" for all boards will change from "Pending Review" to whatever the first board administrator changes it to. After that, status changes

made by any board Administrator only affect the status for that Administrator's board}

"deferred" *{Administrator has acknowledged receipt, deferred to another board to decide whether the record is acceptable}*

"accepted" *{information about the record may have been edited by Administrator before accepting it}*

"rejected" *{Administrator rejected – remains displayed, and can be opened, but designation as "rejected" indicates that Administrator has found it not applicable}*

"submitted" *{Administrator submitted record to another board}*

3. Researcher: View Information about a Project

To access the projects available to the Researcher (the projects that the Researcher created as well as the projects created by others who have shared them with this Researcher), go to the "My Projects" page by either of the following:

> Log in *{"My Projects" page is the page that opens by default}*
>
> OR click "My Projects" in the sidebar menu

"My Projects" page displays existing projects

> Narrow the list by entering search criteria
>
> > "Search" for text string [free text field] *{searches in the fields that are required for any project to be created:*
> >
> > > *"Project Title"*
> > >
> > > *"PI first name"*
> > >
> > > *"PI last name"*
> > >
> > > *"IRBNet ID" – generated on creation of the project}*
> >
> > "Search by Tag" [select from menu of project Tags -- see "Researcher: Manage a Project" for information on creating and assigning tags]
> >
> > > *{searches for projects with the tag selected}*
>
> Click "Search" button

To open a specific project, click on one of the following to => "Project Overview" page

> The "Project Title" on the "My Projects" page
>
> OR the "Project Overview" button in the sidebar menu *{appears when the Researcher has navigated to a different page of the project}*

To view the project information, click "Edit" link above project information on the "Project Overview" page => "Project Information" page, which shows:

> *Institution
>
> *Title
>
> *First Name *{of Principal Investigator}*
>
> *Last Name *{of Principal Investigator}*
>
> Degree(s) *{of Principal Investigator}*
>
> Keywords
>
> Sponsor
>
> Internal Reference Number
>
> (*required)

To view the status of the project for each board to which a package of the project has been submitted, go to the table below "Project Status" on the "Project Overview" page

> For more details about board reviews, click "Reviews" button in the sidebar menu *{only shows for projects that have been submitted for review}* => "Reviews" page *{displays information for each board separately}*

Table of "Reviews" *{information on the submission and board actions for each package}*
Table of "Board Documents" *{documents uploaded by board Administrator}*
To download a board document, click on the entry under "Document Type" OR click the "page" icon under "View"

To view user access to this project, see the table below "Shared" on the "Project Overview" page

To see the history of the project, click "Project History" button in sidebar menu => "Project History" page

To choose the board of interest (or all boards), select the "Reviewing Board" from the drop-down menu
To switch the view between focusing on the board action taken and focusing on the project status, click on the "Board Action View" / "Project Status View" toggle link above the upper right corner of the table
To switch between a display of the result of the most recent action on each package and a display of all actions taken on each package, click on the "Collapse All" / "Expand All" toggle link above the upper right corner of the table
To get information about a package, click on the Submission Type for the package of interest (either view) => "Designer" page for that package

To see messages associated with this project, click "Messages & Alerts" link below the "Project Administration" buttons in the sidebar menu => "Project Messages & Alerts" page
To turn on/off a flag for Researcher's own attention to any item, click the "flag" toggle icon
{does not affect flags for others who may access the project}
To see contents of message, click the "Message Type" for that item => "Message" window
To see information about the project, click the "Project Title" for that item => "Project Overview" page

To access Audit Reports specific to a project, click the "Project Overview" button in the sidebar menu from any package of the project for which an Audit Report was submitted => "Project Overview" page
{allows access to all packages for the project, including Audit Reports}
{Audit Reports specific to a project are submitted as packages to the IACUC by the RCO – include findings, notes, attached documents, board response}

4. Researcher: Manage Projects

To manage the projects displayed on the "My Projects" page

To archive projects that do not require attention
To archive, click on "folder with green 'down' arrow" icon in Project Title column => window to confirm that project is to be archived
Click "Continue" => project will be removed from display of active projects unless there is a Reminder for any package in the project
To see archived projects, click "Show Archived Projects" / "Hide Archived Projects" toggle link above the table

To un-archive, click on "folder with red 'up' arrow" icon in Project Title column when Archived Projects are shown => window to confirm that project is to be un-archived
Click "Continue" => project will reappear in display of active projects

To create tags for projects *{color-coding to organize projects}*, click "Create and Manage Tags" link above the top left corner of the table => "My Tags" page
To name a tag, enter in "Create New Tag" box [free text field]
{Describe what this tag will indicate}
To assign a color to the tag, choose from [drop-down menu of 15 colors]
To save the tag as created, click "Create New Tag" button => Tag appears in table
To remove a tag from all projects and delete it from the table, click the "X" icon
To assign a tag to a project, click on ⊞ in the Project Title column on the "My Projects" page => "Add and Remove Tags" window
Click on the radio button to edit the status of each tag
{personal tag is only visible to the account that created it;
shared tag is visible to all accounts with which the project is shared –
project tags may be shared/removed only by accounts with Full or Write access}
To use the reminder flags *{far left column of the My Projects table, these flag items for the attention of the account owner}*,

{Each new message is flagged by default when it is received
The project flag is turned on, on the "My Projects" page, for each project with at least one flagged message
Each message flagged on the "Project Messages & Alerts" page is displayed on the "My Reminders" page}

Click a flag for a project => "Project Messages & Alerts" page for that project, with a table of all messages and alerts that have been posted for any package of the project

To see information about the project, click the link in the "Project Title" column => "Project Overview" page

To see a message, click on the link in the "Message Type" column => "Message" window, with "Reply" link

To turn personal reminder on/off for any one message, click on the "flag" icon toggle in the far left column

{Each message with the "flag" icon on (red) is displayed in the "My Reminders" table of messages for all projects
Each message that was "silenced" (the "flag" icon is gray) within the last 30 days is only displayed in the "My Reminders" table if "Show Silenced Reminders" is selected
Status of personal reminders has no effect on the flags for other accounts}

To see flagged messages for all projects, as well as Researcher-specific alerts, click the "My Reminders" link just above the "Project Administration" buttons in the sidebar menu => "My Reminders" page

To see information about the project, click the link in the "Project Title" column => "Project Overview" page

To see a message, click on the link in the "Message Type" column => "Message" window, with "Reply" link

To turn personal reminder on/off for any one message, click on the "flag" icon toggle in the far left column

To create a new project, click the "Create New Project" button in the sidebar menu => "Project Information" page
{Anyone with Researcher access can create a new project}

Enter Project Information *{An IRBNet Wizard can pull this "Project Information" into documents created by the Wizard – e.g., the "VA - Project Cover Sheet"}*
Research Institution: [drop down menu of institutions that the account is affiliated with]
Title: [free text field]
Local PI: *{May be a name other than the name on the account creating the project in IRBNet}*
First Name: [free text field]
Last Name: [free text field]
Degree(s): [optional free text field]
Keywords: [optional free text field]

Sponsor: [optional free text field]

Internal Reference Number: [optional free text field] *{This identifier is associated with the project as a whole, and is a field that can be searched by Administrators when filtering submissions.}*

Click "Continue" button => "Designer" page to edit the first package for this project

{For details, go to the "Researcher: View Information About a Package" and "Researcher: Manage a Package" sections, below}

To manage the specifics of any one project, click on the Project Title of interest => the corresponding "Project Overview" page

To view/edit the project information, click "Edit" link above project information on the "Project Overview" page => "Project Information" page, and edit the entries for:

Research Institution [drop down menu of institutions that the account is affiliated with]

Title [free text field]

Local PI: *{May be a name other than the name on the account creating the project in IRBNet}*

First Name [free text field]

Last Name [free text field]

Degree(s) [free text field]

Keywords [optional free text field]

Sponsor [optional free text field]

Internal Reference Number [optional free text field]

To manage the permission of users to access this project, click on one of the following to => "Share Project" page

"Shared" link above the table of users on the "Project Overview" page,

OR the "Share this Project" button in the sidebar menu

OR a name in the table of users *{only to edit access of accounts at the station where the project was created}*

{The account that created the project always has "Full" access, and is considered a "Project Owner"}

{This function is only available to, and displayed for, accounts with "Full" access – may be used at any time (before or after any submission, regardless of signatures}

{Projects are generally shared with all members of the study team – so they can at least see, and possible help edit, projects that they are named as participants on

IRBNet does not cross reference the accounts with which a project is shared against the names entered into the "VA - Project Cover Sheet" document – so a study team member identified on that document will not have access unless someone with "full" access shares the project with that member

Projects may also be shared with others who need to see the project even though they are not members of the study team -- e.g., the director of a core facility that will provide services for the project}

To edit the access of users at the station where the project was created, click on the name of any user shown in the table on the "Project Overview" page => "Share Project" page showing a table of all the users at the same station
> *{the user who created the project is always assigned "Full" access, and is not shown}*

> To specify the level of access for each account, click the radio buttons
>> Full *{no constraints, intended for "project owners"}*
>> Write *{edit or sign, but not manage access, submit, or perform other administrative functions}*
>> Read *{read-only, and sign}*
>> No Access *{default}*
>> *{Each user granted access will receive email notification}*

> To include comments in the notification to be sent to each user who is granted access, enter in the "Your Comments" free text field

> To notify each account that it has been granted access, click "Save" button

To grant access to users at other institutions, click one of the following on the "Project Overview" page => "Share Project" page showing links for sharing options and a table of those with whom the project is currently shared
> "Shared" link above the table of users on the "Project Overview" page,
> OR the "Share this Project" button in the sidebar menu

> To share the project, click the "Share" link on the "Share Project" page => window for identifying the users to be granted access

> Choose the organization with which the users are affiliated, in the menu displayed for "Select an Organization"
> Then click the "Select Organization" button => display of accounts at the selected institution

> To specify the level of access for each account, click the radio buttons
>> Full *{no constraints, intended for "project owners"}*
>> Write *{edit or sign, but not manage access, submit, or perform other administrative functions}*
>> Read *{read-only, and sign}*
>> No Access *{default}*
>> *{Each user granted access will receive email notification}*

To include comments in the notification to be sent to each user who is granted access, enter in the "Your Comments" free text field

To notify each account that it has been granted access, click "Save" button

To create an independent copy of the project to be managed by a local site PI at another site, click the "Multi-site" link on the "Share Project" page => "Multi-Site Project" page
{Each local site PI can edit the copy of the project for the local site, has access to all project documents at the primary site, and can monitor progress at each of the other sites}

Choose the organization with which other local site PI is affiliated, in the menu displayed for "Select an Organization"
Then click the "Select Organization" button => window with drop-down menu of accounts at the selected institution

To select the local Site PI, click on that user in the drop-down menu at "Select a User"

To include comments in the notification to be sent to the selected local site PI, enter in the "Your Comments" free text field

To notify the selected local site PI that access has been granted to a copy of the project, click "Save" button

To pass ownership of the project to another account, click the "Transfer" link on the "Share Project" page => "Transfer Project" page
{The account making the transfer relinquishes all access, and grants "full" access to the recipient.
Others with access before the transfer will continue to have the same access afterward.
Administrative oversight depends on where the packages are "submitted", and also does not change.}

Choose the organization with which recipient of the transfer is affiliated, in the menu displayed for "Select an Organization"
Then click the "Select Organization" button => window with drop-down menu of accounts at the selected institution

To select the recipient of the transfer, click on that user in the drop-down menu at "Select a User"

To include comments in the notification to be sent to the recipient of the transfer, enter in the "Your Comments" free text field

To notify the recipient of the transfer that access has been transferred, click "Save" button

To correspond with Researchers with whom the project has been shared, or Administrators for boards to which the project has been submitted, click the "Send Project Mail" button in the sidebar menu => "New Project Message" page

{Any account with access to a project (Full, Write, or Read) may send Project Mail Messages are archived with the project record}

Use checkboxes to select recipients

Enter Subject [free text field] *{default text is provided, but may be freely edited}*

Enter text of Message [free text field] *{default text is provided, but may be freely edited}*

To send the message, click "Send" button

To manage the contents of the packages in the Project, click on one of the following to => "Designer" page

"Designer" link just below the Project Information on the "Project Overview" page

OR the "Designer" button in the sidebar menu

5. Researcher: View Information about a Package

To access the Researcher's own projects, go to the "My Projects" page by either of the following:
> Log in *{"My Projects" page is the page that opens by default}*
> OR click "My Projects" in the sidebar menu

To open the specific project of interest, click on project title on the "My Projects" page => "Project Overview" page displaying the latest package by default

To see package information, go to "Submitted To" table on the "Project Overview" page

> To choose the package of interest, go to the tools above the upper right corner of the table
>> Use the "Package [number] of [total number]" arrows to select the package of interest
>> OR click "Jump" link and select from drop-down menu

> To see specifics about each submission of the package, click "Review Details" link for that submission in the "Submitted To" table => "Review Details" page
>> Submitted By *{shows who submitted the package, apart from whoever might have signed it}*
>> Details about the review process for each board
>> Board documents attached by each board

> For more details about board reviews of all packages, click "Reviews" button in the sidebar menu => "Reviews" page
>> *{displays information for each board separately}*
>> Table of "Reviews" *{information on the submission and board actions for each package of the project}*
>> Table of "Board Documents" *{documents uploaded by board Administrator}*
>>> To download a board document, click on the entry under "Document Type" OR click the "page" icon under "View"

To view the contents of a package, click on one of the following to => the "Designer" page
> Click "Designer" link on Project Overview page
> Click "Designer" tab under "Project Administration" in the sidebar menu

To choose a different package to view, click the blue triangle next to the package ID at the top of the "Designer" page => menu of all of the existing packages for the project

Information available from the "Designer" page:

> Lock Status of the package is displayed at the right of the same line as the package number
>> *{shown only if package has been submitted}*

Black "closed padlock" icon *{package was locked on submission or relocked by Administrator (without indicating anything about revisions)}*
Red "open padlock" icon *{package has been unlocked by Administrator}*
Green "closed padlock" icon *{package has been re-locked by the Researcher after completing revisions}*

To see the history of locking and unlocking, click "View History" tab to the right of the Lock Status => "Lock History" table for this package
{Link shows for any package that has been locked at least once
Shows any message entered by person who locked or unlocked it}

Package Description in free text field below package ID
{Even if the package is locked, may be edited by
Researcher with "Full" or "Write" access
Administrator}
{Displayed for Reviewers, but Reviewers may not edit}

Click "Review details" link just below the Package Notes field => "Review Details" page for this package
{Displays details of submissions of this package to any board}
{"Reviews" button under "Project Administration" in the sidebar menu shows review details for all packages of this project}

"Documents in this Package" table shows for each document included in the package

Last Modified *{time and date of last modification of the document – hover cursor over the time and date to see the name of the account that made that modification}*

Icons for view actions:
"Page" icon *{opens the document for viewing}*
"Stack of papers" icon => "Document Revision History" table
{Does not show the name of the account that made each modification
To see the account responsible for earlier revisions, use the "blue down triangle" next to the package number at the top of the "Designer" page, to open the list of packages, and click on the package corresponding to the revision of interest, where the earlier revision was the "Last Modified" version in the "Documents in this Package" table.}

To see training documents attached to the package, click on one of the following to => "Linked Training & Credentials" table *{Visible only if there is at least one training record linked to the package}*

"[n] Training & Credentials records linked to this package" just below the table of "Documents in this Package" on the "Designer" page *{[n] is number of records linked}*, to see records linked to this package

OR "View All Links" link on the "Designer" page, to see all training records linked to any package of this project

To switch the "Linked Training & Credentials" table between a display of all records linked to this package and a display of all records for all packages in this project, click the "Show Package Y Only" / "Show All Packages" toggle link on the "Linked Training & Credentials" table

Documents from Previous Packages that you can Revise *{Shows documents attached to previous packages of this project, that may be revised and attached to this one. Visible only if there is at least one such document.}*

6. Researcher: Manage a Package

To access the Researcher's own projects, go to the "My Projects" page by either of the following:
　　　　Log in *{"My Projects" page is the page that opens by default}*
　　　　OR click "My Projects" in the sidebar menu

To open the specific project of interest, click on project title on the "My Projects" page => "Project Overview" page displaying the latest package by default

To initiate work on a new package, choose one of the following options to => the "Designer" page
{Default is to have only one "work in progress" package in a project, with a new package being created only if all previous packages have been submitted and are locked}

　　　　Click the "Create a New Package" tab in the sidebar menu under "Project Administration"
　　　　　　{displayed only when all existing packages for the project have been submitted and are locked}

　　　　OR click the "Designer" link on the "Project Overview" page, or the "Designer" tab in the sidebar menu under "Project Administration"
　　　　　　Click the blue triangle next to the package ID at the top of the page => menu of all of the existing packages for the project, with "Create a New Package" option at the bottom of the list
　　　　　　{displayed only when all existing packages for the project have been submitted and are locked}

　　　　OR if any existing packages has not been submitted yet, or has been submitted but then unlocked, address what needs to be addressed and re-submit them, to lock them again, then use one of the above mechanisms to create a new package

　　　　OR ask an Administrator to create an additional "work in progress" package for the researcher to assemble documents in, even if there is another package for this project that hasn't been submitted yet or has been unlocked after submission.

To select an existing package to manage, scroll through "Package [1-n] of [n]" OR choose from "Jump" [drop-down menu] above the upper right corner of the "Submit To" table on the "Project Overview page", and click on a package

To edit an existing package, click on one of the following to => the "Designer" page
　　　　Click "Designer" link on Project Overview page
　　　　Click "Designer" tab under "Project Administration" in the sidebar menu
　　　　{Researchers with "Full" or "Write" access may edit the package
　　　　Researchers with "Read" access may only view (not edit) the package}

To choose a different package to edit, click the blue triangle next to the package ID at the top of the "Designer" page => menu of all of the existing packages for the project

To re-lock an unlocked package and alert Administrator of re-submission, click "Mark Revisions Complete" link above lock status on the "Designer" page => "Mark Revisions Complete" window

> *{Link is visible only if a submitted package has been unlocked by the Administrator, for revision by the researcher}*

Option to enter a message about this action [free text field]

To complete the action, click "Continue" => lock status updated to "Locked – Revisions Complete"

To enter/edit Package Description, click in free text field below package ID on the "Designer" page

> *{Even if the package is locked, may be edited by*
>> *Researcher with "Full" or "Write" access*
>> *Administrator}*
> *{Displayed for Reviewers, but Reviewers may not edit}*

To get blank forms, document templates, and reference materials made available by the local board in a local board library *{These are the starting point for preparing documents outside of IRBNet, for attaching to a package.}*

Click "Need Forms? Show Form Libraries" / "Hide Form Libraries" toggle link at the right margin below the "Review Details" link on the "Designer" page => Step 1 fields

Select the Library of interest from the drop-down menu {specific to institution and board – loaded on request by station}

Select the file of interest to download *{options in drop-down menu may include blank forms, templates, and reference materials}*

Click "Download" button => file is downloaded by browser, with option to open or save

OR click the "Forms and Templates" button under "Other Tools" in sidebar menu => "Forms and Templates" page

Select the Library of interest from the drop-down menu {specific to institution and board – loaded on request by station}

"Documents in this Library" table displays the options available

To download the option of interest, click on the Document Description or the "page" icon for that option => file is downloaded by browser, with option to open or save

{list of Wizards available is also listed for reference}

To add an existing document to a package, click the "Attach New Document" button at the bottom of the "Designer" page => File Explorer

> Select one or more saved existing files from File Explorer => file(s) is(are) added to the table of "Documents in this Package"

To create a document with a Wizard, click "Start a Wizard" button => [drop-down menu of available Wizards]

> Click one of the Wizards in the menu => "IRBNet Document Wizard" page for that Wizard
>
>> *{"VA - Project Cover Sheet Wizard" is required by VA for every project}*
>
> If the account contains any document has already been created with this Wizard, choose:
>
>> "clone one of my existing wizards" => table of existing documents from this Wizard
>>
>>> *{a way to make multiple versions of the existing document, each edited as needed}*
>>
>> "create a new wizard from scratch" => starts the Wizard for a new document
>
> Respond to the items in the Wizard
>
>> *{Project Information is prefilled into the Wizard as needed*
>> *Information may be entered into a Wizard by any account with "full" access – this information is stored in the Wizard document, but is not accessible for other uses in IRBNet}*
>
> Click "save" => document is added to the table of "Documents in this Package", with the name of the Wizard shown as the "Document Type"

To add a document to the current package that is a revision of a document that was submitted in an earlier package, click pencil icon in the "Documents from Previous Packages that you can Revise" table on the "Designer" page *{displayed only if there is an earlier package with documents in it}*

> Documents that were attached as files
>
>> *{Only documents in previous packages for this project will be displayed*
>> *Designating an attached file as a "revision", documents how it is related to the previous one, even though IRBNet does not check for correspondence between the files attached}*
>
> Documents that were created by Wizards
>
>> *{Documents in previous packages for any project will be displayed*
>> *Wizard creates a copy for editing – the copy contains the information of the previous version, so this is a way to make a new document that is largely the same as the previous version, with just a few changes}*

To edit an attached document, click on the "pencil" icon in the "Documents in this Package" table on the "Designer" page =>

> "Attach Document" page for an attached document created outside of IRBNet

Document Type *{document type for the current version is shown, select from drop-down menu}*
Description: [free text field]
File: Select a from File Explorer *{This file will be managed as a revised version of what was previously uploaded for this document, although IRBNet does not check for correspondence between the files}*
Click "Update" button => save new version

> *{For a package that has not been submitted yet, the new version replaces the previous version, which is not archived or shown in document history*
> *For a package that has already been submitted, the new version is added to the document history, with the previous version archived}*

"IRBNet Document Wizard" page for an attached document created with a Wizard
For a package that has not been submitted yet => current Wizard document opens for further editing

> *{The revised version replaces the original version, no copies of earlier versions are archived or shown in the document history}*

For a package that has already been submitted => Wizard makes a copy of the submitted version and opens the copy for editing

> *{The submitted version is maintained in the document history, and the new copy becomes the working version}*

To remove an attached document, click on the "X" icon in the "Documents in this Package" table on the "Designer" page => confirmation window => document is removed from the table

To edit summary information about "Documents in this Package" on the "Designer page

To change the "Document Type" for a document, click the blue triangle in front of the "Document Type" shown => [drop-down menu of options available for "Document Type"]

> *{Blue triangle does not show for Wizard documents}*
> *{Most of the options do not apply to packages being prepared for submission to the IACUC.}*

Abstract/Summary
Action Plan *{corrective actions to address concerns raised}*
Adverse Event Report *N/A for IACUC package}*
Advertisement *{N/A for IACUC package}*
Amendment/Modification
Application Form *N/A for IACUC package, use "Proposal" instead}*
Budget *{N/A for IACUC package}*
Child Assent *{N/A for IACUC package}*
Closure/Final Report *{not a regulatory requirement, but may be a local requirement}*

Confidentiality/Non-Disclosure *{N/A for IACUC package}*
Conflict of Interest – Declaration *{N/A for IACUC package}*
Conflict of Interest – Management Plan *{N/A for IACUC package}*
Conflict of Interest – Other *{N/A for IACUC package}*
Consent Form *{N/A for IACUC package}*
Consent Waiver *{N/A for IACUC package}*
Continuing Review/Progress Report
Cover Sheet *{N/A for IACUC package}*
CV/Resume
Data Collection *{N/A for IACUC package}*
HIPAA Consent/Authorization *{N/A for IACUC package}*
HIPAA Waiver *{N/A for IACUC package}*
Investigator Agreement *{N/A for IACUC package}*
Investigator's Brochure *{N/A for IACUC package}*
Letter
Other *{e.g., local standard procedure/policy, signed certification pages, documentation -- PHS Assurance, AAALAC accreditation, and IACUC approval -- for work done by a vendor under a fee-for-service arrangement}*
Proposal
Protocol *{Include separate appendix files in this Document Type as well}*
Protocol Deviation/Violation Report *{N/A for IACUC package}*
Publication Materials *{N/A for IACUC package}*
Questionnaire/Survey *{N/A for IACUC package}*
Reportable Event (Non-AE) *{use for any self-report of a potentially reportable matter, "Adverse Event" terminology does not apply to IACUC}*
Study Plan *{N/A for IACUC package}*
Training/Certification *{Instead of linking training records via the "Link Training & Credentials" page, they may be attached to a package simply as documents, but this does not allow IRBNet to track them as training or credentials}*
Unanticipated Problem Report *{N/A for IACUC package}*

To edit the "Description" of the document on the "Designer" page, click on the field in the Description column => [free text field]

To change the training records linked to the package, click the "Link / Un-Link Training Records" link below the "Documents in this Package" table on the "Designer" page => "Link Training & Credentials" page

{"Link/Un-Link Training Records" link appears only for accounts with Full or Write Researcher access to the project}
{"Link Training & Credentials" page displays a table of all Training Records associated with each account with which the project has been shared, including both training records attached to profile and records downloaded from CITI}

Check the "Link" checkbox for each item relevant to this package *{this attaches the training record to the package}*

{Training records may also be added simply as documents attached to the package, but such files will not be recognized by IRBNet for managing and tracking as training documents}

{Optional for VA IACUC} To certify that information in a package is accurate and complete, click the "Sign this Package" button in the sidebar menu => "Sign Package" page

> *{For the VA IACUC functions, VA has no requirements for packages in IRBNet to be signed, personally by any Researcher or on behalf of anyone else.*
> *Signing the Package only certifies that the information in the package is accurate and complete, nothing else, so a package signature does not substitute for any of the signatures needed on certification statements for the final, IACUC-approved version of the ACORP.}*

> *{Any account with access to a package may sign it, at any time.*
> > *The time and date of the signature are recorded.*
> > *The package can be submitted, unlocked, and changed after it is signed. It is up to those looking at the package to decide whether any given signature applies to the version under consideration.*
> > *Anyone who can sign may designate the signature as "on behalf of" someone else -- There is no mechanism for documenting delegation of authority to sign on behalf of the other person.*
> > *The name of a person on whose behalf a package is signed is entered into a free text field and does not have to be related to any IRBNet account.}*

To submit a package to a board, click the "Submit this Package" button in the sidebar menu => "Submit Package" page *{This function is available to, and is displayed for, only accounts with "Full" access.}*

> "Select a Board" to which to submit the package [menu of possible boards provided]
> > *{For initial submission of any new project, Researcher always selects "Research Administration" board (not the IACUC). The local Research Administration is displayed as the default option.]*

> > *{Subsequent submissions related to the same project may go directly to the IACUC.}*
> > To see all boards, uncheck "Only show My Default Boards" option
> > > Select from full menu of possible boards

> > To submit to the CVMO board, submit to the local IACUC *{Only the IACUC Administrator can submit to the CVMO board, Researchers cannot submit directly to the CVMO board}*

> > To proceed with submission, click "Continue" button => statement about signatures

Click checkbox for "I certify that all required electronic signatures have been added to this package", then click the "Continue" button

{For the ACORP, there is no VA requirement for the package to be signed electronically in IRBNet before submission, so package may be submitted without any signatures applied via the "Sign this Package" function. Signatures required for the ACORP are for the certification statements within the ACORP, which are submitted as attached documents.}

Enter a "Submission Type" [menu of options specific to the board] *{This is just for the convenience of the Administrators listed above the "Submission Type" field. The type provides an indication of why the package is being submitted; it has no effect on any functions for submission. The menu is the same for "Research Administration" and for "IACUC"}*

Amendment/Modification
Closure/Final Report
Continuing Review/Progress Report
Facility Inspection/Program Review *{N/A for submission of packages, which are project-specific}*
Funding/Grant *{N/A for submission through Research Administration to IACUC}*
New Project
Other
Publication *{e.g., submission of package to request to publish images/video, for IACUC's awareness / review}*
Reportable Event *{submission of a self-report of a potentially reportable matter related to a specific project}*
Response/Follow-up *{submission of correspondence related to RMSA or potentially reportable matter related to a specific project}*
Revision
Triennial Review

Enter "Your Comments" [free text field]
{information to include in the notification of the Administrators for the receiving board, about the submission}

To finalize the submission, click "Submit" button
{Package is locked on submission}

To remove a package from IRBNet, click the "Delete this Package" button in the sidebar menu => warning that "Deleted packages cannot be recovered"
{This function is available to, and displayed for, only accounts with "Full" access.}
To confirm that package is to be deleted, click the "Delete" button

{Only the last package to be created for a project can be removed, and only if that package has not yet been submitted to any board.}
For packages that have not yet been submitted => warning that deleted packages cannot be recovered

Click "Cancel" => "My Projects" page
Click "Continue" => package is deleted
For other packages => message that only packages that have not been submitted can be deleted
Click "Cancel" => "My Projects" page