How-To Guide

For IACUC Reviewers

VA IACUC Functions in VAIRRS

Office of the CVMO

29 November 2023

IACUC Reviewer: Contents

Contents

| 1. | IACUC Reviewer: Access IRBNet | |
|----|-------------------------------------------------------|----|
| 2. | IACUC Reviewer: Edit account profile | |
| 3. | IACUC Reviewer: Access a Package Submitted for Review | |
| | IACUC Reviewer: Work with a Project | |
| 5. | IACUC Reviewer: View a Package | 14 |
| 6. | IACUC Reviewer: Review a Package | 2 |

IACUC Reviewer: Access IRBNet

1. IACUC Reviewer: Access IRBNet

Those who are to have IACUC Reviewer accounts are identified by the station and the accounts are set up by IRBNet Support

{The list of IACUC Reviewers maintained in IRBNet for a station is edited by IRBNet Support according to instructions from (from least to greatest authority):

Local IACUC administrators
Local administrators of other IRBNet boards
The local ACOS (identified by ORPP&E)
ORPP&E (holder of VA's account with IRBNet)

Those on the list of IACUC Reviewers should include:

All appointed voting (regular and alternate) IACUC members ("Committee Members")

Others who may be expected to review protocols, even though they are not authorized to vote}

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

2. IACUC Reviewer: 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 change this, 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}

Affiliations

To add a Researcher affiliation to another institution, click the "Add an Additional Affiliation" link in the "Affiliations" section of the "User Profile" page => "Add Affiliation" page {Administrator and Reviewer affiliations can only be added by IRBNet Support.}

Select from the dropdown menu of institutions

{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 => "Your Contact Information" form 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

External Accounts {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 in IRBNet for linking}

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

{this is the number under the learner's name, at top of 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

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 an IACUC Reviewer includes all options designated for Reviewers to have access to, for any board at any institution with which the account has a Reviewer affiliation.}

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 course appear}

{Choose the Document Type that seems most appropriate – Reviewers 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: [optional, select from browser]

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

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" {item has not been made available to any board yet}

To make the record available to a board for board tracking purposes, 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

After a record is submitted to at least one board

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

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

"pending review" {item has been submitted to a board, but no board Administrator has acted on the item 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 record is acceptable}

"accepted" {information about the record may be edited by an Administrator, record is designated "accepted" when an Administrator clicks "save"}

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

"submitted" {an Administrator has submitted the record to another board}

3. IACUC Reviewer: Access a Package Submitted for Review

{IACUC Reviewer receives notification of any submission to which the IACUC Administrator has assigned the IACUC Reviewer}

{"Submission Manager" page is displayed on login.}

To get back to the "Submission Manager" page from within any project, click "Submission Manager" button in sidebar menu => "Submission Manager" page

To filter the list of submitted packages, enter selection criteria on "Submission Manager" page

To identify the board {IACUC} that received the submission of interest, select from the [drop-down menu] for "Submissions for"

To search for character strings, enter free text in "Search All" or "Search" {The fields to be searched are those in the Project Information:

Project Title – from "Project Information" entered by Researcher

PI Name – from "Project Information" entered by Researcher

Keywords – from "Project Information" entered by Researcher

Sponsor – from "Project Information" entered by Researcher

Internal Reference Number – from "Project Information" entered by Researcher

Board Reference Number – entered by IACUC Administrator on "Submission Details"

page, specific to the IACUC}

To limit the search to submissions that meet additional criteria, enter the criteria in the blue rectangle

Choose an "Agenda" [dropdown menu] {scheduled IACUC meeting dates for which submissions have been assigned to the agenda}

Check checkboxes for status of submission
"awaiting Board action"
"Review Completed"

Enter "Search" text {searches the same fields as "Search All" above the blue rectangle, but applied only to submissions that meet the other criteria selected}

Choose a tag for "Search By Tag" [drop-down menu of tags that have been created]

{Searches by one tag at a time – tags are created and assigned to packages by an IACUC

Administrator}

Table of Submissions displays all submissions that meet the selected criteria – different views of the table are selected from the menu at the upper right of the table:

Board action View Project status view Review Assignments View

Audit Status View {information about audit reports submitted by the RCO to the IACUC} All-Boards Audit View {information about audit reports submitted by the RCO to any board}

Click on the Project Title for the package of Interest => "Submission Detail" page {Displays information about that submission}

4. IACUC Reviewer: Work with a Project

{"Submission Manager" page is displayed on login.}

To access a specific project, click on the Project Title for any submission of the project of interest, on the "Submission Manager" page => "Submission Detail" page {Displays information for the package}

To get back to the "Submission Manager" page from within any project, click "Submission Manager" button in sidebar menu => "Submission Manager" page

To get back to the "Submission Detail" page from any other page for this project, click the "Back to Submission Detail" in the sidebar menu => 'Submission Detail" page

Project Status is summarized at the top of the "Submission Detail" page {Project Status reflects the entries of the IACUC Administrator on the "Review and Minutes" page with the most recent effective date before the "Project Status as of" date selected}

To see project information, click the "Project Overview" button in the sidebar menu => "Project Overview" page {displays read-only information about the project to which the submission belongs}

Project Information entered by the Researcher

Research Institution

Title {of project}

Principal Investigator [last name, first name]

Keywords

Sponsor

Internal Reference Number {for the project, at the discretion of the Researcher – e.g., R&D Committee number, grant/award number}

"Project Status" table on the "Project Overview" page {shows status for each board to which project has been submitted}

To see more details of the review status for each board, click one of the following to => the "Reviews" page

"Project Status" shown for any board OR "Reviews" button in the sidebar menu

To see which Researcher accounts have access to the project, click "Show Project Team Tracking" / "Hide Project Team Tracking" toggle link for "Project Team Tracking" section on "Submission Detail" page => table of Researcher accounts with which project has been shared

To see review details and board documents for all boards to which any package of the project has been submitted, do one of the following to => "Reviews" page

Click the "Project Overview" button in the sidebar menu => "Project Overview" page

Then click on the Project Status shown for any board on the "Project Status" table on the "Project Overview" page

OR click the "Reviews" button in the sidebar menu

Displays for all packages of the project:

History of review process for each board Table of board documents for each board

To see review details and board documents for all boards, for a specific package of the project, do one of the following => "Review Details" page for that package

Click the "Project Overview" button in the sidebar menu => "Project Overview" page

Then choose the package of interest with the "Package [x] of [total]" or "Jump" links
above the upper right corner of the "Package" table on the "Project Overview" page,
and click the "Review Details" link for any board

OR click on one of the following => "Designer" page

"Designer" link above the "Project Status" table on the "Project Overview" page OR "Designer" link below the "New and Revised Documents in this Package" table on the "Submission Detail" page

OR "Designer" button in the sidebar menu

Then click the "Review details" link above the "Documents in this Package" table on the "Designer" page

Displays:

Review details for the package of interest, for each board

Table of board documents attached to the package of interest, for each board

To see the combined history of submissions and actions of all boards for the project, click the "Project History" button in the sidebar menu => "Project History" page

To see all project messages, click the "Message & Alerts" link in the sidebar menu => "Project Messages & Alerts" page for the project of interest

{Displays list 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 Reviewer-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 submission, click the link in the Project Title column => "Submission Detail" 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 send a communication about the project, click the "Send Project Mail" button in the sidebar menu => "New Project Message" page

{The package from which the "New Project Message" page was accessed is identified, but the message is archived with the project record and posted on the "Project Messages & Alerts" page (accessible by everyone who has access to the project, regardless of who is designated to receive the message by email}

To select recipients of the emailed communication, click on the checkboxes for Project team {Researchers}

Board contacts {IACUC Administrators}

Enter the "Subject" and "Message" for the email to be sent [free text fields with default text provided]

To send the message, click "Send" button

To access Audit Reports specific to a project, do one of the following:

{Audit Reports specific to a project are submitted as packages to the IACUC by the RCO – include findings, notes, attached documents, board response}

Choose the "Audit Status View" or "All-Boards Audit View" above the upper right corner of the table of submissions on the "Submission Manager" page => table of Audit Reports submitted

To see the specifics about a particular Audit Report, click "details" for that item => "Audit Details" page

Board Follow-Up [drop-down menu] {selected by an Administrator}

(blank)

Closed

No Action Required

Open for Follow-Up

Board Notes [free text box]

Review Details: displayed if board reviews during a meeting

OR click the "Agendas and Minutes" button in the sidebar menu => "Agenda Manager" page

Click the "sheet of paper" icon for the meeting of interest => "Agenda Documents" page

Click the "submissions" link below the table of Agenda Documents => "Submission Manager" page showing the all submission for the agenda, including Audit Reports assigned to the Agenda

OR 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}

5. IACUC Reviewer: View a Package

{Reviewer receives notification that access has been granted to a package that has been submitted for IACUC review.}

{"Submission Manager" page is displayed on login.}

To access a package, click on the "Project Title" of the package on the "Submission Manager" page OR click on "Back to Submission Detail" in the sidebar menu => "Submission Detail" page {Displays information for the package}

<u>Package Details</u> section of the "Submission Detail" page {Displays identifying information about the package, including the Lock Status – IACUC Administrator can unlock/lock the package, Researcher can lock }

Black "closed padlock" icon {package was locked on submission or relocked by IACUC Administrator (without indicating anything about revisions)}

Red "open padlock" icon {a locked package has been unlocked by IACUC Administrator}
Green "closed padlock" icon {package has been re-locked by the Researcher who resubmitting it after completing revisions}

To see history of locking and unlocking of the package, do one of the following to => "Lock History" table

Click "View History" link in the "Lock Status" row of the "Package Details" section of the "Submission Detail" page

OR click "View History" above the "Package Description" on the "Designer" page

<u>Submission Details</u> section of the "Submission Detail" page {Information about this submission to the IACUC}

"Submission Date" {date on which the package was submitted to the IACUC}

"Submitted By" {name of user who submitted this package}

"Submission Type" {entered by the account that submitted this package}

"Local Board Reference Number" [free text field] {entered by the IACUC Administrator}

To see information about submissions of each package of this project, to any board, click the "Project Overview" button in the sidebar menu => "Project Overview" page

"Project Status" section of the "Project Overview" page {summarizes project status for each board to which any package has been submitted} – click the link in the Project Status column => "Reviews" page

{Details the processing of each package by each board}

"Package" section of the "Project Overview" page {summarizes the most recent action of each board on any package of this project} -- To see details of what a board has done with a package Click "Review Details" => "Review Details" page

Click "View Workspace" => "Submission Detail" page for that package

Review Details section of the "Submission Detail" page {summarizes status of IACUC reviews of this package, entered by the IACUC Administrator on the "Review and Minutes" page.}

Agenda {meeting date and time to which the IACUC Administrator has assigned this package} "sheet of paper" icon => "Agenda Documents" table

{shows agenda and any other agenda documents attached by Administrator}

Review Type {entered by the IACUC Administrator}

Unassigned

Full Committee Review

Administrative Review

Designated Member Review

"paper and pencil" icon => "Review and Minutes" page

{shows minutes information entered by Administrator for any submission that has been assigned to an agenda}

Action {latest action taken by IACUC on this package, also displayed in the "Review Details" table on the "Submission Detail" page}

(blank) {before committee has met, if the Committee did not take any Action described by one of the other menu options – e.g., determination that a matter is reportable, suspension of approval, suspension lifted}

Acknowledged (for example, for packages that contain self-reports of potential noncompliance, reports from PAM monitor, reports about continuing review, reports of DMR outcomes)

Approved

Closed

Modifications Required {RMSA}

Not Approved {Use this for a determination to deny approval, not for when approval has merely not been approved yet}

Referred to Full Board {can be an outcome of DMR}

Suspended

Tabled Without Action {Choose this option if, for example, the Committee considered the previous minutes but delayed voting on approval. Explain why in the "Discussion and Remarks" (e.g., because quorum was not present, because more information was needed, because revision of the minutes is required)}

Withdrawn {The item was removed from consideration by the IACUC, either by the one who submitted it, or by the IACUC declining to be involved.}

Effective Date {refers to effective date of the IACUC's Action that is recorded here – this may be on or after the date on which the last Designated Reviewer recommends approval, or the date on which the IACUC votes at a convened meeting to act – and is also displayed in the "Review Details" table on the "Submission Detail" page}

Project Information

Project Status {refers to the IACUC-specific status of the project that the package belongs to, not to the status of any single package submitted to the IACUC for this project – may change as a result of the Action taken by the IACUC}

(blank) {applies before the IACUC takes any action that changes the project status (e.g., while the package is in preparation, under review, etc.)}

Active {IACUC approval is in place for the work to proceed}

Closed {The general status of a project that was approved earlier, but the period of approval by the IACUC has ended (e.g. after the approval expires, 3 years after it was granted). "Suspended" is a separate status, below.}

Disapproved {approval denied}

Suspended {result of formal suspension by majority vote of the IACUC at a convened meeting}

Withdrawn {only if the Researcher withdraws the project, or the IACUC declines to review and act on this project at all}

Project Expiration Date, displayed as "Expiration Date" on the "Submission Detail" page {refers to the expiration date of the IACUC approval of the project, not expiration of the specific IACUC Action taken on the package}

{For protocol approvals, this is no later than the third anniversary of approval For suspensions or closures, this is the date the suspension or closure took effect}

Next Report Due Date, displayed as "Report Due" on the "Submission Detail" page {"Report" refers to any formal communication with the IACUC. This can be the next routine report, or any other report that the IACUC asks for.}

{For IACUC approvals, this is the due date for submission of documents for any continuing review or renewal of approval required by the IACUC.}
{For suspensions or potentially reportable matters, this is the due date for submission of information required by the IACUC.}

Initial Approval Date {Depending on local preference, this may be the most recent date when the protocol was granted approval by the IACUC, from which the triennial expiration date is calculated, or the date on which the first protocol for this project was granted IACUC approval, after which it has been renewed}

To see details about reviews of this package by any board, click on one of the following => "Review Details" page

Click on one of the following => "Designer" page

"Designer" link below the "New and Revised Documents in this Package" table on the "Submission Detail" page

OR "Designer" button in the sidebar menu

Then click the "Review details" link above the "Documents in this Package" table on the "Designer page => "Review Details" page

OR click the "Project Overview" button in the sidebar menu => "Project Overview" page
Then click on the "Review Details" link in the "Package" section of the "Project
Overview" page => "Review Details" page

"Review Details" page shows

"Review Details" table for each board

"Board Documents" table of documents uploaded by each board

To see details about reviews of all packages of this project by any board, click the "Reviews" button in the sidebar menu => "Reviews" page

"Reviews" of each package by each board

"Board Documents" uploaded for each package by each board

<u>New and Revised Documents in this Package</u> section of the "Submission Detail" page {displays a list of the documents attached by the researchers (Reviewers have view only access)}

Document Type

Abstract/Summary

Action Plan {may be needed for corrective actions}

Amendment/Modification

Closure/Final Report {not a regulatory requirement, but may be a local requirement}

Continuing Review/Progress Report

CV/Resume

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 feefor-service arrangement}

Proposal

Protocol {Include separate appendix files in this Document Type as well}

Reportable Event (Non-AE) {use for any self-report of a potentially reportable matter, "Adverse Event" terminology does not apply to IACUC}

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}

Description {entered by the Researcher, e.g., filename}

Last modified {hover cursor over the date to show the name of the person who made that modification}

To open a document added to the package by the Researcher, click on Document Type OR "sheet of paper" icon in the "New and Revised Documents in this Package" table, on the "Submission Detail" page

To get more information about documents in the package,

Click "All Project Documents" link above upper right corner of the "New and Revised Documents in this Package" table => "Project Documents" table {shows all documents attached to any package of the project}

To see earlier versions of each document, click "stack of papers" icon => "Document Revision History" table

{To see the name of the person who made earlier modifications of a document, go to the package to which that earlier version as attached, and hover over the "Last Modified" date}

OR click on one of the following => "Designer" page

"Designer" button in the sidebar menu {shown when a submission has been selected}

OR "Designer" link on the "Project Overview" page

OR "Designer" link below the "New and Revised Documents in this Package" table on the "Submission Detail" page

"Package Description" is shown in a field just below the Package ID on the "Designer" page {only Researchers and Administrators can edit, marked with a "sticky note" icon if there is no description entered}

To download documents in the package, click the Document Type or the "sheet of paper" icon for the document of interest, in the "Documents in this Package" table on the "Designer" page

To see previous versions of a document in the package, click the "stack of papers" icon in the "Documents in this Package" table on the "Designer" page => "Document Revision History" window

To download documents in the "Document Revision History", click the "Document Type" or the "sheet of paper" icon for the document of interest

To see "Documents from Previous Packages" of this project, click on the Document Type or the "sheet of paper" icon for the document of interest in the "Documents from Previous Packages" table *{only displayed if there is at least one}* on the "Designer" page

To see who modified that document last, hover over the "Last Modified" date

To see earlier versions of the document, click the "stack of papers" icon => "Document Revision History" window

To download one of the earlier versions, click on the "Document Type" or the "sheet of paper" icon for the document of interest

To see who modified an earlier version, go to the "Designer" page for the package in which that version was the last modified, and hover over the "Last Modified" date there

<u>Training Records</u> section of the "Submission Detail" page {displayed only if there is at least one document, for review by Administrators and Reviewers of any board to which the package has been submitted}

To see the training records that have been linked to this package by the Researcher, click one of the following => "Linked Training & Credentials" window

{links are visible only if there is at least one training record to display}

"[number] Training & Credentials record" link OR the "View Linked Records" link below the "New and Revised Documents in this Package" section on the "Submission Detail" page OR "[number] Training & Credentials record" link OR the "View All Links" link below the "Documents in this Package" table on the "Designer" page

To open a record, click on the Document Type OR the "sheet of paper" icon for the record

To see the board for which Status is displayed, hover over the "Status" for the record

To see Messages & Alerts that have been posted specific to this training record, click the "bell" icon {shown only if accessed from the "Submission Detail" page, not if accessed from the "Designer" page}

Project Team Tracking

To see all of the training of each member of the Researcher Team (regardless of whether the training has been linked to this package), click "Show Project Team Tracking / Hide Project Team Tracking" toggle link on the "Submission Detail" page => "Project Team Tracking" table

To choose reference date for tracking status, click on "Show Current /Show as of Submission / Show as of Board Action" toggle link

"Training & Credentials" column {summarizes the accepted records}

Total number of credits {for training designated by IACUC Administrator to be included}

Flags assigned {flags defined by the IACUC Administrator – hover over the flag to see

Document Type}

{makes it easy for the reviewer to see at a glance whether each person has records of a particular document type}

To see individual training records, click "View Training" for an account => "Training & Credentials for [user name]" table {shows all training records for each member of the Research Team, with its status for the IACUC}

To open a training record, click on the Document Type OR the "sheet of paper" icon for the record

To see the board for which Status is displayed, hover over the Status for the training record

To see details of the board actions on the training document, click the link in the Status column for the record => "Training & Credentials: Board Status" window

To see Messages & Alerts that have been posted specific to this record, click the "bell" icon

This Package has been Signed By section of the "Submission Detail" page {For the IACUC, there is no VA requirement for submission signature for the IRBNet certification statement. VA requires signatures on the certification statements within the ACORP for protocols that are submitted for secondary review.}

Displayed on the "Submission Detail" page
OR click the "Package Signatures" button in the sidebar menu => "Package Signatures" page

To see specifics about each signature, click "Details" => "Signature Details" window {Displays the standard statement certified by each signature: "I ... certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature."}

<u>Board Documents</u> section of the "Submission Detail" page {Table of documents attached to the package by the IACUC Administrator or IACUC Reviewer with Administrator access is shown, below the section on signatures, only if at least one board document has been attached.}

To download a document, click the Document Type or "sheet of paper" icon
To see earlier versions of a document, click "stack of papers" icon => "Document Revision
History" window

To download a document, click the Document Type link or the "sheet of paper" icon To see who published a board document, hover over the "Publish Date"

{only for board documents that have already been published}

To see board documents attached to any package of this project by any board, click the "Reviews" button in the sidebar menu => "Reviews" page

"Reviews" of each package by each board
"Board Documents" uploaded for each package by each board

<u>Share</u> section of the "Submission Detail" page
Table of Reviewers and Administrators with whom the package has been shared {view only}

Includes

All Administrator accounts with IACUC access {as set up by IRBNet Support, on request from the station}

Any Reviewer accounts designated by an IACUC Administrator to have access *{for Reviewers who are assigned administrator access for this submission, see How-To Guide for IACUC administrators for administrator functions}*

Special Designation {any special Reviewer role, as entered by Administrator}

(blank)

Attending Veterinarian – for pre-consult

Designated Reviewer

Primary Reviewer

Secondary Reviewer

To see messages that have been sent internally to selected Reviewers and Administrators, click the "Committee Messages" link below the table of those with shared access, on the "Submission Detail" page => "Committee Messages & Alerts" page {These messages are not available to Researchers, but are accessible to all Reviewers and Administrators with access to the package, regardless of whether they were designated to receive the message by email}

Click the "flag" icon to toggle the flag on and off as a personal reminder

Click the "Project Title" link => "Submission Detail" page

Click the "Message Type" link => "Message" window {displays contents of message}

Reviewer Comments and Documents section of "Submission Detail" page {Records input from each IACUC Reviewer and IACUC Administrator – all can see the inputs of all the others as well as their own, but can only modify their own.}

To see comments and documents provided by IACUC Reviewers of the submission, click one of the following in the table below the link to "Add" comments and reviewer documents, on the "Submission Detail" page => "Reviewer Comments" page for the Reviewer of interest

{table is not displayed if no comments or reviewer documents have been added}

the "View" link, in the table of Reviewers on the "Submission Detail" page {shown only if that the IACUC Administrator or IACUC Reviewer has already provided comments or reviewer documents}

OR the "sheet of paper" icon {only shown if that IACUC Administrator or IACUC Reviewer has already uploaded a reviewer document}

To see individual documents attached by that Reviewer, click on the Document Type, or the "sheet of paper" icon under "View", in the table of "Reviewer Documents" at the bottom of the "Reviewer Comments" page

To see details about reviews of all packages of this project by any board, click the "Reviews" button in the sidebar menu => "Reviews" page

"Reviews" of each package by each board

"Board Documents" uploaded for each package by each board

6. IACUC Reviewer: Review a Package

{Reviewer receives notification that access has been granted to a package that has been submitted for IACUC review.}

{"Submission Manager" page is displayed on login.}

To access a package, click on the "Project Title" of any package for the same project on the "Submission Manager" page OR click on "Back to Submission Detail" in the sidebar menu => "Submission Detail" page {Displays information for the package}

To view the comments and documents of any Reviewer or Administrator, click one of the following to => "Reviewer Comments" page

the "View" link in the Reviewer's row of the table of Reviewers on the "Submission Detail" page {shown if that Reviewer has already provided comments or reviewer documents}

OR the "sheet of paper" icon" in the Reviewer's row of the table of Reviewers on the

"Submission Detail" page

{shown if that Reviewer has already uploaded a reviewer document}

To see individual documents attached by that Reviewer, go to the "Reviewer Comments" page, and click on the "Document Type", or the "sheet of paper" icon under "View", in the table of "Reviewer Documents"

To add/update the Reviewer's own comments and documents, click one of the following to => "Reviewer Comments" page

"Add" link below the table of Reviewers on the "Submission Detail" page

{shown if the Reviewer has not yet provided comments or reviewer documents}

OR "Update" link below the table of Reviewers on the "Submission Detail" page

{shown if Reviewer has already provided comments or reviewer documents}

OR the "View" link in the Reviewer's own row of the table of Reviewers on the "Submission Detail" page

{shown if Reviewer has already provided comments or reviewer documents}

OR the "sheet of paper" icon" in the Reviewer's own row of the table of Reviewers on the "Submission Detail" page

{shown if the Reviewer has already uploaded a reviewer document}

On the "Reviewer Comments" page for the Reviewer's own comments, enter/edit Reviewer Comments [free text box]

Recommendation – [drop-down menu of IACUC Actions that the reviewer may recommend]

(blank) – {use for reviewer recommendations other than official IACUC actions (e.g., protocol describes work that is not "VA Research" or does not involve "animals" and should be withdrawn from IACUC consideration)}

Acknowledge {not an IACUC action outcome of Committee Member review}

Approve

Close

Disapprove {Deny Approval – This is not an option for DMR; recommend "Refer to Full Board" instead}

Information Required {not an IACUC action outcome of Committee Member review; use (blank) instead and explain in comments}

Modifications Required {may be an IACUC action outcome of FCR or DMR}
Not Research {not an IACUC action outcome, may be addressed in the comments}
Refer to Full Board {only an option for DMR}
Suspend

Terminated {do not use this term, as it does not distinguish among different types of termination and will cause confusion; use "close" or "suspend" instead}

Last Updated {IRBNet records the date and time of latest "Save" or "Save & Exit"}
Completed Date {IRBNet records the date and time of the latest "Save" or "Save & Exit" with "Mark my personal review as complete" checked}

On the "Reviewer Comments" page for the Reviewer's own comments, manage the documents attached by the IACUC Reviewer

"Reviewer Documents" table displays all files attached

To change the "Document Type", click on triangle under "Document Type" => [drop-down menu]

Reviewer Worksheet Other

To download the document, click on Document Type or "Sheet of paper" icon in the "View" column

To add a Reviewer document, click "Add New Document" button at the bottom of the "Reviewer Comments" page => "Reviewer Documents" page

Select a "Document Type" [drop-down menu]
(Optional) Enter a description of the document [free text field]
Click "Choose File" button => File Explorer to select file
Click "Attach" button

To change a document that the IACUC Reviewer has already attached, click the "Update" link in the "Reviewer Documents" table => "Reviewer Documents" page {update entries for the document, select a file to replace the existing file with} {No history of revisions is maintained.}

To remove a reviewer document, click the "Delete" link in the "Reviewer Documents" table

To record the changes on the "Reviewer Comments" page, click "Save & Exit" button => "Submission Details" page

{Date and time of revision of entries (not documents) are recorded for "Last Updated"}

