

How-To Guide

# For IACUC Administrators

VA IACUC Functions in VAIRRS

Office of the CVMO

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IACUC Admin

## 1. IACUC Administrator: Access IRBNet

Those who need accounts as IACUC Administrators are identified by the station and the accounts are set up by IRBNet Support

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

*Other local IACUC administrators with existing accounts*

*Other local administrators of other IRBNet boards, with existing accounts*

*The local ACOS (identified by ORPP&E)*

*ORPP&E (holder of VA's account with IRBNet)*

*Any Administrator has all the functions of a Researcher and a Reviewer, plus additional functions assigned according to responses to a questionnaire from IRBNet Support, about what functions are needed (at least one Administrator should be assigned all functions) – the functions are all independent of each other*

*Will they need to be notified each time a package is submitted to the IRB/IBC/IACUC/R&DC/SRS/RA?*

*Will they need access to all past and future submissions (i.e., access by default) or will future submissions be shared with their accounts as needed?*

*Will they be Accepting and managing Training & Credential documents?*

*Will they need access to your Library Manager?*

*Will they be creating/editing Agendas and/or Minutes?*

*Will they be responding to audit events from your RCO?*

*Will you need us to send them your Sandbox logins (training.irbnet.org)?}*

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

## 2. IACUC Administrator: Edit Profile of IACUC Administrator's Account

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

Account Information and Password – 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}*

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

## IACUC Administrator: Edit Profile of IACUC Administrator's Account

*{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 CITI 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

### Training & Credentials *{There is no training required of VA IACUC Administrators, so an IACUC Administrator typically only adds training records to the Administrator's own account if the Administrator also has a Researcher or Committee Member role}*

To add training records manually to 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 Administrator includes all document types that are "active" for any of the boards to which the Administrator is assigned.}*

IRBNet Standard Types *{None are required for VA IACUCs, so all 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. If none of the options shown is appropriate, go to the section of this How-To guide on "Manage Training Records of Others" for instructions on creating a new Custom Type.}*

Description: [optional free text description]

## IACUC Administrator: Edit Profile of IACUC Administrator's Account

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 see 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 ["IACUC" from 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 the 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 the 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" *{an Administrator has acknowledged receipt, defers 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}*

IACUC Admin



### 3. IACUC Administrator: Manage Training Records of Others

To manage training for accounts of others, click “Track Training” button under “Other Tools” in sidebar menu => “Track Training & Credentials” page

*{(Number) displayed after “Track Training” on the button shows the number of training records for accounts affiliated with this institution, that are pending review}*

To edit the document types that users may choose from for training documents, click “Manage Types and Flags” link at the end of the introductory text or above the table of training records on the “Track Training & Credentials” page => “Training & Credentials Types and Flags” page

Choose “IACUC” as the board that the entries on this page will apply to [drop-down menu of boards assigned to this Administrator]

Tables of types *{of training and credential documents}*

“System Types: IRBNet Standard Types” *{Set up by IRBNet for all institutions, for specific training courses. None are required for VA IACUCs, so the “Status” of each of the IACUC related Standard Types has been set to “inactive” by default, for all VA boards. IACUC Administrator can make them active if needed locally.}*

“System Types: Other” *{Set up by IRBNet for training documents other than completion certificates for specific courses. These cannot be inactivated}*

“Custom Types: [Institution Name]” *{Specific to the local IACUC.}*

*{IRBNet has set up Custom Types for all VA stations, for each of the CITI completion certificates for training that meets VA requirements for research with animals, that have been downloaded automatically through the CITI Integration service in IRBNet. For each of these Custom Types, the names assigned by IRBNet reflect the names of the CITI courses.}*

*{For completion certificates that get downloaded later for any additional CITI courses that meet VA requirements (e.g., for additional species), and for completion certificates from ALL for courses that meet VA requirements, new Custom Types must be created, either by the IACUC Administrator or by request to IRBNet. Certificates that are downloaded automatically from CITI for courses for which Custom Types have not yet been created, will be assigned the “Other” System Type – the Type can be changed later.}*

To set up additional “Custom Types”, enter the name of the new “Custom Type” in the free text box under “Create New Type”, and click the “Create New Type” button.

## IACUC Administrator: Manage Training Records of Others

To link a Custom Type to a particular group and stage in CITI, click the small (gray or green) "linked chain" icon at the right end of the row for the training type of interest on the Manage Types and Flags page => "Link to External Training" page, for entering

Institution ID *(This is not the Institution ID assigned by CITI, but is shown for each of the types in the table of Linked Types for your station)*

CITI Group ID

CITI Stage Number

*Contact the IRBNet Support Team ([govsupport@irbnet.org](mailto:govsupport@irbnet.org)) for help with this.*

To edit the name of any existing "Custom Type", click on the "Type Name" and edit the text in the free text field

To edit the availability of a "Type" *{of training and credential documents}*

To remove a type that is not needed for the local IACUC from the drop-down lists that appear when editing training records, click the "Active" / "Inactive" toggle link under "status"

*{The status of type is set separately for each board by that board's Administrators}  
{Inactivation for the IACUC makes the "Type" unavailable to Researchers, IACUC reviewers, and IACUC Administrators for future assignment to records to be submitted to the IACUC. It does not affect records that have already been assigned to a "Type".}*

To limit the availability of a "Type" to users with specific roles, use the checkboxes

For Researchers (Res)

For IACUC Members (Com)

To assign colored flags to Document "Types" *{of training and credential documents}*, click under "Flag Color" [drop-down menu]

*{15 colors available}*

*A single color may be assigned to more than one document type*

*Flags provide a way to tell at a glance whether each member of the project team has currently unexpired documents for the flagged "types" of training.*

*On the "Submission Detail" page, scroll to the Training & Credentials section, and go to the "Training & Credentials" column on the "Project Team Tracking" table, or*

*Click the "Track Training" button in the sidebar menu => "Track Training & Credentials" page, scroll to the table and click "Show Roll-Up by User" to display the "Tracking" column, where flags are displayed}*

## IACUC Administrator: Manage Training Records of Others

To designate whether the credits earned are to be included in the total displayed for a user, use the “Count Credits” checkbox

*{Credit value is entered when a training document is attached to a user profile  
Total credits are calculated as the sum of all accepted currently unexpired documents for which “Count Credits” is checked.}*

*On the “Submission Detail” page, scroll to the Training & Credentials section, and go to the “Training & Credentials” column on the “Project Team Tracking” table, or*

*Click the “Track Training” button in the sidebar menu => “Track Training & Credentials” page, scroll to the table and click “Show Roll-Up by User”, to display the “Tracking” column, where flags are displayed}*

To access training documents for any account affiliated with the institution *{regardless of whether any documents for that account have been submitted to the IACUC}*

Leave all search fields blank on the “Track Training & Credentials” page

*{“Tracking Board” field is ignored, so any option yields the same results  
Entering any part of a User Name for an account affiliated with the institution limits the search to accounts with that text in the User Name}*

Click “Search” button => table displaying every account affiliated with the institution

Click “Show Tracking Records” / “Show Roll-Up by User” toggle link to switch between displays of training documents and display of users,

*{“Show Roll-Up by User” option shows one row for each user affiliated with the institution}*

*“Show Tracking Records” option shows one row for each training record attached to the profile of a user affiliated with the institution, that has been submitted to the Tracking Board selected}*

To see all training documents attached to the user profile of a particular user, click on the “user name” link in the table of training records *{either view}* on the “Track Training & Credentials” page => “Training & Credentials for [user name]” detail window

To view a training document, click on the Document Type OR the “sheet of paper” icon for that document

To see the board to which the status shown applies, hover the cursor over the status *{only for documents that have been submitted to a board}*

Pending Review *{document has been submitted to the IACUC, has not been reviewed by the Administrator yet}*

## IACUC Administrator: Manage Training Records of Others

Deferred *{Administrator acknowledges receipt, but opts not to make a decision on acceptability}*

Accepted *{accepted by the Administrator}*

Rejected *{Administrator has decided that the record is not acceptable for this board}*

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

To filter the search for training documents on the "Track Training & Credentials" page, enter

"Tracking Board" [select from drop-down menu] *{Limits the search to records submitted to the selected board. This is ignored unless other filters are also entered for the documents of interest.}*

"User Name" [free text field] *{Limits the search to accounts with names at least partially entered here.}*

"User Organization" [select from drop-down menu] *{Limits the search to records of users affiliated with the selected institution / board}*

Document Type [select from drop-down menu] *{The menu for an Administrator includes all "Document Types" that are "active" for any of the boards to which the Administrator is assigned. The menu for Researchers and IACUC reviewers includes only "Document Types" that have been assigned to them}*

Document Status [select from drop-down menu] *{reflects whether document has been submitted and if so, what Administrator actions have been taken}*

Range of dates within which the document became effective

Range of dates within which the document is valid

To remove a document from the records being tracked for the IACUC, click the "X" icon in the table of training records ("Show Tracking Records" view) on the "Track Training & Credentials" page *{may be useful after the IACUC Administrator rejects a document, only possible if the document has not been linked to any package submitted to the IACUC}*

To manage the training records attached to a user's profile, click the "User Profile" link in the upper right corner of the "Training & Credentials for {user name}" details window => "User Profile" page for this user

*{Administrator has all the functions of the account owner, to manage the training records attached to the profile}*

To update the status of a training document, do one of the following to => links for the specific actions

click "More Options" in the table on the "Track Training & Credentials" page and click an option [specific actions in the drop-down menu]

OR click on a User Name in the table of training documents on the “Track Training & Credentials” page => “Training and Credentials for [user name]” table, with the links for the specific actions

OR click the “View Training” link in the “Project Team Tracking” table on the “Submission Detail” page => “Training and Credentials for [user name]” table, with the links for the specific actions

OR click the “[n] Training & Credentials record” link OR the “View Linked Records” link on the “Submission Detail” page“ => “Linked Training & Credentials” window, with links for the specific actions

Specific actions that can be taken to manage training records

*{IACUC Administrator can take these actions before or after the training document is linked to a package.}*

*{By default, the Status of a training document is the same for all boards at the institution (a “Cluster”), unless the IACUC Administrator specifically changes it.}*

To edit the details of a document, and accept it for the board, click “Edit/Accept” link

Document Type: [drop-down menu of types available to the Administrator]

Description: [free text field] *{enter file name or other description}*

Credits/Credit Hours (if applicable): [free text field] *{any number up to 5 digits, with up to two decimal places}*

Effective Date: [calendar] *{effective date of training document}*

Expiration Date: [calendar] *{expiration date of training document}*

To accept the changes and the document, click “Save” button

To acknowledge receipt without accepting the document, click “Defer” => document “Status” becomes “deferred”

*{“Submit” to another board, for the other board to act}*

To mark a document as not accepted, click “Reject” => document “Status” becomes “rejected”

To send the document to another board, click “Submit” => “Submit Training & Credentials” page *{submits to the other board, not as part of a package}*

Select a Board [menu of options shown]

Click “Continue” button => window for entering a message for the board that is to receive the document [free text field]

Click “Submit” button

*{After an option is selected, the other options remain available for subsequent actions.}*

## 4. IACUC Administrator: Manage the Local Board Libraries

*{Libraries contain files made available by the IACUC Administrator to users – Researchers, Reviewers, Administrators -- who work with the local IACUC. The files may be forms, templates, or reference documents, and are accessed via the “Forms and Templates” button in the sidebar menu.}*

To manage local IACUC libraries, click the “Library Manager” button in the sidebar menu under “Other Tools” => “Library Manager” page

To select the board that hosts the library of interest, click in “Libraries for” [“IACUC” in drop-down menu]

*{IACUC Administrator may only edit libraries hosted the local IACUC  
IACUC Administrator may view (but not edit) libraries hosted by other boards that have authorized the local IACUC to access them}*

To identify the library of interest, click in “Select a Library” [drop-down menu] => “Documents in this Library” table

Documents for Committee Members

*{Documents in this library are available only to those with Administrator or Reviewer access for the selected board}*

Documents for Researchers

*{Documents in this library are available to all Administrators and Researchers affiliated with the institution.}*

To view a document, click the “page” icon

To update a document already in the library, click the “pencil” icon for the document to be updated => “Library Documents” page

Enter “Document Description” [free text field]

Select file from browser

Click “Update” button => previous document is replaced by the selected file

*{no history of revisions is maintained}*

To remove a document from the library, click the “X” icon => document is deleted

To attach additional documents to the library, click “Add New Document” button below “Documents in this Library” table => “Library Documents” page

Enter “Document Description” [free text field]

Select file from browser

Click “Attach” button => document is added to the “Documents in this Library:” table

To authorize (an) additional institution(s) to access a library of Documents for Researchers, select the institution(s) in the menu on the right and click the "<< Add" button => the selected institution name(s) are moved to the menu of "Authorized Institutions"

To remove the access of an institution to a library of Documents for Researchers, select the institution in the menu of "Authorized Institutions" and click the "Remove >>" button => the selected institution names are moved to the menu on the right

To authorize (an) additional local board(s) to access a library of Documents for Committee Members, select the board(s) in the menu on the right and click the "<< Add" button => the selected board name(s) are moved to the menu of "Authorized Committees"

The library appears on the "Forms and Templates" page as an option in the drop-down menu for "Select a Library"

To remove the access of a local board to a library of Documents for Committee Members, select the board in the menu of "Authorized Committees" and click the "Remove >>" button => the selected board name(s) are moved to the menu on the right

To make a library available to authorized committees and institutions, click the "Publish Library" button  
*{Edits to a published library are immediately effective for all those with access -- no need to Publish again.}*

To take a library completely off-line, click the "Un-Publish" button

To save changes to an un-published library without publishing it, click the "Save & Exit" button

## 5. IACUC Administrator: Manage Tags for Submissions

*{Tags are color-coded labels for searching for groups of submissions to the IACUC}*

*{“Submission Manager” page is displayed on login.}*

To create or edit tags for submissions, click “Create and Manage Tags” link above left corner of the table of submissions on the “Submission Manager” page => “Submission Tags” page


To identify the board for which tags are to be created/managed, click in “Tags for” [“IACUC” in drop-down menu]

To name a tag, enter in “Create New Tag” box [free text field] *{Describe what this tag will indicate – edit any time by clicking in the “Tag Name” field}*

To choose a tag, select a color [drop-down menu of 15 colors]

To save the tag as created, click “Create New Tag” button => Tag appears in the table of tags

To remove a tag from all submissions and delete it from the table, click the “X” icon

To assign a tag to a submission, click on  under “Project Title” for a submission, on the “Submission Manager” page => “Add and Remove Tags” window

To change tag status, click radio buttons

“Off”

“On”

“globe icon” *{applies the tag “globally” to all submissions for the same project}*

*{Multiple tags may be assigned to a single submission}*

*{Submission tags are visible to all IACUC Administrators and Reviewers, not to Researchers}*



## 6. IACUC Administrator: Access a Package Submitted for Review

*{“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 for which submissions are of interest, click in “Submissions for” [“IACUC” in the drop-down menu]

To search for character strings, enter free text in “Search All” or “Search” *{The fields that will 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 specific 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}*

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

Board action View

Project status View

Review Assignments View

## IACUC Administrator: Access a Package Submitted for Review

Audit Status View [\*{information about audit reports submitted by the RCO}\*](#)

All-Boards Audit View [\*{information about audit reports submitted by the RCO}\*](#)

Click on the Project Title for the package of interest => "Submission Detail" page  
[\*{Displays information about that submission}\*](#)

IACUC Admin

## 7. IACUC Administrator: Manage a Project

*{“Submission Manager” page is displayed on login. OR Click on the “Submission Manager” button in the sidebar menu.}*

To access a specific project, click on the Project Title for any package that has been submitted for that project 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 Notes” *{Notes about the project, entered/edited by and visible to only IACUC Administrators}* are displayed in the field at the top of the “Submission Detail” page, just below the package ID

To edit, click in [free text field]

Project Status is summarized just below the “Project Notes” at the top of the “Submission Detail” page *{Project Status is shown for the Reviewing Board selected from the drop-down menu above the upper right corner of the “Project Status” rectangle, and reflects the entries of the corresponding board Administrator on the “Review and Minutes” page with the most recent effective date before the “as of” date selected}*

To edit Project Status, Initial Approval Date, Project Expiration Date, or Next Report Due date, for the IACUC board,

Scroll down to “Review Details” section of the “Submission Detail” page, and click the “pencil and paper” icon for the agenda of interest => “Review and Minutes” page for this package

Update the corresponding fields [drop-down menus]

OR click “Agendas and Minutes” in the sidebar menu => “Agenda Manager” page

Click “Minutes Builder” link for a meeting that has this package submitted for the agenda => “Minutes Builder” page for this agenda

Scroll down to the item of business addressing this package, and click the “pencil and paper” icon for this submission => opens the “Minutes Builder” page for this agenda item

Update the corresponding fields [drop-down menu]

Click “Save & Exit” button => “Submission Detail” page showing updated information

To see more 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}*

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 the Researcher accounts with which the Project Owner has shared the project, go to the “Project Team Tracking” section on “Submission Detail” page, and click “Show Project Team Tracking” / “Hide Project Team Tracking” toggle link for => 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 => the “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 => “Review Details” page

OR click on one of the following => “Designer” page

“Designer” link above the “Project Status” table on the “Project Overview” page

## IACUC Administrator: Manage a Project

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 => “Review Details” 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 create a Special Event Package for a project, click the “Project History” button in the sidebar menu => “Project History” page

*{A Special Event Package is specific to a particular project, but empty of anything entered by a Researcher – This is a mechanism for the IACUC Administrator to provide comments and board documents to the board, apart from any other package}*

Click the “Create Special Event Package” button below the table on the “Project History” page => “Designer” page for a new package. *{There is nothing the IACUC Administrator can do on the “Designer” page with this, or any other, package, but can submit it to the IACUC.}*

To submit a Special Event Package *{same procedure as for submitting any other package}*, click “Submit this Package” button in the sidebar menu => “Submit Package” page

Enter “Submission Type” [drop-down menu]

Enter “Your Comments” [free text field] *{to be included in the notification to IACUC Administrators about the submission}*

Once submitted, IACUC Administrator can add board documents to the package

To make the Special Event Package available to Reviewers *{same procedure as for sharing any other package}*, click the “Share” link on the “Submission Detail” page => “Share Submission” page *{The IACUC Administrator can include an explanatory note with the email notification about access to the Special Event Package that is sent to the Reviewers, but this note is not part of the package}*

To send a communication about the project to the Researchers or other IACUC Administrators, 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)}*

## IACUC Administrator: Manage a Project

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 see all project messages, click the “Message & Alerts” link in the sidebar menu => “Project Messages & Alerts” page

To create a new package for the Researcher to work on, for the project, click the “Create a New Package” button in the sidebar menu => initiates assembly of a new package by the researcher

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 of Board actions] *{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}*

## IACUC Administrator: Manage a Project

To add an Audit Report to an Agenda, click “Add to an Agenda” => adds Audit Event like any other package, to the selected agenda

- Accessible to anyone with access to the Agenda

- May have documents attached by the creator of the Audit Event

IACUC Admin

## 8. IACUC Administrator: Process a Package for Review

*{IACUC Administrator receives notification of any submission to the CVMO board, with comments entered by the submitter.}*

*{“Submission Manager” page is displayed on login.}*

To access a package, click on the “Project Title” of the package of interest on the “Submission Manager” page OR (from any other page of the package) click on “Back to Submission Detail” in the sidebar menu => “Submission Detail” page *{Displays information about the package}*

Package Details section of “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 resubmitting it after revisions are completed}*

To change the lock status of a package, click links under “Lock Status” in the “Package Details” section of the “Submission Detail” page *{e.g., to unlock if additional documents from the Researcher are needed}*

Click “Lock”/ “Unlock” toggle or “Lock – Revisions Complete” link => “Change Lock Status” window

Check/uncheck option to notify Project Owners

Enter a message to be sent with the notification [free text field]

Click “Continue” to change lock status => lock status is updated

*{It is possible, but not recommended, for the IACUC Administrator to unlock and allow revisions even after the board has acted}*

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

Submission Details 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 each 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

To choose a different package of the project, use the arrows for “Package [x] of [total]” or the “Jump” drop-down menu above the upper right corner of the “Package” table on the “Project Overview” page

To see a list of the boards to which the package has already been submitted, click the “Submit this Package” button in the sidebar menu => “Submit Package” page

To submit to another board, use “Select a Board” [menu of options shown]

To change the Submission Type, click the blue triangle after the Type that is shown in the “Submission Details” section of the “Submission Detail” page => [drop-down menu] *{just a label for the convenience of the IACUC Administrator, indicating the reason the package was submitted to the IACUC. The type has no effect on any functions for submission. The menu is the same as for Researchers.}*

Amendment/Modification *{for protocols}*

Closure/Final Report *{for protocols}*

Continuing Review/Progress Report *{for protocols}*

Facility Inspection/Program Review *{N/A for submission of packages, which are project-specific}*

Funding/Grant *{N/A for submission by Researcher to IACUC, or by IACUC Administrator}*

New Project *for submission by Researcher to IACUC, or submission by IACUC Administrator*

Other *{for Special Event packages, examples include:*

*Reports to the IACUC about FOIA requests received*

*Media inquiries received*

*Public communications about specific projects*

*Internal reports – PAM, concerns about specific projects}*

Publication *{e.g., submission of a Special Event Package about publishing images/video, for IACUC’s awareness / review}*

Reportable Event *{for Special Event packages -- potentially reportable matter related to a specific project}*

Response/Follow-up *{package containing Researcher’s correspondence related to RMSA or a Special Events package following up on a potentially reportable matter related to a specific project}*

Revision

Triennial Review *{for protocols}*

To change the “Local Board Reference Number”, click in the [free text field] in the “Submission Details” section of the “Submission Detail” page

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*}

To edit the IACUC agenda (meeting date and time) to which the submitted package has been assigned, click the blue triangle in front of the current agenda assignment in the “Review Details” section of the “Submission Detail” page => [drop-down menu of all currently scheduled meetings, “unassigned”, and “Add a New Agenda”]

Click an existing agenda to assign the package to it

To create a new meeting to which packages can be assigned, click “Add Another Agenda Date” link above right corner of table => adds new “unassigned” agenda to table

To schedule the date, time, and location of the new meeting, click the blue triangle before the “unassigned” agenda, and choose “Add a New Agenda” in drop-down menu => “Add Meeting” window

To select a date and time, click “...” button => Calendar and clock window

To enter a meeting location, click the [free text field] for “Meeting Location”

To save new meeting, click “Continue” => new meeting appears in drop-down menu

To cancel a scheduled meeting, click “X” icon {*visible only when there is more than 1 meeting shown*}

To edit the “Review Type” in the “Review Details” section of the “Submission Detail” page, click the blue triangle in front of the current review type {*visible only if board action is still pending*} => drop-down menu of options corresponding to the board for which the submission detail is displayed

For the IACUC, Review Type options are:

Unassigned {*Use this for packages that are for business other than protocol review*}

Full Committee Review

Administrative Review

Designated Member Review

To edit more review details, click the “pencil and paper” icon in the “Review Details” section of the “Submission Detail” page => “Review and Minutes” page

Review Type [drop-down menu]

(blank) {*Unassigned or N/A -- use this for package that did not involve the specific review processes defined by PHS Policy for protocol review*}

Full Committee Review

## IACUC Administrator: Process a Package for Review

Administrative Review

Designated Member Review

Action [drop-down menu] *{Actions that the IACUC took on the package}*

(blank) *{before the IACUC has met, or if the action taken by the IACUC is not described by one of the other menu options – e.g., determination that a matter is reportable, lifting a suspension of approval}*

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

Forwarded *{not an IACUC Action -- if the package is not one that requires IACUC action, it should be “Withdrawn” from IACUC review and reassigned by R&D Committee}*

Information Required *{not an IACUC Action -- if the IACUC requires more information before it can take action, the item should be “Tabled Without Action” instead}*

Modifications Required *{RMSA}*

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

Not Research *{not a determination that the IACUC makes -- if the R&D Committee makes the determination that the project that has been submitted to the IACUC is actually not VA research, it should be “Withdrawn” from IACUC review}*

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, and 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)}*

Terminated *{Do not use this term, as it does not distinguish among different types of termination and will cause confusion; use “closed”, “suspended”, or “withdrawn”, as appropriate, instead}*

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 [select from calendar] *{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}*

Project information

Project Status *{refers to the project that the package belongs to, not to the status of any single package submitted to the IACUC for this project – changes 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.)}*

## IACUC Administrator: Process a Package for Review

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.}*

Closed – Expired *{use "Closed" instead}*

Closed – Project Complete *{use "Closed" instead}*

Deferred – Information Required *{not a project status – if the IACUC defers taking any action, project status remains unchanged}*

Deferred – Modifications Required *{not a project status – if the IACUC makes a determination of RMSA, project status unchanged}*

Disapproved *{approval denied}*

Not Research *{not a project status, use "Withdrawn" instead}*

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

Terminated *{do not use this term, as it does not distinguish among different types of termination and will cause confusion; use "Closed", "Suspended", or "Withdrawn", as appropriate, instead}*

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

Dates [select from calendar, the dates that apply to the project] *{defined by local policy}*

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 => 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 *{the most recent date when the protocol was granted approval by the IACUC, from which the triennial expiration date is calculated}*

To delete all details and minutes associated with an agenda, click "X" icon in the "Review Details" table on the "Submission Detail" page

*{visible when there is more than 1 meeting shown, this cancels the meeting}*

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

## IACUC Administrator: Process a Package for Review

Click on one of the following to => “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

New and Revised Documents in this Package section of the “Submission Detail” page *{displays a list of  
the documents attached by the Researchers}*

To edit the “Document Type”, click on the blue triangle in front of the current Document Type=> [drop-  
down menu of options] *{for documents created with a Wizard, the Document Type cannot be changed}*

*{IACUC Administrator may only change the “Document Type”, may not change the attached  
documents themselves}*

*{options are the same as for Researcher adding a document to a package, most of which do not  
apply to packages submitted to the IACUC.}*

Abstract/Summary

Action Plan *{may be needed for corrective actions}*

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}*

## IACUC Administrator: Process a Package for Review

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 *{only for IACUC Administrator preparing to submit a package for secondary review}*  
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}*

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 on the "Submission Detail" page, click on Document Type OR "sheet of paper" icon in the "New and Revised Documents in this Package" table

To get more information about documents in the package,

Click "All Project Documents" link above upper right corner of the "New and Revised Document 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 "Submission Detail" page for the package to which that earlier version is 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

To make/edit a note about the package, click in "Package Description" [free text field marked with a "sticky note" icon] below package ID on the "Designer" page

*{Even if the package is locked, the package note may be edited by Researcher with "Full" or "Write" access Administrator}*

*{Displayed for Reviewers, but Reviewers may not edit}*

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

Training Documents section of the “Submission Detail” page *{available for review by Administrators and Reviewers of any board to which the package is submitted}*

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

*{links are visible only if there is at least one training document 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 document, click on the Document Type OR the “sheet of paper” icon for the document

To see the board for which “Status” is displayed, hover over the Status for the document  
*{By default, the Status of a training document is the same for all boards at the institution (a “Cluster”), unless the IACUC Administrator specifically changes it.}*

To see Messages & Alerts that have been posted specific to this training document, click the “bell” icon *{only available to IACUC Administrator, so only if accessed from the “Submission Detail” page, not available if accessed from the “Designer” page, which is also available to Researcher}*

To update the status of the training records,

To edit the details of a document, and accept it for the IACUC, click “Edit/Accept” link

Document Type: [drop-down menu of types available to the Administrator]

Description: [free text field] *{enter file name or other description}*

Credits/Credit Hours (if applicable): [free text field] *{any number up to 5 digits, with up to two decimal places}*

Effective Date: [calendar] *{effective date of training document}*

Expiration Date: [calendar] *{expiration date of training document}*

To accept changes and document, click “Save” button

To acknowledge receipt without accepting the document, click “Defer” => document “Status” becomes “deferred”

*{“Submit” to another board, for the other board to act}*

To mark a document as not accepted, click “Reject” => document “Status” becomes “rejected”



## IACUC Administrator: Process a Package for Review

To send the document to another board, click “Submit” => “Submit Training & Credentials” page *{submits to the other board, not as part of a package}*

Select a Board [from the options shown]

Click “Continue” button => window for entering a message for the board that is to receive the document [free text field]

Click “Submit” button

*{After an option is selected, the other options remain available for subsequent actions.}*

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 documents}*

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 documents, click “View Training” for an account => “Training & Credentials for [user name]” table *{shows all training documents for each member of the Research Team, with its status for the IACUC}*

To open a training document, click on the Document Type OR the “sheet of paper” icon for the document

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

To see details of the board actions on the training document, click the “Status” link for the document => “Training & Credentials: Board Status” window

To see Messages & Alerts that have been posted specific to this document, click the “bell” icon

To send a message about a training document, click the envelope icon in one of the following windows => “New Document Message” page

“Training & Credentials for [user name]” window – to access this, click the “Show Project Team Tracking / Hide Project Team Tracking” toggle

on the “Submission Detail” page to get the “Project Team Tracking” table, then click the “View Training” link for the Researcher of interest

OR the “Linked Training & Credentials” table – to access this, click the “[number] Training & Credentials record” OR “View Linked Records” below the “New and Revised Documents in this Package” section on the “Submission Detail” page

Select recipients *{available options are the Document Owner and the board Administrators with access to the package}*

Enter the “Subject” and “Message” [free text fields]

*{default text shown is just an example, and may be replaced}*

To send the message, click the “Send” button

*{message is emailed to the designated recipients, and also posted in “Project Messages & Alerts” for access by all Committee Members and Administrators}*

This Project has been Signed By section of the “Submission Detail” page *{For the IACUC, VA requires signatures on the certification statements within the ACORP for protocols to be submitted for secondary review. There is no VA requirement for submission signature of the IRBNet certification statement.}*

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.”}*

Board Documents section of the “Submission Detail” page *{Table of documents attached to the package by the IACUC Administrator is shown 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 the “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 change the Document Type for an existing board document, click the blue triangle in front of the Document Type for the document of interest => [drop-down menu]

Acknowledgment

Continuing Review Notice

## IACUC Administrator: Process a Package for Review

Decision Letter

Other

Request for Information

Stamped Document

Worksheet/Checklist

*{Document Type cannot be changed for Wizard documents}*

To edit a Board Document, click the “pencil” icon in the “Board Documents” table on the “Submission Detail” page =>

If the Board Document being edited was created by a Wizard,

Select “Start with a copy of this document to create a new version” OR “Start a new wizard from scratch to create a new version” => “IRBNet Document Wizard page”

*{opens the existing Wizard document OR a new one for the same Document Type, for editing the content and format}*

To see what the document will look like, click “Preview” button => downloads the document

To save edits, click “Save and Exit” button => updates “Last Modified” date  
Publish Date is updated to “Draft”

If the Board Document being edited was an uploaded file, this => “Board Documents” page

Enter “Document Type” [drop-down menu]

Acknowledgment

Continuing Review Notice

Decision Letter

Other

Request for Information

Stamped Document

Worksheet/Checklist

Enter “Description” [free text field]

Choose “File” from browser

*{The file uploaded as a revision of an existing board document may be any file, at the discretion of the IACUC Administrator}*

To replace the existing board document with the updated file, click “Update” button => “Submission Detail” page with updated “Last Modified” date

Publish Date is updated to “Draft” *{Draft versions of a document are not archived in the Document Revision History and are only accessible by Committee Members and Administrators}*

To remove a board document, click “X” icon

*{only for board documents that have not been published yet}*

## IACUC Administrator: Process a Package for Review

To “Add” a new board document, click “Add decision letters and other documents” link on “Submission Detail” page => “Board Documents” page

*{IACUC Administrator may add board documents after package has been approved}*

To attach existing files as board documents *{may be created from forms and templates in the board library}*,

Enter “Document Type” [drop-down menu]

Acknowledgment

Continuing Review Notice

Decision Letter

Other

Request for Information

Stamped Document *{e.g., protocol documents for secondary review after approval date is entered into header and certification statements signed}*

Worksheet/Checklist

Enter “Description” [free text field]

Select “File” from browser

Click “Attach” button => “Submission Detail” page with new Board Document (current date as “Last Modified” date) in the table of “Board Documents”

Publish Date is “Draft” *{Draft versions of a document are not archived in the Document Revision History and are only accessible by IACUC Members and IACUC Administrators}*

To attach a document created with a Wizard

Select the Document Wizard [drop-down menu] *{The name of the Document Wizard will be entered as the Document Type}*

IACUC Approval Letter *{for full and unconditional approval}*

IACUC Approval Re-instatement Letter *{for lifting the suspension of IACUC approval}*

IACUC Approval Suspension Letter *{for suspension of IACUC approval}*

IACUC Notification Letter *{for other IACUC actions, such as*

*Acknowledgement of receipt*

*Completion of a continuing review*

*Approval Withheld*

*Package tabled without action*

*Closure of a protocol*

*Withdrawal of package from IACUC review*

*Guidance about response to secondary review comments}*

IACUC RMSA Letter *{Provides the specific modifications required to secure IACUC approval}*

Click “Add” button => updates “Last Modified” date

Publish Date is updated to “Draft” *{Draft versions of a document are not archived in the Document Revision History and are only accessible by IACUC Members and IACUC Administrators}*

To attach a document that is a revision of a board document from an earlier submission of this project, click “Revise a Board Document from a Prior Submission” link at the end of the “Add decision letters and other board documents” on the “Submission Detail” page => “Project Board Document” table

Click on the “pencil” icon for the document of interest => edit as for board documents already attached to this package *{records that the board document attached to this package is related to the board document attached to an earlier package for this project}*

To make a new or revised board document a permanent part of the package, click “Publish Final” link for the document OR click “Publish All” above the upper right corner of the table *{available when there is >1 document in draft status}* => window to confirm that the document is to be published

To limit access to the board document to just IACUC Members and IACUC Administrators, use the checkbox for “internal only” *{Project Owners do not have access and are not notified}*

To confirm request to publish, click “Continue” button => updates “Publish Date” to current date

*{Project Owners are notified that a board document has been published for them to access}*  
*{Published documents are archived and become part of the Document Revision History}*

To change access to a board document that was initially published internally, click “(internal)” link on the “Submission Detail” page => window showing the option to “change to a fully published document”

Check “yes” and click the “Continue” button => changes status to fully published *{sends notification to Project Owners}*

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

Share section of the “Submission Detail” page *{for granting access to IACUC Reviewers}*

To manage access to the package, click the “Share” link just below the link for adding board documents, on the “Submission Detail” page => “Share Submission” page with table of all accounts to which access may be granted

*{Accounts set up by IRBNet with “Committee Member” access may include some who are not appointed voting members of the committee, but need the same level of access for other purposes. It is the IACUC Administrator’s responsibility to share the package with each voting*

## IACUC Administrator: Process a Package for Review

*member {Reviewer} appointed to the IACUC (regular or alternate), all of whom are required by the regulatory language to have access to each protocol to be reviewed by the IACUC – IRBNet does not maintain a list of voting IACUC members, it is up to the IACUC Administrator to keep track of the membership}*

Radio buttons show Access Type for each user

Administrators *{Administrator access is granted by default, cannot be changed}*

Committee Members – click applicable radio buttons *{IACUC Administrator may assign No Access, Reviewer access, or Administrator access, specific to this submission}*

(Optional) Set a reference date for each account with access to the package [calendar]

*{Significance of the reference date is according to local discretion, not defined in IRBNet – Typically, the date is the due date for the review; reminder emails are sent according to what the station has specified to IRBNet Support with regard to the number of reminders to be sent, the number of days before or after the due date each reminder is to be sent, and the text of the email}*

(Optional) Set an alarm for each account with access, for notifying the IACUC Administrators:

Single bell icon *{notification when the individual IACUC Reviewer marks the review “complete”}*

Double bell icon *{notification when all the IACUC Reviewers with a double bell have marked their reviews “complete”}*

*{IACUC Administrators with no reviewer responsibilities typically do not get alarms set}*

Enter any “Special Designation” for a user [drop-down menu] *{refers to special Reviewer role assigned by the Administrator, not role on the committee}*

(blank) *{Most IACUC Reviewers will not have a Special Designation, and this can be left blank}*

Attending Veterinarian *{This may be used for the veterinary pre-consult, before submission of the protocol for IACUC review. There is no other special reviewer role associated with being the AV.}*

Designated Reviewer *{Each of the two or more reviewers assigned by the Chair to be the reviewers for DMR on this protocol.}*

Primary Reviewer *{VA requires at least 2 “Primary Reviewers” for each protocol, so designate both as “Primary Reviewers”.}*

Secondary Reviewer *{“Secondary Reviewer” may be used to designate reviewers who are not Primary Reviewers but have locally assigned reviewer responsibilities beyond those of reviewers without special designations.}*

To notify users of changes in level of access, check the “Notify” checkbox *{no notification is sent just for changes in “Special Designation”}*

## IACUC Administrator: Process a Package for Review

(Optional) To include comments in the notification to users for whom access is changed, enter in “Your Comments” [free text box]

To save the updates on the “Share Submission page, click the “Save” button => “Submission Details” page with table of sharing updated

To send an internal communication (to just the IACUC Members and IACUC Administrators), click “Send Committee Mail” OR the “envelope” icon below the table of those with shared access, on the “Submission Detail” page => “New Committee Message” page *{These messages are not available to Researchers}*

To select the recipients of the emailed message, use the checkboxes for accounts with access to the submission

*{Message is also posted to “Committee Messages & Alerts” for access by all Committee Members and Administrators (even if no accounts were designated to receive the email)}*

Enter “Subject” and “Message” in free text boxes *{default text shown is just an example, and may be replaced}*

To send the message, click “Send” button

To see all internal communications (to IACUC Members and IACUC Administrators, regardless of which ones received the messages by email), click the “Committee Messages” link below the table of users on the “Submission Detail” page => “Committee Messages & Alerts” page

Click the “flag” icon to toggle the flag on and off as a personal reminder *{just for the IACUC Administrator who sets the flag}*

Click the “Project Title” link => “Submission Detail” page for the package that the message was sent for

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 on the table of Reviewers, 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 “Add” link above the table of Reviewers on the “Submission Detail” page for the IACUC Administrator’s comments and documents

*{for the IACUC Administrator’s Comments and Documents, shown if the IACUC Administrator has not yet provided comments or reviewer documents}*

OR the “Update” link above the table of Reviewers on the “Submission Detail” page for the IACUC Administrator’s comments and documents



## IACUC Administrator: Process a Package for Review

*{for the IACUC Administrator's Comments and Documents, shown if the IACUC Administrator has already provided comments or reviewer documents}*

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

OR the "sheet of paper" icon under "View" in any row of the table of IACUC Reviewers on the "Submission Detail" page  
*{for any IACUC Administrator or IACUC Reviewer, shown if that user has already uploaded a reviewer document}*

On the "Reviewer Comments" page, see (for any IACUC Reviewer) or enter/edit (for the IACUC Administrator's own review only):

"Reviewer Comments" [free text box]

"Recommendation" [drop-down menu of IACUC Actions] *{IACUC Administrator has no authority to formally recommend any IACUC action, so it is best to leave this blank and enter any suggestions only in the comments, for the "Reviewer Comments" of the IACUC Administrator.}*

(blank)

Acknowledge

Approve

Close

Disapprove

Information Required

Modifications Required

Not Research

Refer to Full Board

Suspend

Terminate

"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}*

"Reviewer Documents" table displays all files attached by the IACUC Administrator or IACUC Reviewer

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 the "Sheet of paper" icon in the "View" column



## IACUC Administrator: Process a Package for Review

To add a Reviewer document to the IACUC Administrator's own review, click the "Add New Document" button" at the bottom of the "Reviewer Comments" page => "Reviewer Documents" page

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

To change a document that the IACUC Administrator has already attached, click the "Update" link in the "Reviewer Documents" table *{only displayed for the IACUC Administrator's own Reviewer Documents}* => "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 *{only displayed for the Reviewer's own Reviewer Documents}* 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"}*

### Managing Packages

To remove a package, click the "Delete This Package" button in the sidebar menu *{Option is only available for a package that is being created (in Designer) and hasn't been submitted at all yet}*

To set up a new package for the Researcher to assemble documents for, click on "Create a New Package" in one of the following locations => "Designer" page for a new package for this project

Button in the sidebar menu

OR option in the drop-down menu from the blue triangle in front of the package number on the "Designer" page

*{Researcher can do this when all previous packages for this project have already been submitted. Only the Administrator can do this if there is still an earlier 'work in progress' package that has not been submitted yet.}*

To submit a package to a board, click the "Submit this Package" button in the sidebar menu => "Submit Package" page

"Select a Board" [options displayed in menu]

*{Administrator may select one or more of the boards to which the package has not yet been submitted. IACUC Administrator submits Special Events packages to the IACUC.}*

Local IACUC

## IACUC Administrator: Process a Package for Review

Local R&D Committee

Local Research Administration

VA Chief Veterinary Medical Officer (CVMO), Washington, DC

Click the “Continue” button => window on the “Submit Package” page

*{Notification of submission is sent automatically to the Administrator for the receiving board}*

Enter Submission Type [drop-down menu]

*{Options provided in menu depend on the board to which the package is being submitted, and just serve as labels for the convenience of the Administrator, indicating the reason for submitting the package}*

For submission to Research Admin or IACUC

Amendment/Modification *{for protocols}*

Closure/Final Report *{for protocols}*

Continuing Review/Progress Report *{for protocols}*

Facility Inspection/Program Review *{N/A for submission of packages, which are project-specific}*

Funding/Grant *{N/A for submission by Researcher to IACUC, or by IACUC Administrator}*

New Project *{for protocols}*

Other *{for Special Event packages, examples include:*

*Reports to the IACUC about FOIA requests received*

*Media inquiries received*

*Public communications about specific projects*

*Internal reports – PAM, concerns about specific projects}*

Publication *{e.g., submission of a Special Event Package about publishing images/video, for IACUC’s awareness / review}*

Reportable Event *{for Special Event packages -- potentially reportable matter related to a specific project}*

Response/Follow-up *{package containing Researcher’s correspondence related to RMSA or a Special Events package following up on a potentially reportable matter related to a specific project}*

Revision

Triennial Review *{for protocols}*

For submission to R&D Committee

Subcommittee Minutes

Subcommittee Program Review

For submission to CVMO office

Modification *{submitted because of a modification in the protocol that requires assignment to a higher USDA Category}*

New Project *{submitted to initiate secondary review}*

## IACUC Administrator: Process a Package for Review

On-Going Project *{submitted for re-review of an ongoing project}*  
Other  
Response/Follow-up *{submitted in response to secondary review comments}*

Enter "Your Comments" *[free text box]*  
*{for text to include in notification to be sent to board Administrators about the submission}*

Click the "Submit" button => "Submit Package" page confirming submission  
*{Submission appears in "Reviewing Board" table on "Project Overview" page}*

IACUC Admin

## 9. IACUC Administrator: Manage Review of a Package

*{IACUC Administrator receives notification when a package is submitted to the IACUC.}*

*{“Submission Manager” page is displayed on login.}*

To access a package, click on the “Project Title” of any 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}*

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

To assign the submitted package to an Agenda, go to the “Review Details” section of the “Submission Detail” page, click the blue triangle in front of the current agenda assignment => [drop-down menu of all currently scheduled meetings, “unassigned”, and “Add a New Agenda”]

Click an existing agenda to assign the package to it

To create a new meeting to which packages can be assigned, click “Add Another Agenda Date” link above right corner of table => adds new “unassigned” agenda to table

To schedule the date, time, and location of the new meeting, click the blue triangle before the “unassigned” agenda, and choose “Add a New Agenda” in drop-down menu => “Add Meeting” window

To select a date and time, click “...” button => Calendar and clock window

To enter a meeting location, click the [free text field] for “Meeting Location”

To save new meeting, click “Continue” => new meeting appears in drop-down menu

To view agenda documents for the meeting to which the submission has been assigned, click “sheet of paper” icon on the “Review Details” table on the “Submission Detail” page => “Agenda Documents for [date][time]” window *{shown if agenda has been created}*

To download a document, click on Document Type link or “sheet of paper” icon for the document of interest

To add an agenda document, click the “Manage Documents” link in the banner at the top of the “Agenda Documents for [date][time]” window => “Agenda Documents” page

Click the “Attach” link just below the table of “Agenda Documents” => “Attach Agenda Document(s)” window on the “Agenda Documents” page

## IACUC Administrator: Manage Review of a Package

Enter "Document Type" [drop-down menu]  
Enter "Description" [free text field]  
Choose file from File Explorer  
Click the "Attach" button

To change an existing agenda document, click the "Manage Documents" link in the banner at the top of the "Agenda Documents for [date][time]" window => "Agenda Documents" page

Click the "update" link for the document of interest =>

"Agenda Builder" page if the agenda is to be updated

"Update an Attachment" window on the "Agenda Documents" page  
*{information about the file that was previously attached is shown for reference}*

Enter "Document Type" [drop-down menu]  
Enter "Description" [free text field]  
Choose file from File Explorer  
Click the "Attach" button

To assign the submitted package to IACUC Reviewers, click the "Share" link below the link for adding board documents, on the "Submission Detail" page => "Share Submission" page with table of all accounts to which access may be granted

*{It is the IACUC Administrator's responsibility to share the package with each voting member (Reviewer) appointed to the IACUC (regular or alternate), all of whom are required by the regulatory language to have access to each protocol to be reviewed by the IACUC – IRBNet does not maintain a list of voting IACUC members, it is up to the IACUC Administrator to keep track of the membership}*

Click radio buttons to specify the Access Type for each user, specific to this package

Administrators *{Administrator access is granted by default to IACUC Administrators, and cannot be changed. Administrator access includes access of the IACUC Administrator as an IACUC Reviewer as well.}*

Committee Members *{options include not only appointed voting IACUC members, but also others identified by the station as authorized to have the same access in IRBNet as voting IACUC members have}* – click applicable radio buttons

No Access *{for users set up by IRBNet with "Committee Member" access, who are not actually appointed voting members of the IACUC, and don't otherwise need access to this package}*

## IACUC Administrator: Manage Review of a Package

Reviewer access *{for every appointed voting member of the IACUC who doesn't have Administrator access}*

Administrator access *{includes Administrator function, for just this package}*

(Optional) Set a reference date for each account with access to the package [calendar]

*{Significance of the reference date is according to local discretion, not defined in IRBNet – Typically, the date is the due date for the review; reminder emails are sent according to what the station has specified to IRBNet Support with regard to the number of reminders to be sent, the number of days before or after the due date each reminder is to be sent, and the text of the email}*

(Optional) Set an alarm for each account with access, for notifying the Administrators:

Single bell icon *{notification when the individual Reviewer marks the review “complete”}*

Double bell icon *{notification when all the Reviewers with a double bell have marked their reviews “complete”}*

*{Administrators with no reviewer responsibilities and typically do not get alarms set}*

Enter any “Special Designation” for a user [drop-down menu] *{refers to special reviewer role for this package, not role on the committee}*

(blank) *{Most Reviewers will not have a Special Designation, and this can be left blank}*

Attending Veterinarian *{This may be used for the veterinary pre-consult, before submission of the protocol for IACUC review. There is no other special reviewer role associated with being the AV.}*

Designated Reviewer *{Each of the two or more reviewers assigned by the Chair to be the reviewers for DMR on this protocol.}*

Primary Reviewer *{VA requires at least 2 “Primary Reviewers” for each protocol, so designate both as “Primary Reviewers”.}*

Secondary Reviewer *{“Secondary Reviewer” may be used to designate reviewers who are not Primary Reviewers but have locally assigned reviewer responsibilities beyond those of reviewers without special designations.}*

To notify users of changes in access, check the “Notify” checkbox *{no notification is sent just for changes in “Special Designation”}*

(Optional) To include comments in the notification to users for whom access is changed, enter in “Your Comments” [free text box]

To save the updates on the “Share Submission page, click the “Save” button => “Submission Detail” page

To manage Reviewer Comments and Reviewer Documents, scroll to the table at the bottom of the “Submission Detail” page, and click the “View” link to see the input of each Reviewer *{Administrator cannot change the reviewer comments and documents of others, but can review them administratively and contact the reviewer by email, outside of IRBNet, in case of concerns such as:*

*Missing text in the Reviewer Comments*

*Document referenced in the Reviewer Comment is not attached*

*No recommendation indicated*

*Review not marked as “complete”*

To see summary information about the review of a package, to go the “Review Details” section of the “Submission Detail” page

Agenda (meeting date and time)

*{scheduled IACUC meeting to which the package has been assigned}*

Most recent information about the review *{from “Review and Minutes” page}*

“Review Type”

“Action” *{Most recent board action taken}*

“Effective Date” *{The effective date of the most recent board action taken}*

“Expiration Date” *{The expiration date of the project}*

“Report Due” *{The date when the next report is due from the Researcher}*

To see/edit a summary of the IACUC deliberations and decisions for the Minutes, click “pencil and paper” icon for the Agenda of interest in the “Review Details” table on the “Submission Detail” page => “Review and Minutes” page *{This documents for the IACUC what the IACUC did with this submission, at the meeting selected}*

Review Type [drop-down menu]

(blank) *{Unassigned or N/A -- use this for any package that did not involve the specific review processes defined by PHS Policy for protocol review}*

Full Committee Review

Administrative Review

Designated Member Review

Action [drop-down menu] *{Actions that the IACUC took on the package at this meeting}*

(blank) *{before the IACUC meets, or if the IACUC did not take any Action described by one of the other menu options – e.g., determination that a matter is reportable, suspension of approval 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

Forwarded *{not an IACUC Action -- if the package is not one that requires IACUC action, it should be “Withdrawn” from IACUC review and reassigned by R&D Committee}*

Information Required *{not an IACUC Action -- if the IACUC requires more information before it can take action, the item should be “Tabled Without Action” instead}*

Modifications Required *{RMSA}*

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



## IACUC Administrator: Manage Review of a Package

Not Research *{not a determination for the IACUC to make -- if the R&D Committee makes the determination that the project that has been submitted to the IACUC is actually not VA research, it should be "Withdrawn" from IACUC review}*

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

Suspended *{requires a majority vote of the IACUC at a convened meeting}*

Tabled Without Action *{Choose this option if the IACUC considered the item of business but delayed voting on approval, and explain why in the "Discussion and Remarks" (e.g., because quorum was not present, because part of a protocol under review is missing, because revision of the minutes is required before the IACUC can vote)}*

Terminated *{Do not use this term, as it does not distinguish among different types of termination and will cause confusion; use "closed", "suspended", or "withdrawn", as appropriate, instead}*

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 [select from calendar] *{refers to effective date of the board Action that was recorded, which may be on or after the date on which the board acted}*

Project information *{on the "Review and Minutes" page}*

Project Status *{refers to the project that the package belongs to, not to the status of any single package submitted to the IACUC for this project}*

(blank) *{applies before the IACUC has taken any action that changes the project status (package 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, no more than 3 years after it was granted). "Suspended" is a separate status, below.}*

Closed – Expired *{use "Closed" instead}*

Closed – Project Complete *{use "Closed" instead}*

Deferred – Information Required *{not a project status – if the IACUC defers taking any action, project status remains unchanged}*

Deferred – Modifications Required *{not a project status – if the IACUC makes a determination of RMSA, project status unchanged}*

Disapproved *{approval denied}*

Not Research *{not a project status, use "Withdrawn" instead}*

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

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

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

Dates [select from calendar, the dates that apply to the project] *{defined by local policy}*



## IACUC Administrator: Manage Review of a Package

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 => 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 earlier.}*

*{for 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 requested by the IACUC}*

Initial Approval Date *{the most recent date when the protocol was granted approval by the IACUC, from which the triennial expiration date is calculated}*

To document for the Research Team the outcome of the IACUC’s review, click the “Add” link below the table of “Board Documents” on the “Submission Detail” page => “Board Documents” page *{Table is displayed only if at least one Board Document has already been added.}*

Select an existing document from the browser

OR

Select the Document Wizard appropriate to the IACUC’s action [drop-down menu] *{The name of the Document Wizard will be entered as the Document Type}*

IACUC Approval Letter *{for full and unconditional approval}*

IACUC Approval Re-instatement Letter *{for lifting a suspension of IACUC approval}*

IACUC Approval Suspension Letter *{for suspension of IACUC approval}*

IACUC Notification Letter *{for other IACUC actions, such as*

*Acknowledgement of receipt*

*Completion of a continuing review*

*Approval Withheld*

*Package tabled without action*

*Closure of a protocol*

*Withdrawal of package from IACUC review*

*Guidance about response to secondary review comments}*

IACUC RMSA Letter *{Provides the specific modifications required to secure IACUC approval}*

Edit the text as needed

## IACUC Administrator: Manage Review of a Package

Click “Add” button => attaches .pdf board document to the package and updates the “Last Modified” date

Publish Date is updated to “Draft” *{Draft versions of a document are not archived in the Document Revision History and are only accessible by IACUC Members and IACUC Administrators}*

To make the document a permanent part of the project record, click the “Publish Final” link under Publish Date => confirmation window for publishing  
*{Publishing adds the document to the Document Revision History}*

To limit access to the document to just IACUC Members and IACUC Administrators, check the checkbox for “Publish this document as ‘internal only’” *{document will not be available to the Research Team}*

To make the document available to the Research Team as well as the IACUC Members and IACUC Administrators, leave unchecked the checkbox for “Publish this document as ‘internal only’”

To make a document available to the Research Team that has already been published internally, click the “(internal)” link under “Publish Date” => confirmation window to “change to a fully published document”

To confirm the request to publish, click “Continue” button => updates “Publish Date” to current date

*{Email notification about a board document being published is sent to the Project Owners when the document is published fully.}*

## 10. IACUC Administrator: Manage Agenda

*{The agenda is the plan for what will be discussed at the meeting.}*

To access an agenda, click on “Agendas and Minutes” in sidebar menu => “Agenda Manager” page  
*{Displays scheduled meetings (date, time, location)}*

Select the board of interest in “Agendas for” [drop-down menu]

Then do one of the following => “Agenda Builder” page

Click the “Agenda Builder” link for the meeting of interest on the “Agenda Manager” page

OR click the “Minutes Builder” link for the meeting of interest on the “Agenda Manager” page, and then click “Go to Agenda Builder” link below the name of the page on the “Minutes Builder” page

OR click the “sheet of paper” icon in the “Review Details” table on the “Submission Detail” page => “Agenda Documents for [meeting of interest]” table

*{“sheet of paper” icon is shown only if an agenda has been published}*

Click “Agenda Builder” link at the top of this table

To set up a default template for agendas, click on the “Add/Update/Delete Sections” link above the “Agenda Details” table on the “Agenda Builder” page => Agenda Sections window

Enter/Edit integers in the “Section Order” boxes to show the order in which sections are to be displayed

Enter/Edit “Section Title” for each section of the agenda [free text field]

Click “Delete” link to remove a section from the agenda

Click “Add New Section” button at the bottom of the “Agenda Sections” window => a new (blank) row is added to the table of sections

Check the box to save the template as the default for future agendas

*{There is no requirement to use the sections or order of sections displayed as the default settings by IRBNet. Following are suggestions for sections likely to be useful to VA IACUCs. Grayed text for “Section Titles” is text shown in the IRBNet default setup, that are not important for VA IACUCs. Save a default template for your VA IACUC, then delete from any particular agenda those sections that do not apply for that meeting.}*

Welcome and Opening Remarks *{not required as an agenda item – information will be entered into the “General Information” section of the minutes}*

Attendee Roll Call *{not required as an agenda item – information will be entered into the “Attendance” section of the minutes}*

## IACUC Administrator: Manage Agenda

Next Meeting Date and General Announcements

Review of Previous Minutes

New Protocols Complete Review of Protocols by Full Committee (FCR) *{for protocols newly submitted for initial or renewal approval, or for closure}*

FCR of Protocols Modified in Response to RMSA

Continuing Reviews *{as required by the IACUC}*

Protocols and Modifications Reviewed by Designated Member Review (DMR) *{Depending on local policy, may include new and renewal protocols, responses to RMSA, and modifications, for which the IACUC has agreed to DMR}*

FCR of Protocol Modifications

Protocols Modified by VVC *{Agenda item for informing the IACUC of these, no action is to be taken by the IACUC}*

Administrative Protocol Updates

Revisions *{There's no need to have a separate section of the agenda for these, include with "Protocols and Modifications Reviewed by DMR" or "Full Committee Review of Protocol Modifications", as appropriate}*

Renewals *{There's no need to have a separate section of the agenda for these, include with "New Full Committee Review of Protocols" or "Protocols and Modifications Reviewed by DMR"}*

Terminations *{There's no need to have a separate agenda section for these, include with "New Full Committee Review of Protocols" or "Protocols and Modifications Reviewed by DMR"}*

Adverse Events Other Protocol Matters *{“Adverse events” is not defined in the regulatory language for research with animals, use “Potentially Reportable Matters” instead.}*

Potentially Reportable Matters

Other Business *{examples include: FOIA requests, site visits, public communications, semiannual evaluations, PAM reports, RCO audit reports, overheat test reports}*

Continuing Education

Unassigned

To assign items to an agenda,

To assign to an agenda, packages that have been submitted to the board, click the “Project Title” of the package of interest => “Submission Detail” page for that package

Click the blue triangle in front of the “Agenda” assignment of interest in the “Review Details” table on the “Submission Detail” page => [drop-down menu of agendas to which the package may be assigned]

Click the agenda in the drop-down menu to which the package is to be assigned => package is added to the “Unassigned” section of the “Agenda Builder” for that agenda

Move the item from the “Unassigned” section to the appropriate section on the agenda, go to the “Agenda Builder” *{see next paragraph of this to-do guide, “to re-arrange items on the agenda”}*

## IACUC Administrator: Manage Agenda

To assign an item to the agenda that is associated with a project, but does not originate from a Research Team, create a Special Event Package and assign it to the agenda like any other package

*{IACUC Administrator may attach board documents to a Special Events Package}*

To assign an item to the agenda that is not associated with a project, click the “Add New Agenda Item” link above the “Agenda Details” table on the “Agenda Builder” page => “Add Agenda Item” window

*{Such an agenda item is not a package, so it does not contain any package documents, and cannot have board documents attached specifically to it.}*

*{Documents may be attached to the agenda as a whole, by the IACUC Administrator.}*

Choose the section to which to assign it [drop-down menu]

Enter “Description/Remarks” [free text field] *{500 characters, first ~25 characters are displayed as the “title” of the item on the agenda}*

Click “Save” button

To assign an item to the agenda that is not associated with a particular research project, but requires IACUC review and approval of specific documents, create an “administrative project” with a package to submit to the IACUC *{See “IACUC Administrator: Sequence of Events for an Administrative Project”, below}*

To re-arrange items on the agenda

To move an item to a different section of the agenda, click the “Move” link for the item on the table of agenda items displayed by clicking the “+” button for that agenda section on the “Agenda Builder” page => [drop-down menu of sections]

To remove an item, click the “Delete” link for the item on the table of agenda items displayed by clicking the “+” button for that agenda section on the “Agenda Builder” page *{shown only for non-package items}*

To assign sequence numbers in the current order of presentation of the items in a section, click the “auto-fill” link below the items for the section

To edit the sequence numbers, click the “order” link in the header row for the section

To access the documents attached to an agenda, click on the “sheet of paper” icon on the “Agenda Manager” page => “Agenda Documents” page for that meeting

*{displays “Agenda Documents” table listing all documents attached to the agenda, including any published agenda and any published minutes}*

To download a document, click on the “sheet of paper” icon in the “View” column of the “Agenda Documents” table

To edit a document, click “Update” in the “Agenda Documents” table => the page for editing the document

To remove a document from the agenda (and table), click “Delete” in the “Agenda Documents” table

To add a document to an agenda, click the “Attach” link just below table of agenda documents  
=> “Attach Agenda Documents” window

Select “Document type” [drop-down menu] *{just for convenience, no functional significance}*

Agenda  
Educational  
Memo  
Minutes  
Newsletter  
Other  
Policy  
Report  
Worksheet

Enter “Description” of the document [free text field]

To select an existing file, click the “Choose File” button => Explorer

*{browse to select the file of interest}*

*{Selected file gets added to the table of agenda documents – Description is shown, not filename}*

To make the attached documents available to all IACUC Reviewer accounts, click one of the following => “Agenda Builder” page

the “Agenda Builder” link below the “Agenda Documents” table

Or the “Agenda and Minutes” button in the sidebar menu, then the “Agenda Builder” link in the table

then click the “Publish Agenda” button at the bottom of the page

To identify all the packages that are on an agenda,

Click the “sheet of paper” icon for the agenda on the “Agenda Manager” page => “Agenda Documents” page

Then click the “Submissions” link below the “Agenda Documents” table on the “Agenda Builder” page => “Submission Manager” page with table of submissions for this meeting

## IACUC Administrator: Manage Agenda

OR click the “Submission Manager” button in the sidebar menu => “Submission Manager” page

Then choose the agenda of interest for Agenda [drop-down menu]

And click “search”

To see the agenda as a .pdf document, click the “Preview PDF” button at the bottom of the “Agenda Builder” page

To make the agenda available to all IACUC Reviewers, click the “Publish Agenda” button at the bottom of the “Agenda Builder” page => adds the agenda to, and goes to, the “Agenda Documents” page

*{Agenda may still be edited or deleted after being published}*

*{After the IACUC has met, edits should be limited to correction of administrative errors – new actions taken by the IACUC should be documented by submission of a Special Event package for processing at the next meeting}*

*{All IACUC Reviewers have access to published agendas, regardless of whether they have been granted access to any package on the agenda}*

## 11. IACUC Administrator: Manage Minutes

*{The minutes document the business conducted by the IACUC at the meeting, so the Minutes Builder reflects the sections and items on the corresponding agenda. If an item of business was added to, or removed from, the agenda during the meeting, update the Agenda to reflect these, before proceeding with building the Minutes.}*

*{Minutes may still be edited after being published}*

*{After the IACUC approves the minutes, edits should be limited to correction of administrative errors – new actions taken by the IACUC should be documented by submission of a Special Event package for processing at the next meeting}*

To access the minutes for a meeting, click on “Agendas and Minutes” in sidebar menu => “Agenda Manager” page,

*{Displays scheduled meetings (date, time, location)}*

Then do one of the following => “Minutes Builder” page

Click the “Minutes Builder” link for the meeting of interest on the “Agenda Manager” page

OR click the “Agenda Builder” link for the meeting of interest on the “Agenda Manager” page, and then click “Go to Minutes Builder” link below the name of the page on the “Agenda Builder” page

To edit the General Information for the Minutes, use the “Jump to” drop-down menu to select “General Information”, and click the “Jump” button => display “General Information”

To enter the date/time the meeting was “Called to Order”, click on the “calendar” icon and select the date and time

*{The scheduled date and time are pre-filled, but may be edited. IRBNet does not validate these entries. They are entirely at the IACUC Administrator’s discretion}*

To enter the date/time the meeting was “Adjourned”, click on the “calendar” icon and select the date and time *{This takes care of adjournment, so there is no need to make adjournment an item of business in a separate agenda section}*

*{IRBNet does not validate these entries. They are entirely at the IACUC Administrator’s discretion}*

To document the quorum, click the appropriate radio button for “Was a Quorum Present When Called to Order?”

*{This is of limited value, as IRBNet does not validate the entry, or make any actions contingent on the response shown. The response is entirely at the Administrator’s discretion. Attendance and whether a quorum is present may change over the course of the meeting, and should be noted in the “Discussion and Remarks” for each item of business. It is entirely up to the IACUC Administrator and IACUC to track the number}*



*voting members appointed and the number of voting members present, to determine whether a quorum was present for each item of business conducted by the IACUC. It is the IACUC's responsibility to recognize when it does not have the quorum required to conduct business.}*

To edit the Attendance (lists) for the Minutes, use the "Jump to" drop-down menu to select "Attendance", and click the "Jump" button => display "Attendance"

To set up the Attendance lists of interest,

To edit the name of any list, click the "pencil" icon

To remove any list, click the "X" icon

To create an additional list, click the "Add a New List" button below all existing lists,

*{The only lists needed for the IACUC are:*

*"Voting Members Present"*

*The entire regular voting membership of the IACUC must be identified on the "Voting Members Present" and "Voting Members Absent" lists together (documents that the committee is constituted)  
Include as "Voting Members Present" any Alternates present and serving in place of absent regular members*

*"Voting Members Absent"*

*The entire regular voting membership of the IACUC must be identified on the "Voting Members Present" and "Voting Members Absent" lists together (documents that the committee is constituted)  
Do not include as "Voting Members Absent" any absent Alternates for regular members who are present*

*"Non-Voting Attendees, Staff & Guests Present"*

*Include as "non-Voting Attendees" any Alternates present who are not voting because the regular members are present}*

To populate the Attendance lists, click "-- Add/Remove Names --" toggle link above the list of interest => menus of options

*{The same options are shown for each list – it is entirely at the IACUC Administrator's discretion to decide who belongs on which list. IRB does not validate the lists or check for duplication.}*

To add/remove a name to/from a list, click the "Add/Remove Names" link => [drop-down list of submenus]

Then click the name of a submenu => [drop-down list of names]

And click a name to toggle between adding and removing it

*"Committee" submenu {Contains all of the accounts with which any package on the agenda has been shared. This submenu does not include every account that has been set up with IACUC "Reviewer" access.}*

*{It is a regulatory requirement that every package submitted for review must be made available to (shared with) every appointed member (regular or alternate) of the IACUC. The IACUC Administrator is responsible for sharing each package accordingly, which ensures that every appointed member will be on the "Committee" submenu.}*

*{IRBNet does not track appointments to voting membership. It is the responsibility of the station to submit changes in IACUC membership to IRBNet, for updating the assignment of "Reviewer" access.}*

*{IRBNet additionally assigns Reviewer affiliations to users who are not appointed members (e.g., the ISSO, safety personnel), at the request of the station. If the Administrator shares a package on the agenda with one of these, that name will also be included on the "Committee" submenu.}*

"Manually Add a Name" => "Add a Name" window for entering "First Name" and "Last Name" [free text fields requiring entry of at least one character each] and "Degrees" [optional free text field].

*{This records attendance at the meeting, without granting reviewer access}*

*{The names entered need not correspond to the names on any IRBNet accounts}*

"Other Names" submenu

*{includes all names that have been added manually, so they can be removed}*

To specify "Designations, Specialties and Affiliations" for anyone on an attendance list, click the "-- Add/Remove --" toggle link for that person on the attendance list => [drop-down list of roles]

*{multiple roles can be specified for each person, and are simply added to whatever is already showing}*

*{the roles below that are required by regulatory language are designated with \*, and must appear somewhere in the lists of voting members; all other designations are optional; greyed options are not recommended for VA IACUCs}*

Alternate member *{use "Alternate for" designation, at the bottom of the menu of roles, instead}*

\*Attending Veterinarian

\*Chair

Co-Chair

Community Member *{use "Non-Affiliated" designation instead}*

Consultant

Guest

Institutional Official

Legal Specialist

\*Non-Affiliated

## IACUC Administrator: Manage Minutes

### \*Non-Scientific

Non-Voting Alternate *{no need to designate as “non-Voting”, enter in the Attendance list of “Non-Voting Attendees Present” to indicate that alternate will not be voting}*

### \*Scientific

Staff

Vice Chair

Alternate for *{brings up drop-down “Committee” list, IRBNet does not check whether the regular member is absent}*

Manually add designation

*{free text entered is added to whatever is already showing}*

*{To delete existing text, remove the name and add it back again}*

To edit the Minutes for individual “Agenda Items”, use the “Jump to” drop-down menu to select “Agenda Items”, and click the “Jump” button => display “Agenda Items”

*{The same standard templates are provided for all agenda sections and for all agenda items, regardless of the nature of the IACUC business addressed, so it is up to the IACUC Administrator to select the relevant elements to use in each.}*

*{None of the fields provided is a required field, so any field may be left blank if it does not apply.}*

To edit each agenda section, click the “pencil and paper” icon for that section => “Agenda Section Details [section number]” display

*{The sections of the agenda generally correspond just to headings in the minutes, so most fields may simply be left blank.}*

Review Type [drop-down menu]

(blank) *{Use this for most section headings, as “Review Type” applies only to individual items of business}*

Full Committee Review

Administrative Review

Designated Member Review

Action [drop-down menu of actions that the IACUC can take on an item of business]

(blank) *{Use this for most section headings, as “Action” applies only to individual items of business}*

Acknowledged

Approved

Closed

Forwarded

Information Required

Modifications Required

Not Approved

Not Research

Referred to Full Board

Suspended

## IACUC Administrator: Manage Minutes

Tabled Without Action *{Choose this option if the IACUC decided to put off action on an entire section of the agenda, and explain in the “Discussion and Remarks” (e.g., because quorum was lost, because the meeting had to be adjourned early)}*

Terminated

Withdrawn

Effective Date [select from calendar] *{Generally not applicable for section headings – leave blank}*

Votes (for, opposed, abstained) [free text field for integers] *{N/A for section headings, leave all blank or 0 for section headings}*

*{votes are displayed on the “Agenda Items” table of the “Minutes Builder” page only if at least one non-zero value is entered}*

Recused [drop-down “Committee” list] *{N/A for section headings – do not add any names}*

Discussion and Remarks [free text] *{Generally N/A for section headings, but notes may be entered here as needed to provide information about the entire section.}*

To edit each individual item of business, click the “pencil and paper” icon for that item =>

“Agenda Section Details [section number . item number]” display

*{For individual items of business within a section, the template contains each of the fields in the template for a section, with additional fields for details about the project, describing how the IACUC action on the package impacts the project}*

Review Type [drop-down menu]

(blank) *{use for items of business that do not involve the specific review processes defined by PHS Policy for protocol review}*

Full Committee Review

Administrative Review

Designated Member Review

Action [drop-down menu of actions that the IACUC can take on the item of business]

(blank) *{Use this before the committee takes up the item – if the board simply didn’t address an item on the agenda, update the agenda to remove the item.}*

Acknowledged *{For items of business that are only to be brought to the attention of the IACUC. For example: packages that contain self-reports of potential noncompliance, reports from the PAM monitor, reports about continuing review, reports of DMR outcomes}*

Approved

Closed

Forwarded *{not an IACUC action -- if the item is not one that requires IACUC action, it should be “Withdrawn” from IACUC review and reassigned by R&D Committee}*

Information Required *{not an IACUC action -- if the IACUC requires more information before it can take action, the item should be “Tabled Without Action” instead}*

## IACUC Administrator: Manage Minutes

Modifications Required *{Use this for a determination of RMSA}*

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

Not Research *{not a determination that the IACUC is authorized to make -- if the R&D Committee makes the determination that the project that has been submitted to the IACUC is actually not VA research, it should be "Withdrawn" from IACUC review}*

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

Suspended *{formal action that can only be taken with a majority vote at a convened meeting}*

Tabled Without Action *{Use this if the IACUC considered an item of business but delayed taking any action, and explain in the "Discussion and Remarks" (e.g., because quorum was not present, because more information was needed, because revision of a document is needed before action can be taken)}*

Terminated *{Do not use this term, as it does not distinguish among different types of termination and will cause confusion; use "closed", "suspended", or "withdrawn", as appropriate, instead}*

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 [select from calendar] *{For individual items of business, this refers to the board Action recorded, not the date on which the board acted, which for actions taken during a meeting is already recorded as the meeting date.}*

*{IRBNet does not validate this date or use it for anything. The Administrator is responsible for recording the date that reflects the intent of the board}*

Project Status *{refers to the project that the package belongs to, not to the status of any single package submitted to the IACUC for this project}*

*{Does not reflect the status of the project being managed by any other board}*

*{Displays the current status when brought to the IACUC for action, to be updated in the minutes to reflect the status of the project after the IACUC action shown was taken}*

*{Some IACUC actions do not impact project status (e.g., potentially reportable events not specific to any project), so project status may be unchanged after IACUC action}*

(blank) *{applies before the board has taken any action that changes the project status (package in preparation, under review, etc.)}*

Active *{the project has the approval of the IACUC for work to proceed}*

Closed *{Explain in Discussion and Remarks whether the project approval expired or was formally closed before expiration, and if formally closed, why (project complete, PI moved, funding no longer available, etc.). "Suspended" is a separate status, below.}*

Closed – Expired *{use "Closed" instead}*

Closed – Project Complete *{use "Closed" instead}*

## IACUC Administrator: Manage Minutes

Deferred – Information Required *{not a project status – if the IACUC defers taking any action, leave project status unchanged, and provide an explanation in the Discussion and Remarks}*

Deferred – Modifications Required *{not a project status – if the IACUC makes a determination of RMSA, leave project status unchanged, and provide an explanation in the Discussion and Remarks}*

Disapproved *{approval denied}*

Not Research *{not a project status, use “Withdrawn” instead}*

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

Terminated *{do not use this term, as it does not distinguish among different types of termination and will cause confusion; use “Closed”, “Suspended”, or “Withdrawn”, as appropriate, instead}*

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

Dates [select from calendar, the dates that apply to the project] *{at the Administrator’s discretion}*

Project Expiration Date

*{for approvals, this is no later than the third anniversary of the effective date of approval}*

*for suspensions or closures, this is the date the suspension or closure took effect}*

Next Report Due *{“report” refers to any formal communication with the IACUC -- e.g., the next routine report, or any other report that the IACUC asks for.}*

*{for approvals, this may be 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 *{the most recent date when approval granted by the IACUC took effect, from which the triennial expiration date is calculated}*

Votes (for, opposed, abstained) [free text field for integers]

*{displayed on “Agenda Items” table of “Minutes Builder” page only if at least one non-zero value is entered}*

*{Leave 0 if no vote was taken}*

Recused [drop-down “Committee” list] *{list includes all those with whom packages on this agenda were shared}*

*{Names selected here have no impact on the “Quorum” recorded under “General Information”. It is up to the Administrator to note in the “Discussion and Remarks” whether the recusals affected the quorum.}*

## IACUC Administrator: Manage Minutes

Discussion and Remarks [free text] *{This contains the substance of the minutes. Provide enough detail to document the issues discussed/considered, concerns raised, etc. Clarify specifics not fully captured by the entries in the summary fields. Address any changes in quorum, etc.}*

To see the minutes as a .pdf document, click the “Preview” button at the bottom of the “Minutes Builder” page

To make the minutes available to all IACUC Reviewers *{includes appointed voting members and also others designated by the station to have this level of access}*, click the “Publish Minutes” button at the bottom of the “Minutes Builder” page => adds the minutes to the agenda documents, and goes to the “Agenda Documents” page

To hide the minutes from the Committee Members, click the “Un-publish” button at the bottom of the “Minutes Builder” page => removes the minutes from the “Agenda Documents” page

## 12. IACUC Administrator: Suggested Minutes -- Next Meeting Date and General Announcements

### Section

*{leave all fields blank except ..}*

### Discussion and Remarks

*{Date and time of next scheduled meeting*

*Announcements about matters not specific to any other sections of the minutes, such as*

*FOIA requests received*

*site visits scheduled*

*public communications received/released*

*semiannual evaluations scheduled}*

IACUC Admin



### 13. IACUC Administrator: Suggested Minutes -- Review of Previous Minutes

Section

Review Type

[blank]

*{The minutes of the last meeting may be considered by the full committee during a meeting, but this is not specifically by the "FCR" mechanism defined for protocol review.}*

*{The minutes of the last meeting may also be approved by a poll of the members before the meeting (polling is not "DMR" or "Administrative Review")}*

*{Explain in the "Discussion and Remarks" how the minutes were approved}*

Action *{action taken by the IACUC at this meeting}*

[blank] *{Choose this option if the previous minutes were not considered during the meeting}*

[Acknowledged] *{Choose this option if the minutes were approved by a poll of the members before the meeting}*

[Approved]

[Tabled Without Action] *{Choose this option if the IACUC considered the previous minutes but delayed voting on approval. Explain why in the "Discussion and Remarks" (e.g., because quorum was not present, because minutes document was incomplete, because revision of the minutes is required)}*

Effective Date

[date of the meeting]

*{Choose this option for minutes that were approved during the meeting}*

[date when a majority of the total voting membership indicated their approval in a poll before this meeting]

*{Choose this option for minutes that were approved by a poll of the members before the meeting}*

Votes (for, opposed, abstained)

*{record numbers for IACUC votes by either method}*

Recused

*{N/A if approved by poll of members}*

Discussion and Remarks

*{Note any changes that the IACUC specified be made for its approval to be granted}*

*{Note how the minutes were approved – by a poll before the meeting, or by a vote during the meeting}*

*{If the minutes were approved by a vote during the meeting, note whether a quorum was present when the IACUC voted}*

## 14. IACUC Administrator: Suggested Minutes – Complete Review of Protocols by Full Committee Review (FCR)

### Section

*{This is only a header, not an agenda item in itself – leave all fields blank}*

Each item *{For each package for a complete protocol review by FCR -- Includes new protocols, protocols submitted for renewal of approval, protocols being closed}*

Review Type [Full Committee Review]

Action *{action taken by the IACUC at this meeting}*

[Acknowledged] *{Explain in the “Discussion and Remarks” what the IACUC has acknowledged -- e.g., expiration of IACUC approval on the 3<sup>rd</sup> anniversary of approval}*

[Approved]

[Closed] *{There is no requirement for protocols to be formally closed by IACUC action, but if the IACUC chooses to take this action, explain why in “Discussion and Remarks” (e.g., project complete, PI moved, funding no longer available, etc.)}*

[Modifications Required] *{RMSA – explain in “Discussion and Remarks” what modifications are required}*

[Not Approved] *{approval denied – explain in “Discussion and Remarks” the reasons for denying approval}*

[Tabled Without Action] *{Choose this option if the IACUC put off voting, and explain why in the “Discussion and Remarks” (e.g., because quorum was not present, because the package was incomplete, because the IACUC ran out of time at the meeting)}*

[Withdrawn] *{The IACUC has decided that this package is not one that it can act on – explain in “Discussion and Remarks” why the package was withdrawn (e.g., if the R&D Committee has made the determination that the item is actually not research, if the IACUC has determined that the project does not involve animals, or if the Researcher has decided to withdraw it from review)}*

Effective Date *{generally the date of the meeting, but may be a later date that the IACUC specifies as the effective date of its action.}*

Project Status *{Leave unchanged if the IACUC action at this meeting did not change the status of the project}*

[blank] *{if the IACUC has not taken any action yet that has changed the project status (e.g., the package is still under review)}*

[Active] *{IACUC approval is currently in place for work to proceed}*

[Closed] *{This option applies regardless of whether the closure was due to scheduled expiration of approval or formal closure by the IACUC}*

[Disapproved] *{approval denied}*

[Suspended]

[Withdrawn]

Dates [select from calendar] *{refer to the project/protocol, not the individual package}*

Project Expiration Date

*{If approved, approval expires most commonly on the third anniversary of the effective date of IACUC approval, but the IACUC has the authority to limit its approval to periods of less than three years}*

*{Leave blank if approval hasn't been granted yet}*

Next Report Due

*{At the IACUC's discretion, e.g., for continuing review of approved protocols, triennial renewal, or any other requirement of the IACUC}*

*{Leave blank if approval hasn't been granted yet}*

Initial Approval Date *{The most recent date when IACUC approval of the protocol took effect, from which triennial expiration is calculated}*

Votes (for, opposed, abstained) *{Refers to the IACUC action taken, leave all 0 if IACUC did not vote on this item}*

Recused *{leave blank if IACUC did not vote on this item}*

Discussion and Remarks *{In addition to details about the actions taken:*

*Document whether a quorum was present for this item of business*

*Record (if an approval was granted) whether this was for continuation of approval after triennial expiration*

*Identify the primary reviewers}*

IACUC Admin

## 15. IACUC Administrator: Suggested Minutes – FCR of Protocols Modified in Response to RMSA

### Section

*{This is a header only, not an agenda item in itself – leave all fields blank}*

Each Item *{For each package for FCR of Protocols Modified in Response to RMSA}*

### Review Type

[Full Committee Review]

Action *{action taken by the IACUC at this meeting}*

[Approved]

[Modifications Required] *{another RMSA, if modifications submitted did not fully resolve the concerns raised – explain in “Discussion and Remarks” what further modifications are required}*

[Not Approved] *{approval denied – explain in “Discussion and Remarks” the reasons for denying approval}*

[Tabled Without Action] *{Use this option if the IACUC put off voting, and explain why in the “Discussion and Remarks” (e.g., because quorum was not present, because the package was incomplete, because the IACUC ran out of time at the meeting)}*

[Withdrawn] *{The IACUC has decided that this package is not one that it can act on – explain in “Discussion and Remarks” why the package was withdrawn e.g., the Researcher has decided to withdraw it from review, the IACUC has declined to consider the protocol further after some period of lack of response from the Researcher}*

Effective Date *{generally the date of the meeting, but may be a later date that the IACUC specifies as the effective date of the approval}*

### Project Information

Project Status *{Leave unchanged if the IACUC action at this meeting did not change the status of the project}*

[blank] *{if the IACUC has not taken any action yet that has changed the project status (e.g., the package is still under review)}*

[Active] *{IACUC approval is currently in place for work to proceed}*

[Disapproved] *{approval denied}*

[Withdrawn]

Dates [select from calendar] *{refer to the project/protocol, not the individual package}*

Project Expiration Date

*{If approved, most commonly the third anniversary of the effective date of IACUC approval}*

*{Leave blank if approval hasn’t been granted yet}*

Next Report Due

*{At the IACUC’s discretion, e.g., for continuing review of approved protocols, triennial renewal, or any other requirement of the IACUC}*

*{Leave blank if approval hasn’t been granted yet}*

Initial Approval Date *{The most recent date when IACUC approval for the protocol was effective, from which triennial expiration is calculated}*

Votes (for, opposed, abstained) *{Refers to the IACUC action taken, leave all 0 if IACUC did not vote on this item}*

Recused (names) *{leave blank if IACUC did not vote on this item}*

Discussion and Remarks *{In addition to details about the actions taken:*

*Document whether a quorum was present for this item of business*

*Record (if an approval was granted) whether this was for continuation of approval after triennial expiration*

*Identify the primary reviewers}*

IACUC Admin

## 16. IACUC Administrator: Suggested Minutes – Continuing Reviews

### Section

*{This is only a header, not an agenda item in itself – leave all fields blank}*

*{Continuing Review is a review of an approved protocol, at the discretion of the IACUC, in a locally defined process that does not impact the approval status of the protocol. If the IACUC instead wishes to limit its approval of a protocol to less than 3 years, it has the authority to specify an earlier expiration date beyond which work may not continue without the IACUC granting renewed approval. Such a renewal of approval would be a Complete Review by FCR or a Protocol Reviewed by DMR, not a Continuing Review.}*

Each Item *{For each package for Continuing Review}*

Review Type *{as specified by local policy}*

[Blank] *{if local policy requires anything other than one of the mechanisms defined by OLAW for protocol approval, including if local policy requires only acknowledgement by the IACUC that a qualified reviewer has completed the continuing review – this is all that was required by USDA when the AWR required annual continuing reviews.}*

[Full Committee Review]

[Administrative Review]

[Designated Member Review]

Action *{action taken by the IACUC at this meeting, as specified by local policy}*

[Acknowledged] *{Note in “Discussion and Remarks” any findings that need to be addressed, and what actions the IACUC recommends (e.g., modify the protocol, investigate potentially reportable matters, require PI to provide more information)}*

[Approved] *{if required by local policy – approval refers to the continuing review, not the protocol}*

[Tabled Without Action] *{Choose this option if local policy requires the IACUC to vote, but the IACUC put off voting, and explain why in the “Discussion and Remarks” (e.g., because quorum was not present, because package was incomplete, because the IACUC ran out of time at the meeting)}*

[Effective Date] *{Refers to the IACUC’s action, so is generally the date of the meeting}*

Project Information *{Leave mostly unchanged as the IACUC action on Continuing Review does not change the status of the project}*

Project Status [Active]

*{Continuing Review is only conducted for active protocols, any action taken to change the project status is related to IACUC responses to the findings of the continuing review (which would be addressed in other sections of the minutes), not here as part of the Continuing Review}*

Dates [select from calendar] *{refer to the project/protocol, not the individual package}*

Project Expiration Date *{should be unchanged}*

Next Report Due *{update to the due date for the next report required by the IACUC -- e.g., for the next continuing review, triennial renewal, or any other requirement of the IACUC}*

IACUC Administrator: Suggested Minutes – Continuing Reviews

Initial Approval Date *{should be unchanged}*

Votes (for, opposed, abstained) *{Refers to the IACUC action taken. If local policy does not require the IACUC to vote on Continuing Reviews, leave all 0}*

Recused (names) *{if local policy does not require the IACUC to vote on Continuing Reviews, leave blank}*

Discussion and Remarks *{Include the information required by local policy, such as:*

*Identify the person who performed the continuing review*

*Note whether continuing review has been completed or is still underway, and whether the continuing review was completed in time*

*Describe any findings to be addressed*

*Document any recommended action(s) (e.g., modifications to update personnel, procedures, etc.)}*

IACUC Admin

## 17. IACUC Administrator: Suggested Minutes – Protocols and Modifications Reviewed by Designated Member Review (DMR)

### Section

*{This is only a header, not an agenda item in itself – leave all fields blank}*

**Each Item** *{Regulatory and policy language allows use of DMR for any protocol review, including complete review of protocols, DMR after RMSA, and modifications of approved protocols. Local policy may be more restrictive. For each package reviewed by DMR, the minutes only document the action taken by DMR}*

**Review Type** [Designated Member Review]

**Action** [Acknowledged] *{The action of the IACUC during the meeting is only to acknowledge the outcome of the DMR review}*

*{If the Committee did not take up this item, remove it from the agenda.}*

**Effective Date** *{Refers to the date of the action decided by DMR – i.e., the date of approval by the Designated Reviewer who makes the approval unanimous, the date on which the first Designated Reviewer recommends RMSA or denying approval, or the date on which the first IACUC member calls for FCR}*

**Project Information**

**Project Status** *{Leave unchanged if the IACUC action by DMR did not change the status of the project}*

[Active] *{If approval was granted by DMR}*

**Dates** [select from calendar] *{refer to the project/protocol, not the individual package}*

**Project Expiration Date**

*{Most commonly the third anniversary of the effective date of IACUC approval of the protocol}*

*{Leave blank if approval hasn't been granted yet}*

**Next Report Due**

*{At the IACUC's discretion, e.g., for continuing review of approved protocols, triennial renewal, or any other requirement of the IACUC}*

*{Leave blank if approval hasn't been granted yet}*

**Initial Approval Date** *{The most recent effective date of IACUC approval for the protocol, from which triennial expiration is calculated}*

**Votes** (for, opposed, abstained) *{Refers to the IACUC action taken. Leave all 0 – DMR approval requires unanimous recommendation from Designated Reviewers, the IACUC members at the meeting do not vote}*

**Recused** (names) *{Leave blank, as IACUC does not vote on results of DMR}*

**Discussion and Remarks** *{In addition to summarizing any discussion, note:*

*The names of the Designated Reviewers assigned to this protocol*

*Whether this was for continuation of approval after triennial expiration (if an approval was granted)*

*The date of any referral to FCR}*



## 18. IACUC Administrator: Suggested Minutes – FCR of Protocol Modification

### Section

*{This is a header, not an agenda item in itself – leave all fields blank}*

Each Item *{For each modification of an approved protocol reviewed by FCR}*

Review Type [Full Committee Review]

Action *{action taken by the IACUC at this meeting}*

[Approved]

[Modifications Required] *{RMSA – explain in “Discussion and Remarks” what modifications are required}*

[Not Approved] *{approval denied – explain in “Discussion and Remarks” the reasons for denying approval}*

[Tabled Without Action] *{Choose this option if the IACUC put off voting, and explain why in the “Discussion and Remarks” (e.g., because quorum was not present, because package was incomplete, because the IACUC ran out of time at the meeting)}*

[Withdrawn] *{The IACUC has decided that this package is not one that it can act on – explain in “Discussion and Remarks” why the package was withdrawn (e.g., the Researcher has decided to withdraw it from review)}*

Effective Date *{generally the date of the meeting, but may be a later date that the IACUC specifies as the effective date of the approval}*

### Project Information

Project Status *{Approval of a modification generally does not change the status of the project, so this would remain unchanged}*

[Active] *{only approved/active protocols can be modified}*

Dates [select from calendar] *{refer to the project/protocol, not the individual package – generally not changed by approval of a modification}*

Project Expiration Date *{leave unchanged}*

Next Report Due *{leave unchanged, unless IACUC requires an earlier report because of the modification}*

Initial Approval Date *{leave unchanged}*

Votes (for, opposed, abstained) *{Refers to the IACUC action taken, leave all 0 if IACUC did not vote on this item}*

Recused (names) *{leave blank if IACUC did not vote on this item}*

Discussion and Remarks *{In addition summarizing the deliberations:*

*Document whether a quorum was present for this item of business  
Identify the primary reviewers}*

## 19. IACUC Administrator: Suggested Minutes – Protocols Modified by VVC

### Section

*{This is only a header, not an agenda item in itself – leave all fields blank}*

*{Applies only to approved protocols}*

Each Item *{For each modification by VVC, the minutes only document the action already taken.}*

Review Type [Full Committee Review] *{VVC is a mechanism for applying modifications allowed by FCR approval of VVC policy}*

Action *{action taken by the IACUC at this meeting}*

[Acknowledged] *{The action of the IACUC during the meeting is only to acknowledge that the protocol was modified by VVC (if IACUC has concerns that VVC was applied inappropriately, or that IACUC policy needs to be revised, this should be taken up in Other Business)}*

*{If the Committee did not take up this item, remove it from the agenda.}*

Effective Date *{Refers to the date of the veterinary verification and consultation}*

### Project Information

Project Status *{Approval of a modification generally does not change the status of the project, so this would remain unchanged}*

[Active] *{only approved/active protocols can be modified by VVC}*

Dates [select from calendar] *{refer to the project/protocol, not the individual package – generally not changed by approval of a modification}*

Project Expiration Date *{leave unchanged}*

Next Report Due *{leave unchanged, unless IACUC requires an earlier report because of the modification}*

Initial Approval Date *{leave unchanged}*

Votes (for, opposed, abstained) *{Refers to the IACUC action taken, leave all 0 as the IACUC does not vote on modifications by VVC}*

Recused (names) *{leave blank as the IACUC does not vote on modifications by VVC}*

Discussion and Remarks *{In addition to summarizing any discussion during the meeting:*

*Note the name of the veterinarian consulted*

*Identify the IACUC-approved policy applied*

*Confirm that the consultation with the veterinarian has been documented*

*Confirm that the modification has been incorporated into the protocol documentation}*

## 20. IACUC Administration: Suggested Minutes – Administrative Protocol Updates

### Section

*{This is only a header, not an agenda item in itself – leave all fields blank}*

Each Item *{For each administrative update of an approved protocol, the minutes only document the action already taken}*

Review Type [Administrative Review] *{Administrative updates of an approved protocol do not involve review by the IACUC.}*

Action *{action taken by the IACUC at this meeting}*

[Acknowledged] *{The action of the IACUC during the meeting is only to acknowledge that the protocol has been updated administratively. If the IACUC has concerns that the change should not have been handled administratively, but that IACUC approval was required, this should be taken up in Other Business, and the change re-submitted for IACUC consideration by FCR or DMR at a later meeting, if necessary. Any work that the IACUC determines to have been done without appropriate IACUC approval will have to be addressed in Potentially Reportable Matters, at a later meeting)}*

*{If the IACUC did not take up this item, remove it from the agenda.}*

Effective Date *{refers to the date the administrative update was made}*

### Project Information

Project Status *{Administrative updates do not change the status of the project, so this should remain unchanged}*

[Active] *{Administrative updates can only be made to approved/active protocols}*

Dates [select from calendar] *{refer to the project/protocol, not the individual package – are not changed by administrative updates}*

Project Expiration Date *{leave unchanged}*

Next Report Due *{leave unchanged, unless IACUC requires an earlier report because of the administrative update}*

Initial Approval Date *{leave unchanged}*

Votes (for, opposed, abstained) *{Refers to the IACUC action, leave all 0 as the IACUC does not vote on administrative updates}*

Recused (names) *{leave blank as the IACUC does not vote on administrative updates}*

Discussion and Remarks *{In addition to summarizing any discussion during the meeting:*

*Describe the change made*

*Note the name of the Administrator who made the change*

*Confirm that the modification has been incorporated into the protocol documentation}*

## 21. IACUC Administrator: Suggested Minutes – Other Protocol Matters

### Section

*{This is a header only, not an agenda item in itself – leave all fields blank.}*

*{Items of business addressed in this section are mostly those created as Special Event packages by the Administrator, notifying the IACUC of matters related to a specific protocol, but not related to securing approval. These include, but are not limited to:*

*Secondary review comments received*

*Notification to the IACUC of a protocol in preparation for submission, but not submitted yet (may be important for IACUC to be aware of this for a protocol involving a sensitive species)*

*Notification that work on a protocol is paused, with the expectation that no further work will be needed, although the protocol remains active in case data analysis or manuscript review results in the decision that additional work with the animals is needed*

*Protocol Audit Event – created by RCO}*

Each Item *{For each package documenting a protocol matter other than protocol review}*

Review Type [blank] *{These items are considered by the full committee during a meeting, but this is not specifically by the “FCR” mechanism defined for protocol review.}*

Action *{The IACUC’s actions for these items are mainly acknowledgement and making determinations about how to proceed with addressing them. The actions to actually address them are largely managed as items in other sections of the agenda/minutes of future meetings.}*

[blank] *{The “Action” for most items in this section is best left blank, as it may be misleading to summarize the IACUC actions with any one of the terms used for protocol review. Instead, the actions taken by the IACUC are best described in the “Discussion and Remarks” section. Actions appropriate to this section include, but are not limited to:*

*Determinations about how the PI will be required to address concerns raised in secondary review (most commonly, this involves modifying the protocol, either to correct inaccuracies or to clarify what is intended)*

*Determinations about what must be done to address an Audit Event}*

[Acknowledged] *{For notifications for IACUC awareness only, that do not require IACUC action}*

[Tabled Without Action] *{Choose this option if the IACUC put off voting, and explain why in the “Discussion and Remarks” (e.g., because quorum was not present, because the package was incomplete, because the IACUC ran out of time at the meeting)}*

Effective Date *{This refers to the action of the IACUC, so is generally the date of the meeting.}*

### Project information

Project Status *{The actions taken by the IACUC on items in this section generally have to do with determinations about how to proceed with addressing the matters in question, and not with taking actions on the project status, so this should generally remain unchanged.}*

[blank] *{Matters may be brought to the IACUC’s attention about protocols that have not yet been submitted, and therefore have no “Project Status” yet.}*

[Active] *{Most protocol matters requiring IACUC attention in this section are related to currently approved protocols.}*

[Closed] *{Matters may be brought to the IACUC's attention about protocols that have been closed – e.g., arrangement for disposition of remaining animals}*

[Disapproved] *{Matters may be brought to the IACUC's attention about protocols for which approval has been denied – e.g., a request from the Researcher for guidance on preparation of a new protocol for submission. Work done without IACUC approval should be addressed in Potentially Reportable Matters.}*

[Suspended] *{Matters may be brought to the IACUC's attention about protocols that have been suspended – e.g. if a period of suspension continues longer than anticipated and the arrangements for the animals must be revised. Work done while IACUC approval has been suspended should be addressed in Potentially Reportable Matters.}*

Dates [select from calendar] *{refer to the project/protocol, not the individual package – actions taken by the IACUC on the items in this section generally do not change these dates}*

Project Expiration Date *{leave unchanged}*

Next Report Due *{leave unchanged, unless IACUC has decided to ask for an earlier report because of this matter}*

Initial Approval Date *{leave unchanged}*

Votes (for, opposed, abstained) *{Refers to the IACUC action taken, which may or may not involve voting – record votes only if the IACUC voted}*

Recused [drop-down menu of names] *{Only enter names if the IACUC voted on this item}*

Discussion and Remarks *{Provide the specifics of what the item of business involved, summarize the discussion, and describe the decision of the IACUC. For an item that was tabled, document how the IACUC intends to address it (e.g., at a special meeting to be convened, at the next regularly scheduled convened meeting, by email.}*

## 22. IACUC Administrator: Suggested Minutes – Potentially Reportable Matters

### Section

*{This is only a header, not an agenda item in itself – leave all fields blank.}*

*{Items of business addressed in this section are matters brought to the IACUC’s attention from any source, including the public, VA personnel, research personnel, oversight entities including the RCO, a PAM monitor, members of the IACUC, ORO, AAALAC, OLAW, and the office of CVMO}*

Each Item *{For any package related to a Potentially Reportable Matter that is associated with a particular project. For these, the IACUC Administrator generally creates a Special Event package. See below for Potentially Reportable Matters that are not associated with a particular project.}*

*{To create a Special Event package, click the “Project History” button in the sidebar menu => “Project History page, then click the “Create a Special Event Package” at the bottom of that page (the IACUC Administrator may attach board documents to a Special Event package)}*

Review Type – [blank] *{These items are considered by the full committee during a meeting, but this is not specifically by the “FCR” mechanism defined for protocol review.}*

Action *{action taken by the IACUC at this meeting}*

[blank] *{The “Action” for most items in this section is best left blank, as the IACUC will generally have to take a set of actions to address the potentially reportable matter, and no single one of the terms used for outcomes of protocol review would appropriately summarize the complete set of actions. Actions appropriate to this section may include one or more of the following (provide specifics in the “Discussion and Remarks” section of the minutes):}*

*Determination that further investigation is needed*

*Determination that a matter is or is not reportable to each oversight entity*

*Determinations about the corrective actions needed (e.g., develop new standard procedures or forms for record-keeping, require re-training of research personnel, require personnel actions)*

*Determination to instruct the research team to put work on the protocol on hold until further notice by the IACUC*

*Determination to suspend (and subsequently lift the suspension of) the IACUC approval of a protocol}*

[Closed] *{if the IACUC receives confirmation from the oversight entities to which the matter was reported earlier, that the matter requires no further action, the matter is “closed”.}*

[Tabled Without Action] *{Choose this option if the IACUC put off voting, and explain why in the “Discussion and Remarks” (e.g., because quorum was not present, because more information was needed before the IACUC could act, because the IACUC ran out of time at the meeting)}*

Effective Date *{The effective date of the IACUC’s action is generally the date of the meeting, but may be a later date that the IACUC specifies as the effective date.}*

### Project information

Project Status *{The actions taken by the IACUC on items in this section generally have to do with determinations about how to proceed with addressing the potentially reportable matters, which may or may not involve taking actions on the project status, so project status may be unaffected}*



*by the IACUC actions taken. Matters related to a specific protocol are only potentially reportable if the protocol at some point had IACUC approval.}*

*[Active] {Most potentially reportable matters related to a protocol are related to currently approved protocols. “Active” status would also be restored when the IACUC votes to lift a suspension.}*

*[Closed] {A potentially reportable matter could be related to a protocol that was active at the time of the event, but was subsequently closed. E.g., it could still require IACUC attention if it reflects a programmatic concern that needs to be addressed, or closure could be one of the actions taken by the IACUC.}*

*[Disapproved] {A potentially reportable matter could be related to a protocol for which approval was denied. E.g., it could still require IACUC attention if the concern has to do with the process involved in denying the approval, or if work was done in spite of the denial of approval.}*

*[Suspended] {A potentially reportable matter could be related to a protocol that was active at the time of the event, but for which approval was subsequently suspended by the IACUC. E.g., it could still require IACUC attention if the suspension was necessary because the matter involves a programmatic concern that needs to be addressed. It could also be that the IACUC voted to suspend its approval, so the project status changed to “Suspended”.}*

*Dates [select from calendar] {refer to the project/protocol, not the individual package – actions taken by the IACUC on potentially reportable matters generally do not change these dates}*

*Project Expiration Date {leave unchanged}*

*Next Report Due {leave unchanged, unless IACUC has decided to ask for an earlier report, addressing the potentially reportable matter}*

*Initial Approval Date {leave unchanged}*

*Votes (for, opposed, abstained) {Refers to the IACUC action taken, which may or may not involve voting – record votes only if the IACUC voted}*

*Recused [drop-down menu of names] {Only enter names if the IACUC voted on this item}*

*Discussion and Remarks [free text] {Provide the specifics about the potentially reportable matter, including the details of any specific actions taken by the IACUC, as well as, for example:*

*The names of the members appointed to the investigative subcommittee by the Chair*

*Confirmation of any preliminary pre-decisional notifications provided*

*Any report from the investigative subcommittee*

*A summary of the discussion*

*Any determination about whether or not the matter is reportable to specific oversight entities.}*

**Each Item** *{For any package related to a Potentially Reportable Matter that is not associated with a particular project. For these, the IACUC Administrator generally simply adds an agenda item (without a package) to the agenda.}*

*{To add an item without a package to the agenda, click the “Add New Agenda Item” link above the table of “Agenda Details” on the “Agenda Builder” page.}*

**Review Type** [blank] *{These items are considered by the full committee during a meeting, but this is not specifically by the “FCR” mechanism defined for protocol review.}*

Action {action taken by the IACUC at this meeting}

[blank] {The “Action” for most items in this section is best left blank, as the IACUC will generally have to take a set of actions to address the potentially reportable matter, and no single one of the terms used for outcomes of protocol review would appropriately summarize the complete set of actions. Actions appropriate to this section may include one or more of the following (provide specifics in the “Discussion and Remarks” section of the minutes):

*Determination that further investigation is needed*

*Determination that a matter is or is not reportable to each oversight entity*

*Determinations about the corrective actions needed (e.g., develop new standard procedures or forms for record-keeping, require re-training of research personnel, require personnel actions)*

*Determination to instruct research personnel on multiple protocols to put the work on hold until further notice by the IACUC*

*Determination to suspend (and subsequently to lift the suspension of) IACUC approval for multiple protocols (e.g., all those with the same PI or for the same research group)}*

[Closed] {if the IACUC receives confirmation from the oversight entities to which the matter was reported earlier, that it requires no further action, the matter is “closed”.}

[Tabled Without Action] {Choose this option if the IACUC put off voting, and explain why in the “Discussion and Remarks” (e.g., because quorum was not present, because more information was needed before the IACUC could act, because the committee ran out of time at this meeting)}

Effective Date {The effective date of the IACUC’s action is generally the date of the meeting, but may be a later date that the IACUC specifies as the effective date.}

Project Information {Leave unchanged, as items in this section do not apply to a single project}

Votes (for, opposed, abstained) {Refers to the IACUC action taken, which may or may not involve voting – record votes only if the IACUC voted}

Recused [drop-down menu of names] {Only enter names if the IACUC voted on this item}

Discussion and Remarks [free text] {Provide the specifics about the potentially reportable matter, including the details of any specific actions taken by the IACUC, as well as, for example:

*The names of the investigative subcommittee appointed by the Chair*

*Any preliminary pre-decisional notifications provided*

*Any report from the investigative subcommittee*

*A summary of the discussion*

*Any determination about whether or not the matter is reportable to specific oversight entities.*

*A listing of the protocols affected, or of the criteria defining the protocols affected (e.g., all those with a particular PI, all those for a specific research team, all those for a specific species or involving a specific procedure)}*



## 23. IACUC Administrator: Suggested Minutes – Other Business

### Section

*{This is only a header, not an agenda item in itself – leave all fields blank.}*

*{This section is for business related to the program as a whole, and not specific to individual projects.}*

*This may include:*

*Semiannual evaluations*

*Concerns about the program or facilities such as aging infrastructure, maintenance or security concerns, staffing adequacy*

*Preparation for, debriefing about, reports received after, and responses to reports received after site visits*

*external -- representatives of external oversight entities (e.g., ORO, AAAALAC)*

*internal – PAM, overhear tests, infrastructure inspections*

*Drafting, reviewing, and updating IACUC policies and standard procedures*

*Notification about FOIA requests received, media inquiries received, press releases}*

### Each Item

**Review Type** [blank] *{These items are considered by the full committee during a meeting, but this is not specifically by the “FCR” mechanism defined for protocol review.}*

**Action** *{action taken by the IACUC at this meeting}*

[blank] *{The “Action” for items in this section is best left blank here and described in the “Discussion and Remarks” section instead, as the action taken by the IACUC is unlikely to be appropriately summarized by any one of the terms used for outcomes of protocol review.}*

[Acknowledged] *{This may be appropriate for some items that do not require IACUC action at all (e.g., notification about FOIA or media requests received).}*

[Approved] *{This is appropriate for final documents, such as reports of semiannual evaluations, and final versions of updated policies or standard procedures.}*

[Tabled Without Action] *{Choose this option if the IACUC put off taking action, and explain why in the “Discussion and Remarks” (e.g., because quorum was not present, because more information was needed before the IACUC could act, because the IACUC ran out of time at this meeting)}*

[Effective Date] *{The effective date of the IACUC’s action is generally the date of the meeting, but may be a later date that the IACUC specifies as the effective date.}*

**Project Information** *{Leave unchanged, as items in this section do not apply to a single project}*

**Votes** (for, opposed, abstained) *{Refers to the IACUC action taken, which may or may not involve voting – record votes only if the IACUC voted}*

**Recused** [drop-down menu of names] *{Only enter names if the IACUC voted on this item}*

**Discussion and Remarks** [free text] *{Provide the specifics about the item, summary of the IACUC’s deliberations about it, and the details of any specific actions taken by the IACUC, as well as, for example:*

*For semiannual evaluations, summarize determinations about whether deficiencies are minor or significant, underlying causes of deficiencies that have been identified and corresponding corrective actions required, and the overall condition of the program and facilities*

*For other concerns about the program or facilities, the specifics of the concerns raised, their implications for the program, and the actions needed*

IACUC Administrator: Suggested Minutes – Other Business

*For reports received from other oversight entities, summarize the IACUC deliberations about the report, and determinations about actions/responses required*

*For IACUC policies and standard procedures, summarize the IACUC deliberations about policies and procedures, and any about actions needed before approval can be granted*

*For notification about communications with the public, summarize the IACUC deliberations about information requested and provided}*

IACUC Admin

## 24. IACUC Administrator: Suggested Minutes – Continuing Education

### Section

*{This is only a header, not an agenda item in itself – leave all fields blank.}*

Each Item *{For each item of Continuing Education presented}*

Review Type [blank] *{N/A -- Continuing Education does not involve review.}*

Action *{action taken by the IACUC at this meeting}*

[blank] *{N/A -- Continuing Education does not involve action by the IACUC as a body.}*

*{If the Committee did not do the planned Continuing Education, remove it from the agenda.}*

Effective Date *{The effective date of the Continuing Education is the date of the meeting at which it was provided}*

Project Information *{Leave blank, as Continuing Education does not apply to a single project}*

Votes (for, opposed, abstained) *{N/A – leave all 0}*

Recused [blank] *{N/A as no vote is involved}*

Discussion and Remarks [free text field] *{Describe the topic covered by the Continuing Education}*

IACUC Admin

## 25. IACUC Administrator: Sequence of Events for Protocol Review

(To show here how different roles interact in IRBNet, IACUC Administrator actions are shown in black font, **Researcher actions are shown in red font**, and **Reviewer actions are shown in navy font**.)

Receive a protocol package from a Research Administrator, who received it **from a Researcher**

Check over the protocol package for all elements needed

ACORP main body

Applicable ACORP appendices

Documentation (in the ACORP) of training required for each member of the research team

Information (in the ACORP) about veterinary pre-consult

If no veterinary pre-consult has been documented, share the package with the AV member of the IACUC, with an individual alarm set to notify the IACUC Administrator when the AV's response is complete

Check the box on the "Share Submission" page to **notify the AV** that access has been granted

Enter in the "Your Comments" box:

that this is for the veterinary pre-consult,

instruct the AV to enter comments in the Reviewer Comments for this package,

and instruct the AV to check "Mark my personal review as complete" when finished with the pre-consult

**The AV enters pre-consult comments as Reviewer Comments, and checks "Mark my personal review as complete"**

Copy the **AV's Reviewer Comments** into a memo with instructions **to the Project Owners** to create a new package containing the ACORP revised to address the concerns raised.

Attach the memo as a board document and publish it => notification goes **to Project Owners** that a board document is available

Unlock the package for the Researcher to revise

**Researcher revises the protocol as appropriate in the existing package, and resubmits it to the IACUC**

When package is ready for IACUC review, check whether the protocol is eligible for review by DMR according to local policy

## IACUC Administrator: Sequence of Events for Protocol Review

If eligible for review by DMR, go to guidance section on “Sequence of Events for Protocol Review by DMR” (next section of this guide)

If FCR is required, go to the guidance section on “Sequence of Events for Protocol Review by FCR” (the section after the next, in this guide)

After IACUC decision is made, prepare the appropriate board document using the Wizards

If IACUC voted “Approved”, use the “IACUC Approval Letter” Wizard

If IACUC voted “Modifications Required”, use the “IACUC RMSA Letter” Wizard

For any other outcome of the IACUC’s review, use the “IACUC Notification Letter” Wizard

Attach the board document to the package and, click “Publish Final” in the table of “Board Documents” on the “Submission Detail” page => notification goes to the **Project Owners** that a board document is available

Unlock the package if necessary for the Researcher to revise the protocol

**Researcher responds by revising the protocol if necessary and resubmitting the package**

IACUC Administrator

## 26. IACUC Administrator: Sequence of Events for Protocol Review by DMR

(To show here how different roles interact in IRBNet, IACUC Administrator actions are shown in black font, **Researcher actions are shown in red font**, and **Reviewer actions are shown in navy font**.)

Share the package with the IACUC Chair, with an individual alarm set to notify the IACUC Administrator when IACUC Chair's response is complete

Check the box on the "Share Submission" page to **notify the IACUC Chair** that access has been granted

Enter in the "Your Comments" box:

that this is for consideration for review by DMR,  
instruct the IACUC Chair to enter response in Reviewer Comments for this package,  
including the names of the Designated Member Reviewers if the Chair decides to  
proceed with DMR  
and instruct the IACUC Chair to check "Mark my personal review as complete" when  
determination has been made whether to submit the protocol for DMR

The IACUC Chair reviews the package and enters the IACUC Chair's determination in the Reviewer Comments for this package

If the IACUC Chair finds DMR appropriate,

Identify in the "Reviewer Comments" [free text field], the Designated Reviewers to assign

Leave "Recommendation" blank *{None of the options in the drop-down menu are appropriate for this. "Approve" is too easily misinterpreted as a recommendation to approve the protocol, rather than the Chair's recommendation to approve the use of DMR}*

IACUC Administrator proceeds with the "Sequence of Events for Protocol Review by DMR", below

If the Chair deems FCR necessary,

Enter in the "Reviewer Comments" [free text field], any comments the Chair wishes to provide (optional)

For "Recommendation", select [Refer to Full Board]

IACUC Administrator proceeds with the "Sequence of Events for Protocol Review by FCR" (next section of this guide)

## IACUC Administrator: Sequence of Events for Protocol Review by DMR

To continue with DMR, share the package with [Reviewer access for every appointed IACUC member](#) (regular or alternate)

Set the due date for responses to call for FCR *{according to local policy, usually 3-5 days}*

Set an individual alarm for each Reviewer, so the IACUC Administrator will be notified when any Reviewer indicates a completed review

Check the box on the “Share Submission” page to [notify each Reviewer](#) that access has been granted

Enter in the “Your Comments” box:

that this protocol is being considered for DMR,  
instruct Reviewer to recommend “Refer to Full Board” in the Reviewer Comments for this package by [due date], if Reviewer feels that FCR is necessary  
and instruct Reviewers to check “Mark my personal review as complete” when finished

[Any Reviewer who decides that FCR is necessary, recommends “Refer to Full Board”](#)

[In the “Reviewer Comments” \[free text field\], enter any comments the Reviewer wishes to provide \(optional\)](#)

If any Reviewer recommends “Refer to Full Board”, IACUC Administrator proceeds with the “Sequence of Events for Protocol Review by FCR” (next section of this guide)

If no Reviewer calls for FCR by the specified date, IACUC Administrator proceeds with the “Sequence of Events for Protocol Review by DMR”, below

Add the Special Designation of “Designated Reviewer” for those identified as such by the IACUC Chair

update the due date for responses (turn off the due date for Reviewers who were not assigned as Designated Reviewers) *{allow the review period established by local policy}*

leave individual alarms on for all Reviewers

for Designated Reviewers to indicate when their reviews are complete  
for any other Reviewer to call for FCR at any time

To notify the Designated Reviewers of their assignment by the IACUC Chair, click the “Send Committee Mail” link below the table of IACUC Reviewers and IACUC Administrators on the “Submission Detail” page => “New Committee Message” page  
*{There is no automatic notification after Special Designations are modified}*

Select the Designated Reviewers as recipients of the emailed message

## IACUC Administrator: Sequence of Events for Protocol Review by DMR

Edit the Subject [free text field] and Message [free text field] to instruct the Designated Reviewers to enter their responses in the Reviewer Comments for this package and check “Mark my personal review as complete” when finished, by [due date]  
Click the “Send” button => email is sent to the selected recipients, message is posted to “Committee Messages & Alerts”

Each Designated Reviewer enters review on “Reviewer Comments” page

In the “Reviewer Comments” [free text field], enter any comments the Reviewer wishes to provide (optional)  
For “Recommendation”, select [drop-down menu] *{Reviewer must choose one of the possible outcomes of DMR}*  
Approve  
Modifications Required  
Refer to Full Board

If any Designated Reviewer recommends “Refer to Full Board”, IACUC Administrator proceeds with the “Sequence of Events for Protocol Review by FCR” (next section of this guide)

If no Designated Reviewer recommends “Refer to Full Board”, but any Designated Reviewer recommends “Modifications Required”, IACUC Administrator creates a board document using the “IACUC RMSA Letter” Wizard, enters the description of each required modification shown in the comments of any Designated Reviewer, and adds the board document to the package

To make the board document available to the Research Team, click “Publish Final” in the table of “Board Documents” on the “Submission Detail” page => notification sent to the Project Owners that the board document is available

Unlock the package for the Researcher to revise

Researcher revise the documents in the package to address the requirement for modifications, and resubmits it

Share the new package to allow IACUC Reviewer access by every appointed IACUC member (regular or alternate), with the same IACUC Reviewers identified with the Special Designation of “Designated Reviewer” as for the original review

Set an individual alarm for each IACUC Reviewer

Check the box on the “Share Submission” page to notify each Reviewer that access has been granted

Enter in the “Your Comments” box:  
that this package is in response to the RMSA outcome,



## IACUC Administrator: Sequence of Events for Protocol Review by DMR

and instruct Reviewers to check “Mark my personal review as complete” when finished, by [due date]

If all Designated Reviewers recommend “Approve”, IACUC Administrator creates a board document using the “IACUC Approval Letter” Wizard and entering the comments of any Designated Reviewer, and adds it to the package

To make the board document available **to the Research Team**, click “Publish Final” in the table of “Board Documents” on the “Submission Detail” page => notification is sent **to the Project Owners** that the document is available

Add this package to the agenda for the appropriate convened meeting, and move it to the section for Protocols and Modifications Reviewed by DMR

IACUC Admin

## 27. IACUC Administrator: Sequence of Events for Protocol Review by FCR

(To show here how different roles interact in IRBNet, IACUC Administrator actions are shown in black font, **Researcher actions are shown in red font**, and **Reviewer actions are shown in navy font**.)

Add the package to the appropriate agenda for a convened meeting of the IACUC

Move the package to the “Complete Review of Protocols by FCR” section of the agenda

Share the package to allow Reviewer access by every appointed IACUC member (regular or alternate)

Enter the Special Designation of “Primary Reviewer” for at least two IACUC Reviewers *{at the IACUC Administrator’s discretion, with optional input from the IACUC Chair}*

Set the due date for comments of the Primary Reviewers to be entered  
*{Comments of other Reviewers are optional.}*

Set an individual alarm for each Primary Reviewer, so the IACUC Administrator will be notified when they complete their reviews

Check the box on the “Share Submission” page to **notify each IACUC Reviewer** that access has been granted

Enter in the “Your Comments” box:

that this package is submitted for FCR,  
identify the Primary Reviewers,  
instruct Primary Reviewers to enter their reviews in the Reviewer Comments for this package,  
and instruct the Primary Reviewers to check “Mark my personal review as complete” when finished, by [due date]

**Reviewers enter reviews on the “Reviewer Comments” page**

In the minutes for the convened IACUC meeting, document the IACUC deliberations, vote, and outcome. Copy relevant comments submitted by Reviewers into the “Discussion and Remarks” [free text field].

Prepare the appropriate board document using the Wizards *{Wizards automatically attach the document to the package}*

If IACUC voted “Approved”, use the “IACUC Approval Letter” Wizard

If IACUC voted “Modifications Required”, use the “IACUC RMSA Letter” Wizard

For any other outcome of the IACUC’s review of the protocol, use the “IACUC Notification Letter” Wizard *{For example, use this if the IACUC votes to deny approval.}*

To make the board document available to the Research Team, click “Publish Final” in the table of “Board Documents” on the “Submission Detail” page => notification is sent to the Project Owners that the document is available

Unlock the package if necessary for the Researcher to revise the protocol

Researcher revises the package documents as needed and re-submits

IACUC Admin

## 28. IACUC Administrator: Sequence of Events for Secondary Review

*{Any protocol for work with a sensitive species of animals (cats, dogs, and non-human primates) OR that is required for JIT processing before release of VA funds, must be submitted to the office of the CVMO for secondary review.}*

To show here how different roles interact in IRBNet, IACUC Administrator actions are shown in black font, **Researcher actions are shown in red font**, **IACUC Reviewer actions are shown in green font**, and CVMO Office actions are shown in navy font.

After the IACUC grants approval for the protocol, attach the following as IACUC board documents to the package approved by the IACUC, for submission for secondary review:

The final approved version of the protocol, with headers and signatures

Download the version of the protocol (including all applicable appendices) that was approved by the IACUC

Enter identifying information into the header of the approved protocol so the PI name, any locally assigned protocol ID, and date of IACUC approval of this version of the protocol appear on every page of the Main Body and each applicable appendix of the protocol.

Get applicable ACORP certification statements signed

For those who will sign in-person, the IACUC Administrator prints out a copy of the approved protocol with identifiers in the header

**Each signer personally provides a dated wet signature in each required location**

IACUC Administrator scans the signed pages, and adds the scanned pages as an IACUC board document

For signers who are not present in person, but have access to IRBNet (IACUC Chair, AV, PI), click the “Send Project Mail” button in the sidebar menu to send a message with instructions about where to sign (most commonly, Z.1.a and b, Z.3.a and b, and Z.5)

Attach the protocol (with headers) to the package as a board document

## IACUC Administrator: Sequence of Events for Secondary Review

Each signer (IACUC Chair, AV, PI) downloads the approved protocol that is attached as an IACUC board document to the secondary review package

Signer may print it out, wet sign and date it in each required location, then scan the signed pages, OR may sign digitally (e.g., with the certificates function of Adobe Acrobat)

IACUC Chair and AV then attach the signed document(s) as Reviewer Document(s) to the secondary review package

PI attaches the signed document(s) to the package

IACUC Administrator attaches as (a) board document(s) the signed document(s) attached to the package or received as (a) reviewer document(s).

For signers who are not present in person, and do not have access to IRBNet, use email to provide the final approved protocol with identifiers in the header {These may include, but are not limited to, the biosafety officer, personnel responsible for human clinical space or equipment, the PI, etc.}

Signer may print out the protocol, wet sign and date it in each required location, then scan the signed pages, OR may sign digitally (e.g., with the certificates function of Adobe Acrobat)

Signer returns the signed document(s) to the IACUC Administrator as attachment(s) by email

IACUC Administrator attaches as (a) board document(s) the signed document(s) received by email

Prompt the PI to provide to the IACUC Administrator a copy of each locally approved procedure or policy referenced in the final approved protocol

The PI provides a copy of each locally approved procedure or policy referenced in the final approved protocol, either identifying them as already included in the package that was approved by the IACUC, or sending them to the IACUC Administrator for attaching as board documents

Fill out the "Coversheet for Secondary Review of Protocols by the Office of the CVMO" and get it signed by the ACOS/R&D or designee delegated in writing

## IACUC Administrator: Sequence of Events for Secondary Review

Signer may print out the protocol, wet sign and date it, then scan the signed page, and return the scanned version to the IACUC Administrator by email

Signer may sign digitally (e.g., with the certificates function of Adobe Acrobat) and return the signed document to the IACUC Administrator by email

IACUC Administrator uploads as a board document each signed document received.

Submit the package to the CVMO board.

Assign "Submission Type" *{just a label for the convenience of the Administrator, indicating the reason the package is being submitted}*

Modification *{use when an IACUC-approved modification of a protocol for work with a sensitive species is being submitted for secondary review because it requires assignment of animals to a higher USDA Category}*

New Project *{use to initiate secondary review}*

On-Going Project *{used for re-review of an ongoing project involving sensitive species}*

Other

Response/Follow-up *{submit in response to secondary review comments}*

To respond to Project Mail from the CVMO Administrator about something missing from the IACUC board documents submitted for secondary review, add the missing document(s) as IACUC board documents and publish them *{these become available to the CVMO board when they are published}*

The CVMO board addresses the package – CVMO Administrator adds comments and documents from the CVMO Secondary Reviewer as CVMO board documents, and publishes them, making them accessible to the station *{When a CVMO board document is published, the Researcher and the IACUC Administrator are notified.}*

Manage IACUC process for addressing secondary review comments

Add the package to the agenda for the next scheduled IACUC meeting, and move it to the section on "Other Protocol Matters" *{For the IACUC to decide what to require in response to the secondary review comments. Possibilities include:*

*Acknowledge the comments and discuss implications for future protocol development and review*

*Require the PI to modify the protocol to address the concerns raised}*

Create and publish a board document with the "IACUC Notification Letter" Wizard *{to advise PI what the IACUC has decided needs to be done in response to secondary review comments – Research Team is notified when the board document is published}*

## IACUC Administrator: Sequence of Events for Secondary Review

If the secondary review score is “Triage”, “Level 0”, or “Level 1”, and the protocol is for work that does not involve a sensitive species *{cats, dogs, or non-human primates}*, secondary review process is complete. Further actions are at the discretion of the IACUC.

CVMO Administrator approves Animal Subjects Research Review JIT area in eRA, to allow release of VA funding.

If the secondary review score is “Level 2” or “Level 3” for protocols with any species, or “Level 1” for a protocol for work with a sensitive species *{cats, dogs, or non-human primates}*, a response is required.

Researcher prepares the response and modifies the protocol as needed

Researcher submits the modified protocol to the IACUC in a new package

When the modified protocol has been approved by the IACUC, prepare the package for submission to the CVMO board (as when it was initially submitted to the CVMO board), and submit to the CVMO board

If the protocol is for work with a sensitive species *{cats, dogs, or non-human primates}*, regardless of the source of funding support, expanded secondary review applies. *{See Chapter 29, “Institutional Administrator: Sequence of Events for Expanded Secondary Review”}*

## 29. IACUC Administrator: Sequence of Events for Expanded Secondary Review

To show here how different roles interact in IRBNet, IACUC Administrator actions are shown in black font, **Researcher actions are shown in red font**, the IACUC Reviewer actions are shown in green font, and CVMO Office actions are shown in navy font.

*{The expanded secondary review process begins when the secondary review score is Level 0.}*

CVMO office coordinates veterinary ethical review of protocol

Packet is submitted by email to ethics reviewers, and includes:

- The approved protocol
- A synopsis of the approved protocol
- The final secondary review comments
- Independent literature search results

On receipt of comments from veterinary ethics reviewers, CVMO office documents completion of veterinary ethics review

CVMO Administrator adds the comments from the veterinary ethics reviewers as a CVMO board document

CVMO uses the "CVMO Reviewer Comments Memo" Document Wizard to create/edit a CVMO board document instructing the PI to

- Respond to the concerns raised in ethics review
- Provide the response to the IACUC Administrator to attach to the package as a new IACUC board document.

**PI responds in writing to the concerns raised in the veterinary ethics review comments, and emails the response to the IACUC Administrator**

IACUC Administrator adds the response as an IACUC board document to the package

CVMO office coordinates CRADO review

Packet is submitted by email to the CRADO, and includes:

- The approved protocol
- A synopsis of the approved protocol
- The final secondary review comments



## IACUC Administrator: Sequence of Events for Expanded Secondary Review

- Independent literature search results
- Veterinary ethics review comments
- PI response to concerns raised in veterinary ethics review

If CRADO requires additional information from the Researcher, CVMO office notifies the Researcher by email

**Researcher provides the information required by the CRADO to the IACUC Administrator**

IACUC Administrator adds the new information to the package as an IACUC board document

CVMO office forwards the information to the CRADO

On receipt of signed CRADO approval document (e.g., Form 4265, Concurrence and Summary Sheet), CVMO office documents CRADO approval, adding the signed CRADO approval document as a CVMO board document

CVMO office coordinates review by senior VHA managers (e.g., AUSH/DEAN, DUSH, etc.), as needed to secure VA Secretary approval

Packet is submitted by email to senior VHA managers, and includes:

- The approved protocol
- A synopsis of the approved protocol
- The final secondary review comments
- Independent literature search results
- Veterinary ethics review comments
- PI response to concerns raised in veterinary ethics review
- CRADO approval document

If a senior VHA manager requires additional information from the Researcher, CVMO office notifies the Researcher by email

**Researcher provides the information required by the senior VHA manager to the IACUC Administrator**

IACUC Administrator adds the new information to the package as an IACUC board document

CVMO office forwards the information to the senior VHA manager

## IACUC Administrator: Sequence of Events for Expanded Secondary Review

On receipt of signed recommendation from senior VHA managers for VA Secretary to approve, CVMO office documents the recommendation, adding the signed recommendation as a CVMO board document

CVMO office coordinates documentation of VA Secretary approval

Packet is submitted by email to the VA Secretary, and includes:

- The approved protocol
- A synopsis of the approved protocol
- The final secondary review comments
- Independent literature search results
- Veterinary ethics review comments
- PI response to concerns raised in veterinary ethics review
- CRADO approval document
- Signed recommendation of senior VHA managers to VA Secretary

If VA Secretary requires additional information from the Researcher, CVMO office notifies the Researcher by email

Researcher provides the information required by the VA Secretary to the IACUC Administrator

IACUC Administrator adds the new information to the package as an IACUC board document

CVMO office forwards the information to the VA Secretary

On receipt of signed approval of the VA Secretary, CVMO office documents the approval, adding the signed approval of the VA Secretary as a CVMO board document

CVMO office prepares report to Congress as required by appropriations legislation

May be processed by Congressional Appropriations – Office of Management, through GOAL, as a CTR

On receipt of a copy of the report submitted to Congress, CVMO office documents the recommendation, adding the submitted report as a CVMO board document

CVMO office notifies the station when 30-day waiting period after submission of the report to Congress is completed

CVMO office approves the Animal Subjects Research Review JIT area in eRA, to allow release of VA funding.

IACUC Admin

### 30. IACUC Administrator: Sequence of Events for an Administrative Project

To show here how different roles interact in IRBNet, IACUC Administrator actions are shown in black font, **Researcher actions are shown in red font**, and Reviewer and CVMO Office actions are shown in navy font.

*{An “Administrative Project” is a mechanism for the IACUC members to work collaboratively on business related to work with animals, but not associated with a specific research project, that requires review by the IACUC outside of a convened meeting. Examples include (but are not limited to):*

*“Administrative protocols” are protocols for work with animals that supports research but is not specific to any one research project – these are reviewed and approved by the IACUC just as any other protocol is*

*Protocols for establishment and maintenance of a breeding colony  
Protocols for holding animals originally assigned to research protocols for which approval has expired or been suspended  
Protocols for managing sentinel animals  
Protocols for core services (e.g., imaging, behavioral testing)*

*“Non-protocol administrative projects” address IACUC business other than protocols, that is not specific to any one research project*

*Local policies and standard procedures, such as (but not limited to):*

*For IACUC business  
For acceptable vendors of animals  
For animal husbandry practices*

*Investigations of potentially reportable matters*

*Semiannual evaluations}*

IACUC Administrator adds a Researcher affiliation with the station, to own account

**IACUC Administrator in a Researcher role creates a new project by clicking the “Create New Project” button in the sidebar menu => “Project Information” page**

**Enter Project Information on the “Project Information” page**

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

**Title: [free text field]**

## IACUC Administrator: Sequence of Events for an Administrative Project

*{Begin each title with ALL CAPS designation that identifies it as and administrative project, e.g.:*

*BREEDER*

*SENTINEL*

*HOLDING*

*CORE*

*STD PROCEDURE*

*INVESTIGATION*

*SEMIANNUAL}*

Local PI: *{Name of protocol PI, or Administrator in Researcher role}*

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] *{leave blank}*

Internal Reference Number: [optional free text field] *{Choose according to local requirements.}*

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

Enter/edit Package Description on the "Designer" page

Assemble documents in the package, by clicking the "Attach New Document" button at the bottom of the "Designer" page => File Explorer

*{There are no Wizards for packages in administrative projects for the IACUC.}*

*{Training Records are N/A for administrative projects for the IACUC}*

*{Package signatures are not required for administrative projects for the IACUC}*

Grant access to other Researcher accounts that are to contribute to assembly of packages for this project *{generally not necessary for administrative projects}*

Submit the package to the IACUC by clicking the "Submit this Package" button in the sidebar menu => "Submit Package" page

"Select a Board" on the "Submit Package" page *{select "IACUC"}*

Enter a "Submission Type" [menu of options specific to the board] *{choose "Other"}*

As the IACUC Administrator, access the package from the "Submission Manager" => "Submission Detail" page

To add documents to the package, add them as board documents on the "Submission Detail" page

## IACUC Administrator: Sequence of Events for an Administrative Project

To assign the administrative package to an agenda, go to the “Review Details” section of the “Submission Detail” page

To assign the submitted package to IACUC Reviewers, click the “Share” link below the link for adding board documents, on the “Submission Detail” page => “Share Submission” page with table of all accounts to which access may be granted

*{It is the IACUC Administrator’s responsibility to share the package with each voting member {Reviewer} appointed to the IACUC (regular or alternate) – IRBNet does not maintain a list of voting IACUC members, it is up to the IACUC Administrator to keep track of the membership}*

To see documents in the package, IACUC Reviewer goes to “New and Revised Documents in this Package” section of the “Submission Detail” page

To open a document on the “Submission Detail” page, click on Document Type OR “sheet of paper” icon in the “New and Revised Documents in this Package” table

To see board documents attached to the package by the IACUC Administrator, go to the “Board Documents” section of the “Submission Detail” page *{Table of documents attached to the package by the IACUC Administrator is shown only if at least one board document has been attached. Reviewer cannot add or edit board documents}*

To download a document, click the Document Type or “sheet of paper” icon

To see comments and documents provided by Reviewers of the submission, click one of the following in the table below the link to “Add” or “Update” comments and reviewer comments, 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  
OR the “sheet of paper” icon *{only shown if there are reviewer documents attached}*

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 add/update the Reviewer’s own comments and documents, click one of the following to => “Reviewer Comments” page

“Add” link above the table of Reviewers on the “Submission Detail” page  
*{shown if the Reviewer has not yet provided comments or reviewer documents}*

OR “Update” above 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

## IACUC Administrator: Sequence of Events for an Administrative Project

*{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, enter/edit

Reviewer Comments [free text box]

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

(blank) *{use for most reviewer recommendations about non-protocol administrative projects – for providing comments and suggestions}*

Acknowledge *{not an option for review of administrative projects}*

Approve *{for administrative protocols, and for non-protocol administrative projects that the Reviewer deems acceptable}*

Close *{only for administrative protocols}*

Disapprove *{Deny Approval – This is only an option for FCR of administrative protocols. For DMR of administrative protocols, recommend “Refer to Full Board” instead.}*

Information Required *{N/A -- For administrative protocols, use (blank) instead and explain in comments}*

Modifications Required *{RMSA, may be an IACUC action outcome of FCR or DMR of administrative protocols; not an option for review of administrative projects}*

Not Research *{not an option for review of administrative projects}*

Refer to Full Board *{only an option for DMR of administrative protocols}*

Suspend *{only an option for administrative protocols}*

Terminated *{do not use this term for administrative protocols, as it does not distinguish among different types of termination and will cause confusion (use “close” or “suspend” instead; not an option for review of administrative projects)}*

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, manage any documents that IACUC Reviewer wants to attach

“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

## IACUC Administrator: Sequence of Events for an Administrative Project

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”}*

For IACUC Administrator to see summary information about the review of a package, to go the “Review Details” section of the “Submission Detail” page

Agenda (meeting date and time)

*{scheduled IACUC meeting to which the package has been assigned}*

Most recent information about the review *{from “Review and Minutes” page}*

“Review Type”

“Action” *{Most recent board action taken}*

“Effective Date” *{The effective date of the most recent board action taken}*

“Expiration Date” *{The expiration date of the project}*

“Report Due” *{The date when the next report is due from the Researcher}*

To see/edit a summary of the IACUC deliberations and decisions for the Minutes, click “pencil and paper” icon for the Agenda of interest in the “Review Details” table on the “Submission Detail” page => “Review and Minutes” page *{This documents for the IACUC what the IACUC did with this submission, at the meeting selected}*

Review Type [drop-down menu]

(blank) *{Unassigned or N/A -- use this for any package that did not involve the specific review processes defined by PHS Policy for protocol review, including all non-protocol administrative projects}*

Full Committee Review *{only for administrative protocols}*

Administrative Review *{only for administrative protocols}*

Designated Member Review *{only for administrative protocols}*

Action [drop-down menu] *{Actions that the IACUC took on the package at this meeting}*



## IACUC Administrator: Sequence of Events for an Administrative Project

(blank) *{for most non-protocol administrative projects}*

Acknowledged *{not an option for review of administrative projects}*

Approved *{for administrative protocols, and for non-protocol administrative projects that are acceptable}*

Closed *{only for administrative protocols, N/A for non-protocol administrative projects}*

Forwarded *{not an option for review of administrative projects}*

Information Required *{Not an action for administrative protocols, use (blank) instead and explain in comments; not an option for review of non-protocol administrative projects}*

Modifications Required *{RMSA for administrative protocols; not an option for review of non-protocol administrative projects}*

Not Approved *{Deny Approval – This is only an option for FCR of administrative protocols; use “Refer to Full Board” instead for DMR. This is not an option for review of non-protocol administrative projects}*

Not Research *{not an option for review of administrative projects}*

Referred to Full Board *{only an option for DMR of administrative protocols}*

Suspended *{only an option for administrative protocols; requires a majority vote of the IACUC at a convened meeting}*

Tabled Without Action *{Choose this option if the IACUC considered the item of business but delayed voting on approval, and explain why in the “Discussion and Remarks” (e.g., because quorum was not present, because part of a protocol under review is missing, because revision of the minutes is required before the IACUC can vote)}*

Terminated *{Do not use this term, as it does not distinguish among different types of termination and will cause confusion; use “closed” or “suspended” as appropriate, instead}*

Withdrawn *{if a decision is made to remove an administrative project from further consideration}*

Effective Date [select from calendar] *{refers to effective date of the board Action that was recorded, which may be after the date on which the board acted}*

Project information *{on the “Review and Minutes” page}*

Project Status *{refers to the administrative project that the package belongs to, not to the status of any single package submitted to the IACUC for this administrative project}*

(blank) *{appropriate for most administrative projects}*

Active *{This refers specifically to approved research protocols. **Do not use this** for any administrative projects, as all projects with this designation are included in ORPP&E analyses of VA research projects.}*

Closed *{The general status of an administrative protocol that was approved earlier, but the period of approval by the IACUC has ended (e.g. after the approval of a protocol expires, 3 years after it was granted). “Suspended” is a separate status, below. Does not apply to non-protocol administrative projects}*

Closed – Expired *{use “Closed” instead for administrative protocols; N/A for non-protocol administrative projects}*

## IACUC Administrator: Sequence of Events for an Administrative Project

Closed – Project Complete {use “Closed” instead for administrative protocols; N/A for non-protocol administrative projects}

Deferred – Information Required {not a project status – if the IACUC defers taking any action, project status remains unchanged}

Deferred – Modifications Required {not a project status – if the IACUC makes a determination of RMSA, project status unchanged}

Disapproved {approval denied – only an option for administrative protocols reviewed by FCR, not for non-protocol administrative projects}

Not Research {N/A for administrative projects}

Suspended {only an option for administrative protocols; requires a majority vote of the IACUC at a convened meeting}

Terminated {do not use this term, as it does not distinguish among different types of termination and will cause confusion; use “Closed”, “Suspended”, or “Withdrawn” instead}

Withdrawn {This rarely applies to administrative projects. An example might be if the IACUC is working on a policy for VVC and then decides before completing it that VVC will not be used at all.}

Dates [select from calendar, the dates that apply to the project] {defined by local policy}

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 approvals of administrative projects, this is no later than the third anniversary of approval

For suspensions or closures, this is the date the suspension or closure took effect

For non-protocol administrative projects, this is whatever date the IACUC specifies, in compliance with regulatory and policy requirements}

Next Report Due => 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 earlier.}

{for 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 requested by the IACUC.

This rarely applies to non-protocol administrative projects, which are initiated and managed by the IACUC, and do not involve correspondence with a Researcher.}

Initial Approval Date {the most recent date when an administrative project was granted approval by the IACUC. For administrative protocols, this is the date from which the triennial expiration date is calculated.}

## 31. IACUC Administrator: Managing Protocols Reviewed Outside of IRBNet

*{This applies when protocol review is managed by a mechanism other than IRBNet, e.g., for a VA station with an internal IACUC that processes protocol review outside of IRBNet. As of 11/29/23, IRBNet has not set up an IACUC board workspace within IRBNet for VA stations with external IACUCs of record, so these instructions do not apply. These instructions will apply when IRBNet sets up an IACUC board workspace within IRBNet for a VA station with an external IACUC of record, which includes granting IACUC Administrator access to someone at that station. This chapter addresses how to archive in IRBNet the documents relevant to the program of research with animals so that access to the documents is consistent enterprise-wide, regardless of whether the IACUC overseeing the program is internal or external.}*

To get a protocol that was reviewed outside of IRBnet into the document archive in IRBNet:

The IACUC Administrator adds to the IACUC Administrator's own account a Researcher affiliation to the station

The Research (owner) of the project shares the project with the IACUC Administrator in the role of a Researcher.

The IACUC Administrator in the role of a Researcher creates a new package for the project and attaches the approved protocol

The IACUC Administrator in the role of a Researcher submits the package containing the approved protocol to the IACUC board workspace

To document the approval of the protocol reviewed outside of IRBNet:

Assign the submitted package to an Agenda for the date the external IACUC met and voted to approve, or the effective date of the approval of the protocol

Go to the "Review Details" section of the "Submission Detail" page

To create a new meeting for which the package can be assigned to the Agenda, click "Add Another Agenda Date" link above right corner of table => adds new "unassigned" agenda to table

To schedule the date, time, and location of the new meeting, click the blue triangle before the "unassigned" agenda, and choose "Add a New Agenda" in drop-down menu  
=> "Add Meeting" window

To select a date and time, click "..." button => Calendar and clock window

To enter a meeting location, click the [free text field] for “Meeting Location” and enter the name of the institution hosting the external IACUC

To save new meeting, click “Continue” => new meeting appears in drop-down menu

Click the date of the newly created agenda to assign the package to it

To document the action taken by the external IACUC on this protocol, click on the “paper and pencil” icon => “Review and Minutes” page

Review Type [drop-down menu] *{select the Review Type used by the external IACUC}*

(blank) *{N/A for a protocol approved by an external IACUC}*

Full Committee Review

Administrative Review

Designated Member Review

Action [drop-down menu]: Approved

*{None of the other options in the drop-down menu apply for a protocol approved by an external IACUC}*

Effective Date [select from calendar] *{refers to effective date of approval of the protocol by the external IACUC}*

Project information *{on the “Review and Minutes” page}*

Project Status *{refers to the status from the perspective of the external IACUC, of the project that the package belongs to, not to the status of the specific package}: Active*

*{None of the other options in the drop-down menu apply for a protocol approved by an external IACUC}*

Dates [select from calendar, the dates that apply to the project] *{defined by local policy}*

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}*

Next Report Due => displayed as “Report Due” on the “Submission Detail” page *{“Report” refers to any formal communication with the external IACUC. This can be the next routine report, or any other report that the IACUC asks for earlier -- for approvals, this is the due date for submission of documents for any continuing review or renewal of approval required by the IACUC}*

Initial Approval Date *{the most recent date when the protocol was granted approval by the external IACUC, from which the triennial expiration date is calculated}*

Votes *{leave blank}*

Recused *{leave blank}*

Discussion and Remarks *{enter any notes about the external IACUC approval, if needed}*

To submit a protocol that was approved by an external IACUC to the office of the CVMO for secondary review, follow the sequence of events in Chapter 28 (IACUC Administrator: Sequence of Events for Secondary Review), copied here. To show here how different roles interact in IRBNet, IACUC Administrator actions are shown in black font, **Researcher actions are shown in red font**, IACUC Reviewer actions are shown in green font, and CVMO Office actions are shown in navy font.

Attach the following as IACUC board documents to the package approved by the IACUC, for submission for secondary review:

The final approved version of the protocol, with headers and signatures

Download from the package the version of the protocol (including all applicable appendices) that was approved by the external IACUC

Enter identifying information into the header of the approved protocol so the PI name, any locally assigned protocol ID, and date of approval of this version of the protocol by the external IACUC appear on every page of the Main Body and each applicable appendix of the protocol.

Get applicable ACORP certification statements signed

For those who will sign in-person, the IACUC Administrator prints out a copy of the approved protocol with identifiers in the header – after each signer personally provides a dated wet signature in each required location, the IACUC Administrator scans the signed pages, and adds the scanned pages as an IACUC board document

For signers (e.g., the PI) who are not present in person, but have access to IRBNet, click the “Send Project Mail” button in the sidebar menu to send a message with instructions about where to sign (most commonly, Z.1.a and b, Z.3.a and b, and Z.5)

Attach the protocol (with headers) to the package as a board document

**PI downloads the approved protocol that is attached as an IACUC board document to the secondary review package**

**PI may print it out, wet sign and date it in each required location, then scan the signed pages, OR may sign digitally (e.g., with the certificates function of Adobe Acrobat)**

**PI attaches the signed document(s) to the package**

IACUC Administrator attaches as (a) board document(s) the signed document(s) attached to the package.

For signers who are not present in person, and do not have access to IRBNet,  
use email to provide the final approved protocol with identifiers in the header  
*{These may include, but are not limited to, the IACUC Chair, the AV, the biosafety officer, personnel responsible for human clinical space or equipment, the PI, etc.}*

Signer may print out the protocol, wet sign and date it in each required location, then scan the signed pages, OR may sign digitally (e.g., with the certificates function of Adobe Acrobat)

Signer returns the signed document(s) to the IACUC Administrator as attachment(s) by email

IACUC Administrator attaches as (a) board document(s) the signed document(s) received by email

Prompt the PI to provide to the IACUC Administrator a copy of each locally approved procedure or policy referenced in the final approved protocol

*The PI provides a copy of each locally approved procedure or policy referenced in the final approved protocol, either identifying them as already included in the package that was approved by the IACUC, or sending them by email to the IACUC Administrator*

IACUC administrator adds these documents as IACUC board documents

Fill out the “Coversheet for Secondary Review of Protocols by the Office of the CVM0” and get it signed by the ACOS/R&D or designee delegated in writing

Signer may print out the protocol, wet sign and date it, then scan the signed page, OR sign digitally (e.g., with the certificates function of Adobe Acrobat)

Signer returns the signed document to the IACUC Administrator by email

IACUC Administrator uploads as a board document each signed document received.

Submit the package to the CVM0 board.

Assign “Submission Type” *{just a label for the convenience of the Administrator, indicating the reason the package is being submitted}*

Modification *{use when an IACUC-approved modification of protocol for work with a sensitive species is being submitted for secondary review because it requires assignment of animals to a higher USDA Category}*

New Project *{use to initiate secondary review}*

On-Going Project *{used for re-review of an ongoing project involving sensitive species}*

Other

Response/Follow-up *{submit in response to secondary review comments}*

To respond to Project Mail from the CVMO Administrator about something missing from the IACUC board documents submitted for secondary review, add the missing document(s) as IACUC board documents and publish them *{these become available to the CVMO board when they are published}*

The CVMO board addresses the package – CVMO Administrator adds comments and documents from the CVMO Secondary Reviewer as CVMO board documents, and publishes them, making them accessible to the station *{When a CVMO board document is published, the Researcher and the IACUC Administrator are notified.}*

#### To manage responses to secondary review comments

Forward the secondary reviewer comments to the external IACUC for its determination of what to do in response

If the secondary review score is “Triage”, “Level 0”, or “Level 1”, and the protocol is for work subject to JIT processing and does not involve a sensitive species *{cats, dogs, or non-human primates}*, secondary review process is complete. Further actions are at the discretion of the IACUC.

CVMO Administrator approves Animal Subjects Research Review JIT area in eRA, to allow release of VA funding.

If the secondary review score is “Level 2” or “Level 3” for protocols with any species, or “Level 1” for a protocol for work with a sensitive species *{cats, dogs, or non-human primates}*, a response is required.

**Researcher prepares the response and modifies the protocol as needed**

**Researcher submits the modified protocol to the external IACUC for review and approval**

When the modified protocol has been approved outside of IRBNet, a copy of the approved final revised version of the protocol, is provided by the IACUC to the IACUC Administrator, who prepares the package for submission to the CVMO board (as when it was initially submitted to the CVMO board), and submits it to the CVMO board



## IACUC Administrator: Managing Protocols Reviewed Outside of IRBNet

If the protocol is for work with a sensitive species *{cats, dogs, or non-human primates}*, regardless of the source of funding support, expanded secondary review applies, as described next.

To manage the expanded secondary review process for a protocol with a sensitive species *{cats, dogs, or non-human primates}* that was approved by an external IACUC, follow the sequence of events in Chapter 29 (IACUC Administrator: Sequence of Events for Expanded Secondary Review), copied here. To show here how different roles interact in IRBNet, IACUC Administrator actions are shown in black font, Researcher actions are shown in red font, IACUC Reviewer actions are shown in green font, and CVMO Office actions are shown in navy font.

*{The expanded secondary review process begins when the secondary review score is Level 0.}*

CVMO office coordinates veterinary ethical review of protocol

Packet is submitted by email to ethics reviewers, and includes:

- The approved protocol
- A synopsis of the approved protocol
- The final secondary review comments
- Independent literature search results

On receipt of comments from veterinary ethics reviewers, CVMO office documents completion of veterinary ethics review

CVMO Administrator adds the comments from the veterinary ethics reviewers as a CVMO board document

CVMO Administrator uses the "CVMO Reviewer Comments Memo" Document Wizard to create/edit a CVMO board document instructing the PI to

- Respond to the concerns raised in ethics review
- Provide the response to the IACUC Administrator to attach to the package as a new IACUC board document.

PI responds in writing to the concerns raised in the veterinary ethics review comments, and emails the response to the IACUC Administrator

IACUC Administrator adds the response as an IACUC board document to the package

CVMO office coordinates CRADO review

Packet is submitted by email to the CRADO, and includes:



## IACUC Administrator: Managing Protocols Reviewed Outside of IRBNet

The approved protocol  
A synopsis of the approved protocol  
The final secondary review comments  
Independent literature search results  
Veterinary ethics review comments  
PI response to concerns raised in veterinary ethics review

If CRADO requires additional information from the Researcher, CVMO office notifies the Researcher by email

Researcher provides the information required by the CRADO to the IACUC Administrator

IACUC Administrator adds the new information to the package as an IACUC board document

CVMO office forwards the information to the CRADO

On receipt of signed CRADO approval document (e.g., Form 4265, Concurrence and Summary Sheet), CVMO office documents CRADO approval, adding the signed CRADO approval document as a CVMO board document

CVMO office coordinates review by senior VHA managers (e.g., AUSH/DEAN, DUSH, etc.), as needed to secure VA Secretary approval

Packet is submitted by email to senior VHA managers, and includes:

The approved protocol  
A synopsis of the approved protocol  
The final secondary review comments  
Independent literature search results  
Veterinary ethics review comments  
PI response to concerns raised in veterinary ethics review  
CRADO approval document

If a senior VHA manager requires additional information from the Researcher, CVMO office notifies the Researcher by email

Researcher provides the information required by the senior VHA manager to the IACUC Administrator

IACUC Administrator adds the new information to the package as an IACUC board document

CVMO office submits the information to the senior VHA manager

## IACUC Administrator: Managing Protocols Reviewed Outside of IRBNet

On receipt of signed recommendation from senior VHA managers for VA Secretary to approve, CVMO office documents the recommendation, adding the signed recommendation as a CVMO board document

CVMO office coordinates documentation of VA Secretary approval

Packet is submitted by email to the VA Secretary, and includes:

- The approved protocol
- A synopsis of the approved protocol
- The final secondary review comments
- Independent literature search results
- Veterinary ethics review comments
- PI response to concerns raised in veterinary ethics review
- CRADO approval document
- Signed recommendation of senior VHA managers to VA Secretary

If VA Secretary requires additional information from the Researcher, CVMO office notifies the Researcher by email

**Researcher provides the information required by the VA Secretary to the IACUC Administrator**

IACUC Administrator adds the new information to the package as an IACUC board document

CVMO office forwards the information to the VA Secretary

On receipt of signed approval of the VA Secretary, CVMO office documents the approval, adding the signed approval of the VA Secretary as a CVMO board document

CVMO office prepares report to Congress as required by appropriations legislation

May be processed by Congressional Appropriations – Office of Management, through GOAL, as a CTR

On receipt of a copy of the report submitted to Congress, CVMO office documents the recommendation, adding the submitted report as a CVMO board document

CVMO office notifies the station when 30-day waiting period after submission of the report to Congress is completed

CVMO office approves the Animal Subjects Research Review JIT area in eRA, to allow release of VA funding.

IACUC Admin