

Animal Research Online

ARO

USER'S GUIDE

A Resource Provided by the IACUC Office

Revised July 1, 2021

Access to ARO

All University of Pittsburgh Health Science and Dietrich School of Arts & Sciences faculty and certain staff designations may access ARO to create IACUC protocols. In order to gain access, however, a few basic requirements must be satisfied.

Because ARO depends on the data in the [HSConnect](#) training website for all of its personnel data, all ARO users must have an HSConnect account and complete the complete the basic IACUC training requirements. These requirements are:

- Completion of the [Responsible Conduct of Research](#) course.
- Completion of the [Working with Large Animals](#) and/or [Working with Small Animals](#) courses within the last four years.

To log in to ARO, go to www.aro.pitt.edu and log in using your HSConnect account. If you are not able to log in, first check [HSConnect](#) to make sure that you have satisfied the training requirements.

Please note that ARO receives information from HSConnect nightly and uploads the information the following evening. As such, it could take up to 48 hours for your account to be activated.

IACUC Protocols in ARO

ARO combines many features to improve productivity and make more information accessible to researchers, animal care staff and the IACUC:

- Protocol applications make use of intelligent branching, so researchers don't have to answer questions that do not pertain to their own work.
- Instant access to approval letters and the approved versions of all protocols.
- Real-time access to all approved personnel listed on a protocol.
- Automated email reminders.
- State transparency, meaning that you will always know where your protocol is in the review process.
- The system is self-contained, and doesn't require the separate submission of an EHS workbook with every protocol.
- Because it is internet-based, it is accessible from any computer with an internet connection.

What if I Have More than One HSConnect Account?

ARO will only be able to pull you HSConnect account into the system if you have a single account that satisfies the training requirements. If you have multiple accounts, with IACUC-specific training modules completed between them, your account will not be recognized and you will not have access to ARO. If you have multiple HSConnect accounts that are preventing ARO access, you should contact the Health Sciences Technical Support team by submitting a help request at their [website](#) or by calling the Help Desk at 412-648-2222.

Your ARO Workspace

After logging in, you will see on the left side of the screen, “**My Site Roles.**” Below this are all of the roles you have in ARO. Most users will only see **IACUC Researcher**, but you may have others, if you are involved with the IACUC as a committee member or DLAR staff member, for instance. Other roles will be discussed later in this guide. To create a protocol or perform other tasks, like responding to reviewers’ questions or submitting a modification request, you should make sure that “**IACUC Researcher Role**” has been selected. For most users, this is the default role.

Once the IACUC Researcher role has been selected, you should see a large button on the left side of the screen under your site roles labeled, “**Create IACUC Protocol.**” Click this button to launch the protocol **Smart Form**. If you do not see this button, please call the IACUC Office.

You should also be able to see the **Researcher Inbox**. This is where you will find any items that require your attention when one of your protocols is under review. Note that this list is sortable by clicking on the top of each column. The list is also filterable by protocol ID, protocol name, PI last name, and state using the **Filter By** tool.

General Access Role

By clicking **General Access** under My Site Roles you will display a tabbed chart displaying all approved protocols, protocols in the review process and under-review modification and renewal requests to which you have access (as PI or other personnel). Just click the appropriate tab to display the desired information. As with your inbox, each of these lists is sortable and filterable to make it easy to find the information that you need.

Protocol Workspace

The protocol workspace is where all available actions, called Activities, can be found, along with many other features. It is the “home base” for all protocols.

States

A protocol’s current state – a short description of its review status -- is found in the upper left-hand corner of its workspace. As an ARO user, you will always be able to tell how far along your protocol is in the review process.

A protocol’s State determines what actions – referred to as “Activities” -- can be taken. For instance you can only run the Submit Changes Activity while the protocol is in the “Changes Required in Designated Review” State. Other Activities, like Request Withdraw, are available in every state leading up to approval.

If your protocol's current State is "Flagged for Full Committee Review," no action can be taken until the IACUC reaches a decision at the next full committee meeting. These are typically held on the third Monday of every month. You will receive word of the committee's decision after the meeting.

An addition discussion of States and what individual States entail can be found in the section on the review process.

Activities

Activities are those actions that can be taken by a user while the protocol is in a given state. The available Activities can be found on the left-hand side of a protocol's workspace. Only those Activities that can be run at a given time will be displayed.

The Activities that can be run also depend on *who* you are, as well. Not just anyone can log in and withdraw your protocol from review, for instance. Not even the IACUC staff can respond to reviewers' questions on your behalf.

Most Activities are self-explanatory, but note the following:

Create 3rd Year Renewal or Major Modification: This activity will make a copy of the current protocol. Upon approval, the original protocol will be closed. A link to the previous protocol will appear on the new protocol's workspace.

Request Withdraw sends a message to the IACUC office requesting that the item (protocol, modification request, annual renewal) be withdrawn from review. Please be specific in explaining your reasons for making the request.

History Log

The History Log, found in the center of a protocol's work space, is a time-stamped history of all actions taken during the life of the protocol, from creation to expiration. The submission of modification requests and annual renewals will also appear in the main protocol's history log, though they also have work spaces and history logs of their own, accessible from the **Modifications** and **Annual Renewals** tabs.

Protocol Documents

The Protocol Documents tab is where you can find any documents that you have uploaded (charts, graphs, pictures, etc.) with the research plan portion of your protocol, any documents uploaded by the IACUC reviewers (publications, policies, etc.) and the EHS Risk Assessment.

Comments on Form

The Comments on Form tab is where you will find a collated list of all of the reviewers' questions. From this tab you may jump to the page of the smart form on which the question appears. You may also respond to questions within the tab, but if the questions require an update of the protocol, you must

open the smart form and make the required changes as well. Please see the walkthrough of the review process below for more information on responding to questions.

Training Records

The Training Records tab contains a link to the HSConnect training records for each personnel member listed on the protocol. You can consult this tab to find out if all of the personnel on your protocol have completed the IACUC-required species-specific as well as certain EHS-required training modules.

Forms

Just under the Current State, you will find three buttons:

The **View/Edit Protocol Form** button opens your protocol smart form and will allow you to edit it at certain times during review.

The **Printer Version** button creates a printer-friendly version of your protocol. ARO may take a minute or two to complete this process.

The **View Differences** button opens a version of the smart form that compares your protocol to a previous version and highlights changes made to the smart form. Click on the drop down menu to select the version to which you would like to compare the current version of the protocol. The screen will display the first page of the protocol smart form that contains any changes from the selected protocol. The page is displayed in the Changed Steps window. If there are no changes, the changed steps window will indicate as much. To cycle through the changes pages, click one of the Arrows beside the changed steps window.

Changed items are indicated in a red box below the applicable question. New text will be highlighted in green.

To exit the View Changes function, click **Close**.

Approval Letter

All users with access to the protocol can view and print out the protocol's original approval letter. The link to it can be found on the protocol's workspace.

Most Recent Letter

If you have modified or renewed your protocol, the most current approval letter can be accessed by following this link on the protocol's workspace.

EHS Risk Assessment

Users also have access to the risk assessment document. The link to it can be found on the protocol's workspace.

Completing the Smart Form

Starting a New Protocol

Click **My Home** at the top left-hand side of the page, and then make sure that the **IACUC Researcher Role** is highlighted. You should see the **Create IACUC Protocol** button. Click it to open the protocol smart form.

Note that *only the PI, Protocol Administrator or Protocol Sponsor may create a protocol*. Other editors may subsequently work on the protocol, however.

Navigating the Smart Form

There are two simple ways to navigate the protocol smart form. The first method is to complete each page presented, then click the **Continue** button at the top and bottom left of each page. Clicking **Continue** will automatically save your work from the page and advance you to the next appropriate page until you reach the end of the protocol.

You may find it useful or necessary to jump back and forth between pages while working on it. You can do so by clicking the drop-down menu labeled **Jump To**, which is found along the top blue bar of the smart form (the same bar as the top **Continue** button). This will display all pages that ARO currently requires based on your answers. Jumping to another page using this method will also save your work before proceeding to the desired page.

Note: Some pages require you to answer certain questions before moving on to the next page via the **Continue** button. If you want to move to another page before completing required questions, use the **Jump To** feature.

Branching

ARO uses intelligent branching. This means that ARO uses your responses to some questions to determine which additional questions are appropriate for your project, such that pages that don't pertain to your research aren't displayed. Consequently, ARO depends on users to accurately describe their projects. Make sure to read the questions carefully, especially if this is your first time completing a protocol in ARO, as the IACUC Office cannot send inconsistent or incomplete protocols out for review.

For instance, if your research protocol contains surgical manipulations, make sure to click the Surgery box on the Procedure Classification page. Doing so will cause ARO to direct you to page(s) pertaining to surgery. Not clicking this box will result in pertinent questions never being asked.

In order to minimize the number of pages in the IACUC protocol, some pages branch to additional questions right on the page. For example, on the Funding Information page, clicking the Internal box in

Saving Your Work

At any time while completing your protocol you may save your work by clicking the **Save** link along the top blue bar. Then you may safely close your browser.

Note: In order for ARO to create your protocol document, the PI, Protocol Administrator or Protocol Sponsor must at least complete the first page and click the **Continue** button.

1.0 causes questions 1.2 and 1.3 to appear below it. It is important that you answer all follow-up questions when ARO displays them.

Hide/Show Errors

At any time while completing the protocol smart form, you may check to see if any required portion of the protocol has not been completed. To do this, click the **Hide/Show Errors** link found along the top blue bar of the smart form. Doing so will cause a window to appear at the bottom of the page that contains a list of all required items to which you have not yet responded, if any. Each entry in this window contains a link in the Jump To column that will take you to the page in question. This list can be refreshed with the **Refresh** button at the top of the window to remove any items that you have completed. To close this window, click the **Hide/Show Errors** link at the top of the page again.

Note that ARO does not check to see if your responses are appropriate. ARO cannot recognize incomplete responses or temporary placeholders inserted as responses to required questions, so please double-check any pages that were not fully completed.

Pop-Up Windows

Some questions require the entry of data into a pop-up window. After the entry is complete, your responses will appear in chart form. Click “Add” next to the chart to open the pop-up window, answer the required questions and click “OK.” To add additional line entries, click “Add” again and repeat. To edit a line entry, click the “Update” button to the left of the line, make the necessary changes and click “OK.” To delete a line entry, click the “Delete” button to the left of the line.

The Principal Investigator (PI)

The Principal Investigator is responsible for all aspects of the projects, including the health and well-being of the animals and the adherence to all regulations and University policies by all personnel listed on the protocol. While others may be designated the ability to complete the protocol Smart Form and respond to reviewers’ questions, only the PI may submit the protocol initially. The PI must also be listed in either General or Surgical Staff.

What if the PI is Not a Full-Time Faculty Member?

Only full time faculty at the University of Pittsburgh may serve as PI on Pitt IACUC protocols.

Postdoctoral fellows, graduate students, and undergraduate students submitting applications as principal investigators must obtain sponsorship from an appropriate academic advisor (who must also be a full-time faculty member).

If you have a pending faculty appointment, you will need to obtain a faculty sponsor and enter that person’s name in 4.0. After your appointment, the sponsor may be removed via a modification request.

Faculty sponsors take responsibility for all experimental studies performed pertaining to the protocol and agree to assure compliance with all federal regulations applicable to the research activities. The sponsor will be copied on all correspondence related to the protocol.

Protocol Sponsor

A protocol sponsor must be listed only in cases when the PI is *not* a full-time faculty member at the University of Pittsburgh. Part-time or adjunct faculty, new faculty whose appointments have not been finalized, graduate students or senior staff members may only serve as PI with faculty sponsorship. It is the responsibility of the PI to obtain this sponsorship. The Protocol Sponsor will be copied on all correspondence from ARO relating to the protocol.

Protocol Administrators and Editors

Although the PI must initially submit each protocol, PIs may designate others to complete the protocol, answer reviewers' questions and perform other administrative tasks. These may be laboratory personnel or office staff. Because they may not necessarily work with animals, individuals given these roles are not required to complete species-specific IACUC training unless they are also listed under either General Staff or Surgical Staff. The **Protocol Administrator** can edit any portion of the protocol while it is in the pre-submission state and when responding to questions. This individual also may submit Annual Renewal and Modification requests and will be copied on all reminder emails pertaining to the protocol that are sent to the PI.

Protocol Editors can edit any portion of the protocol while it is in the pre-submission state and when responding to questions, but they are not copied on all emails.

Personnel

All personnel who will come into contact with animals during the course of the project *must* be listed either under General Staff or Surgical Staff. As such, these individuals are responsible for completing species-specific IACUC training for all species used in the project as well as all EHS-mandated requirements.

Observers

Only those who will have *no possible contact with animals* (i.e., will not enter animal holding rooms or laboratories where animals are taken). The IACUC Coordinator will request a training waiver for these individuals (you may be contacted by a representative from the Education and Compliance Office). Those listed are exempted from species-specific training, but may still have to satisfy EHS requirements, at the discretion of EHS.

Do PI's Have to Complete the Protocol Smartform Themselves?

No, The PI can designate a Protocol Administrator to be an alternate point of contact with the IACUC for the PI's research group. This individual may read and edit the protocol form and submit some items to the IACUC office on behalf of the PI (though the PI must make the initial submission).

Keep in mind that the Protocol Administrator is not necessarily a member of the Study Team (he or she may be an administrator). If the Protocol Administrator will also participate in the procedures described in the protocol, you should list them in either the Study Team or Surgical Staff sections as well.


Spell Checker

You may find a spell check tool useful while working with the ARO system. Several browsers (Chrome, Safari) have built in spell checkers. Firefox has a built-in spell checker with limitations. Internet Explorer does not have an integrated spell checker, but you may install one of the free spell checker applications listed below.

Internet Explorer:

Internet Explorer users can download either the [Google Toolbar](#) or [iespell](#) add-on to spell check web-based forms. Both applications are free of charge. If you have the Google Toolbar installed, but do not see the spell check option, you may need to enable the feature (see below).

Enabling Spell Check on the Google Toolbar:

1. Click the Toolbar's wrench  icon.
2. On the **Tools** tab, select the 'Spell check'  checkbox.
3. Click **Save**.

Firefox

Firefox will automatically check the spelling of words that you enter in text boxes, but only text boxes containing more than one line.

If you want the ability to spell check on text boxes containing more than one line, we recommend that you install the Google Toolbar with spell checker.

The Review Process

The review process begins the moment the Principal Investigator submits a completed protocol smart form (see Fig. 1 below). To do so, the PI must click the **Submit Protocol** Activity while the protocol is in the **Pre Submission** State. A pop up screen will open that describes the PI's responsibilities. Click the checkbox, indicating that you accept the statements, and then click the **OK** button. The protocol will immediately enter the **Submitted** State.

While in the **Submitted** State, the protocol will be assigned an IACUC Coordinator, who will guide the protocol through the review process. When this assignment has been made, the protocol will enter the **IACUC Staff Review** State. You will find the name of the IACUC Coordinator assigned to your protocol on the protocol's workspace, above the History Log tab. If you have any questions or concerns during the course of your protocol's review, you should contact the assigned IACUC Coordinator.

The IACUC Coordinator will read your protocol carefully. If there are inconsistencies or if the protocol is incomplete, the protocol will be returned to you for revisions before being sent to reviewers. Should this occur, the protocol will be in the **Changes Required by IACUC Staff** State. Please see the section, "Responding to Questions" below for detailed instructions on how to correctly respond to reviewers' questions. The PI, The Protocol Administrator or the designated Protocol Editors may respond to the questions and make revisions to the protocol at this time and submit them. Once the requested changes have been made, click the **Submit Changes** Activity, which will send the protocol back to the **IACUC Staff Review** State. If all of the IACUC Coordinator's concerns have been addressed, the protocol will enter designated member review.

Designated Member Review

The assigned IACUC Coordinator will assign the protocol to at least five anonymous reviewers (more may be necessary if the project involves nonhuman primates, radiation or research at another institution, for instance) and click the **Forward to Reviewers** activity. This will put the protocol into the **Designated Member Review** State.

Assigned reviewers have two weeks to perform their review before ARO will send an automatic reminder. Reviewers may approve the protocol, ask questions or request changes to the protocol, or flag the protocol for Full Committee Review. Questions are asked by entering them directly on the protocol smart form. When an IACUC reviewer has completed a review, they will click the **Perform**

How do I Withdraw My Protocol from Review?

You may withdraw your protocol at any time before submission. If you would like to withdraw your protocol after submission, click the **Request Withdrawal** Activity and enter a reason in the pop up window. The assigned IACUC Coordinator will receive your request and withdraw the protocol, which will enter the **Withdrawn** State. Note that once a protocol has been withdrawn from review, it cannot reenter the review process.

Designated Member Review Activity. Once all reviewers have run this activity, the protocol will automatically enter the **Coordinator Evaluation State**.

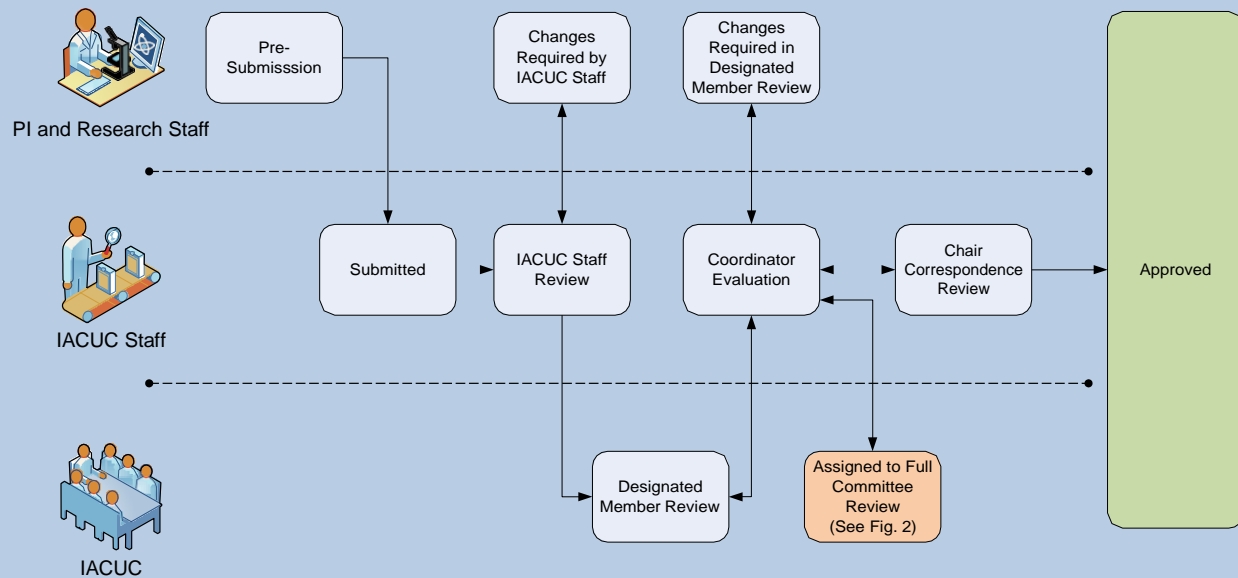


Fig. 1: IACUC Designated Member Review Process

While in the **Coordinator Evaluation State**, the IACUC Coordinator reviews each question/comment and reenters them onto the protocol smart form. This process de-identifies the reviewers who issued them, such that all of the questions will appear to the PI and the study team as if they were asked by the IACUC Coordinator. Any problems with the questions (inconsistencies or inaccuracies) are managed at this time, which may incur some delay. If all of the questions are appropriate (which is usually the case), the IACUC Coordinator clicks the **Send Questions to PI** Activity, which will cause the protocol to enter the **Changes Required in Designated Review State**.

The PI and the designated Protocol Administrator and editors will receive an email informing them that the reviewers have questions. Follow the link in the email to the protocol work space, and then follow the instructions detailed in the section **Responding to Questions** below. When all of the questions have been addressed and the protocol appropriately revised, click the **Submit Changes** Activity to return the protocol to the **Coordinator Evaluation State**.

The IACUC Coordinator will review your responses, ensuring that the PI and study team have answered all questions and revised the protocol smart form in accordance with the responses. If necessary, the IACUC Coordinator will request additional changes. If this is the case, the protocol will reenter the **Changes Required in Designated Review State**. You must then respond to the IACUC Coordinator's comments, make sure that the protocol smart form have been revised appropriately and click the **Submit Changes** Activity. This will cause the protocol to enter the **IACUC Staff Review State**.

If your responses are satisfactory and the protocol has been appropriately revised, the IACUC Coordinator will click the **Forward to Reviewers** Activity, which will send the protocol back to the **Designated Member Review** State.

The IACUC Reviewers have six days to issue their approval or additional questions. They will be reminded automatically several times after this period if late. This process continues until all reviewers have approved the protocol, at which time the IACUC Coordinator will set the approval period of the protocol and prepare the approval letter. When these two Activities have been completed, the IACUC Coordinator clicks the **Submit Letter to IACUC Chair** Activity, which causes the protocol to enter the **Chair Correspondence** State.

The IACUC Chair will then evaluate the review. If there are issues with the review, the IACUC Chair will click the **Request Changes** Activity, which causes the protocol to reenter the **Coordinator Evaluation** State. From that state, additional questions from the IACUC Coordinator may be raised or additional reviewers may be assigned, causing another round of questions. If the IACUC Chair is satisfied with the review, the Chair will click the **Send Correspondence to PI** Activity, which will cause the protocol to enter the **Approved** State. An email will be sent to the PI and Protocol Administrator informing them of the approval.

Responding to Questions

You will receive an email when the committee requires you to answer questions regarding your protocol submission. Follow the link and log in or log in to your IACUC Researcher Role's Inbox and click on the protocol title. You will be taken to the protocol's work space.

Click the Comments on Form tab. The reviewers' questions will be displayed. In the first question's entry, click the link next to the words "Jump To." This will open the protocol smart form to the first page that had questions.

You will see the first question at the top of the smart form. The question number should precede the question, so that you know which question to which the question refers. Click the link next to **Response Required!** A pop up box will appear containing the question, the user's name and a box in which to type your response. Enter your response. Please take care to fully respond to the question. If the question has multiple parts, you must respond to each part. Once you have finished entering your response, click **OK**. Your response will appear below the question. You can edit your response by clicking the **Research Team Response** link in your response's header.

Find the question or questions on the smart form referred to in the reviewer's question and make any required changes. Remember that if you agreed to change your protocol in your response to the

Can't I Just Answer the Questions under the Comments on Form Tab?

If the reviewers aren't requesting changes, yes, you can simply answer the questions under the Comments on Form tab without opening the protocol smart form. However, most questions will require you to revise your protocol.

question, you must make that change in your protocol. Only answering the question is not sufficient, because the questions are not a part of your protocol.

Repeat this process for all of the questions on the page.

To advance to the next page with questions, find the gold **Comment** bar near the top of the page and click the **Next** button. If the next button does not appear, then there are no further questions.

Click **Exit** to exit to the protocol work space. Click the **Submit Changes** Activity. If any questions have not been responded to, they will display. If all of the questions have been responded to, type in a short summary of your changes (1-2 sentences) and click the **OK** button.

Full Committee Review

At any time during review, your protocol may be flagged for Full Committee Review and placed on the agenda for the next IACUC meeting. These meetings are typically held on the third Monday of each month, but there are a few exceptions. See the schedule posted on the IACUC website for meeting dates. No final decision regarding protocol approval may be made until the protocol is discussed at the IACUC meeting. When the IACUC Coordinator places the protocol on the agenda for the next meeting, the protocol enters the **Assigned for Full Committee Review** State (see Fig. 2 below).

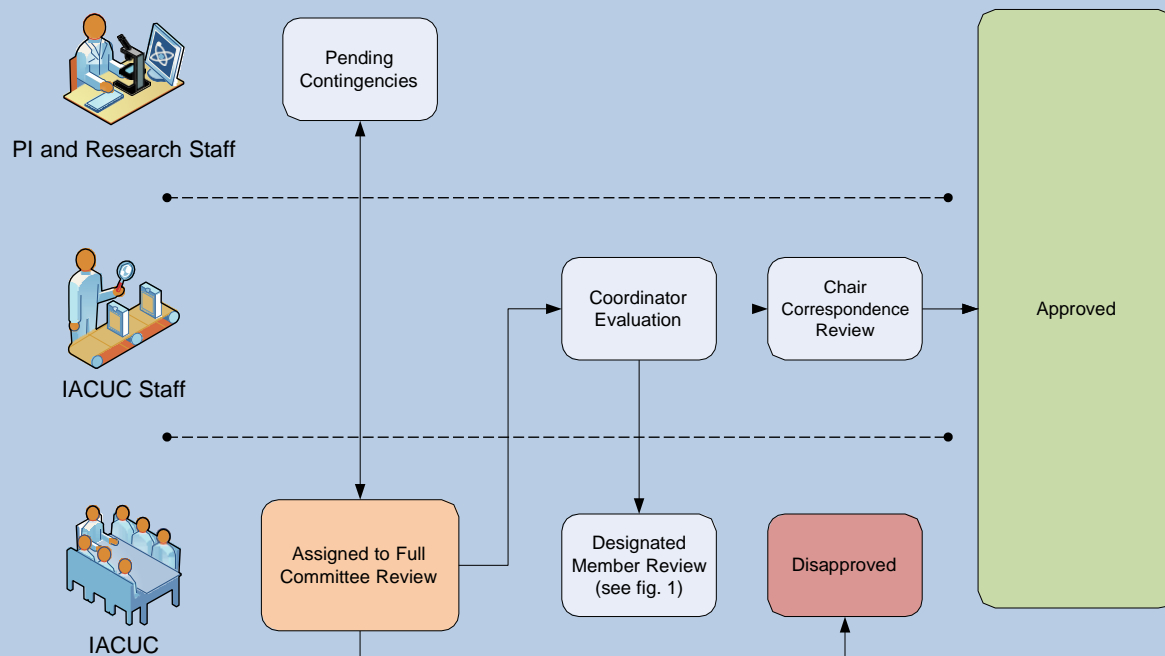


Fig. 2: Full Committee Review

Post-Approval Evaluation and States

All approved protocols with USDA Category E designations are reviewed at the next full IACUC meeting. If the committee decides that your written justification is not satisfactory, a request to make changes will be sent to you via email. Please respond to this request as soon as possible so that it can be presented at the following full IACUC meeting.

All approved protocols that requested an exemption to the *Guide for the Care and Use of Animals* are reviewed at the next full IACUC meeting. At the committee's discretion, you may be asked to make further modifications to your protocol. If so, a request to submit a modification request will be sent to you via email.

The IACUC may also reevaluate any approved protocol. This can be done if the committee votes to reopen the protocol for review. This measure is usually only taken in cases where the welfare of animals is deemed at risk or if, due to a mistake by the committee, the protocol is found to describe procedures that violate IACUC policy or federal regulations. If a protocol is found to be in serious violation of federal regulations or University policy, it may be **Suspended** temporarily until it is appropriately revised.

After the first and second year of a project, the PI or Protocol Administrator must submit an **Annual Renewal** Application to keep the protocol active. If the renewal application is not submitted or not yet approved by the expiration date, the protocol will enter the **Expiration Pending** State. If a renewal application is not *approved* thirty days after the expiration date, the protocol enters the **Expired** State and cannot be reactivated.

After three years, all active protocols enter the **Completed** state.

See Fig. 3 on the following page for a flowchart illustrating post-approval states.

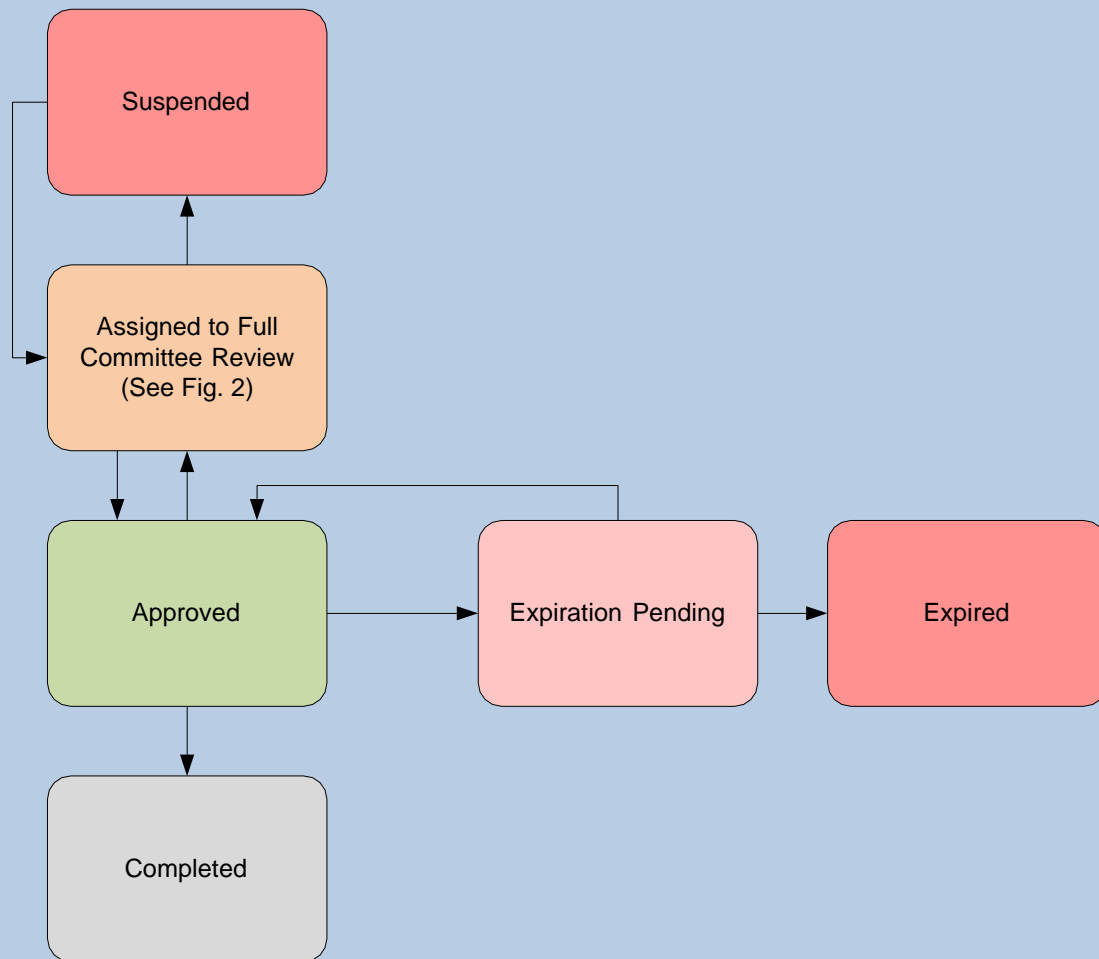


Figure 3: Post-Approval States

Modification Requests

All proposed changes to IACUC protocol, including personnel additions, *must* be requested via a modification request.

To begin a new modification request, follow these steps:

Click the **Create Modification** Activity from the protocol’s work space. This will launch the modification smart form. If you are adding personnel or making other changes to *only* the first page of the protocol form, you may click the **Create Mod Lite** Activity, which will launch an abbreviated modification form. (Note: the Mod Lite form cannot be used to change the principal investigator of a protocol.)

Select the categories that describe your request and complete the short modification request form. The questions are fairly self explanatory, but if you need assistance, please contact the IACUC office. After you have completed the short form, click **Finish** on the final page to exit to the modification work space.

Why am I Being Asked New Questions that Don't Relate to My Mod Request?

Occasionally, the IACUC will vote to add new questions to the protocol smart form. To ensure that these issues are addressed on as many protocols as possible, as soon as possible, ARO will require you answer any new applicable questions when you try to submit a modification request. If this occurs, simply respond to the question(s) and note in the justification that it is a new question.

After you click **Finish**, ARO will begin constructing a copy of your protocol for you to revise in accordance with your modification request. The submission of a revised protocol along with your request is a requirement. Modification requests not accompanied by a fully revised protocol will be returned for revisions *before being sent to reviewers*.

ARO may take several minutes to make a copy of your protocol. Click the refresh button on your browser to check if the copy has been made. When it is finished, you will see an **Edit**

Protocol Copy Form button on the left hand side of the screen.

Click the **Edit Protocol Copy Form** to launch the copy of your protocol. You will find instructions on how to properly revise your protocol for review. The instructions are reproduced below. Click **Continue** to go to the first page of the protocol.

First, identify the appropriate page(s) to be revised. If you are adding additional experimental procedures, make sure to check the Procedure Classification page to make sure that all of the appropriate procedures have been selected.

For each page to be revised, make the desired changes to each applicable question, then click the **Add** button in the gold bar at the top of the page. A pop up box will appear. Enter a justification for *each change* that you have made to the form. Your justification should describe the change and why it is being made. Be as specific as possible. This will assist reviewers in their evaluation and prevent unnecessary delays in processing.

Once you have made all of your changes and entered the required justifications, click the **Exit** link in the top blue bar. This will cause ARO to exit to the modification work space. If you want to make modifications to the modification form or protocol copy, you may do so now. When your modification is complete, click the **Submit Modification** Activity, which will move the request into the **Submitted** state.

Highlighting Changes to Uploaded Documents

While it is not necessary (or technically possible) for you to highlight changes made to the smart form during the review process, you must make sure to highlight changes to any documents that you upload, including uploaded research plans.

When highlighting changes in uploaded documents, use the **highlight** tool in Word. Please **do not** use the Track Changes feature.

The review process for modification requests is almost identical to that of new protocols, except that there are fewer reviewers, and questions may be asked on the modification request form *and* the protocol copy. Make sure that you check both to make sure that you have answered all questions. Pay close attention when adding new procedures and make sure that the protocol's Procedure Classification page accurately reflects the new procedures.

Administrative Modifications

Certain modification requests can be approved without being reviewed by a subcommittee of reviewers.

Personnel Addition requests are sent to EHS for review. When the personnel being added have completed all IACUC-mandated training and all EHS-required training and registration requirements, the request can be approved. A separate approval letter will not be issued upon approval.

Title changes, funding source changes, changes in animal vendor or source or requests for commercial rederivation of rodents are assigned to one administrative reviewer, then approved.

Modifications Flagged for Full Committee Review

Any modification can be flagged by the reviewers for full committee review at the next IACUC meeting.

Certain modification requests are automatically flagged for full committee review and can only be approved after the committee have met and discussed the request. Modifications requesting over 25% of the original number of animals approved, per species (and every subsequent modification, once this threshold has been passed) must be approved by the full committee. Modifications requesting to house animals outside a university-run animal facility for over twelve hours must also be approved by the full committee before approval.

Common Questions about Modifications

Can I Submit Modification and Annual Renewals at the Same Time?

No. ARO can only handle one item (modification or renewal) at a time for any protocol. Please keep this mind when submitting items for review. When in doubt, submit your annual renewal application first, as these can usually be approved faster.

Can I Submit Multiple Modifications at a Time?

No. ARO can only manage one set of proposed changes at a time.

What if I Need a Modification Request Approved while Another Mod or Renewal is Under Review?

Contact the IACUC Coordinator handling the item under review. Depending on how far along it is in the review process, your best option may be to:

- Wait until the item under review has been approved.
- Withdraw the item under review so that the new item may be processed.

Keep in mind that it will never be possible to process two or more modifications for the same protocol at the same time.

Annual Renewals

All protocols must be renewed after the first and second years with an **Annual Renewal** application. The annual expiration date for all protocols is the last day of the month of original approval. For example, if your protocol was originally approved on April 13, 2011, your annual renewal must be *approved* by April 30, 2012. If your protocol is not approved by the expiration date, your protocol will expire and any animals associated with your protocol that are currently in-house will be undergo confiscation procedures by the DLAR.

The PI and Protocol Administrator will receive monthly reminders to submit an Annual Renewal beginning ninety days before the annual expiration date.

Annual Renewals may be submitted as early as ninety days prior to expiration. The IACUC office will not approve annual renewals later than one month beyond the expiration date. For example, if your protocol's expiration date is April 30, the IACUC office will not approve your renewal after May 30, *regardless of when it was submitted*. After this date, a new protocol *must* be submitted for review. If you have submitted your annual renewal application late, make sure that you satisfy all IACUC and EHS mandated requirements immediately.

To submit your Annual Renewal application, go to the protocol's workspace by either logging in normally and locating the protocol under the Approved Protocols tab while in your General Access Role, or simply following the link in the email reminder that is sent. Click the **Create Annual Renewal** Activity and complete the renewal smart form. After you have completed the renewal smart form ARO will exit to the renewal's work space. Click the **Submit Annual Renewal** Activity. A pop up box will appear. Click the box certifying that you agree to the statements on the form, and then click **OK**.

All personnel listed on the protocol must be compliant with all IACUC- and EHS-mandated requirements before the renewal can be approved. An IACUC Coordinator will return the renewal application to the PI if any personnal is currently out of compliance with these requirements.

How Do I Delete Personnel During the Annual Renewal Process?

If personnel that no longer work on the protocol must be removed, enter their names in Question 5.0 on the Project Update page of the Annual Renewal smart form.

Note that you *cannot* add personnel using the Annual Renewal smart form. If you must add new personnel, submit a modification request after the renewal has been approved.

What If I Have Reported Unanticipated Adverse Events?

Any Annual Renewal application that reports unanticipated adverse events must be sent out for designated member review. As this process takes longer than the normal annual renewal process, make sure to submit your application early to make sure that your renewal is approved by the expiration date.

If the renewal is returned to the PI, the requirements will be noted on the renewal smart form just as questions are added during the review process for new protocols. First, ensure that all personnel have completed the noted requirements, respond to the IACUC Coordinator's message on the renewal smart form, then exit the smart form. From the Annual Renewal's work space, click the **Submit Changes** Activity.

3-Year Renewals

All protocols must be resubmitted for review every three years. The expiration date for all protocols is the last day of the month of expiration. For example, a protocol that was originally approved on April 13, 2011, will expire on April 30, 2014.

The PI and Protocol Administrator will receive reminders to submit a 3-Year Renewal every month beginning ninety days before final expiration.

ARO makes it easy to resubmit your protocol. Go to the protocol's workspace by either logging in normally and locating the protocol under the Approved Protocol's tab while in your General Access Role or simply following the link in the email reminder that is sent. Click the **Create 3rd Year Renewal or Major Modification** Activity. ARO will make and open a complete copy of your protocol.

Examine each page of the protocol smart form carefully to make sure that any desired changes have been made. Then exit the protocol and click the **Submit 3rd Year Renewal** Activity. The review process is then exactly the same as a new protocol.

When your protocol has been approved, it will receive a new IACUC approval number. Make sure to submit an animal transfer form with the DLAR to transfer any in-house animals to the new protocol.

Protocol Walkthrough

You will find on the following pages a walkthrough of all smart form pages of the IACUC protocol form. For each page, all of the questions are displayed, including those that may not be initially visible to you, but will be revealed when the appropriate response is given to one of the questions. Some pages have a sidebar, on which you will find helpful explanations of the questions and a description of how some answers will require the completion of additional pages.

When a question asks you to open up a popup box in order to answer a list of related questions, those questions will be indented underneath the applicable question.

Protocol Identification

- 1.0 Main Title
- 2.0 Additional Titles
- 3.0 Principal Investigator
- 4.0 Protocol Sponsor
- 5.0 Protocol Administrator
- 6.0 Other Protocol Editors
- 7.0 General Staff
- 8.0 Surgical Staff
- 9.0 Observers
- 10.0 If any personnel listed above are affiliated with an institution outside the University of Pittsburgh, please indicate the person's name and the University or Institute.
- 11.0 If any aspect of this protocol will involve individuals who are not listed above, you must describe in detail what training will be provided prior to any animal experimentation. Your description must include the topics to be covered,

Guidance

- 1.0 – The Main Title is the title that is sortable and filterable. Enter only one title.
- 2.0 – Please separate each additional title with a line break to ensure that each appears on your approval letter legibly. These titles are not sortable or filterable, and will be displayed on the approval letter only.
- 3.0 – Enter the name of the PI. This must be a full-time faculty member if no Sponsor (4.0) is listed. Receives email reminders. Must submit initial protocol application. Must be listed in either General or Surgical Staff as well.
- 4.0 – A Sponsor is necessary if the PI is not a full-time faculty member. The Sponsor takes responsibility for the conduct of the research and the welfare of the animals.
- 5.0 – Assign one individual to receive email reminders and submit materials in place of PI.
- 6.0 – Editors can work on protocol.
- 7.0 & 8.0 – All project staff must be listed in at least one of these categories.
- 9.0 – Non-essential staff who will observe, but not handle animals.
- 10.0 – List names of any personnel not associated with Pitt or UPMC.
- 11.0 – This question is required for projects that hold training or education sessions, the participation of which is unknown until shortly before the session.
- 12.0 – If yes, ARO cannot process your submission.
- 13.0 – Naturally, this information should be kept up to date.
- 14.0 – Persons named here should be named in General or Surgical Staff.
- 15.0 – Make sure that the number given is not a lab location, unless someone will be available in the lab 24 hours/day.
- 15.0 – If marks “Yes,” you will be directed to the Protocol Continuations page.

who will perform the training, the expected length of time for the training session, a description of the individuals attending and how you will document the training.

- 12.0 Does the funding source/sponsor of this study require compliance with GLP (Good Laboratory Practice) Standards?
- 13.0 PI Contact Information (Mailing Address, Phone Number):
- 14.0 Provide the name of one or more persons (other than the PI) that may be contacted in the event of an emergency regarding animal health..
- 15.0 Provide the 24 hour phone or pager number for the PI and person(s) named above that may be contacted in the event of an emergency.

“Why can’t I find my staff member in ARO?”

All staff listed on ARO protocols must complete the [Research Integrity](#) module and complete the [Use of Laboratory Animals in Research and Teaching](#) module within the last three years. This ensures that all members of your team have completed the basic training required of all animal users at the University of Pittsburgh.

Note that ARO receives information from HSCconnect nightly and uploads the information the following evening. As such, it could take up to 48 hours for your account to be activated.

Protocol Continuations

(Answer these questions only when initially completing the protocol smart form. Do not change your response to these questions when submitting a modification request -- they are used to track information about your previous protocol).

- 1.0 Number of animals used on the prior protocol.
- 1.1 Are live animals currently in-house under the prior protocol?
- 2.0 Will you transfer the remaining animals to this protocol?
- 2.1 How many of each species will be transferred?

Guidance

1.0 – If you do not know the exact figure, please provide an estimate.

1.1 – Mark yes only if live animals are currently covered under your current protocol.

2.0 – Mark yes only if you will transfer animals from the old protocol to the new one.

7.0 – Make sure to address each species.

Funding Information

- 1.0 Select the funding source which best describes the sponsor of this research (check all that apply).
- 1.1 Because either 'Internal' or 'Industry or private foundation...' was selected, you must attach a letter from your departmental chairperson, center director or dean acknowledging or addressing the financial responsibility for the study and attesting to its scientific merit.
- 1.2 Identify the department(s) or division(s) funding the project.
- 1.3 Indicate the federal agencies or private foundations that award grants based on peer-reviewed proposals.
 - 1.0 Source of Grant.
 - 1.1 If Other was selected, provide source of grant details.
 - 2.0 Grant Title.
 - 3.0 Grant Number (if known).
 - 4.0 Project Period Begin.
 - 5.0 Project Period End.
- 1.4 Indicate industry or private foundation support NOT based on peer-reviewed proposals.
 - 1.0 Source of Support.
 - 2.0 If Other was selected, provide source of support details.
 - 3.0 Grant Title.
 - 4.0 Project Period Begin.
 - 5.0 Project Period End.
- 2.0 Are all research funds associated with this protocol administered by the University of Pittsburgh?

Branching & Guidance

1.0 - 1.2 – Internal and other support not based on peer-reviewed proposals must be accompanied by a letter, on departmental letterhead, from the PI's departmental supervisor. In the case of internal funding, the letter should be written by the chair of the department supporting the project.

1.3 & 1.4 – Make sure that you provide as much information as possible, including the grant number issued by the awarding agency. If it is not provided, it will not be displayed on the approval letter.

2.0 & 2.1 – Enter “No” only if collaborating with another institution that provides funds directly to you.

- 2.1 Indicate the outside (non-Pitt) institution that will administer the funds associated with this protocol.
- 2.2 Enter the name, telephone number and email address of a contact person at the Administering Institution.

Who Must Write My Scientific Merit Letter?

For projects with internal funding, merit letter should be written by the Chair of the funding department (or the Chair's supervisor, if the Chair is listed on the protocol).

For externally funded projects for which a merit letter is required, the Chair of the PI's primary department is ideal, but letters from Chairs or Directors of Departments, Centers, etc... concerned with the specific research in the protocol are also appropriate.

Declared Conflicts of Interest

If you declare a conflict of interest on your smart form, the Conflict of Interest Office (COI) will be notified automatically when your protocol is submitted for review. Protocols with a declared conflict of interest cannot be approved until the COI office issues its approval.

Conflict of Interest Declaration

1.0 Is this study funded in part or whole by a PHS Agency?

2.0 Does any investigator involved in this study (select all that apply):

2.1 If any of the above boxes were selected, please provide the name of the investigator(s) and describe the nature of the Significant Financial Interest(s):

Animal Species and Study Summary

Animal Species, Strain and Numbers

1.0 Animal Species, Strain and Numbers.

1.0 Species.

2.0 Strains.

3.0 Weights.

4.0 Ages.

5.0 Sexes.

6.0 Total Number of Animals.

2.0 Have any of the animals to be used on this protocol been previously used on a different protocol?

2.1 Since "Yes" was selected, provide the protocol number(s) and a brief description of the procedures that these animals have previously undergone (survival surgeries, infections, unrelieved pain or distress, etc...).

Dogs and Nonhuman Primates

If your research involves dogs or nonhuman primates, you will be directed to the pages **Special Husbandry – Dogs** or **Special Husbandry – Nonhuman Primates** later in the application.

“I use a *lot* of strains! Do I Have to List Every Single One?”

Only list background strains. If using multiple transgenic strains under the same background, enter, *"Multiple transgenic strains under X background."*

Study Summary and Animal Use Rationale

- 1.0 Briefly summarize the aim(s) of the study and state why the study is important to human or animal health, the advancement of knowledge or the good of society.
- 2.0 Explain the rationale for animal use, including why non-animal models cannot be used.
- 3.0 Justify the appropriateness of each species that will be used.
- 4.0 Justify why phylogenetically lower or other species will not be used.

Housing and Use Sites

- 1.0 Will animals be housed in a University-managed animal facility?
- 2.0 Will animals be housed in, or transferred from the holding room for use to, another location outside of the University-managed animal facility?
- 3.0 Will you transport hazardous tissues to a laboratory outside the University-managed animal facility?
- 4.0 Will you contract with another institution or commercial business for the production of custom antibodies?
- 5.0 Will any animals associated with this project be housed at a commercial business or another institution for any reason (including rederivation of genetically modified animals)?
- 6.0 Will any aspect of this study (housing or use) be performed in the Regional Biocontainment Laboratory (RBL)?
 - 6.1 Has a pre-project form been submitted to the RBL?
 - 6.2 Describe the pathogens that will be used in the RBL.

Branching & Guidance

1.0 – Answering “Yes” will require completion of the Housing Facilities page.

2.0 – Answering “Yes” will require completion of the Outside Housing and Use Sites Specification page. If you manipulate animals only within a DLAR procedure room or surgery site, you should answer “No” to this question.

3.0 -- Answering “Yes” will require completion of the Hazardous Tissue Use Sites page.

4.0 -- Answering “Yes” will require completion of the Custom Antibody Production at Another Institution page.

5.0 -- Answering “Yes” will require completion of the Housing or Experimentation at a Company or Another Institution page.

6.0 -- Answering “Yes” requires completion of 6.1 and 6.2.

Housing Facilities

- 1.0 Enter the name of the HOUSING FACILITIES (DLAR or CLC) where animals will be housed.

Do not enter outside housing and use locations (housing in a laboratory, etc...) on this page. These locations will be addressed on a subsequent page.

- 1.0 Housing Location.
- 1.1 If Location is Other, enter the location here:
- 2.0 Species.
- 3.0 Housing Duration.
- 4.0 Maximum Number of Animals Housed at One Time:
- 5.0 ID Method in Addition to Cage Card (ear clip, punch method, etc.).
- 6.0 Will surgery be performed in a procedure room or surgical suite located within this facility?
- 6.1 If the surgery involves a USDA-regulated species, indicate where (within the facility) the surgery will be performed.
- 2.0 Will you transport animals from one housing facility to another for any reason?
- 2.1 Explain why animals must be taken from one housing site to another.
- 2.2 Provide the transport routes (both ways) used to transport the animals.
- 2.3 Provide a description of the animal containment and transport mechanisms.

My Housing Site isn't on the List! Should I Select "Other?"

Are you sure? Some buildings are known by more than one name. All currently active housing facilities are on the list. If you need assistance, please contact the IACUC Office.

What if I Don't Know My Housing Facility Yet?

This would be a good time to use "Other," and enter To Be Decided in 1.1. Keep in mind, however, that you must submit a modification request to update the housing location when your animals are housed.

My Animals are Being Housed in More Than One Location.

Simply click the **Add** button and complete a new record for the additional housing site.

Outside Housing and Use Sites Specification

- 1.0 Enter the location of all OUTSIDE HOUSING/USE SITES to which animals will be taken during the course of this study.
- 1.0 Building.
- 1.1 If building is Other, enter building here.
- 2.0 Species.
- 3.0 Room Number.
- 4.0 Are animals held in this location for greater than 12 hours?
- 5.0 Will these animals be returned to the housing facility?
- 6.0 Explain why animals must be taken to this location and why this work cannot be completed in DLAR-managed space (or otherwise approved housing facility).
- 7.0 Provide the transportation route from the housing facility to the outside use site.
- 8.0 Provide a description of the animal containment and transport mechanisms.
- 9.0 Will surgery be performed in this location?

Hazardous Tissue Use Sites

- 1.0 Indicate the building and room number of all laboratory sites where hazardous tissues will be taken.
- 2.0 Describe the tissue containment and transport mechanisms.

The Building to Which I Want to Take My Animals is Not Listed. What do I do?

Please take a minute to double-check. Some buildings are known by different names. If you are sure that your building is not on the list, select "Other" and enter the name of the building (not an abbreviation) in 1.1.

I Want to Take My Animals to More Than One Outside Housing/Use Site.

Simply click the **Add** button and complete a new record for each additional use site.

Does Moving My Animals To Another Housing Facility for Surgery Count as an Outside Use Site?

No. You should add the new site on the Housing Facilities page and answer "Yes" to 2.0 on that page.

Custom Antibody Production at another Institution

- 1.0 Institution or Company where custom antibody production will occur:
 - 1.0 Institution or Company where custom antibody production will occur.
 - 2.0 Species in which antibodies are produced.
 - 3.0 Duration of Housing.
 - 4.0 Housing Facility Name.
 - 5.0 Housing Facility Location.
 - 6.0 PHS/NIH Assurance Number.
 - 7.0 USDA Registration Number.
 - 8.0 AAALAC Accreditation Status.
 - 9.0 Contact Person at Facility include Email address and phone number.
 - 10.0 Attending Veterinarian at housing facility.
 - 11.0 License Number of Attending Veterinarian.

Housing or Experimentation at a Company or another Institution

- 1.0 Other Institution or Company Details:
 - 1.0 Other Institution or Company:
 - 2.0 Species.
 - 3.0 Duration of Housing.
 - 4.0 Housing Facility Name.
 - 5.0 Housing Facility Location.
 - 6.0 PHS/NIH Assurance Number.
 - 7.0 USDA Registration Number.
 - 8.0 AAALAC Accreditation Status.
 - 9.0 Contact Person at Facility include Email address and phone number.
 - 10.0 Attending Veterinarian at housing facility.
 - 11.0 License Number of Attending Veterinarian.
 - 12.0 Explain the need to have animals housed outside the University.
 - 13.0 Will this company provide rodent rederivation services for this project?
 - 14.0 Attach the IACUC Protocol and IACUC approval letter from the Outside Institution or Company. For University-paid work performed at a company, a statement of work may be acceptable in place of the IACUC protocol

Research at Another Institution – Additional Requirements

If your research involves work performed at another institution or you are contracting with a company to perform services involving live animals for the sake of your research (such as custom animal production), you must provide the IACUC Office with the performing institution's valid and approved protocol and approval letter. Such institutions must have a PHS Assurance and be Accredited by AAALAC International. For more information, see [Accepting IACUC Reviews from Other Institutions \(SOP\)](#).

Housing – Rodent Caging Requirements

- 1.0 Indicate rodent caging requirements.
- 1.1 Enter your justification for housing rats in wire-bottom caging below.
- 1.2 The option 'Other Caging' was selected, describe your caging requirements.

Housing - Special Caging/Husbandry Requirements

- 1.0 Indicate required caging or housing procedures.
- 1.1 Describe the special caging requirements required by your study, making sure to specify the size of the required caging.
- 1.2 Why is special caging necessary?
- 1.3 What caging modifications are required by your study?
- 1.4 Why are these caging modifications necessary?
- 1.5 What special husbandry requirements are necessary as part of the proposed animal use?
- 1.6 Why are these husbandry requirements necessary?
- 1.7 What special diet requirements are necessary as part of the proposed animal use?
- 1.8 Why are these special diet requirements necessary?
- 1.9 What caging or special husbandry requirements that do not deviate from the Guide or the AWA are necessary as part of the proposed animal use?
- 1.10 Why are these caging or special husbandry requirements that do not deviate from The Guide or the AWA necessary?

What Are Examples of Special Husbandry Requirements?

Special husbandry may include: individual housing, more frequent bedding changes, special diets, water or feed restrictions, special feed or water treatments, etc...

Useful Links:

[The Guide for the Care and Use of Laboratory Animals](#)

[Animal Welfare Act](#)

Housing - Special Caging/Husbandry Requirements

- 1.0 Indicate required caging or housing procedures.
- 1.1 Describe the special caging requirements required by your study, making sure to specify the size of the required caging.
- 1.2 Why is special caging necessary?
- 1.3 What caging modifications are required by your study?
- 1.4 Why are these caging modifications necessary?
- 1.5 What special husbandry requirements are necessary as part of the proposed animal use?
- 1.6 Why are these husbandry requirements necessary?

Special Husbandry – Dogs

- 1.0 Does your study require exemption from the University's plan for exercise for dogs?
- 1.1 Describe the terms of exemption being requested (duration and frequency of exemptions, if the requested exemption is for a select period of time) and offer scientific justification below.

Special Husbandry - Nonhuman Primates

- 1.0 Does your study require exemption from one or more of the five elements of the University's enrichment plan for nonhuman primates?
- 1.1 Describe the terms of the dispensation being requested (duration and frequency of dispensations, if the requested dispensation is for a select period of time) and justify for each element of the plan from which you require a dispensation.
- 2.0 Please supply an enhanced enrichment plan that will be employed for any single housed nonhuman primate under this protocol. Your response must include a description of the enrichment that will be provided, specific frequencies, the name of the person responsible for providing the enrichment, and an example of the documentation that you will use. As exceptions are usually unanticipated and unavoidable, every investigator housing nonhuman primates must supply this plan to be employed as needed.
- 3.0 Please indicate in what situations the NHPs on this study may be socially housed. Each grouping is unique, and will be discussed with the enrichment specialist prior to initiation.
- 3.1 Justification.

Special Husbandry - Additional Information

- 1.0 Do any animals in your study (excepting dogs or nonhuman primates) require exemption from the animal program's routine species-specific environmental cage enrichment plan?
 - 1.1 Justify exemption below and indicate if you plan to provide alternatives to the plan.
- 2.0 Are animals on this protocol immunocompromised due to the nature of their phenotype or as a result of experimental manipulation?
 - 2.1 If you will not adhere to the standard Immunocompromised Rodent Husbandry policy, describe and scientifically justify your alternative husbandry plans. (Do not answer if not using rodents).
- 3.0 Will animals be exposed to biological or chemical hazards that necessitate special caging or other containment measures?
 - 3.1 Describe the hazard and the safety precautions that you will take.

Type of Protocol

1.0 Select the option that best describes your protocol.

- Behavioral Investigations
- Biomedical Investigation
- Carcinogenesis/Cancer Prevention or Treatment
- Cardiology Research
- Central Neurological Mechanisms Research
- Developmental Biology Research
- Endocrinology Investigations
- Gene Therapy
- Immunology Research
- Infectious Disease Research
- Physiological Investigations
- Pulmonary Inhalation, Toxins Research
- Reproductive Physiology Research
- Resuscitation Research (Anesthesiology, Critical Care Medicine, Shock, Sepsis & Trauma)
- Surgical Modeling, Implants, Biomaterials Testing
- Teaching
- Toxicity Testing Research
- Transplantation Research
- Breeding Only (With Drug Use)
- Holding Only

Holding Protocols

Holding protocols are intended for use by new faculty needing to move their animals into Pitt facilities from another institution before initiating a research protocol. Established University of Pittsburgh faculty should not submit a holding protocol.

When asked to complete the Experimental Design portion of the protocol, describe the circumstances necessitating a holding protocol and for how long animals will be held before transfer to an active research protocol.

Experimental Groups

- 1.0 Provide the number of experimental and control groups and the number of animals per group. If the experimental design is complex or requires the use of a table or flow chart, attach a document containing this information.
- 1.1 If necessary upload related charts, tables or other documentation.
- 2.0 How was the sample size determined? Check all that apply.
- 3.0 Describe the power analysis used and cite your method of statistical analysis. If a power analysis is not possible, thoroughly justify the sample size required for the study, including appropriate literature citations.

Procedure Classification

1.0 Indicate the procedures you will employ in this study from the list below. Check all that apply.

- Surgery - Please check 'Drug Administration' below to account for drugs used during surgery.
- Drug Administration (for pain management and therapeutic treatment of animals)
- Chemical Agent Use (including drugs used as test agents)
- Biological Agent Use
- Cells, Tumor Line, Antibody, Serum or Body Fluid Use
- Radioactive Isotope Use
- X-Ray Equipment, CT Scanners, Irradiators, Accelerators or External Beam Radiation Use
- Breeding
- rDNA or Genetic Engineering
- Human Stem Cell Use
- Physical Restraint
- Stress Paradigms
- Blood Sampling
- Food Regulation
- Water Regulation
- Photography
- Only live tissues or cell use (no live animals)

Important!

It is very important that you select all of the applicable procedures from the list. ARO depends on the user for this information so that it can present the necessary follow up pages. If all of the procedures applicable to the project are *not* selected, the protocol must be returned to you for revision before review.

Surgery

- 1.0 Please provide details regarding the surgical manipulations in this protocol for each species.
 - 1.0 Specify related species.
 - 1.1 Will survival surgery be performed on any animals on this protocol?
 - 2.0 Will multiple survival surgeries be performed on any single animal during separate anesthetic events?
 - 2.1 If 2.0 is 'Yes', will two or more survival surgeries be performed under separate anesthetic events on the same animal, involve major procedures?
 - 2.2 If 2.1 is 'Yes', explain why the procedures cannot be performed during the same anesthetic event. If you answered yes to the above question, federal guidelines require substantial scientific justification.
 - 3.0 Will non-survival surgery be performed?
- 1.1 List all major and minor surgery types performed on animals.
- 2.0 Describe the methods you will use to assess and alleviate pain and distress in animals following surgery. Include
 - 2.1 Describe your monitoring and recovery criteria for all survival surgeries.
- 3.0 Have the individuals performing surgery previously performed the procedures on the species requested?
- 4.0 Below is a list of the Housing Location(s) and/or Outside Use Site(s) where surgery will be performed.

Drug Administration

1.0 Indicate the type(s) of drugs you will administer to animals during the course of this study. Only list those drugs used for pain management/paralysis, therapy and euthanasia here.

Drugs used as test agents should be included in the Chemical Agents section.

2.0 Please press "Add" and complete the chart below for each drug used in this protocol. (Please note that you will be asked to provide further information for each drug on subsequent pages.)

1.0 Drug.

1.1 If 'Other' was selected above, enter name of drug.

1.2 CAS Registry Number, if known.

1.3 Is this drug a controlled substance?

2.0 Will a non-pharmaceutical version of this drug be used?

2.1 If the answer to 2.0 is "Yes," explain why you must use a non-pharmaceutical version of the drug (e.g., a pharmaceutical version is not available). Also indicate the source, proposed sterilization technique, sterile packaging, labeling and expiration information along with proposed methods to determine efficacy.

3.0 Storage Building.

4.0 Storage Room

5.0 Use Building

6.0 Use Room

Drug List

1.0 of the pop-up screen contains a drop-down list of many commonly-used drugs. Please make sure that the drug you are proposing is not listed, or perhaps listed under another name, before selecting "Other," which is intended to be used only when a drug is not on the list. Doing so will help the IACUC and EHS to maintain accurate records and prevent unneeded delays in review.

When Did CO₂ Become A Drug?

Obviously carbon dioxide is not a drug. However, for the purpose of collecting information about euthanasia agents, CO₂ is considered a drug.

To repeat, if you are using CO₂ to euthanize animals, create a record for it in 2.0. You will then be directed to the euthanasia drug page.

Should I enter drugs being used as test agents on this page?

No. Only enter those drugs used therapeutically, for pain management or for euthanasia. Drugs being tested should be entered on the Chemical Agent page (make sure Chemical Agent Use is checked on the Procedure Classification page).

Anesthetics, Analgesics, Tranquilizers and Paralytics

- 1.0 Please press "Add" and complete the chart below for each drug used as an anesthetic, analgesic, tranquilizer or paralytic. (Do not include drugs used for therapeutic purposes).
 - 1.0 Select Drug.
 - 2.0 Specify the species to which you will administer this drug.
 - 3.0 Dose (in mg/kg).
 - 3.1 Maximum volume or volume range.
 - 4.0 Route of administration.
 - 5.0 Frequency of administration (a range is acceptable) (Note: "As needed" is not an acceptable response).
 - 6.0 Duration of treatment (a range is acceptable).
 - 7.0 Effect of drug and method of monitoring efficacy.

Multiple Dose Sizes or Routes for a Drug?

If your protocol requires multiple specific dosages or multiple routes of administration for a single drug or agent, create a new entry for each dosage or route.

Paralytic Drugs - Additional Information

- 1.0 Identify the proposed paralytic drug and explain why a paralytic drug is necessary for this study.
- 2.0 Demonstrate that the proposed anesthetic regimen is adequate for proper anesthesia without the paralytic agent. Use literature citations that refer to the same regimen, the PI's own documented experience with the regimen or previous documented performance of a "sham" procedure utilizing the regimen.
- 3.0 Provide a plan to titrate the amount of anesthetic to establish a verifiably adequate plane of anesthesia in each animal prior to inducing paralysis.
- 4.0 Describe how paralyzed animals will be monitored (for example, via EEG, EKG, blood pressure, etc...).

Therapeutic Drugs

- 1.0 Please press "Add" and complete the chart below for each therapeutic drug used.
 - 1.0 Select Drug.
 - 2.0 Specify the species to which you will administer this drug.
 - 3.0 Dose (in mg/kg).
 - 3.1 Maximum volume of volume range.
 - 4.0 Route of administration.
 - 5.0 Frequency of administration (a range is acceptable) (Note: "As needed" is not an acceptable response):
 - 6.0 Duration of treatment (a range is acceptable).
 - 7.0 Effect of drug and method of monitoring efficacy.
- 2.0 Describe any adverse effects associated with the administration of these drugs and a detailed plan for monitoring and alleviating these effects, if applicable.

Euthanasia Drugs

- 1.0 Please press "Add" and complete the chart below for each drug used for euthanasia purposes.
 - 1.0 Select Drug
 - 2.0 Specify species to be euthanized with this drug.
 - 3.0 Dose.
 - 4.0 Route of Administration.

Chemical Agents

1.0 Please press "Add" and specify the chemical agent(s) associated with this study. (Please note that you will be asked to provide further information for each agent on the next page.)

Do not include drugs used for therapeutic purposes in this section.

- 1.0 Chemical Agent.
- 2.0 If 'Other' was selected above, enter the name of the chemical.
- 3.0 Storage Building.
- 4.0 Storage Room.
- 5.0 Use Building.
- 6.0 Use Room.

Chemical Agent List

1.0 of the pop-up screen contains a drop-down list of many commonly-used chemical agents. Please make sure that the agent you are proposing is not listed, or perhaps listed under another name, before selecting "Other," which is intended to be used only when an agent is not on the list. Doing so will help the IACUC and EHS to maintain accurate records and prevent unneeded delays in review.

Chemical Agents Details

1.0 Please press "Add" and complete the chart below for each chemical agent used.

- 1.0 Select appropriate chemical agent.
- 2.0 Select related species.
- 3.0 Dose.
 - 3.1 Maximum volume or volume range.
- 4.0 Route.
- 5.0 Frequency.
- 6.0 Duration.
- 7.0 Effect.

2.0 Describe any adverse effects associated with the administration of these chemicals and a detailed plan for monitoring and alleviating these effects, if applicable.

Multiple Dose Sizes or Routes for a Test Agent?

If your protocol requires multiple specific dosages or multiple routes of administration for a single drug or agent, create a new entry for each dosage or route.

Biological Agents

- 1.0 Please press "Add" and specify each biological agent used in this protocol. (Please note that you will be asked to provide further information for each agent on the next page.)
 - 1.0 Biological Agent.
 - 2.0 Source.
 - 3.0 Storage Building.
 - 4.0 Storage Room.
 - 5.0 Use Building.
 - 6.0 Use Room.
 - 7.0 Transport procedures for animals infected with BSL-2 or higher agents.
 - 8.0 Storage and transportation procedures for tissue or material with BSL-2 or higher agents:
 - 9.0 Risk Mitigation.

Biological Agents Details

- 1.0 Please press "Add" and complete the chart below for each biological agent used.
 - 1.0 Agent.
 - 2.0 Species.
 - 3.0 Dose.
 - 4.0 Route.
 - 5.0 Frequency.
 - 6.0 Duration.
 - 7.0 Effect.
- 2.0 Describe any adverse effects associated with the administration of these biological agents and a detailed plan for monitoring and alleviating these effects, if applicable.

Cells, Tumors, Antibodies, Serum and Bodily Fluids

1.0 Please press "Add" and specify each type of cells, tumors, antibodies, serum or bodily fluids used in this protocol. (Please note that you will be asked to provide further information for each item on the next page.)

1.0 Cells, Tumor, Antibody, Serum or Bodily Fluid Unique Identifier.

2.0 Originating Source.

3.0 Storage Building.

4.0 Storage Room.

5.0 Use Building.

6.0 Use Room.

Cells, Tumors, Antibodies, Serum and Bodily Fluids Exposure Details

1.0 Please press "Add" and complete the chart below for each type of cells, tumors, antibodies, serum or bodily fluids used. (Do not include drugs used for therapeutic purposes).

1.0 Agent.

2.0 Recipient Species.

3.0 Biological Category.

4.0 Tissue Source of Biological Material.

5.0 Species of Origin.

6.0 Dose.

7.0 Route of Administration.

8.0 Effect.

9.0 MAP, PCR or RAP Tested?

2.0 If any of the materials listed above have passed through live rodents or been exposed to any products of rodent origin, describe the precise circumstances.

3.0 Describe how these biological agents are stored or propagated in your laboratory.

Radiation Exposure Details

1.0 Please press "Add" and complete the chart below for each radioactive substance used in this protocol.

1.0 Isotope.

2.0 Species.

3.0 Activity.

2.0 Attach Use of Radioactivity in Animal Studies form.

Irradiating Equipment Exposure Details

1.0 Enter all irradiating equipment used on live animals below.

1.0 Equipment.

2.0 Species.

3.0 Location of Use.

4.0 Dose (not applicable to imaging studies/equipment).

5.0 Who will operate this equipment?

Irradiation Guidance

If any staff members who operate this equipment may need to touch or handle the animals, they should be listed as general personnel on the first page of this protocol application and must complete all IACUC-mandated training.

If animals will be moved to a location other than a University-managed housing facility, you must include this location on the Housing and Use Site Specification page.

Breeding Section 1

- 1.0 Indicate those individuals (other than the PI) who will be involved in breeding colony maintenance below.
 - 1.0 Species.
 - 2.0 Identify the individuals involved in breeding colony maintenance.
 - 3.0 Describe the training and experience of these individuals as it relates to colony maintenance and the breeding of animals.
 - 4.0 Provide a description of the lines to be bred.
 - 5.0 Provide a justification for establishing and maintaining a breeding colony.
- 2.0 Provide details about breeding colony housing location and any special requirements (special diet, special housing, immunocompromised strains, etc...)
 - 1.0 Species.
 - 2.0 Where will the breeding colony be housed?
 - 3.0 Describe any special housing requirements needed for colony maintenance below.
- 3.0 Provide details about your breeding scheme.
 - 1.0 Species.
 - 2.0 Breeding Scheme.
 - 3.0 If you selected 'Other Breeding', describe your breeding scheme.
 - 4.0 If you selected 'Harem Breeding', what techniques will you use to ensure that multiple litters are not present within one cage?
 - 5.0 Weaning Scheme.
 - 6.0 If Other was selected, describe.
 - 7.0 Describe any health concerns (immunocompromised, behavioral, anatomical and/or physiological) associated with the development of the phenotypes for strains described and how the health of these animals will be managed.

Breeding Section 2

- 1.0 Provide genotyping procedures for each species to be bred.
 - 1.0 Species
 - 2.0 How will animals be identified genetically?
 - 2.1 Elaborate on your identification method, as indicated above.
 - 3.0 At what age will animals be genotyped?
 - 3.1 If 'Other' was selected, describe.
 - 4.0 If you will not use anesthesia during genotyping, provide a justification.
- 2.0 Please complete the following for each species to be bred.
 - 1.0 Species.
 - 2.0 What method of animal identification will be used?
 - 2.1 If 'Other' was selected, specify the method.
 - 3.0 If animals will not be euthanized in the manner described in the protocol, describe method to be used.
 - 4.0 Indicate if breeder animals will be manipulated in any of the ways listed below.
- 3.0 Provide an estimate of the number of animals needed to establish and maintain the colony.
 - 1.0 Species.
 - 2.0 Estimate the number of weaned and adult bred animals that will be subjected to experimental manipulations.
 - 3.0 Estimate the number of suckling animals that will be subjected to experimental manipulations.
 - 4.0 Estimate the number of breeder animals that will be held but not subjected to experimental manipulations.
 - 5.0 Estimate the number of suckling animals to be euthanized at or prior to weaning and will not be subjected to experimental manipulations.

rDNA and Genetic Engineering

- 1.0 Enter each IBC protocol associated with this protocol.
 - 1.0 If your IBC protocol is already approved, enter the protocol number.
 - 2.0 Enter your IBC protocol title; if your protocol is not yet approved provide the submission date:
 - 3.0 If the study PI is not the PI of the IBC protocol, provide their name.

Questions for the rDNA Office?

If you have any questions regarding whether the activities, materials or animals used in your research qualify under the rules of recombinant DNA use, please contact the IBC Office at 412-383-1768 or by email at

Human Stem Cell Use

- 1.0 Indicate the nature of your study's human stem cell use.
 - Protocol involves transplantation of human:
 - Non-embryonic stem cells (adult, fetal, cord blood, etc.)
 - Cells that originated from iPS cells or hESCs
 - Embryonic stem cells included in the NIH's hESC Registry
 - Protocol involves transplantation of:
 - ANY human stem cells or cells originating from human iPS cells/hESCs into an animal CNS, embryo, blastocyst, germline (requires hSCRO approval prior to IACUC approval).
- 2.0 Has an application been submitted to the Human Stem Cell Research Oversight Committee (hSCRO)?
- 2.1 Has the hSCRO protocol been approved?
- 2.2 What is the approved protocol number?

hSCRO Approval

If your project uses human stem cells not in NIH's Stem Cell Registry or you will inject human stem cells into the germ line or CNS of animals (the second option of the two options to the left), approval for these uses of human stem cells must be secured from the hSCRO before the IACUC will approve this protocol.

The hSCRO application can be downloaded from: <http://www.rcco.pitt.edu/hscro/index.htm>.

Physical Restraint

- 1.0 Please press "Add" and provide details about physical restraint for each applicable species.
 - 1.0 Species.
 - 2.0 Describe the method of restraint used in this study.
 - 3.0 Provide the rationale for restraining animals.
 - 4.0 What is the duration and frequency of restraint? Also describe how animals will be acclimated to the restraint device.

How Does the IACUC Define Restraint?

For these purposes, restraint is defined as more than momentary immobility. Briefly immobilizing an animal for the purposes of blood collection or to administer injections, for example, would not be considered restraint.

Stress Paradigms

- 1.0 Please press "Add" and provide details regarding stress paradigms for each applicable species.
 - 1.0 Species.
 - 2.0 Describe the type of stress paradigm utilized used in this study.
 - 3.0 Provide the rationale for using a stress paradigm.
 - 4.0 For how long and how often will animals be subject to the paradigm? Also describe the criteria for early intervention if the animals experience undue stress.

Blood Sampling

- 1.0 Please press "Add" and provide blood sampling details for each applicable species.
 - 1.0 Species.
 - 2.0 Describe the method for blood sampling utilized used in this study.
 - 3.0 Provide the rationale for blood sampling.
 - 4.0 For how long and how often will blood sampling occur?

Food Regulation

- 1.0 Please press "Add" and provide food regulation details for each applicable species.
 - 1.0 Species.
 - 2.0 Describe the food scheduling plan or food regulation utilized in this study.
 - 3.0 Why is this necessary for the study?
 - 4.0 For how long and how often will animals be subject to food regulation?

Water Regulation

- 1.0 Please press "Add" and provide water regulation details for each applicable species.
 - 1.0 Species.
 - 2.0 Describe the water scheduling plan or food regulation utilized in this study.
 - 3.0 Why is this necessary for the study?
 - 4.0 For how long and how often will animals be subject to water regulation?

How Does the IACUC Define Food and Water Regulation?

The ARO application must capture information regarding scheduled food and water regulation performed for the sake of a specific scientific study. If you are only fasting animals as a standard procedure before performing surgery, then you need not complete this section. Please return to the Procedure Classification section and un-check this section.

Photography

- 1.0 Fully describe how images will be captured, including the nature of the recording device.
- 2.0 Why are these images necessary?
- 3.0 How will you store and safeguard the images?

Uploaded Documents

Any document that you upload from this page will be accessible from this page and from the Protocol Documents tab on the protocol's workspace.

PLEASE NOTE: Documents uploaded on this page will not be included in the Printer Version. They must be printed out separately.

Consistency

Make sure to be consistent when referring to the names of drugs and test agents that you have mentioned in previous sections. Always use the same term that was used in previous sections to avoid confusion and possible delays in review.

Guidance on Obtaining Approval for Image Recording

Coordination and communication with the animal program prior to recording animal images is essential to avoid security concerns. Therefore, camera or video recording is permitted to be used in the animal facilities only after prior approval of the IACUC **and** coordination with the University Attending Veterinarian (or designee).

If you have questions regarding how to obtain approval for image recording, contact the University Attending Veterinarian at 412-648-8950 or dlar@pitt.edu.

Experimental Design and Endpoints

1.0 EXPERIMENTAL DESIGN

Provide a description of the specific experimental manipulations and treatments of animals in terms that are intelligible to non-specialists. This description should be a chronological description that will allow IACUC reviewers to understand exactly what will be done to all animals from entry into the study to its endpoint.

- 1.1 If necessary, upload documents which will further describe your experimental design.
- 2.0 At what timepoint and/or how many days will experiments be completed on animals?

Final Disposition

- 1.0 Please press "Add" and enter a description of the final disposition of each species used.
 - 1.0 Species.
 - 2.0 What is the final disposition of the animals? (Check all that apply)
 - 2.1 If you have chosen Other, please describe and justify.
 - 2.2 If you have selected the Euthanasia option, please describe all euthanasia procedures. If using CO2 asphyxiation, indicate secondary method of euthanasia and/or how death will be verified (see IACUC policy information to the right).
 - 2.3 Is the described euthanasia method consistent with the standards set in the current IACUC Guidelines?

Secondary Method of Euthanasia

To ensure death in an animal following CO2 exposure, another method of euthanasia (e.g., decapitation, thoracotomy, perfusion, etc...) must be added while the animal is under CO2 narcosis.

For further guidance, please see the IACUC's Euthanasia Guidelines at <http://www.iacuc.pitt.edu/sop/restricted/EuthanasiaRodents.pdf>.

Anticipated Effects - Assessment of Animals' Well-Being

- 1.0 Describe in detail the species-specific criteria that the PI will monitor in order to ascertain the health and well-being of the animals in this study, including the presence of pain and distress?
- 2.0 With what frequency will the animals be monitored?

Anticipated Effects - Health and Well-Being Complications

- 1.0 Describe the likely consequences of the experimental manipulations performed on the animals. If the genetic background of the animals gives rise to physiological manifestations that effect their health and well-being, include this information as well.
- 2.0 Describe any additional potential complications resulting from the experimental manipulations that may affect the animals' health and well-being. In addition, indicate the expected frequency of these complications.
- 3.0 How will you manage the complications noted in the questions above?

Responsibility of Animals' Health and Well-Being

The IACUC holds the PI (and not the animal care or veterinary staff) principally responsible for monitoring the well-being of animals. The DLAR can assume more of this responsibility if a specific contract is established for this purpose; for more information about contracting for animal welfare monitoring, contact the DLAR at dlar@pitt.edu or 412-648-8950.

Anticipated Effects - Pain and Distress

- 1.0 If pain or distress is either anticipated as a consequence of, or occurs as a complication resulting from experimental manipulations, how will it be alleviated?
- 2.0 Describe in detail the clinical, laboratory or other diagnostic criteria utilized to determine when an experimental animal will be euthanized or removed from the study prior to reaching the noted experimental endpoints.
- 3.0 Indicate the frequency at which you expect to remove animals from the study for the reasons given above.
- 4.0 If any animals are expected to die due to complications prior to being euthanized, indicate the expected percentage of animals to which this will occur AND the procedures to be employed to minimize this occurrence.

Pain and Distress Classification

- 1.0 Please enter the percentage of animals in each category for each species.
 - 1.0 Species.
 - 2.0 Indicate the USDA pain and distress classification applicable to all animals in this study. (Only select the appropriate checkboxes and provide the related %).

NOTE: Percentages are not required for mice, rats, wild-caught birds and other animals not covered by the Animal Welfare Act. For these entries, check the appropriate categories and leave the percentage section blank.

What is a “Painful Procedure?”

According to PHS policy, painful procedures are defined as

"Any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which the procedure was applied..."

[http://www.aphis.usda.gov/animal_welfare/policy.shtml].

Also be aware that the preemptive use of analgesics must be employed for painful procedures as default methodology (versus their employment based on clinically perceived need), unless specific scientific justification is provided (See IACUC Policy for Pain Management Guidelines in Designing and Implementing a Small Animal Study section). Unanticipated pain or distress from experimental manipulations that is detected clinically or pain or distress that is not successfully managed by the analgesic regime employed should be addressed through immediate consultation with the DLAR Veterinary Services unit.

Pain and Distress Classifications

Classification B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes. The Pitt IACUC also considers pre-weaned animals provided with analgesic medications for the sole purpose of genotyping to also fall under this classification.

Classification C: Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, no distress, or no use of pain-relieving drugs. Euthanasia must precede any invasive procedure (i.e. tissue harvesting) to be in Classification C.

Classification D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used. Acute or terminal surgery is considered a painful procedure, which is alleviated by anesthesia.

Classification E: Animals upon which teaching, experiments, research, surgery (survival or non-survival), or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests and/or animals upon which teaching, experiments, research, surgery (survival or non-survival), or tests will be conducted resulting in either death as an endpoint or permanent physiological impairment that may lead to chronic pain or distress.

Category E Justification

1.0 Add an entry below for each species with animals in Category E.

1.0 Species.

2.0 Provide a scientific justification to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressing procedures is contraindicated.

3.0 Number of animals Year 1.

4.0 Number of animals Year 2.

5.0 Number of animals Year 3.

Important!

Please be careful in preparing your Category E justification. An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided to satisfy USDA requirements. The information that you provide must be reported to that agency and will be publicly available under the Freedom of Information Act via USDA's website.

Alternatives to Pain and Distress – Refinement

- 1.0 Database Search.
 - 1.0 Database(s) searched.
 - 2.0 Date of Search:

Enter format 'MM/DD/YYYY' or use the Calendar widget.
 - 3.0 Inclusive Dates.
 - 4.0 Upload search strategy and its results.
- 2.0 Consultant Information.
 - 1.0 Source of Information.
 - 2.0 Qualifications.
 - 3.0 Extent, Nature and Content of Consultation.
 - 4.0 Date of Consultation.
- 3.0 Provide a written narrative based solely and exclusively on the information gathered from the literature searches and expert consultations cited on the previous page. If a possible refinement was discovered or is known but will not be employed, discuss why this is so.
- 4.0 If your narrative is extensive or requires charts or tables, you may attach a Word document.

What Does *Refinement Alternatives* Mean?

Refinement alternatives concern the many ways to think about reducing the potential pain and distress in the realm of animal care and use. Your search strategy should address all potential sources of pain and distress to ensure that your research activities are *refined* such that they cause the least possible pain and distress to animal subjects.

What Should My Uploaded Search Strategy Include?

You should upload a chart, which can be cut and pasted from the search engine results, with each line including search terms and the number of results that were returned by the database that was searched. See Fig. 1 below for an example of the acceptable format.

Alternatives to Pain and Distress – Replacement

1.0 Database Search.

1.0 Database(s) searched.

2.0 Date of Search:

Enter format 'MM/DD/YYYY' or use the Calendar widget.

3.0 Inclusive Dates.

4.0 Upload search strategy and its results.

2.0 Consultant Information.

1.0 Source of Information.

2.0 Qualifications.

3.0 Extent, Nature and Content of Consultation.

4.0 Date of Consultation.

3.0 Provide a written narrative based solely and exclusively on the information gathered from the literature searches and expert consultations cited on the previous page. If a possible refinement was discovered or is known but will not be employed, discuss why this is so.

4.0 If your narrative is extensive or requires charts or tables, you may attach a Word document.

Alternatives to Pain and Distress – Reduction

1.0 Database Search.

1.0 Database(s) searched.

2.0 Date of Search:

Enter format 'MM/DD/YYYY' or use the Calendar widget.

3.0 Inclusive Dates.

4.0 Upload search strategy and its results.

2.0 Consultant Information.

1.0 Source of Information.

2.0 Qualifications.

3.0 Extent, Nature and Content of Consultation.

4.0 Date of Consultation.

3.0 Provide a written narrative based solely and exclusively on the information gathered from the literature searches and expert consultations cited on the previous page. If a possible refinement was discovered or is known but will not be employed, discuss why this is so.

4.0 If your narrative is extensive or requires charts or tables, you may attach a Word document.

Fig. 1

Ovid MEDLINE(R) Daily Update, Ovid MEDLINE(R)

#	Searches	Results
1	animal testing alternatives/	1755
2	"animal use alternatives"/	169
3	computer simulation/	82535
4	disease models, animal/	141555
5	limit 7 to yr="1998 - 2009"	110

PI Certification

When you are ready to submit your protocol, click the **Submit Protocol** Activity. If all required questions have been answered, you will see the following list of assurances in the pop up window that appears:

- I understand that as Principal Investigator, I assume full responsibility for the conduct of this research, the training and the supervision of research personnel.
- I certify that I have determined that the research proposed herein is not unnecessarily duplicative.
- I certify that I will notify the IACUC before initiating any changes in this protocol.
- I understand that unauthorized animal use is reportable to the funding agency and/or the Office of Laboratory Animal Welfare (OLAW).
- I certify that I will notify the IACUC regarding any unexpected results that impact animals. Any unanticipated pain, distress, morbidity or mortality will be reported to the attending veterinarian.
- I understand that if I cannot be contacted in the event that animals in this project show evidence of distress, illness or pain, emergency care, including euthanasia if necessary, will be administered at the discretion of the veterinary medical staff.
- For all USDA Classification D and E proposals: I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted in this protocol and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
- For any animal body fluids or tissues, derived from the studies described in this application and transferred to persons not listed as personnel in this protocol, I certify that I will notify the recipient of all hazards associated with these materials and will instruct them to register with the EHS Department (624-9505).
- I certify that I will ensure that all members of personnel listed on this protocol have read and understand all elements described for the study.
- I certify that all surgeons involved in this project have read the Surgical Guidelines. (The Surgical Guidelines are available on the IACUC web site under the Policies section for Designing & Implementing Animal Studies).

To submit your protocol, indicate that you agree with these statements by clicking the checkbox, then click **OK**.

Help!

If you need assistance completing an IACUC protocol in ARO or at any time during the review process, please contact the IACUC Office. If you know the name of the coordinator handling your protocol, you should call them directly.

Main Office	412-383-2008	iacuc@pitt.edu
Michael Kessler Director of Regulatory Affairs and ARO Administrator	412-383-2018	mckessle@pitt.edu
Marissa Arlet Protocol Review Manager	412-383-2004	marissa@pitt.edu
Sierra Lasko Regulatory Coordinator Coordinator	412-383-2014	sbl25@pitt.edu
Anna Jackson Communications Coordinator	412-383-2008	afb26@pitt.edu