arc
Applications for Research Compliance PORTAL

eIACUC Study Team Manual

This guide serves to aid IACUC study teams become familiar with the basic functions of the ARC system.

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Welcome to *ARC*

Our on-line *ARC* system streamlines the process of submitting, approving, tracking, and managing eIRB eCOI, and eIACUC applications.

ARC is available via Internet connection 24 hours a day, 7 days a week.

If you have any questions about the ARC system, the *ARC* HelpDesk is available during regular business hours at (813) 974-2880 and by email at RSCH-arc@usf.edu.

Accounts

In order to create and submit applications in ARC, you will first need to obtain an account by submitting a new user registration request.

New Account Registration

To open your new *ARC* account:

1. Go to the *ARC* Web Site: https://ARC.research.usf.edu/prod/
2. Click **Register Here** on the right hand side of the page.

3. Complete the required fields (*****) and provide your USF Net ID, Employee ID, and USF or affiliate email address.
4. Select all relevant roles, such as Study Staff, PI, Department Approver, etc.
5. Click **Register.**
6. Within two business days your new account will be activated and you will receive an e-mail containing your account information (i.e., User Name & Temporary Password).

Log In

1. Type your **User Name** in the login section on the right side of the *ARC* screen.
2. Type in your **Password.**
3. Click **Log In**.

Forgot Your User Name or Password?

If you ever forget your account credentials, you can have them emailed to you on the ARC Home page.

1. The **Forgot Password** and **Forgot User Name** options are available under **Need Help?.**

1. If you select **Forgot user name?**, you will be prompted to confirm your email address. Once confirmed, your user name will be emailed to you.
2. If you select **Forgot password?**, you will be prompted to confirm your user name and email address. Once confirmed, a new temporary password will be emailed to you. Upon log in, you will be required to change your password.

If you have forgotten both your user name and your password, select **Forgot user name?** first as it only requires your primary email address. After receiving your username, you can select **Forgot password?**.

Account Changes

It is important to keep your account information current. To make changes to your account, click your name in the upper right hand corner of your screen to open your account properties.
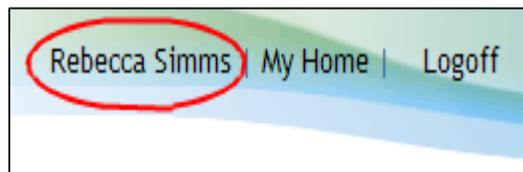
Then make the necessary changes and click **Apply**. **Note** - For changes to your department affiliation and assigned roles, you will need to contact the helpdesk.

To change your password, click on your name (as described above). On your Account page, click the **Account** tab. Type in your old password, your new password, and your new password again in their respective boxes. Click **Apply**.

After receiving your username and a temporary password, you can log in to the ARC system.

Navigation

My Home Page

After logging in, the screen displays your **Home Page[1]** which allows you to view and manage those applications relevant to your **Role**. The eIACUC applications include an initial study, modification, and continuation.

When you are in other sections of the *ARC* system, you can easily get back to your home page by clicking the link to **My Home**.

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[1] Users that registered in the ARC system prior to 2011 may see "Folder" in place of "Page." There is no difference in functionality or navigation beyond the terminology.
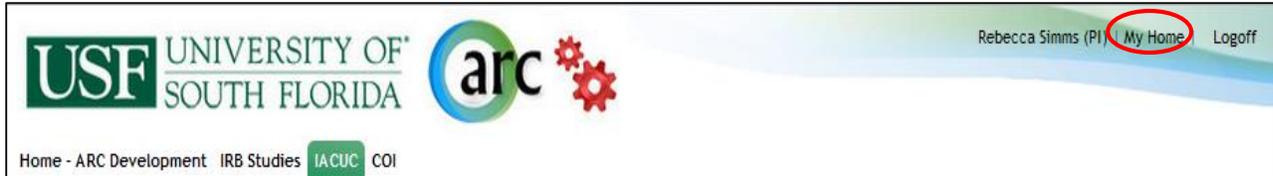
Roles

A person can have multiple **Roles** in *ARC* such as Study Staff, Veterinarian, IACUC Coordinator, IRB Committee member, etc. Different Roles provide access to different applications, information, and activities. The "Study Staff" role encompasses all of the study team positions. Principal Investigator, Secondary Investigator, Research Staff, and Secondary Study Contact are the study team positions for eIACUC.

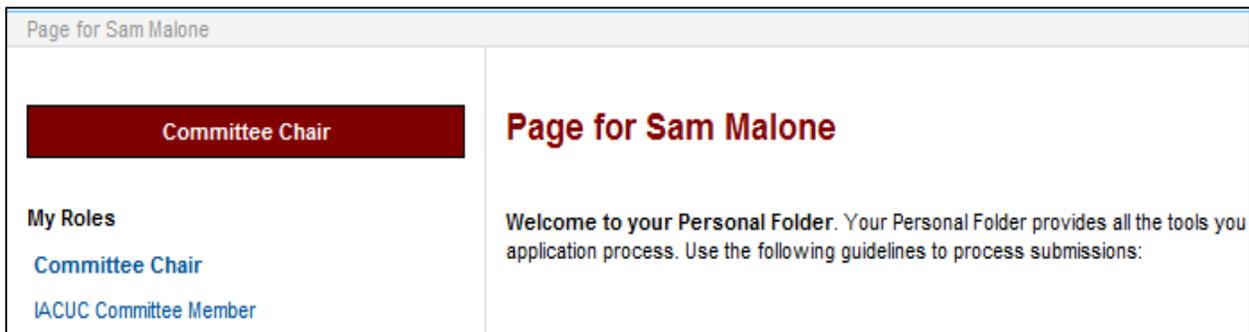Your current **Role** will be displayed in the red banner at the top of the column on the left side of your home page. Your current role will be **Bold** in the listing of your available Roles If you have more than one role, each time you log in, be sure that the correct role is selected.

Navigation Tabs

The central area of your home page provides a row of navigation tabs. These tabs provide access to your applications based upon their type or status.
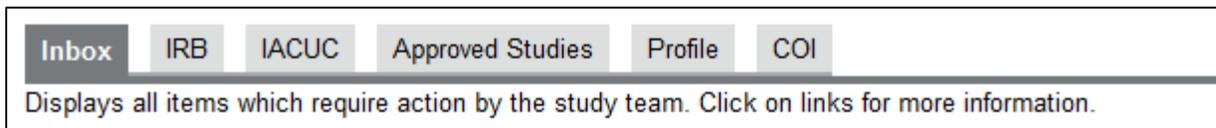
Inbox Tab

The **Inbox** tab is displayed by default after logging in to the ARC system. The **Inbox** tab lists all applications (studies, modifications, continuations) that require action by you or other staff on your study team in your current Role.[2]

Below is an example of your **Inbox**:

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[2] An application can be in multiple users' Inboxes (e.g. a study in Pre-Submission).
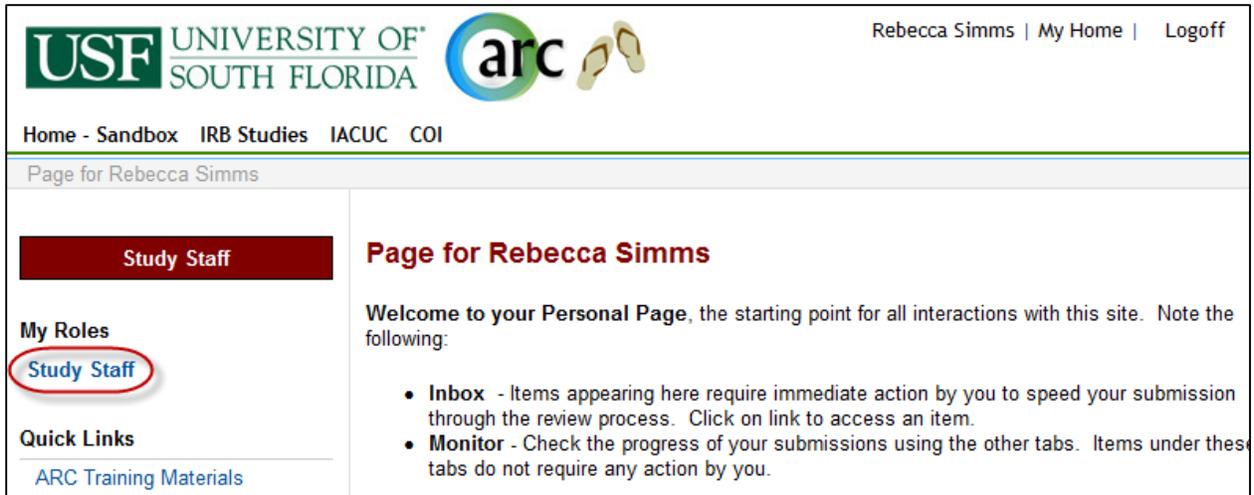
Key to the **Inbox** page:

1. The **Inbox** tab. Displays all applications requiring attention by you or your study team.
2. **Name** column. Displays the name of applications in your Inbox. Clicking the name will bring up that application's workspace.
3. **Type** column. Displays the type of application (Study, modification, etc.)
4. **State** column. Displays where the application is in the review process.

Once you have completed the required activities, the application is moved electronically from one respective Inbox to the next according to whose attention it requires. If an application is not in your Inbox, it's someone else's turn to work on it. **If an item is in your Inbox, it still requires your attention.**

Profile Tab and Uploading IACUC Training

The **Profile** tab provides information regarding training records/certifications and access to your researcher profile. In order to upload IACUC training documents, you will need to first navigate to your researcher profile. First, select the "Study Staff" role under *My Roles* if it is not already selected.

Once selected, select the "Profile" tab. This will provide access to your researcher profile link.

Uploading IACUC Training

From the researcher profile page, you update your training documents by selecting **Edit Researcher Profile**.

This will bring you to the Researcher Profile SmartForm. To branch to the IACUC training section, check the IACUC box in question 1.2 and select **Continue**.

Section 3 of your researcher profile displays your IACUC training materials. Use the **Add** or **Upload Revision** buttons to upload the required documents and information.

After uploading the necessary documents, select **Save** from the navigation bar and **Exit** the Smartform. This will bring you back to your researcher profile page. Once completed an IACUC staff member will be notified to validate your training documents.

IACUC, Approved Studies, and COI Tabs

The IACUC tab lists all applications with which you are associated regardless of the state. In the IACUC tab, you can monitor the State of all of your IACUC applications. You can view applications under the IACUC tab by clicking the application Name.

The Approved Studies tab lists all of your studies that been approved by the IACUC and IRB.

The COI tab lists all of your conflict of interest applications.

Application Workspace

Work on an application begins in the application's **Workspace** which is like a home page for the application. Open an application's Workspace by clicking on its **Name** in your **Inbox** or other tab.

The application Workspace provides:

- information about the application
- links to specific sections and documents related to the application

- buttons to initiate **Activities** and move the application to the next step in the review process
- history of all activities performed on the application

After a study has been approved, tabs for Modifications and Continuations are displayed next to the History tab in the study workspace.

Below is an example of a study Workspace screen:

Key to the study **Workspace** screen:

1. **Current State** indicates the stage in the review process for this application. This changes as Activities are completed.
2. The summary panel displays information about this study. The information changes when a study becomes active.
3. IACUC Study Number (also referred to as the IS#).
4. **Edit Study** button opens the application SmartForm for editing (while the application is in your study team's Inbox only). When the application is not in your Inbox, the button is **View Study** and will provide read-only access.[3]
5. **Printer Version** button opens all of the relevant SmartForm screens in one easy-to-print window.

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[3] Edit/View will show Modification or Continuation if those applications are selected.

6. The left column lists actions and **Activities** that can be performed on the study in its **Current State**. The list will vary depending on the Current State and role. The legend on each button indicates which Role (i.e., PI only or any study team member) can perform this activity. Click the button/link to open the Activity screen.

7. The **History** tab lists chronologically all actions that have been performed on the study. Click the Activity name in the listed History to view details.

8. The **Attachments** tab lists all documents that have been uploaded for this application. Successive versions are archived automatically so that you have access to the most currently approved versions, e.g., protocol, grant document, funding, etc.

Create a New Study

In the role of Study Staff, you can create a new IACUC study (Initial Application) by clicking the **New IACUC Study** button in the column on the left side of your home page.

This will open the study **SmartForm** which uses branching to present only those questions relevant to your study. The IACUC Study Number is assigned automatically the first time you save the study (or after you complete the first page of the application and click **Continue**).

Working with Smart Forms

All applications in *ARC* use **SmartForms**. Since these forms only present questions relevant to your study, it is important that you respond to each question displayed on the SmartForms.

Required fields are marked with a red asterisk *****. Guidance on how to answer many of the SmartForm questions is available by selecting **>>Get Help** located near the end of the question.
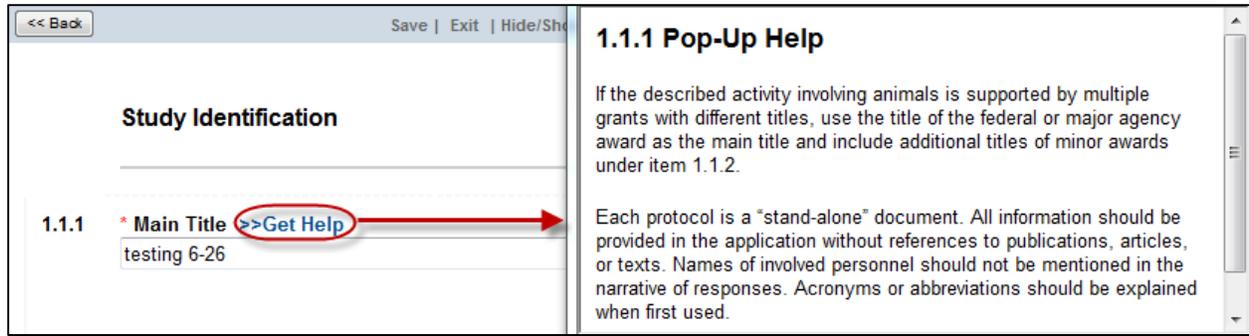
You can answer text questions by typing directly into the text box or by pasting in text from other documents. The **Add** function allows you to attach relevant documents or select your answer from a pre-populated list depending on the question.

Navigation controls are located in the navigation bar at the top and bottom of each page. Use the **Continue** and **Back** buttons to move to the next or last-viewed screen.

Use the SmartForm navigation controls instead of the controls in the browser bar (e.g., Internet Explorer, Firefox, Chrome, Safari, Opera).

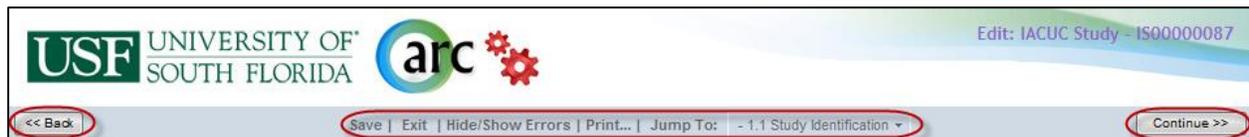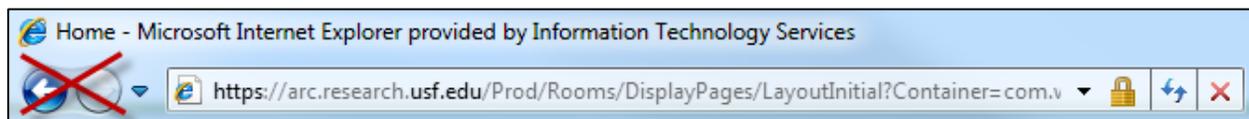Save your application by clicking **Save** or **Continue**.

> **WARNING:** The **Back** button does not save changes. After you enter or edit data on a screen, click **Save** before going **Back**!

Use **Exit** to close the application and return to that application's Workspace.

> **WARNING:** Always **Save** before exiting!

Each section and question is numbered for easy navigation and reference. Numbering is consistent through all SmartForm applications; however, remember that only the relevant questions for each specific application are displayed.

Once new or revised data on a page has been saved, you can navigate directly to other sections and questions by using the **Jump To** drop-down menu. The title of the displayed page will be red.
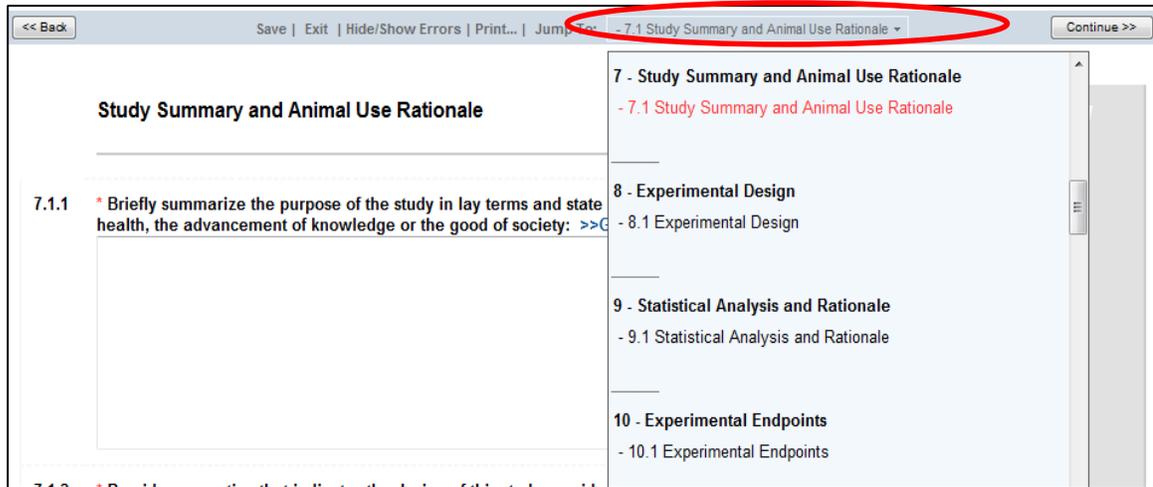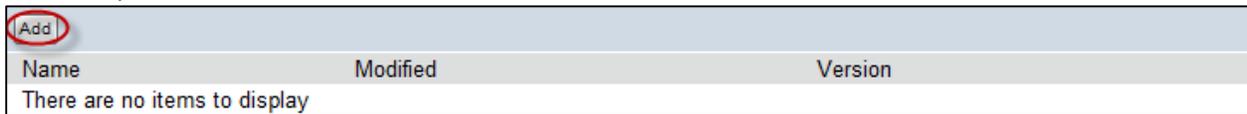
> **WARNING:** After you enter or edit data on a screen, click **Save** before using **Jump To**! The Jump To menu does not save.

Attaching Documents and Tables

Attach documents, such as the protocol or grant document, by using the **Add** button associated with the relevant question in the SmartForm.

Before attaching a document, be sure you have named it using an accurate description as your approval letter may contain references to these documents as named in the SmartForm. Use the **Browse** button to locate the file, name it in the **Title** field, and select **OK** to add the document to the SmartForm.

Several sections in the IACUC study SmartForm require adding information that is populated in a table. In some cases, this information is utilized to provide pre-populated choices to other questions in the SmartForm. Similar to documents, select the **Add** button to begin completing the table. This will create a pop-up window containing additional questions.

Hide/Show Errors

Within a SmartForm, use this tool to gauge your progress with the application. In the menu bar, click **Hide/Show Errors** to list the required fields that need to be completed.
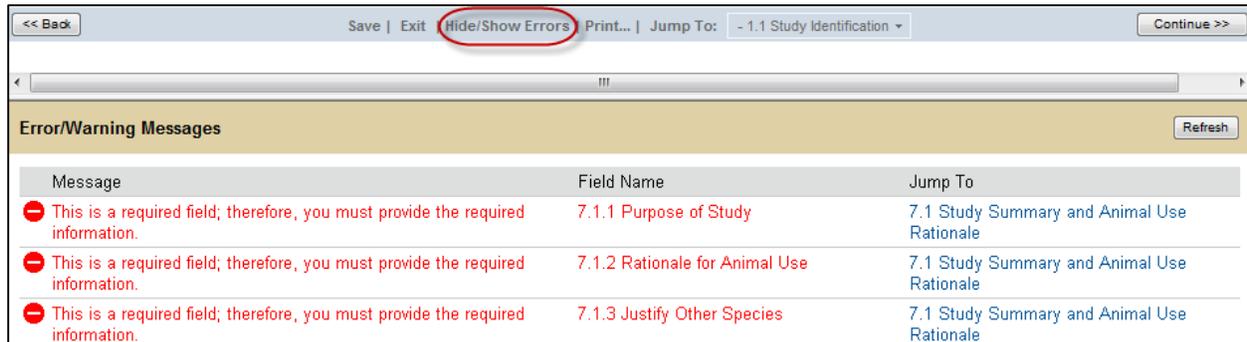
Click the link again to hide Error/Warning Messages.

Completion and Submission: A Two-Part Process

All applications in ARC follow the same basic procedure for submission:

1. **Complete the application**: The PI and Study Staff create and complete the application SmartForm. The application remains in your Inbox.

2. **Submit the application**: The PI submits the completed application for review. Submission moves the application from your Inbox to the next State.

Part 1 – Complete the Application

When a study is created, it starts out in the Pre-Submission State. In this State, all Study Team members can work on the study SmartForm, attach documents, and save changes. They can access the study by selecting **Edit Study** on the main workspace.

Before submission, all study team members should verify that the personnel certification information displayed on section 1.3 of the application is current.

Part 2 – Submit the Application

After the study SmartForm is complete, it can be submitted for initial review. The first stage of the review process for new studies and modifications is *Veterinary Review*.

Veterinary Review

1. To submit the initial study, the PI or Secondary Study Contact will open the application Workspace and click **Submit Study For Veterinarian Review** under *My Activities*.
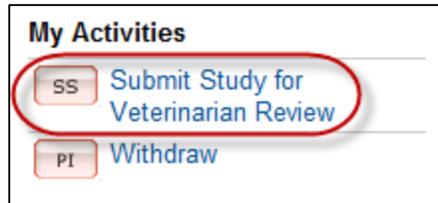
2. *ARC* will run a final validation check on the entire application before submission. If there are any required fields that have been left blank, they will be indicated and your application will not be submitted. The application must be error-free before it can be submitted.

3. After the application has been submitted, it moves from the Pre-Submission State to the next State: Veterinarian Assignment. Once submitted, it cannot be edited (unless changes are requested by a reviewer and it is returned to the Study Team Inbox).

While in *Veterinary Review*, a veterinarian(s) will review your application and may suggest revisions or request additional information.

Submitting to IACUC

After the veterinary review has been completed, the study will be returned to the study team's Inbox.

1. If the veterinary reviewer has not requested any revisions, the study can be submitted to IACUC for review via the **Submit for IACUC Review** activity. **Only the Principal Investigator for the study can submit the initial study to IACUC for review.**

2. If additional revisions have been requested by the veterinarian, the study team may need to address these questions and submit the study back to veterinary review (see responding to revisions section for more details). After answering the reviewer notes, the PI or study coordinator should select **Submit Study for Veterinarian Review**.
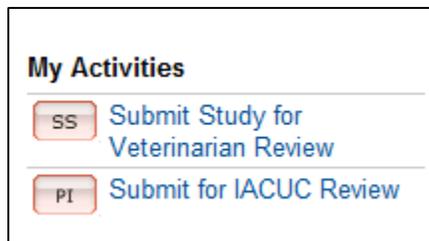
IACUC Review and Approval

After the study has been submitted to the IACUC, it may be reviewed at an IACUC meeting or by a designated member of the IACUC committee. In both cases the ARC system will provide system notifications regarding the status of the application.

Progress Notifications

ARC automatically sends e-mail notifications to the study team when significant events occur in the review process. Be sure to keep your e-mail address current in the *ARC* system. To change your e-mail address, see Account Changes on page 3.

The Study team will receive e-mail notifications at the following times:

- Requests for information or changes to the application.
- Official actions from the IACUC (i.e., when the application is scheduled for a board meeting, once an application is approved/disapproved, etc.)
- When studies are due for Continuation

You can also check the progress of your application at any time by checking the **History** log or your study's **state**.

Respond to Requests for Revisions or Information

Throughout the review process, your application may be returned with requested revisions or information. When revisions are requested, the application will return to your Inbox for revision. To access the application:

1. Click the study Name in your ARC **Inbox** to open the application workspace.
2. Under the **Reviewer Notes** tab, you will find all notes that have been added to the study. Each note provides a **Jump To** link that will take you to the page where the requested change needs to be made.

3. Respond to each change requested. Some changes may require changing your answer to a question in the SmartForm in addition to answering the note.

4. Be sure to **Save** before you **Exit** the SmartForm.
5. When the Study Staff have completed all of the requests in the application workspace, you will need to **Submit** the requested revisions. The name of the activity will depend on who asked for the revisions (e.g. **Submit Responses to IACUC** or **Submit Study for Veterinarian Review**.)

After you have submitted your response, the application will no longer be displayed in your Inbox because it has moved to the reviewer for further review. However, it will be listed under the **IACUC** tab on your home page, where you can view a read-only copy.

Approval Letter

When the IACUC has approved your study, you will receive an e-mail notification of approval. The approval letter will also be available in the study Workspace.

To view the approval letter in *ARC*:

1. On your home page, click the **Approved Studies** tab.

2. In the Approved Studies folder click the study name.

3. In the study workspace, the summary panel will now display a link to view the Letter of Approval. Click on **file** next to **Letter of Approval** (**3**).

Modifications and Continuations

After a study has obtained IACUC approval, you can create two sub-projects: modification and annual continuation applications. The activity buttons to create these applications are available from your approved study's main workspace. You can access your approved study's workspace under the **Approved Studies** tab of your homepage (pictured above in the Approval Letter instructions).

Workspaces for study sub-projects are similar to the initial study Workspace. After a modification or annual continuation application has been created, it can be accessed in your Inbox until it is submitted for review. Modifications and Continuations follow the same general procedure of the initial application: 1) study teams complete the SmartForm and 2) submit the application for review.

Modification

Modifications allow study teams to make changes to an already approved IACUC study. After creating a new modification by selecting **New Modification**, you will be routed to the Modification Smartform. There are two types of eIACUC Modifications: Amendment and Procedural Change.

Only one modification request is allowed at any given time, i.e: Modification 1 must be approved, denied or withdrawn before Modification 2 can be created. **Written IACUC approval is required prior to implementing any changes to an existing IACUC study.**

An **amendment** is limited to the following types of changes:

- A new or additional title
- A new or additional funding source other than federal or major agency sources
- A change in the certified research personnel other than PI
- Addition of another strain of the same species without a change in procedures or an increase in animal numbers
- An additional laboratory or a relocation of an existing laboratory for an approved activity outside of animal facilities

Selecting the amendment type requires that you indicate which type(s) of change you are requesting and will only allow edits to be made to these sections.

A **procedural change** can include any of the amendment types and any changes to the protocol which remain within the scope of the original research hypothesis, and involve the original species. After indicating a procedural change, you will be required to outline and justify all proposed changes. You will then be routed to the **Modified Study** to make changes directly to the initial study SmartForm.

As with initial studies, Modifications must be submitted to IACUC after the SmartForm has been completed. Amendments are submitted directly to the IACUC via the *Submit Amendment to IACUC* activity whereas Procedural Changes are routed to Veterinary Review via *Submit for Veterinarian Review.***Only the Principal Investigator can submit the Modification to the IACUC for review.**

(Example Amendment)

(Example Procedural Change)

Continuation and Study Closure

Study teams are required to submit an annual continuation requesting the IACUC study remain open. The Continuation SmartForm is much shorter than the other projects and only requires you indicate the protocol will continue as approved. You can create a modification by selecting **Annual Continuation** from the approved study's workspace.

Wildlife studies are routed to an additional page in the SmartForm requesting details regarding the number of animals encountered during the 12 month approval period. Once the SmartForm is complete, submit the Continuation via the *Submit Continuation* activity.

If you have completed your research or the study will not be activated, the Principal Investigator or Secondary Study Contact should select the *Request Study Closure* activity on the study's main workspace.

The study team will need to indicate a reason for closure and for wildlife studies, the number of animals encountered or used. IACUC staff will be notified that you have requested your study be closed and will finalize the closure process.