



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.

Table of Contents

Welcome to ARC	3
Accounts	3
New Account Registration.....	3
Log In.....	4
Forgot Your User Name or Password?	4
Account Changes.....	5
Navigation	6
My Home Page	6
Roles.....	7
Navigation Tabs.....	7
Inbox Tab	7
Profile Tab and Uploading IACUC Training.....	8
IACUC, Approved Studies, and COI Tabs.....	11
Application Workspace	11
Create a New Study	13
Working with Smart Forms	13
Attaching Documents and Tables.....	15
Hide/Show Errors	16
Completion and Submission: A Two-Part Process	16
Part 1 – Complete the Application	16
Part 2 – Submit the Application	16
Veterinary Review.....	16
Submitting to IACUC	17
IACUC Review and Approval	17
Progress Notifications	18
Respond to Requests for Revisions or Information.....	18
Approval Letter	19
Modifications and Continuations	20
Modification	21
Continuation and Study Closure.....	23

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.

The screenshot shows the ARC web site home page. At the top left, there is a navigation menu with links: Home, Institutional Animal Care and Use Committee, Research Conflict of Interest, Institutional Review Board, What's New, Training Materials, Regulation and Guidance, and Contact Us. The main content area is titled 'Home' and contains a welcome message from the Division of Research Integrity & Compliance, followed by a section on 'Full AAHRPP Accreditation!'. On the right side, there is a 'Need an account?' section with a 'Register Here' link, and a 'Have an account?' section with 'User Name' and 'Password' input fields and a 'Log In' button. Below these is a 'Need Help?' section with 'Forgot Password' and 'Forgot User Name' links. At the bottom right, contact information for the ARC Help Desk is provided, including a phone number, email address, and physical address. A copyright notice is at the very bottom.

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**.

The screenshot shows the ARC Home page. At the top left is the USF University of South Florida logo and the ARC logo. A navigation menu on the left includes links for Institutional Animal Care and Use Committee, Research Conflict of Interest, Institutional Review Board, What's New, Training Materials, Regulation and Guidance, and Contact Us. The main content area features a 'Home' heading, a welcome message, and a 'Full AAHRPP Accreditation!' announcement. On the right, there is a 'Need an account?' section with a 'Register Here' link, and a 'Have an account?' section with a 'Log In' button. The 'Log In' button is highlighted with a red box. Below the login section is a 'Need Help?' section with links for 'Forgot Password' and 'Forgot User Name'. At the bottom, contact information for the Division of Research Integrity & Compliance is provided, including phone, email, and mail addresses, along with a copyright notice for 2011.

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?**.

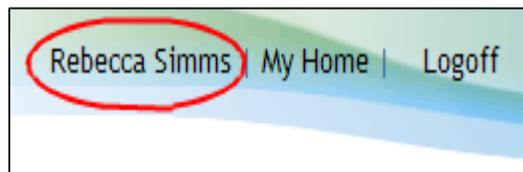
The screenshot shows the eIACUC website home page. At the top left are the logos for USF University of South Florida and ARC. A 'Login' link is in the top right. A 'Home' button is highlighted in the navigation bar. Below the navigation bar is a sidebar with links: Institutional Animal Care and Use Committee, Research Conflict of Interest, Institutional Review Board, What's New, Training Materials, Regulation and Guidance, and Contact Us. The main content area has a 'Home' heading and a welcome message. It also features a 'Full AAHRPP Accreditation!' announcement. On the right side, there are sections for 'Need an account?' with a 'Register Here' link, 'Have an account?' with 'User Name' and 'Password' input fields and a 'Log In' button, and 'Need Help?' with 'Forgot Password' and 'Forgot User Name' links. The footer contains contact information for the Division of Research Integrity & Compliance and a copyright notice for 2011.

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.

Page for Lilith Sternin-Crane

Study Staff

My Roles
Study Staff

Quick Links
Division of Research Integrity & Compliance

Human Subjects
New IRB Study
Convert Paper Study

Animal Subjects
New IACUC Study

Conflict of Interest
New COI Disclosure

Page for Lilith Sternin-Crane

Welcome to your **Personal Page**, the starting point for all interactions with this site. Note the following:

- Inbox** - Items appearing here require immediate action by you to speed your submission through the review process. Click on link to access an item.
- Monitor** - Check the progress of your submissions using the other tabs. Items under these tabs do not require any action by you.

Inbox IRB IACUC Approved Studies Profile COI

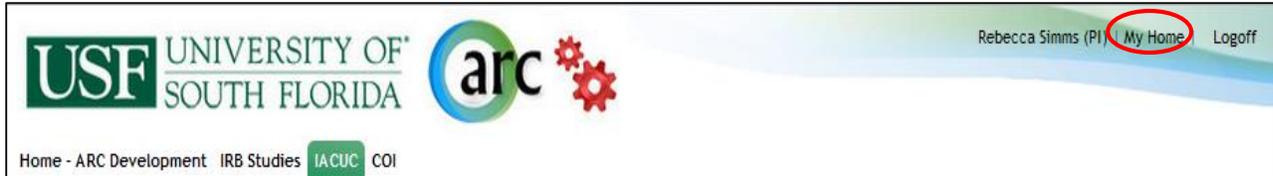
Displays all items which require action by the study team. Click on links for more information.

Filter by ID Go Clear Advanced

ID	Name	Date Modified	Type	Owner	State	Last State Change
IS00000113	Workflow Testing	7/18/2012 11:20 AM	IACUC Study		1. Pre Submission	7/16/2012 12:15 PM
IS00000112	RP Test	7/12/2012 10:12 AM	IACUC Study		1. Pre Submission	7/12/2012 10:12 AM
IS00000089	03/30/2012 Testing Session	7/5/2012 12:36 PM	IACUC Study	Crane, Eric	4. Changes Recommended By	6/28/2012 2:17 PM

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**.

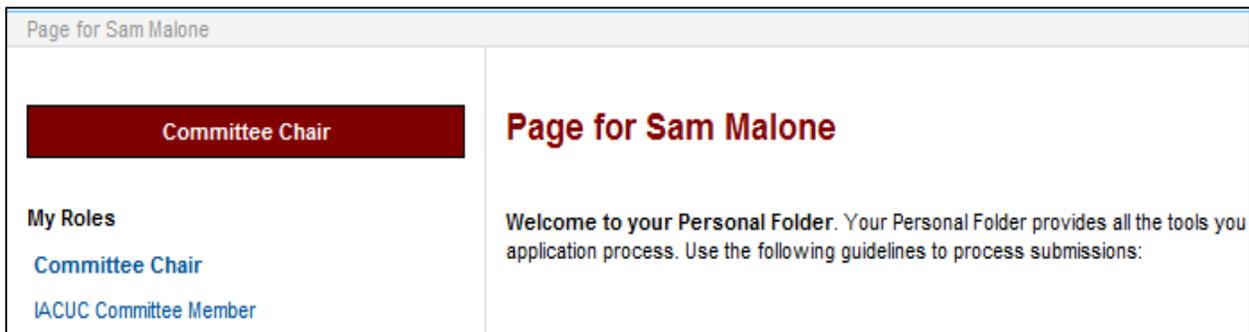
¹ Users that registered in the ARC system prior to 2011 may see "Folder" in place of "Page." There is no difference in functionality or navigation beyond the terminology.



Roles

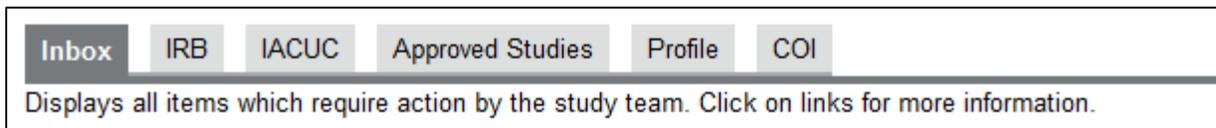
A person can have multiple **Roles** in ARC such as Study Staff, Veterinarian, IACUC Coordinator, IRB Committee member, etc. Different Roles provide access to different applications, information, and activities. The “Study Staff” role encompasses all of the study team positions. Principal Investigator,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

² An application can be in multiple users' Inboxes (e.g. a study in Pre-Submission).

1

Inbox IRB IACUC Approved Studies Profile COI

Displays all items which require action by the study team. Click on links for more information.

Filter by ID Go Clear Advanced

ID	Name 2	<input checked="" type="checkbox"/> Date Modified	Type 3	Owner	State 4	Last State Change
 IC00000021	2013 Review for IS00000087	6/13/2012 3:33 PM	IACUC Continuation	Simms (PI), Rebecca M	1. Pre Submission	6/13/2012 2:48 PM
 IS00000108	asdf	6/11/2012 9:20 AM	IACUC Study		1. Pre Submission	6/11/2012 9:10 AM
 IS00000099	Farah is testing the system	6/5/2012 4:50 PM	IACUC Study		1. Pre Submission	5/23/2012 3:54 PM
 IS00000100	IACUC Title	5/31/2012 4:43 PM	IACUC Study		1. Pre Submission	5/29/2012 3:49 PM

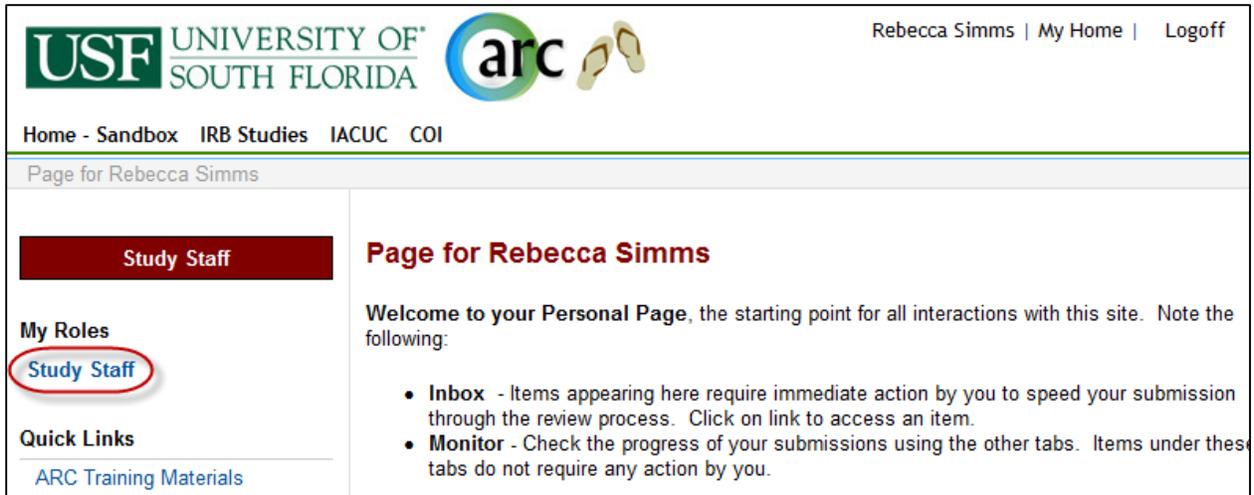
Key to the **Inbox** page:

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.



USF UNIVERSITY OF SOUTH FLORIDA arc

Rebecca Simms | My Home | Logoff

Home - Sandbox IRB Studies IACUC COI

Page for Rebecca Simms

Study Staff

Page for Rebecca Simms

Welcome to your **Personal Page**, the starting point for all interactions with this site. Note the following:

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- **Monitor** - Check the progress of your submissions using the other tabs. Items under these tabs do not require any action by you.

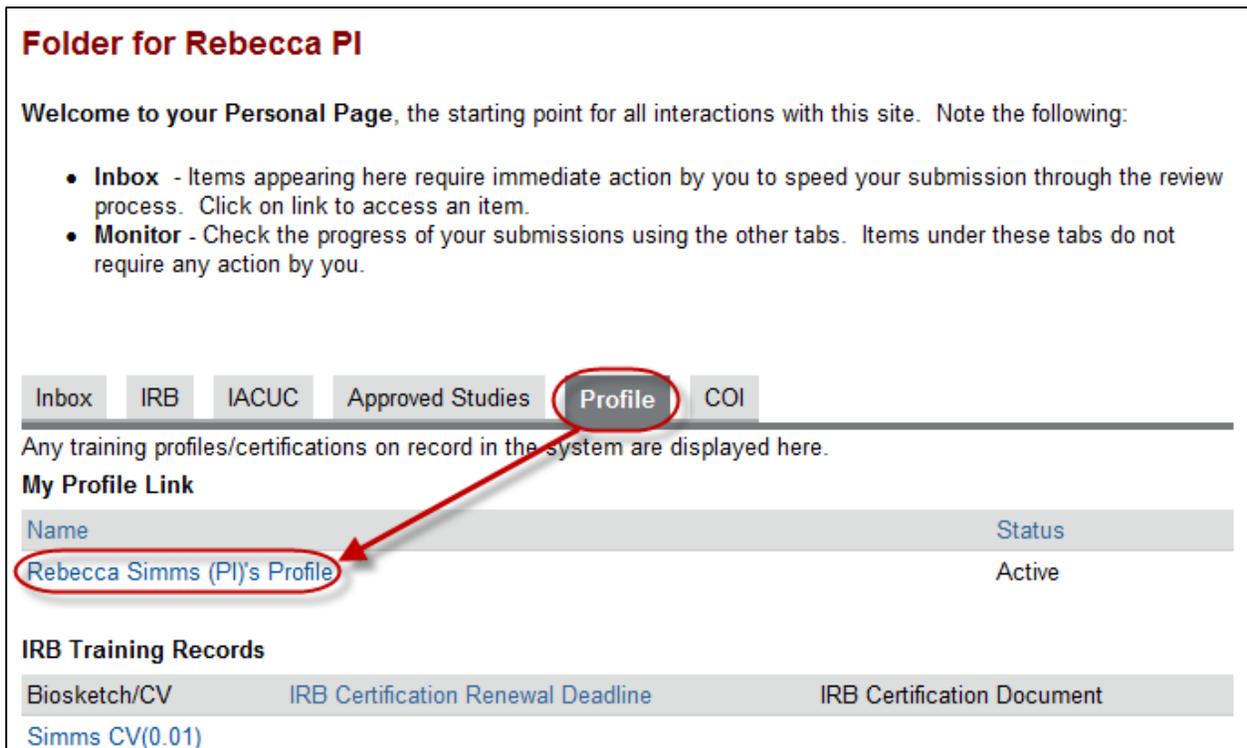
My Roles

Study Staff

Quick Links

[ARC Training Materials](#)

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



Folder for Rebecca PI

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- **Monitor** - Check the progress of your submissions using the other tabs. Items under these tabs do not require any action by you.

Inbox IRB IACUC Approved Studies **Profile** COI

Any training profiles/certifications on record in the system are displayed here.

My Profile Link

Name	Status
Rebecca Simms (PI)'s Profile	Active

IRB Training Records

Biosketch/CV	IRB Certification Renewal Deadline	IRB Certification Document
Simms CV(0.01)		

Uploading IACUC Training

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

Current State

Active

Edit Researcher Profile

Printer Version

My Activities

Verify IACUC Training and Certification

Rebecca Simms (PI)'s Profile

Department: GASTROENTEROLOGY

Created: 12/13/2010 4:55 PM

Last Modified: 6/13/2012 9:18 AM

My Research Associates:

Last Name	First Name	E-Mail	Phone	Mobile	Profile
There are no items to display					

History Log IRB IACUC Research

Activity	Author	Activity Date
IACUC Certification Status Updated	Tortelli, Carla	6/13/2012 9:18 AM EDT

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**.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 1 Master Profile Settings >> Continue >>

Researcher Profile

1.1 * Profile Name:
Rebecca Simms (PI)'s Profile

1.2 * Select all that apply to your research activities at USF:

IRB I conduct research requiring approval from Institutional Review Board(IRB)

IACUC I conduct research requiring review by an Institutional Animal Care and Use Committee(IACUC)

1.0

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.

Animal Researcher Training & Experience

The following information is required for IACUC Certification. Once all fields have been completed, the IACUC will be notified to verify this information.

Pending IACUC Review? no
This record was last verified by the IACUC on: 3/30/2012

3.1 * **Animal Experience - click add and complete the form for each species with which you will be working:**

Species	Years Experience
Mouse	5

3.2 **Documentation of Facility Orientation and/or Wildlife Orientation:**
 Facility Orientation (LSC)(0.01)

3.3 **Documentation of Online Training Completion:**
 Training (LSC)(0.01)

3.4 **Documentation of Health and Risk Assessment:**
 Health and Risk (LSC)(0.01)

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:

USF UNIVERSITY OF SOUTH FLORIDA arc

Rebecca Simms (PI) | My Home | Logoff

Home - ARC Development | IRB Studies | IACUC | COI

IACUC > 3/30/2012 Testing Session

Current State 1

1. Pre Submission

Edit Study 4

Printer Version 5

View Differences

View Smartform Progress

Pending Ancillaries

Biosafety Reviewer

My Activities 6

Submit Study for Veterinarian Review

Withdraw

Script Execution Activity

(Template: Initial)

Study: 3/30/2012 Testing Session (IS00000087)

Additional Titles:

Principal Investigator: Lilith Stermin-Crane

Secondary Study Contact(s): Rebecca Simms (PI)

Last Updated: 6/6/2012 8:34 AM

Protocol Type: Research or Teaching

History | Attachments | Ancillary Review Status | Change Log | Reviewer Notes

Activity	Author	Activity Date
Study Created	Stermin-Crane, Lilith	3/30/2012 1:42 PM EDT

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.

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

- 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.
- 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.
- 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.

Page for Lilith Sternin-Crane

Study Staff

Page for Lilith Sternin-Crane

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- Monitor** - Check the progress of your submissions using the other tabs. Items under these tabs do not require any action by you.

Inbox **IRB** **IACUC** **Approved Studies** **Profile** **COI**

Displays all items which require action by the study team. Click on links for more information.

Filter by ID [Advanced](#)

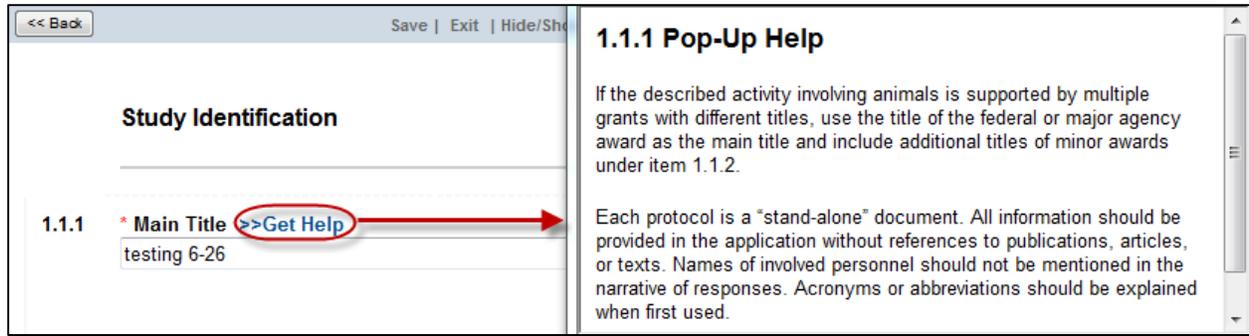
ID	Name	Date Modified	Type	Owner	State	Last State Change
IS00000112	RP Test	7/12/2012 10:12 AM	IACUC Study		1. Pre Submission	7/12/2012 10:12 AM
IS00000089	03/30/2012 Testing Session	7/5/2012 12:36 PM	IACUC Study	Crane, Frasier	4. Changes Recommended By Veterinarian	6/28/2012 2:17 PM

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

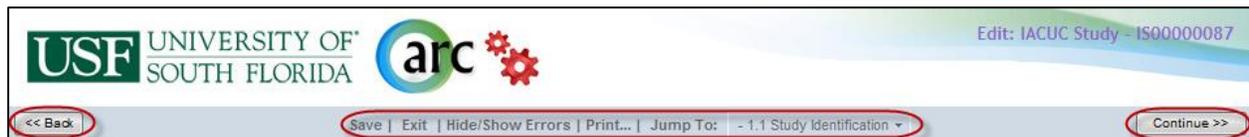
All applications in ARC use **SmartForms**. Since these forms only present questions relevant to your study, it is important that you respond to each question displayed on the SmartForms.

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.

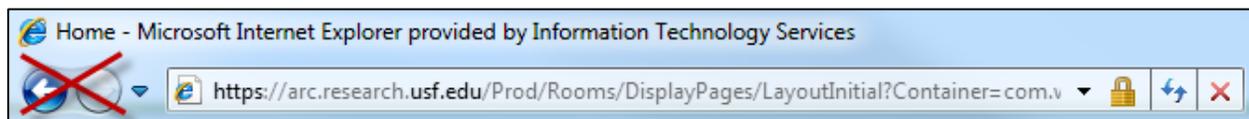


You can answer text questions by typing directly into the text box or by pasting in text from other documents. The **Add** function allows you to attach relevant documents or select your answer from a pre-populated list depending on the question.

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**!

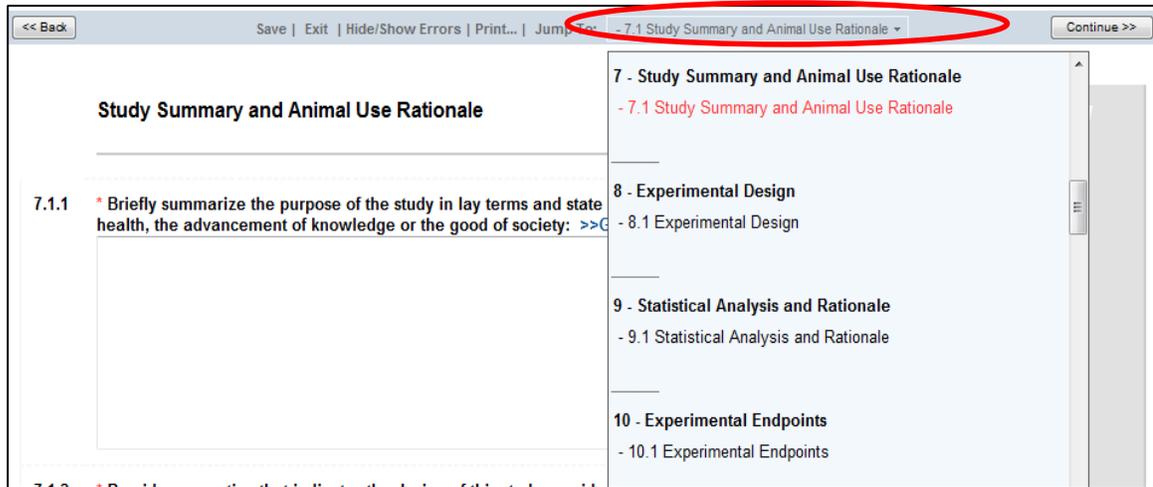
Use **Exit** to close the application and return to that application's Workspace.

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.

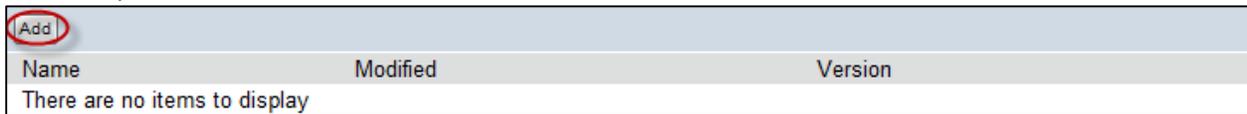
Once new or revised data on a page has been saved, you can navigate directly to other sections and questions by using the **Jump To** drop-down menu. The title of the displayed page will be **red**.

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.



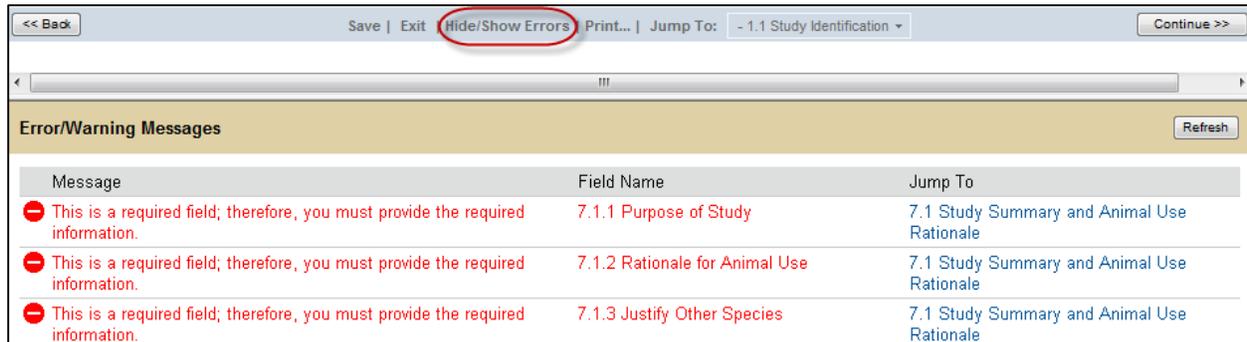
Before attaching a document, be sure you have named it using an accurate description as your approval letter may contain references to these documents as named in the SmartForm. Use the **Browse** button to locate the file, name it in the **Title** field, and select **OK** to add the document to the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

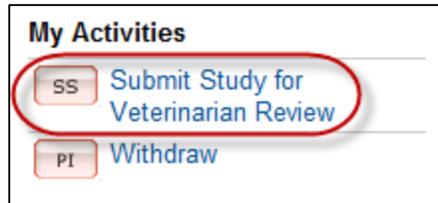
Before submission, all study team members should verify that the personnel certification information displayed on section 1.3 of the application is current.

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*.



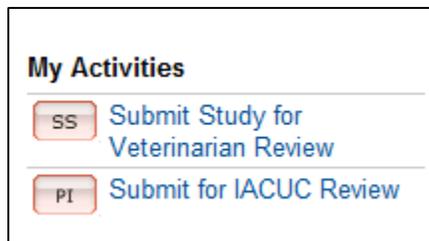
2. ARC will run a final validation check on the entire application before submission. If there are any required fields that have been left blank, they will be indicated and your application will not be submitted. The application must be error-free before it can be submitted.
3. After the application 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.

Type	Reviewer	Date Created	Date Modified
Veterinarian Change Request Jump To: 1.1 Study Identification	Coach Ernie	4/11/2012 3:00 PM	4/11/2012 3:00 PM

note 1

Response Required! Click here to respond...

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.

Reviewers can respond to a request by clicking on the **Response Required! Click here to respond...** link.

Type	Reviewer	Date Created	Date Modified
VET Veterinarian Change Request	Coach Ernie	4/11/2012 3:00 PM	4/11/2012 3:00 PM

note 1

Response Required! Click here to respond...

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**.)

Study Staff can submit their responses by clicking on the **Submit Study for Veterinarian Review** activity.

Activity
VET Changes Recommended by Veterinarian
5 Reviewer Notes Logged.
VET Assigned to Frasier Crane
SS Study submitted for Veterinarian Review
Study Created

My Activities

- SS **Submit Study for Veterinarian Review**
- PI Submit for IACUC 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.

1

ID	Name	Date Modified	Type	Owner	State	Last State Change
IC00000021	2013 Review for IS00000087	6/13/2012 3:33 PM	IACUC Continuation	Simms (PI), Rebecca M	1. Pre Submission	6/13/2012 2:48 PM
IS00000108	asdf	6/11/2012 9:20 AM	IACUC Study		1. Pre Submission	6/11/2012 9:10 AM

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

ID	Name	Date Modified	State
IS00000088	Surgical Techniques in Nonhuman Primate Cataract Surgery	6/22/2012 10:46 AM	18. Approved
IS00000092	Targeting cancer with calorie restriction, ketogenesis and hyperbaric oxygen	6/21/2012 9:14 AM	18. Approved

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).

Study: Mod/Continuation Testing (IS00000106)

Additional Titles:

Principal Investigator: [Rebecca Simms \(PI\)](#) **Secondary Study Contact(s):** [Rebecca Simms \(PI\)](#)

Approval Date: 6/8/2012 **Protocol Type:** VA ACORP

Expiration Date: 6/8/2013 **Letter of Approval:** [View](#) **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).

IACUC > Mod/Continuation Testing

Current State
18. Approved

View Study
Printer Version
View Differences

My Activities
Request Study Closure
New Modification
Annual Continuation

Study: Mod/Continuation Testing (IS00000106)

Additional Titles:

Principal Investigator: Rebecca Simms (PI) Secondary Study Contact(s): Rebecca Simms (PI)

Approval Date: 6/8/2012 Protocol Type: VA ACORP

Expiration Date: 6/8/2013 Letter of Approval: [View](#)

History Modifications Continuations Change Log

Activity	Author	Activity Date
Coor Reset Approval Period	Tortelli, Carla	6/8/2012 3:27 PM EDT
Project Snapshot Generated	Tortelli, Carla	6/8/2012 3:27 PM EDT

View Project Snapshot

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.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 1.1 - Modification Request Continue >>

Modification Request for IACUC Study

Mod 1.1

- 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

1.1.1 * Please select the appropriate modification type:

Amendment Amendments to existing protocols are limited to:

- 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

Written IACUC approval is required prior to implementing any changes.

Procedural Change Procedural changes can include any amendment topic mentioned above and any changes to the protocol which remain within the scope of the original research hypothesis, and involve the original species. Written IACUC approval is required prior to implementing any changes.

Clear

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)

IACUC > Procedural Change Guidance > Modification 4 for IACUC Study #IS00000188

Current State

1. Pre Submission

[Edit Modification](#)

[Print-Friendly Modification](#)

[View Differences](#)

My Activities

PI [Submit Amendment to IACUC](#)

SS [Withdraw](#)

C [Create Print SmartForm](#)

Modification: Modification 4 for IACUC Study #IS00000188

Principal Investigator: Lilith Stermin-Crane	Secondary Study Contact(s): Lilith Stermin-Crane
Protocol Type: Research or Teaching	Modification Type: Amendment
Date Submitted: Unsubmitted	

History
Reviewer Notes
Change Log

Activity	Author	Activity Date
Created Modification	Stermin-Crane, Lilith	7/24/2014 9:46 AM

(Example Procedural Change)

IACUC > Mod/Continuation Testing > Modification 1 for IACUC Study #IS00000106

Current State

1. Pre Submission

Edit Modification
Print-Friendly Modification
View Differences

Edit Modified Study
Print-Friendly Study
View Differences

My Activities

Submit for Veterinarian Review
Withdraw

Modification: Modification 1 for IACUC Study #IS00000106

Principal Investigator: Rebecca Simms (PI) Secondary Study Contact(s): Rebecca Simms (PI)

Protocol Type: VA ACORP Modification Type: Procedural Change

Date Created: 6/8/2012 4:10 PM Date Submitted: *Unsubmitted*

History Attachments Reviewer Notes

Activity	Author	Activity Date
Created Modification	Simms (PI), Rebecca M	6/8/2012 4:10 PM EDT

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.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 1.1 - Continuation Continue >>

Reviewer Note

Type	Reviewer	Date Created	Date Modified
There are no items to display			

Continuation of IACUC Animal Use Protocol

1.1.1 * Study Status:

Protocol will continue as approved and requires IACUC Approval for Continuation
Clear

If you have completed all activities related to this protocol, or if the protocol will not be activated, click the back button and select "Request Study Closure" to close the protocol.

Animals ordered and maintained in support of this study cannot be used on or after the closure date. Animals maintained under a protocol scheduled for closure must be reassigned to an approved protocol prior to the closure date. In the event any animals have not been appropriately reassigned by the closure date, these animals will be placed in Comparative Medicine "care-taker status", not available for research use until resolution of non-compliance.

CR 1.1

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.

IACUC > Mod/Continuation Testing > 2013 Continuation for IS00000106

Current State
1. Pre Submission
[Edit Continuation](#)
[Printer Version](#)
[View Differences](#)

My Activities
SS [Submit Continuation](#)
SS [Withdraw](#)

Continuation: 2013 Continuation for IS00000106 IC3_IS00000106
Principal Investigator: [Rebecca Simms \(PI\)](#) **Secondary Contact(s):** [Rebecca Simms \(PI\)](#) GASTROENTEROLOGY

Study Status: Protocol will continue as approved and requires IACUC Approval for Continuation

History **Change Log** **Reviewer Notes**

Activity	Author	Activity Date
Created Continuation	Drake, Cara	6/25/2012 11:55 AM EDT

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.

Current State
18. Approved
[View Study](#)
[Printer Version](#)
[View Differences](#)

My Activities
PI [Request Study Closure](#)
[New Modification](#)

Study: 3/30/2012 Testing Session (IS00000087)
Additional Titles: Revision testing - Take 2
Principal Investigator: [Lilith Stermin-Crane](#) **Secondary Study Contact(s):** [Rebecca Simms \(PI\)](#)
Approval Date: 6/13/2012 **Protocol Type:** Research or Teaching
Expiration Date: 6/13/2013 **Letter of Approval:** [View](#)

History **Modifications** **Continuations** **Change Log**

Activity	Author	Activity Date
Modification Completed	Tortelli, Carla	6/13/2012 3:19 PM EDT
Continuation Opened	Simms (PI), Rebecca M	6/13/2012 2:48 PM EDT

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.