

iStar IACUC PI Reference Guide

Last Updated: 12/21/17

Table of Contents

Questions and Issues	1
New Protocols	2
Authorized Submitters	6
Addressing Stipulations	7
Amendments and Renewals	8
Withdrawing Protocols, Amendments & Renewals	10

Questions and Issues

For policies related questions and issues including how to fill out the application, please contact the **Department of Animal Resources**:

Email: daradm@usc.edu

Phone: (323) 442-1689

For technical related issues, please contact the **iStar Technical Support**:

Email: istar@usc.edu

Phone: (323) 276-2238

New Protocols

1. After logging into the iStar system, click on the **IACUC** tab under the red banner. Click on **New Animal Protocol** to start a new animal protocol.

USC University of Southern California

IACUC Development

Hello, John Doe

- Dashboard
- IRB
- IACUC**
- IBC
- RSC
- Home

Amendments Renewals Monitoring Reports Non Compliance Reports

Sub Pages

- Amendments
- Renewals
- Monitoring Reports
- Non Compliance Reports

Create Protocol

New Animal Protocol

USC Institutional Animal Care and Use Committee

This page contains IACUC Protocols for USC. To view **Amendments** and **Renewals**, please use the left hand navigation menu.

[IACUC PI Reference Guide](#) | [Submission Deadlines](#) | [FAQs](#)

For **Policy-Related** questions, please contact the USC Department of Animal Resources at (323) 442-1689.
For **Technical issues**, please contact the iStar Technical Support at (323) 276-2238.

In Progress Pre Submission Approved Archived or Expired All Protocols

Filter ID Enter text to search for Go + Add Filter x Clear All

No data to display.

page 1 no results 25 / page

Need Help?
Contact the iStar Technical Support Desk:
(323) 276-2238
istar@usc.edu
Copyright © 2017 University of Southern California

Quick Links:
CHLA Institutional Review Board | (323) 361-2265
USC Health Sciences Institutional Review Board | (323) 223-2340
USC University Park Institutional Review Board | (213) 821-5272
USC Institutional Animal Care and Use Committee | (213) 821-5272
USC Environmental Health and Safety | (323) 442-2200

2. After clicking on the button for a new protocol, you will be directed to the first page of the application. Be sure to save often by clicking on **Save** towards the middle top or middle bottom of the page. Clicking on the **Continue** button will also save your work. However, clicking on **Back** button will not.

USC University of Southern California

IACUC Development

New: IACUC Protocol

« Back Save Print Continue »

"Back" will not save your work

"Save" and "Continue" will save your work

1. General Information, Project Personnel and Funding

You must complete all items on this first page and save this page to establish a new electronic protocol file. Once the electronic file is established, you will be able to complete other sections, save your work, log off, and return to the protocol file as many times as necessary to complete the protocol before submission.

1.1. * Project Title (must match that listed in the grant proposal): Guidance

1.2. Submission Type:

- New Protocol
- Competitive Renewal
- Stipend/Fellowship
- Program Project/Core Grant

Clear

Continue filling out different parts of the form and save your progress. It is not necessary to fill out the form completely to save. You can always save changes and fill out remaining sections at a later time.

IMPORTANT: It is highly recommended that you can complete the protocol chronologically since your answers in earlier sections would dictate what would be required to be completed in subsequent sections.

3. Section 1.4 – Add Personnel

Add IACUC_Other Study Staff

: (0)

Add Person to Protocol Staff:

Every person who will come into contact with the animals used on this project must be represented.

If you cannot find the person in iStar, have them request an iStar account by clicking on the "Obtaining an iStar Account" link at <http://istar.usc.edu>.

Select the role that best fits the work that he or she will do. If you cannot find a suitable one, select "Other" and type in the role in the box provided.

IMPORTANT: Personnel designated as PI, Co-PI, Study Contact Person will get email notifications at various phases of the protocol including, but not limited to, reminders of renewals and approvals.

* Person: ...

* Role:

All protocol staff members must complete all training requirements. This includes principal investigators and co-investigators regardless of whether they answer yes or no to whether they will have contact with study animals. However, administrative staff members and others performing tasks such as statistical analysis who truly do not handle or have contact with animals may check no and will be exempted from training requirements.

* Required

OK OK and Add Another Cancel

When you reach Section 1.4, make sure a PI is specified. If there are any other people working on the protocol, please specify them in this section as well. For individuals doing administrative work, you can designate the person as a **Study Staff Member**. Depending on the role, you can specify whether or not the person will be in contact with animals. If there is no contact with animals, no training is required for the individual.

IMPORTANT: Personnel designated as PI, Co-PI, Study Contact Person will get email notifications at various phrases of the protocol.

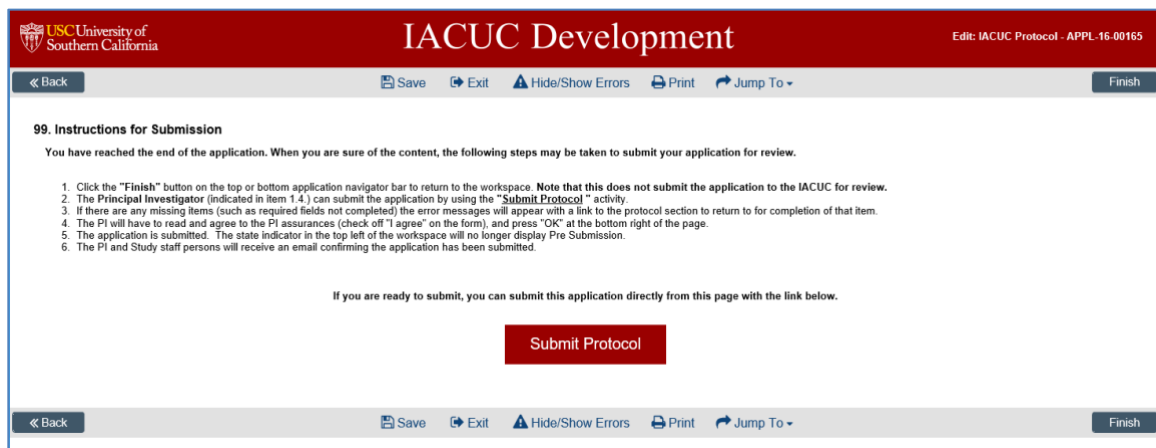
4. Section 3 involves **Species**:



You need to first click on the **Add Species** button to add the species related to your protocol. A popup will appear allowing you to select the species to be added. Once the species are added, an **Edit Procedures** button will appear to allow you to modify its associated pages. The **Remove** button next to the species will remove it from your protocol.

After everything is completed in the Species section, be sure to click **Exit** in the upper middle section or lower middle section of the page to exit the Species section and return back to the main protocol section. You can add as many species as necessary in section. Repeat editing all the associated pages for all the species that you have added to your protocol. You will need to complete all of the relevant sections for each of the species selected.

5. Go through the additional sections of the protocol to the last section. Once you in the last section, select the **Finish** button. If you ready to submit, you can click on the **Submit Protocol** button.



6. Alternatively, you can also submit the protocol by clicking on the **Submit Protocol** activity in the main protocol page. If you change your mind about submitting the protocol, you can choose to **Withdraw** the protocol. If you have

questions regarding your protocol, you can **Send Message to IACUC**. All these things can be accessed in the **Activities** section in the left hand navigation of the main protocol page.

The screenshot shows the IACUC Development web application. At the top, there is a red header with the USC University of Southern California logo and the text "IACUC Development". Below the header is a navigation menu with tabs for "Dashboard", "IRB", "IACUC", "IBC", "RSC", and "Home". The "IACUC" tab is selected. Below the navigation menu, there are sub-tabs for "Amendments", "Renewals", "Monitoring Reports", and "Non Compliance Reports". The main content area is divided into several sections. On the left, there is a "Current State" section with buttons for "Pre Submission", "Edit Protocol", "Printer Friendly Version", and "View Changes". Below this is an "Activities" section with a red border, containing options like "Move Forward", "Submit Protocol", "Manage", "Copy IACUC Protocol", "General", "Send Message to IACUC", and "Withdraw or Close". The main content area displays "test" and "Protocol APPL-16-00165". A "Summary" section shows protocol details: Principal Investigator: John Doe, Submission Type: New Protocol, Project Type: Research, Species: Mouse, and Study Contact: Jerry To. Below the summary, there are status indicators: "Not Reviewed by IBC" and "Not Reviewed by RSC". A "History" section shows a table with columns for "Activity", "Author", and "Activity Date". The table contains one entry: "Protocol Created" by "Doe, John" on "2/24/2016 11:39 AM".

IMPORTANT: Only the Principal Investigator can initially submit and withdraw the protocol. Authorized Submitters can do subsequent submissions of changes, renewals and amendments on the behalf of Pis.

Congratulations, you have submitted a new protocol!

Authorized Submitters

Beginning in late 2017, PIs can now designate individuals to do submissions of changes, renewals, amendments and withdrawals on their behalf at the time of protocol submission and anytime thereafter in activity called **Adjust Authorized Submitters**.

The screenshot shows the IACUC Development web application. The top navigation bar includes 'Dashboard', 'IRB', 'IACUC', 'IBC', 'RSC', and 'Home'. The main content area shows details for 'Protocol 20817' with a 'Current State' of 'Approved'. A sidebar on the left contains a menu with 'Adjust Authorized Submitters' highlighted by a red arrow. Below the protocol details is a 'History' table with columns for 'Activity', 'Author', and 'Activity Date'.

Activity	Author	Activity Date
20817: Approved	Kwong, Johnson	12/21/2017 11:24 AM
Changes Submitted	Doe, John	12/21/2017 11:17 AM
Changes Requested	Kwong, Johnson	12/21/2017 11:09 AM
Protocol Submitted	Doe, John	12/21/2017 11:08 AM

Authorized Submitters

If you wish, you can designate individuals who will be able to do subsequent submissions of changes, renewals and amendments on your behalf by checking off the checkbox next to their name:

First Name	Last Name	Department	
<input type="checkbox"/>	Johnson	Kwong	USC-CHLA iStar Information Technology

These settings can be modified by you at any time using the **Adjust Authorized Submitters** activity.

* I Agree to let the selected individuals above to submit on my behalf. I understand that I still remain fully responsible for the contents of the protocol:

Authorized Submitter section in Submit Protocol activity

The PI still needs to do the initial submission. However, after the initial submission, authorized submitters can do everything else. In order for an individual to appear in the checkbox list to be selected, they need to be added as personnel in section 1.4.

Addressing Stipulations

Protocols, amendments, and renewals can be returned to the PI to address stipulations. These stipulations can be found in the History Log. Anybody listed in section 1.4 of the protocol can address the stipulations by using the **Edit Protocol** button. However, only the PI and Authorized Submitters will have the **Submit Changes** activity to submit the changes. The **Submit Changes** activity is located in the **Activities** section on the left hand navigation of the main protocol page.

The screenshot displays the ISTAR system interface. On the left, the 'Activities' section includes 'Submit Changes'. A red arrow points to the 'History Log' tab, with the text 'Stipulations can be found in the History Log'. The main content area shows a 'Summary' section with fields for 'Principal Investigator', 'Submission Type', 'Project Type', and 'Species'. Below this is a 'History' section with a filter set to 'Activity' and a list of activities: 'Changes Requested', 'Please make changes to Mouse 1.5', 'Protocol Submitted', and 'Protocol Created'. A red arrow points to the 'Protocol Submitted' activity. On the right, a modal dialog titled 'Submit Changes' is open. It contains a text area for 'Description of Changes Made:' and an 'Attachments' section. A red arrow points to the text area with the text 'Add a description of the changes and click OK to submit the changes'. At the bottom of the dialog are 'OK' and 'Cancel' buttons.

A new popup would appear after clicking the **Submit Changes** activity:

In the space provided, describes the changes that were made. You can also attach any related documents. When you are finished, click the **OK** button to submit.

Amendments and Renewals

Amendments and Renewals can be created in Approved and Expired protocols by clicking on the respective activity in the **Activities** section of the left hand navigation.

The screenshot displays the IACUC Development web application interface. At the top, there is a navigation bar with tabs for Dashboard, IRB, IACUC, IBC, RSC, and Home. Below this, there are sub-tabs for Amendments, Renewals, Monitoring Reports, and Non Compliance Reports. The main content area is divided into several sections:

- Current State:** Shows the protocol is in an "Approved" state. There are buttons for "View Protocol" and "Printer Friendly Version".
- Activities:** A section with a "Manage" sub-section containing "Create New Amendment" and "Create New Renewal" buttons, which are highlighted with a red box. Other options include "Copy IACUC Protocol", "Send Message to IACUC", and "Adjust Authorized Submitters".
- Summary:** A table providing key details for Protocol 20817:

Principal Investigator:	John Doe	Study Contact:	
Submission Type:	New Protocol	Approval Date:	12/21/2017
Project Type:	Research	Expiration Date:	12/20/2020
Species:	Mouse	Renewal Due Date:	12/20/2018
		Approval Letter:	View
- History:** A table showing a list of activities related to the protocol:

Activity	Author	Activity Date
20817: Approved	Kwong, Johnson	12/21/2017 11:24 AM
Changes Submitted	Doe, John	12/21/2017 11:17 AM
Changes Requested	Kwong, Johnson	12/21/2017 11:09 AM
Protocol Submitted	Doe, John	12/21/2017 11:08 AM
Protocol Copied	Doe, John	2/24/2016 11:41 AM
Protocol Created	Doe, John	2/24/2016 11:39 AM

Main workspace for IACUC Protocol

If you are due for an Annual Renewal and you need to make changes, it is recommended that you create a renewal and choose the **Continuation with Changes** category. If you are due for a **Third Year** Renewal, you can select it here as well. Through this method, you can renew your protocol and make the necessary changes to it at the same time.

If you are due for **Annual Renewal without Changes**, you can submit your renewal directly after creating the renewal because no changes need to be made.

IMPORTANT: Only one Amendment or Renewal can be opened at one time.

Security

IACUC Protocol: test (20817)

Create New Renewal

If any unanticipated adverse effects of pilot studies not described in the original protocol have occurred during the course of the study, a complete description of those adverse effects or results of pilot studies, any actions taken in response to them, and a description of associated humane endpoints, must be submitted to the IACUC as an amendment to this protocol.

- Renewal Category:**
 - Continuation Without Changes
 - Continuation with Changes
 - Third Year Renewal

[Clear](#)
- Were there any unanticipated problems / adverse effects of your procedures on animals encountered?**
 - Yes No [Clear](#)
- Was a pilot study conducted during the previous year that resulted in new funding, changes to experimental procedures, or changes to humane endpoints?**
 - Yes No [Clear](#)
- Have you been cited for non compliance issues?**
 - Yes No [Clear](#)
- Does the Funding Agency require a letter of approval?**
 - Yes No [Clear](#)
- Have you completed the annual laboratory refresher training on animal care and use with your laboratory staff during the past 12 months?**
 - Yes No [Clear](#)

Note that completion of the annual refresher training is mandatory. However, do not send your checklist or personnel sign in sheet to the Department of Animal Resources. This documentation should be maintained with your laboratory records and should be available for inspection by the IACUC on request.

The refresher training checklist and sign-in sheet are available on the Department of Animal Resources web site:
<https://dar.usc.edu/files/2012/04/Animal-Care-and-Use-Annual-Refresher-Training-for-Lab-Staff-1.pdf>

IACUC Protocol: test (20817)

Create New Amendment

If your protocol is entirely on iStar and changes need to be made, you can create an Amendment electronically.

Please note that only one Amendment or Renewal can be opened at one time.

- Amendment Name:**
Undescribed Changes
- Description of Changes:**
 - Change of Title
 - Change of Funding Agency
 - Addition or deletion of study personnel (other than PI)
 - Change or addition of procedures that do require anesthesia
 - Change or addition of procedures that do not require anesthesia
 - Increase in animal numbers with justification
 - Change of the animal strain
 - Change or addition of procedures involving biohazards
 - Change or addition of procedures involving radiation
 - Other
- Description of Amendment:** Provide a brief description of the changes you will be making to the protocol. If you are changing the title, funding agency, or increasing the animal numbers, provide justification for the changes.

IMPORTANT!

After you click "OK" below, you will still have to make the changes noted above inside the protocol application in all relevant sections.

In some cases, this may involve changes to multiple sections. For example, addition of a new mouse strain may involve changes to sections 5.2 (experimental study groups), 1.3 and 1.4 (animal numbers), 7 (biohazards), 9 (breeding), and 12 (genetically engineered animals).

To make the changes, please click "Edit Protocol" in the Amendment page. You can access the Amendment page by clicking on the "Amendments" tab towards the middle of the Protocol page once this popup closes.

Popups for Create New Renewal and Amendment activities

Withdrawing Protocols, Amendments & Renewals

Protocols, Amendments, and Renewals can be withdrawn at any time by using the **Withdraw** activity located in the **Activities** section of the left hand navigation by the PI or Authorized Submitter. This activity is only available when the item is Pre Submission.

The screenshot shows the IACUC Development web application. The top navigation bar includes 'Dashboard', 'IRB', 'IACUC', 'IBC', 'RSC', and 'Home'. The main content area shows 'Current State' with 'Pre Submission' selected, and 'Activities' with 'Withdraw' highlighted by a red arrow. A summary box displays 'Principal Investigator: John Doe', 'Submission Type: New Protocol', and 'Project Type: Research'. A history table shows a 'Public Comment Logged' activity by 'Doe, John' on '2/24/2016 11:41 AM'.

A new popup would appear after clicking on the **Withdraw** activity.

The screenshot shows the 'Withdraw' popup window. It contains a text area for 'Please provide reason for withdrawal:', a section for 'Please attach all documents related to your decision:' with an '+ Add' button, and 'OK' and 'Cancel' buttons at the bottom. Red arrows point to the text area, the '+ Add' button, and the 'OK' button, with numbered instructions: '1. Provide a Reason', '2. Attach Documents', and '3. Click "OK"'. The text area is empty, and the document list is also empty.

In the space provided, state the reason for the withdrawal. You also attach any documents related to the decision. When you are finished, click the **OK** button.