

KUALI QUICKGUIDE

CREATING AND SUBMITTING IACUC PROTOCOLS IN KUALI

This document describes procedures for creating and submitting new and post-approval IACUC protocol applications in Kuali.

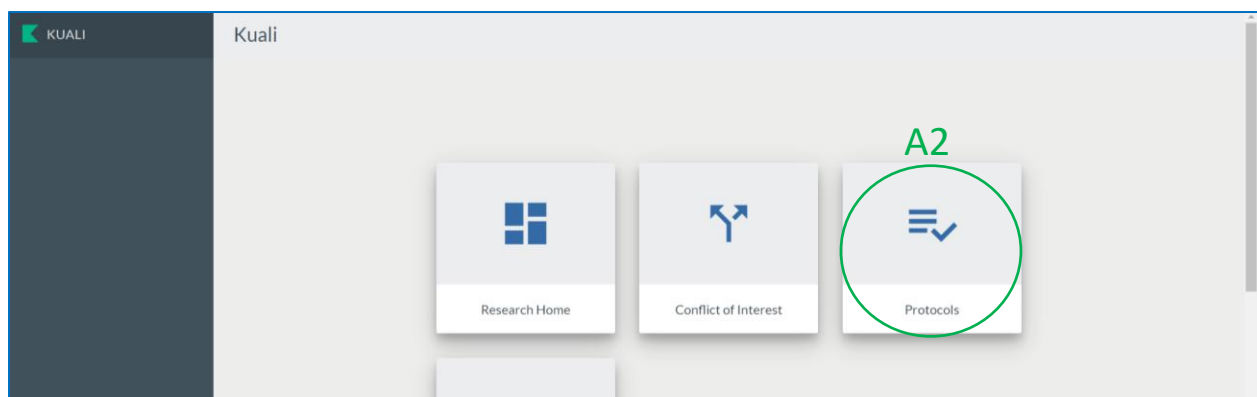
- A. [New Protocol – Initial Submission](#)
- B. [New Protocol - Resubmission](#)
- C. [Amendment](#)
- D. [Renewal](#)
- E. [Renewal & Amendment](#)
- F. [Reportable Event](#)
- G. [Closure](#)

A. NEW PROTOCOL - INITIAL SUBMISSION

1. Log into Kuali:

- LSUHSC Personnel (individuals **with** an active @lsuhsc.edu email address): <https://lsuhsc.kuali.co/cor/main/#/apps>.
- Non-LSUHSC Personnel (individuals **without** an active @lsuhsc.edu email address): <https://lsuhsc.kuali.co/auth/kuali>.
- Please contact the IACUC Office (IACUCOffice@lsuhsc.edu) if you have any problems logging into Kuali.

2. Click on the **Protocols** button.



3. Next:

- On the **Manage Protocols** page;
- Click the **+ New Protocol** button; and
- Select **IACUC**.

The screenshot shows the 'Manage Protocols' page in Kuali. The left sidebar has a 'Manage Protocols' button circled in blue and labeled 'A3a'. The main content area has a '+ New Protocol' button circled in green and labeled 'A3b'. Below this button is a dropdown menu with 'IACUC' and 'IRB' options; 'IACUC' is circled in orange and labeled 'A3c'. The page also features a search bar, a table of protocols, and a 'Load 25 at a Time' dropdown.

Title	Number	PI Name	Submission Type	Review Type	Status	Assignment	Continuing Review Date
#3832 - Understanding and Addressing Cancer Health Disparities in Louisiana	1243	Ochoa, Augusto	New		In Progress		
Pilot Study of the effect of Bariatric Surgery on Obesity, Weight Loss and New Inflammatory Pathways	709	Ochoa, Augusto	Initial	Expedited	Expired		June 21, 2020
COVID-19 Biospecimen Collection	599	Ochoa, Augusto	Initial	Expedited	Approved		April 05, 2023

4. You will arrive at the **General Information** page of the IACUC Protocol Form. Provide the requested information and then click **Next**.

← Hide Menu
Manage Protocols

IACUC - General Information

Project Title:
Understanding and Addressing Cancer Health Disparities in Louisiana

Principal Investigator:
Start typing the name of the individual and select from the drop down list.
Ochoa, Augusto

Department:
Click on the down arrow and select the department.
Center of excellence-Cancer

Projected start date:
August 2, 2021

Estimated Duration of Project (months or years):
3 years

If desired, designate a person whom Animal Care staff should initially contact for animal welfare issues within the vivarium before contacting the PI:
This person must be listed in the Project Personnel table below:
Zheng, Liqin

Cancel
→ Next **A4**

5. The core **IACUC Protocol Form** will be displayed including the information entered on the previous page.
- a) The **Type** and **Status** of the protocol will be indicated.
 - b) The **right side panel** will allow several different actions. The **Submit** button will be grayed out (not active) unless the person preparing the submission is the Principal Investigator. (Submission instructions are provided below starting at Step A9).
 - c) The **left side panel** will display the core sections of the Protocol Form.

← Back Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in Louisiana

PROTOCOL ACTIVITY LOG

Pages Expand Navigation
PROTOCOL FORM
INTRODUCTION
GENERAL INFORMATION...
FUNDING SOURCE(S)

Version: 1 | New | In Progress

Protocol Information

Submission Type: New Status: In Progress **A5a**

IACUC PROTOCOL FORM

In Kual, a research project or study application is referred to as a "protocol." This protocol module (form) is used for submitting all new protocols to the IACUC for initial review. Please place your pointer on the Help icon, ? to view important information and instructions about this module.

GENERAL INFORMATION

A5c **A5b**

Notify PI To Submit
Admin Notes & Files
Abandon
Submit
Print

6. Scroll down the Protocol Form and answer the displayed questions. Additional sections of the form will appear as questions are answered.

A6

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PROTOCOL ACTIVITY LOG

Pages Expand Navigation

PROTOCOL FORM

- INTRODUCTION ✓
- GENERAL INFORMATION... ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓
- PROJECT PERSONNEL ✓
- OTHER REGULATORY APP... ✓
- PROGRESS REPORT
- NON-SCIENTIFIC SUMMARY
- EXPERIMENTAL DESIGN
- ANIMAL IDENTIFICATION ...
- PAIN & DISTRESS CLASSIF...
- DRUGS & OTHER AGENTS
- BIOLOGICAL MATERIALS &...
- ADVERSE EFFECTS
- END OF USE ANIMAL DISP...
- NON-ANIMAL ALTERNATIV...

PROJECT SCOPE

As part of this project, will any animal work be conducted at an institution external to LSUHSC-NO?

☐ Yes ☒ No

Does this project involve the use of non-human primates?

☐ Yes ☒ No

Are you requesting an exception from social/pair housing of social animal(s)?

☐ Yes ☒ No ☐ Not Applicable

Will blood be collected from any live animals?

☐ Yes

Notify PI To Submit
Admin Notes & Files
Abandon
Submit
Print

7. Some questions require an answer while others do not. In some, but not all, sections an error message will display if a required field is left empty.
 - a) **NOTE:** In the **Project Personnel** section, the status of KDS and CITI required training automatically will be displayed for the listed researcher. You will have to provide information about other training such as DOAC courses conducted in classrooms. If training is missing but the submission is otherwise complete, the protocol will move forward for review. However, all required training must be complete prior to approval of the protocol.

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in Louisiana

PROTOCOL ACTIVITY LOG

Pages Expand Navigation

PROTOCOL FORM

- INTRODUCTION ✓
- GENERAL INFORMATION... ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓
- PROJECT PERSONNEL 1
- OTHER REGULATORY APP... ✓
- PROGRESS REPORT
- NON-SCIENTIFIC SUMMARY
- EXPERIMENTAL DESIGN
- ANIMAL IDENTIFICATION ...
- PAIN & DISTRESS CLASSIF...
- DRUGS & OTHER AGENTS
- BIOLOGICAL MATERIALS &...
- ADVERSE EFFECTS
- END OF USE ANIMAL DISP...
- NON-ANIMAL ALTERNATIV...

PROJECT PERSONNEL

Columns + Add Line

NAME	RESEARCHER ROLE	ACTIVITIES	TRAINING IN SYSTEM
Ochoa, Augusto	Principal Investigator	Required	KDS - COI in Research 06/14/18 - 06/14/22 KDS - BBP High Risk 05/25/20 - 05/21/21 Expired KDS - BBP Low Risk 06/11/18 - 06/11/23 KDS - AC Tri-annual OHSP Questionnaire 09/10/18 - 09/10/21 KDS - Laboratory Safety 08/16/19 - 08/16/21

Notify PI To Submit
Admin Notes & Files
Abandon
Submit
Print

8. Answer all questions or enter all data into fields.
 - a) **Green checkmarks** next to section names indicate completion.
 - b) Once the Protocol Form is complete, click **Next** to go to the **Protocol Submission** page.

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PROTOCOL FORM

NON-ANIMAL ALTERNATIVES

SUPPORTING DOCUMENTS

TABLE: SUPPORTING DOCUMENTS

List all supporting documents being submitted with this application:
If needed, click the "Add Line" button for additional rows.

	DOCUMENT TYPE	DOCUMENT DESCRIPTION	ATTACHMENT
	SOP	Cyclophosphamide	3832 2 CYCLOPHOSPHAMIDE SOP.PDF

Columns + Add Line

Next
PROTOCOL SUBMISSION

9. **Only the PI may submit the initial version of the protocol.**
 - a) If you are not the PI, the **Submit** button will be inactive.
 - b) Click **Notify PI to Submit**; then click **Send** in the pop-up window.

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in Louisiana

SUBMISSION INSTRUCTIONS

This Protocol may be submitted **ONLY** by the Principal Investigator.

- If you are not the PI, click the **Notify PI to Submit** button to alert the PI that the Protocol is ready for review and submission. Successful notification will be indicated by a gray bar across the button.
- If you are the PI, please go to the next section, **PI Certification & Submission**, to complete the process.

PI CERTIFICATION & SUBMISSION

Principal Investigator Certifications:

- I have overall responsibility for the work described here.

Notify PI to Submit

Submit

Notify PI to Submit

Are you sure you want to notify the PI that the protocol is ready for them to submit?

Cancel Send

10. The PI will receive an email notification that the protocol is ready for submission. The PI can access the protocol directly from a link in the email.

11. Once the **PI** has opened the protocol...

- a) He/She should click on the **down arrow** on the **Protocol Submission** tab and then click on the **PI Certification & Submission** section.

A11a

A11

PROTOCOLS

kuali

Ochoa, Augusto

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in Louisiana

PROTOCOL FORM

Version: 1 | New | In Progress

Protocol Information

Submission Type: New

Status: In Progress

IACUC PROTOCOL FORM

In Kualu, a research project or study application is referred to as a "protocol." This protocol module (form) is used for submitting all new protocols to the IACUC for initial review. Please place your pointer on the Help icon, ? , to view important information and instructions about this module.

GENERAL INFORMATION

PROTOCOL SUBMISSION

Notify PI To Submit

Admin Notes & Files

Abandon

Submit

Print

12. The PI must:

- a) **Certify & Acknowledge** the attestations and then ...
- b) **Submit** the protocol for review.

A12a

A12b

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in Louisiana

PI CERTIFICATION & SUBMISSION

As the Principal Investigator, I _____ the accuracy of the statements listed above and the responsibilities conveyed therein:

☒ Certify & Acknowledge

☐ Do Not Certify & Acknowledge

Submit for Review

Click "Submit" for the application to be sent to the IACUC Office for review. A member of the IACUC Office staff will contact you through KR if additional information or revisions are needed. You will receive a system-generated notification after the review has been completed and a determination has been made.

Notify PI To Submit

Admin Notes & Files

Abandon

Submit

Print

13. If any required questions or data fields are incomplete, an **error message** will appear. **Sections requiring attention** will also be indicated by **error icons**.

a) These errors may be corrected by the PI or the person who initially prepared the protocol but only the PI will be able to submit the protocol.

The screenshot shows the 'Manage Protocols' interface for IACUC #1252. The 'PI CERTIFICATION' section is highlighted with a red box and an 'Incomplete' error message: '4 fields have validation errors.' The left sidebar shows a list of sections with checkmarks, and the right sidebar shows action buttons: 'Notify PI To Submit', 'Admin Notes & Files', 'Abandon', 'Submit', and 'Print'.

14. Once all corrections have been fixed, the error icons and message will disappear; PI clicks **Submit**.

The screenshot shows the 'Manage Protocols' interface for IACUC #1252, now showing the 'NON-ANIMAL ALTERNATIVES' section. The 'Submit' button in the right sidebar is highlighted with a red circle and labeled 'A14'. The left sidebar shows a list of sections with checkmarks, and the right sidebar shows action buttons: 'Notify PI To Submit', 'Admin Notes & Files', 'Abandon', 'Submit', and 'Print'.

15. The **Status** of the protocol will change to **Submitted for Review** and...

a) The applicant will have a new option: **withdrawing** the protocol.

The screenshot displays the 'Manage Protocols' interface for IACUC #1252. The left sidebar lists protocol sections: INTRODUCTION, GENERAL INFORMATION, FUNDING SOURCE(S), PROJECT SCOPE, PROJECT PERSONNEL, OTHER REGULATORY, PROGRESS REPORT, NON-SCIENTIFIC SUMMARY, EXPERIMENTAL DESIGN, ANIMAL IDENTIFICATION, and PAIN & DISTRESS CARE, each with a green checkmark. The main content area is titled 'PROTOCOL' and shows 'Version: 1 | New | Submitted for Review'. Below this, the 'Protocol Information' section contains a table with four columns: Submission Type (New), Review Type (--), Status (Submitted for Review, circled in green with 'A15' above it), and Time in Current Status (Since June 19 - a few seconds). A right sidebar contains 'Admin Notes & Files' with 'Withdraw' (circled in red with 'A15a' next to it) and 'Print' buttons. A footer note explains that in Kuali, a research project or study application is referred to as a 'protocol' and provides instructions on how to use the module.

16. A system generated email will notify the **IACUC Office** of the submission.

17. The IACUC Admin will facilitate administrative and Committee review of the protocol.

NOTE: *If the protocol is incomplete and requires revisions prior to committee review, it will be returned with action items. If the protocol is ready for committee review and training is still needed, you can check to see what is pending by clicking on the "General Action Items" tab to view administrative pre-review notes.*

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B. NEW PROTOCOL - RESUBMISSION

After administrative or committee review, additional information or clarifications may be required before a final determination can be made. Through a system generated email, the IACUC Administrator will notify the PI and study personnel when protocol revisions are requested.

1. Access the protocol using the link in the email notification or log into Kuali as described in [Section A](#) and click on the appropriate protocol in the protocols table.
2. Once you have opened the protocol, please note the following:
 - a) A **2nd version** of the protocol will exist.
 - b) The status of the new version will be **Revisions In Progress**. Please make sure you are working on this version.
 - c) A text box labelled **Feedback** will be visible in this version. This text box will contain **general information or instructions from the IACUC Administrator** regarding the requested revisions. Please read any entries.
 - d) Some form sections will be marked with an **Action Item icon (numbered orange circle)**. These sections contain one or more action items/issues that you will need to address.
 - e) On the right side panel, you can click on the **Admin Notes & Files** tab to view any additional information provided by the IACUC Administrator. You can also click on **Action Items Summary** to view **all issues** that need to be addressed. The action items' authors will be anonymous; the reviewer names will not be identified.

The screenshot displays the Kuali protocol management interface for protocol #1252, 'Understanding and Addressing Cancer Health Disparities in Louisiana'. The interface is divided into several sections:

- Header:** Includes a 'Back' button and the protocol title.
- Protocol Details:** Shows 'Version: 2 | New | Revisions In Progress' and 'Status: Revisions In Progress'. A callout B2a points to the version information, and B2b points to the status.
- Protocol Form:** A list of sections on the left, including 'INTRODUCTION', 'GENERAL INFORMATION...', 'FUNDING SOURCE(S)', 'PROJECT SCOPE', 'PROJECT PERSONNEL', 'OTHER REGULATORY A...', 'PROGRESS REPORT', 'NON-SCIENTIFIC SUM...', 'EXPERIMENTAL DESIGN', 'ANIMAL IDENTIFICATI...', 'PAIN & DISTRESS CLAS...', 'DRUGS & OTHER AGEN...', and 'BIOLOGICAL MATERIA...'. Callout B2d points to the 'PAIN & DISTRESS CLAS...' section, which has an orange circle icon.
- Feedback Section:** A yellow box labeled 'Feedback' with a callout B2c pointing to it. It contains a text area for 'Revision Required Comment' and a prompt 'Please address all action items.'
- Right Panel:** Contains tabs for 'Action Items Summary' and 'Admin Notes & Files', and buttons for 'Resubmit', 'Abandon', and 'Print'. Callout B2e points to the 'Admin Notes & Files' tab.

Action Items Summary for Protocol #1252

^ Collapse All

^ PROTOCOL FORM / PAIN & DISTRESS CLASSIFICATION / Number of Animals / Item 1

Anonymous 06/24/21 · 10:43AM

Shouldn't all animals be listed under Category C since no analgesia, anesthesia, or sedatives are being used? Please confirm that 360 C57 mice are being requested not 340.

Show less

^ PROTOCOL FORM / DRUGS & OTHER AGENTS / Drug List / Item 1

Anonymous 06/24/21 · 10:33AM

Please add the cell lines being injected to this table. The Experimental Design section indicates that drugs will be administered once or twice daily but some drugs in this table are listed at a different frequency; please clarify.

Show less

^ PROTOCOL FORM / SUPPORTING DOCUMENTS / Attachments / Item 1

Anonymous 06/24/21 · 10:48AM

Please clarify if Cyclophosphamide will be used in this protocol; an SOP may not be necessary.

B2e

3. To view and address the action items:

- Click on the **section with an action item** to go to that section of the form.
- Click **Action Item**.
- The right side panel will display the **comments from the reviewer**.
- If edits are warranted, **edit the field** or text, as applicable.
- Click **Reply** on the right side panel.

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PROTOCOL

Pages Expand Navigation

PROTOCOL FORM

INTRODUCTION ✓

GENERAL INFORMATION ✓

FUNDING SOURCE(S) ✓

PROJECT SCOPE ✓

PROJECT PERSONNEL ✓

OTHER REGULATORY A... ✓

PROGRESS REPORT ✓

NON-SCIENTIFIC SUM... ✓

EXPERIMENTAL DESIGN ✓

ANIMAL IDENTIFICATI... ✓

PAIN & DISTRESS CLAS... **B3a**

DRUGS & OTHER AGEN... **B3b**

BIOLOGICAL MATERIA... ✓

ADVERSE EFFECTS ✓

END OF USE ANIMAL D... ✓

PAIN & DISTRESS CLASSIFICATION

List all animals (by species and, if applicable, individual strains) proposed for use in this study. Quantify the number of each species/strain that will be used under each listed USDA pain category. Count the animal only once. If an individual animal will be used in multiple experimental/pain categories, count the animal only in the highest pain category.

TABLE: ANIMAL TYPE AND NUMBER

If needed, click the "Add Line" button for additional rows.

Columns Add Line

SPECIES	OTHER SPECIES	STRAIN
Mouse		C57BL/6
Mouse		FVB

No Action Items

In the table below, calculate the total number of animals of each species listed in the previous table:

ACTIVITY LOG

Number of Animals / Item 1

Action Items **B3c**

Anonymous 06/24/21 · 10:43AM

Shouldn't all animals be listed under Category C since no analgesia, anesthesia, or sedatives are being used? Please confirm that 360 C57 mice are being requested not 340.

Show less

Visibility

Admins Assigned Reviewers Researchers Meeting

Reply **B3e**

4. Next:
 - a) **Summarize your response** to this action item.
 - b) Click **Post**.

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in Louisiana

PROTOCOL

ACTIVITY LOG

Number of Animals / Item 1

Action Items

Anonymous 06/24/21 · 10:43AM

Shouldn't all animals be listed under Category C since no analgesia, anesthesia, or sedatives are being used? Please confirm that 360 C57 mice are being requested not 340.

Show less

Visibility

Admins Assigned Reviewers Researchers Meeting

Animals moved to Cat C.

Cancel Post

B4a

B4b

B5a

B3d

B5b

5. Repeat this procedure for all action items left by the reviewer or IACUC Admin.
 - a) When you post your response to an action item, the **action item icon will disappear**.
 - b) Click **Resubmit**. *All study personnel with full access to the protocol can resubmit a protocol, not just the PI.*

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in Louisiana

PROTOCOL

ACTIVITY LOG

Jump to:

INTRODUCTION ✓

GENERAL INFORMATI... ✓

FUNDING SOURCE(S) ✓

PROJECT SCOPE ✓

PROJECT PERSONNEL ✓

OTHER REGULATORY ... ✓

PROGRESS REPORT ✓

NON-SCIENTIFIC SUM... ✓

EXPERIMENTAL DESI... ✓

ANIMAL IDENTIFICATI... ✓

PAIN & DISTRESS CLA... ✓

DRUGS & OTHER AGE... ✓

BIOLOGICAL MATERIA... ✓

PAIN & DISTRESS CLASSIFICATION

List all animals (by species and, if applicable, individual strains) proposed for use in this study. Quantify the number of each species/strain that will be used under each listed USDA pain category. Count the animal only once. If an individual animal will be used in multiple experimental/pain categories, count the animal only in the highest pain category.

Columns

SPECIES	OTHER SPECIES	STRAIN	CATEGORY B	CATEGORY C
Mouse		C57Bl/6		360
Mouse		FVB		

In the table below, calculate the total number of animals of each species listed in the previous table:

Columns

Species

Other Species

Total Animals

Action Items Summary

Admin Notes & Files

Resubmit

Abandon

Print

B5a

B3d

B5b

6. When the protocol is resubmitted:
 - a) A **new version** will be created.
 - b) The **status** will be updated to **Resubmitted**.
 - c) Several options on the **right side panel** will disappear or be grayed out.

The screenshot displays the 'Manage Protocols' interface for protocol #1252, 'Understanding and Addressing Cancer Health Disparities in Louisiana'. The interface is divided into a left sidebar, a main content area, and a right sidebar. The left sidebar lists various protocol sections with checkmarks, indicating they are complete. The main content area shows the 'Version' as '3 | New | Resubmitted' with a green box around it and a green 'B6a' label. Below this, the 'Protocol Information' section shows 'Submission Type' as 'New', 'Review Type' as 'Full Board', 'Status' as 'Resubmitted' (with a green box and a green 'B6b' label), and 'Time in Current Status' as 'Since June 24 - 2 days'. A text box below explains that in Kuali, a research project or study application is referred to as a 'protocol'. The right sidebar contains a 'B6c' label and a box with 'Admin Notes & Files', 'Withdraw', and 'Print' options.

7. A system generated email will be sent to the IACUC Administrator and PI notifying them of the resubmission.
8. The IACUC Admin will facilitate subsequent administrative and Committee review of the protocol.
9. **NOTE:** *Multiple resubmission-review cycles may be necessary before a final determination is made.*

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C. AMENDMENT

Investigators may propose modifications to approved protocols by submitting an amendment application for IACUC review.

1. Log into Kuali as described in [Section A](#) and click on the protocol in the protocols table.
2. Click the **Amend** button on the right side panel.

The screenshot shows the 'Manage Protocols' interface for IACUC #1252. The 'PROTOCOL' tab is active. On the right sidebar, the 'Amend' button is highlighted with a red box and labeled 'C2'. The main content area shows 'Protocol Information' for a 'Full Board' review, which is 'Approved'. The 'Version' dropdown is set to '3 | Initial | Approved'. The 'Feedback' section is empty.

3. Please note:
 - a. A **new version** of the protocol will be created.
 - b. The **Submission Type and Status** of this version will be **Amendment** and **In Progress**, respectively.
 - c. Only the PI can submit the initial version of the amendment application. If the person preparing the application is the PI, then the Submit button will be active. Otherwise, the **Submit** button will be grayed out and the **Notify PI to Submit** button will be active.

The screenshot shows the 'Manage Protocols' interface for IACUC #1252. The 'PROTOCOL' tab is active. The 'Version' dropdown is set to '5 | Amendment | In Progress' and is highlighted with a green box and labeled 'C3a'. The 'Protocol Information' section shows the 'Submission Type' as 'Amendment' and the 'Status' as 'In Progress', both highlighted with green boxes and labeled 'C3b'. The 'Feedback' section is empty. On the right sidebar, the 'Notify PI To Submit' button is highlighted with a red box and labeled 'C3c', and the 'Submit' button is also highlighted with a red box and labeled 'C3c'.

4. The **Amendment Form** will appear right below the Protocol Information section. Please read and follow the instructions.

The screenshot shows the 'AMENDMENT FORM' page. The header bar includes a 'Back' button and the text 'Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in Louisiana'. Below the header, there are three tabs: 'PROTOCOL', 'REPORTABLE EVENTS', and 'ACTIVITY LOG'. The 'PROTOCOL' tab is active. On the left, a 'Pages' sidebar lists various sections with checkmarks: INTRODUCTION, GENERAL INFORMATION, FUNDING SOURCE(S), PROJECT SCOPE, PROJECT PERSONNEL, OTHER REGULATORY A..., PROGRESS REPORT, NON-SCIENTIFIC SUM..., and EXPERIMENTAL DESIGN. The main content area is titled 'AMENDMENT FORM' and contains an 'Introduction & Instructions' section. The text explains that all amendments must be approved by the IACUC prior to implementation, except when necessary to eliminate apparent immediate hazards to animals. It also states that to request a modification to an approved study, the user must complete this AMENDMENT FORM AND edit the relevant sections of the currently approved PROTOCOL FORM. A link to 'Additional Instructions' is provided. On the right, there is an 'ACTIVITY LOG' sidebar with buttons for 'Notify PI To Submit', 'Admin Notes & Files', 'Abandon', 'Submit', and 'Print'.

5. In the **Amendment Questionnaire** section:
- Select the type of submission being prepared; **Amend alone** in this case.
 - Select the **type of modification** being proposed; more than one may be selected.

The screenshot shows the 'Amendment Questionnaire' page. The header bar is the same as the previous screenshot. The 'PROTOCOL' tab is active. The 'Pages' sidebar is the same. The main content area is titled 'Amendment Questionnaire' and contains a section titled 'Please select the option that best describes the application you are preparing:'. There are two radio buttons: 'Amend alone' (selected) and 'Renew + Amend'. A green box labeled 'C5a' is drawn around the 'Amend alone' radio button. Below this, there is a section titled 'Which modifications are being proposed for this study (select all that apply)?'. There are several checkboxes: 'Change of Principal Investigator', 'Change in personnel (other than PI)', 'Change of protocol title' (checked), 'Change in funding source', 'Change in animal location', 'Change in animal type or number' (checked), and 'Change in drugs or research material being used'. A green box labeled 'C5b' is drawn around the 'Change of protocol title' and 'Change in animal type or number' checkboxes. The right sidebar is the same as the previous screenshot.

6. Answer all questions on the Amendment Form.

7. The **justification** for the proposed changes is provided on the Amendment Form...

The screenshot shows the 'Manage Protocols' interface for IACUC #1252. The 'PROTOCOL' tab is active, and the 'Rationale/Justification' section is highlighted with a green box and labeled 'C7'. The section contains a text area for providing the reason for changing the protocol title and a rich text editor for providing a thorough justification of the proposed changes. The left sidebar shows the 'PROTOCOL FORM' with various sections like INTRODUCTION, GENERAL INFORMATION, etc., each with a checkmark. The right sidebar shows the 'ACTIVITY LOG' with options like Notify PI To Submit, Admin Notes & Files, Abandon, Submit, and Print.

8. But the actual modifications to the protocol are made on the **Protocol Form that follows the Amendment Form.**

a. To modify the protocol, simply **edit the text or field** as desired (examples shown below).

The screenshot shows the 'Manage Protocols' interface for IACUC #1252. The 'PROTOCOL' tab is active, and the 'END OF AMENDMENT FORM' section is highlighted with a green box and labeled 'C8'. Below this section is the 'IACUC PROTOCOL FORM' section, which includes a 'Project Title' field (labeled 'C8a') and a 'Principal Investigator' field. The left sidebar shows the 'PROTOCOL FORM' with various sections like INTRODUCTION, GENERAL INFORMATION, etc., each with a checkmark. The right sidebar shows the 'ACTIVITY LOG' with options like Notify PI To Submit, Admin Notes & Files, Abandon, Submit, and Print.

The screenshot shows the 'Manage Protocols' interface for IACUC #1252. The 'PROTOCOL' tab is active, and the 'GENERAL INFORMATION' section is highlighted with a green box and labeled 'C8a'. This section includes a 'Project Title' field and a 'Principal Investigator' field. The left sidebar shows the 'PROTOCOL FORM' with various sections like INTRODUCTION, GENERAL INFORMATION, etc., each with a checkmark. The right sidebar shows the 'ACTIVITY LOG' with options like Notify PI To Submit, Admin Notes & Files, Abandon, Submit, and Print.

← Back Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL REPORTABLE EVENTS ACTIVITY LOG

PROTOCOL FORM ^

PAIN & DISTRESS CLASSIFICATION

List all animals (by species and, if applicable, individual strains) proposed for use in this study. Quantify the number of each species/strain that will be used under each listed USDA pain category. Count the animal only once. If an individual animal will be used in multiple experimental/pain categories, count the animal only in the highest pain category.

TABLE: ANIMAL TYPE AND NUMBER
If needed, click the "Add Line" button for additional rows.

Columns + Add Line

	SPECIES	STRAIN	CATEGORY C	CATEGORY D	CATEGORY E
	Mouse	C57Bl/6	360		
	Mouse	FVB		240	

Notify PI To Submit
Admin Notes & Files
Abandon
Submit
Print

← Back Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL REPORTABLE EVENTS ACTIVITY LOG

Pages Expand Navigat

PROTOCOL FORM ^

PAIN & DISTRESS CLASSIFICATION

List all animals (by species and, if applicable, individual strains) proposed for use in this study. Quantify the number of each species/strain that will be used under each listed USDA pain category. Count the animal only once. If an individual animal will be used in multiple experimental/pain categories, count the animal only in the highest pain category.

TABLE: ANIMAL TYPE AND NUMBER
If needed, click the "Add Line" button for additional rows.

Columns + Add Line

	SPECIES	STRAIN	CATEGORY C	CATEGORY D	CATEGORY E
	Mouse	C57Bl/6	360		
	Mouse	FVB		240	
	Mouse	Arginase KO	100		

C8a

Notify PI To Submit
Admin Notes & Files
Abandon
Submit
Print

9. Once all modifications have been made to the protocol,
 - a. If the person preparing the application is the PI, go to Step 10.
 - b. If not the PI, click **Notify PI to Submit** and then click **Send** in the pop-up window.

← Back Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL REPORTABLE EVENTS ACTIVITY LOG

PROTOCOL FORM ^

PAIN & DISTRESS CLASSIFICATION

List all animals (by species and, if applicable, individual strains) proposed for use in this study. Quantify the number of each species/strain that will be used under each listed USDA pain category. Count the animal only once. If an individual animal will be used in multiple experimental/pain categories, count the animal only in the highest pain category.

TABLE: ANIMAL TYPE AND NUMBER
If needed, click the "Add Line" button for additional rows.

Columns + Add Line

	SPECIES	STRAIN	CATEGORY C	CATEGORY D	CATEGORY E
	Mouse	C57Bl/6	360		
	Mouse	FVB		240	
	Mouse	Arginase KO	100		

Notify PI To Submit

Are you sure you want to notify the PI that the protocol is ready for them to submit?

Cancel Send

C9b

Notify PI To Submit
Admin Notes & Files
Abandon
Submit
Print

10. An email notification will be sent to the PI to review, certify and submit the amendment application.
 - a. The quickest way for the PI to access the amendment application is through the protocol link in the email itself.
 - b. Alternatively, the PI can log into Kuali as described in [Section A](#) and access the protocol from the protocols table on the Manage Protocols page. **NOTE:** *More than one protocol of the same number will be present on the page. Make sure to open the protocol corresponding to the **amendment submission in progress**.*

Title	Number	PI Name	Submission Type	Review Type	Status	Assignment	Continuing Review Date
Understanding and Addressing Cancer Health Disparities in Louisiana	1252	Ochoa, Augusto	Initial	Full Board	Approved	IACUC	June 27, 2022
Understanding and Addressing Cancer Health Disparities in the Gulf South	1252	Ochoa, Augusto	Amendment		In Progress		

11. Because the PI has opened the protocol, the **Notify PI to Submit** button will be grayed out and the **Submit** button will be active.
 - a. The PI should review **all the modifications** and then....

Amendment Questionnaire

Please select the option that best describes the application you are preparing:

☒ Amend alone
☐ Renew + Amend

Which modifications are being proposed for this study (select all that apply)?

☐ Change of Principal Investigator
☐ Change in personnel (other than PI)
☒ Change of protocol title
☐ Change in funding source
☐ Change in animal location
☒ Change in animal type or number
☐ Change in drugs or research material being used

12. Go to the last section, **Submission**, of the Amendment Form.
 - a. **Certify** to the attestations, and...
 - b. Click **Submit**.

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL REPORTABLE EVENTS ACTIVITY LOG

Pages Expand Navigation

PROTOCOL FORM

- INTRODUCTION ✓
- GENERAL INFORMATION ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓
- PROJECT PERSONNEL ✓
- OTHER REGULATORY A... ✓
- PROGRESS REPORT ✓
- NON-SCIENTIFIC SUM... ✓
- EXPERIMENTAL DESIGN ✓
- ANIMAL IDENTIFICATI... ✓
- PAIN & DISTRESS CLA... ✓
- DRUGS & OTHER AGEN... ✓
- BIOLOGICAL MATERIA... ✓
- PAIN & DISTRESS CLA... ✓
- DRUGS & OTHER AGEN... ✓
- BIOLOGICAL MATERIA... ✓
- ADVERSE EFFECTS ✓
- END OF USE ANIMAL D... ✓
- NON-ANIMAL ALTERN... ✓

Submission C12

This Amendment application may be submitted ONLY by the Principal Investigator.

- If you are not the PI, click the **Notify PI to Submit** button to alert the PI that the Amendment application is ready for review and submission. Successful notification will be indicated by a gray bar across the button.
- If you are the PI, please go to the next step, PI Certification.

As the Principal Investigator on this project, I certify that I am responsible for the overall conduct of the research and, to the best of my knowledge, the information included herein is accurate and complete. I also agree:

- that no additional change, whether minor or major, will be made without IACUC approval, except where necessary to eliminate apparent immediate hazards;
- that all amendments approved within the three-year protocol approval period are bound to the approval date of the protocol, which they amend;
- that after three years, all modifications approved via amendment(s) that are anticipated to remain as a component of the study must be incorporated into the triennial renewal application;
- to report to the IACUC any emergent problems, serious adverse reactions, or any procedural changes that may affect the status of the investigation; and
- to periodic review of this project by the IACUC at intervals appropriate to assure that the project is being conducted in compliance with the IACUC's understanding and recommendation.

☒ I certify and agree C12a

☐ I DO NOT certify and agree

Submit for Review

Click "Submit" for the application to be sent to the IACUC Office for review. A member of the IACUC Office staff will contact you through KR if additional information or revisions are needed. You will receive a system-generated notification after the review has been completed and a determination has been made.

Activity Log:

- Notify PI To Submit
- Admin Notes & Files
- Abandon
- Submit C12b**
- Print

13. If any fields are incomplete, an error message will appear.

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL REPORTABLE EVENTS ACTIVITY LOG

Pages Expand Navigation

PROTOCOL FORM

- INTRODUCTION ✓
- GENERAL INFORMATION ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓
- PROJECT PERSONNEL ✓
- OTHER REGULATORY A... ✓
- PROGRESS REPORT ✓
- NON-SCIENTIFIC SUM... ✓
- EXPERIMENTAL DESIGN ✓
- ANIMAL IDENTIFICATI... ✓
- PAIN & DISTRESS CLA... ✓
- DRUGS & OTHER AGEN... ✓
- BIOLOGICAL MATERIA... ✓
- PAIN & DISTRESS CLA... ✓
- DRUGS & OTHER AGEN... ✓
- BIOLOGICAL MATERIA... ✓
- ADVERSE EFFECTS ✓
- END OF USE ANIMAL D... ✓
- NON-ANIMAL ALTERN... ✓

Rationale/Justification C13

Please provide the reason for changing the protocol title:

Type here

Required

If you are proposing modifications to, or addition of, procedures or experiments, drugs or research materials, animal type or number, and/or the PI, please provide a thorough justification of the proposed changes:

At minimum, an acceptable justification should answer the following questions: Why is it necessary to modify the approved protocol? If and how do the proposed modifications impact the goals and objectives of the approved project? What is the rationale for the specific modifications (i.e., specific procedure or experiment, specific drug or reagent, specific animal type or number, specific PI) being proposed?

Activity Log:

- Notify PI To Submit
- Admin Notes & Files
- Abandon
- Submit C13b**
- Print

14. **Correct all errors** and click **Submit** again.

← Back Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL REPORTABLE EVENTS ACTIVITY LOG

Pages Expand Navigati

PROTOCOL FORM

INTRODUCTION ✓
GENERAL INFORMATIO... ✓
FUNDING SOURCE(S) ✓
PROJECT SCOPE ✓
PROJECT PERSONNEL ✓
OTHER REGULATORY A... ✓
PROGRESS REPORT ✓
NON-SCIENTIFIC SUM... ✓
EXPERIMENTAL DESIGN ✓
ANIMAL IDENTIFICATI... ✓
PAIN & DISTRESS CLA... ✓
DRUGS & OTHER AGEN... ✓
BIOLOGICAL MATERIA... ✓

Yes
No

Rationale/Justification

Please provide the reason for changing the protocol title:

To match the title with the title of the grant award. C14

If you are proposing modifications to, or addition of, procedures or experiments, drugs or research materials, animal type or number, and/or the PI, please provide a thorough justification of the proposed changes:

At minimum, an acceptable justification should answer the following questions: Why is it necessary to modify the approved protocol? If and how do the proposed modifications impact the goals and objectives of the approved project? What is the rationale for the specific modifications (i.e., specific procedure or experiment, specific drug or reagent, specific animal type or number, specific PI) being proposed?

Sans Serif Normal B I G U A

Notify PI To Submit
Admin Notes & Files
Abandon
Submit C14
Print

15. The **status** of the application will change to **Submitted for Review** and the **Submit** button will disappear.

← Back Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL REPORTABLE EVENTS ACTIVITY LOG

Jump to:

Amendment ✓
INTRODUCTION ✓
GENERAL INFORMATIO... ✓
FUNDING SOURCE(S) ✓
PROJECT SCOPE ✓
PROJECT PERSONNEL ✓
OTHER REGULATORY ... ✓
PROGRESS REPORT ✓
NON-SCIENTIFIC SUM... ✓
EXPERIMENTAL DESI... ✓

Version: 5 | Amendment | Submitted for Review

Show Latest Changes

Protocol Information

Submission Type: Amendment

Review Type: --

Status: Submitted for Review C15

Time in Current Status: Since June 28 - a few seconds

Approval Date: --

Continuing Review Date: Jun 27, 2022

Expiration Date: Jun 27, 2024

Initial Approval Date: Jun 28, 2021

Initial Review Type: Full Board

Admin Notes & Files
Withdraw
Print C15

16. A system generated email will be sent notifying the IACUC Office of the submission.

17. The IACUC Admin will facilitate administrative and Committee review of the amendment application.

18. Additional information or revisions may be requested before a final determination is made on the amendment application. Submission of additional information or revisions will follow the same process as that for resubmission of new protocols (described in [Section B](#)).

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D. RENEWAL

IACUC protocols are approved for three (3) years. Federal regulations and institutional policy, however, requires continuing review of approved protocols on at least an annual basis. Use the Renewal Form to submit protocols for continuing review. You will receive several email notifications starting 30 days before the continuing review deadline.

1. Access the protocol using the link in the email notification or log into Kualu as described in [Section A](#) and click on the protocol title in the protocols table. After opening the **most recently approved version** of the protocol, click **Renew**.

The screenshot shows the 'Manage Protocols' interface for protocol #1252. The 'Version' dropdown is set to '6 | Amended | Approved' with a green 'D1' label. The 'Protocol Information' table shows the status as 'Approved' and the 'Continuing Review Date' as 'Jun 27, 2022'. On the right sidebar, the 'Renew' button is highlighted with an orange box and a red 'D1' label.

Protocol Information			
Review Type	Status	Approval Date	Continuing Review Date
Designated Member Review	Approved	Jun 30, 2021	Jun 27, 2022
Expiration Date	Initial Approval Date	Initial Review Type	
Jun 27, 2024	Jun 28, 2021	Full Board	

2. A **new version of the protocol** will be created.
 - a. Only the PI can submit the initial version of a renewal application. If the person preparing the application is not the PI, the **submit** button will be grayed out; **Notify PI to Submit** will be active.

The screenshot shows the 'Manage Protocols' interface for protocol #1252. The 'Version' dropdown is set to '7 | Renewal | In Progress' with a green 'D2' label. The 'Protocol Information' table shows the status as 'In Progress' and the 'Continuing Review Date' as '--'. On the right sidebar, the 'Submit' button is highlighted with an orange box and a red 'D2a' label.

Protocol Information			
Submission Type	Status	Approval Date	Continuing Review Date
Renewal	In Progress	--	--
Expiration Date	Initial Approval Date	Initial Review Type	
--	Jun 28, 2021	Full Board	

3. Scroll down to the **Renewal Form**; then...
 - a. Read the **instructions**,
 - b. Complete the **questionnaire**, and
 - c. Click **Notify PI to Submit**.

Jump to:

Renewal Progress Report

INTRODUCTION ✓

GENERAL INFORMATI... ✓

FUNDING SOURCE(S) ✓

PROJECT SCOPE ✓

PROJECT PERSONNEL ✓

OTHER REGULATORY ... ✓

PROGRESS REPORT ✓

NON-SCIENTIFIC SUM... ✓

EXPERIMENTAL DESI... ✓

ANIMAL IDENTIFICATI... ✓

ANNUAL RENEWAL FORM

Introduction

D3a

Complete this **RENEWAL FORM** to request annual re-approval of research previously approved by the IACUC.

Unless otherwise specified, information reported in this form should primarily reflect activities having occurred since the most recent review of the study (which may be the initial review or an annual continuing review).

Please note the following:

- If you do not wish to continue this project as currently approved by the IACUC for another year, please *Abandon* this **Renewal** application and complete a **Closure Request** application.
- If you accessed this form by clicking on the *Renew* button but intend to simultaneously request study modifications, or are required to do so based on your responses to certain questions below, then click the *Abandon* button to terminate this application. Start a new application by selecting *Renew & Amend* which will give you access to both the **Renewal** and **Amendment** forms.
- Additional instructions are available in the *Renewal* and *Amendments* **Kuali Quickguides** which are found [here](#).

Questionnaire

D3b

Which post-approval application are you submitting?

☒ Renew

☐ Renew & Amend

During the current approval period, did you make any modifications, including changes to personnel, to the research without first submitting an amendment application to the IACUC for review and approval?

☒ No

☐ Yes

Are you aware of any incidents, adverse events, instances of non-compliance and/or other reportable events that have occurred during the current approval period but have **NOT** been reported to the IACUC?

☒ No

☐ Yes

Were any changes in animal usage reported to NIH or other federal agencies during the most recent approval period?

☒ N/A; the project is not funded by a federal agency

☐ No

☐ Yes

Notify PI To Submit

Admin Notes & Files

Abandon

Submit

Print

D3c

4. The PI will receive an email notification to submit the Renewal application.

5. After opening the protocol, the PI should...

- Review the entries on the form,
- Certify and agree** to the attestations, and
- Submit** the application.

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL REPORTABLE EVENTS ACTIVITY LOG

Jump to:

- Renewal Progress Rep... ✓
- INTRODUCTION ✓
- GENERAL INFORMATI... ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓
- PROJECT PERSONNEL ✓
- OTHER REGULATORY ... ✓
- PROGRESS REPORT ✓
- NON-SCIENTIFIC SUM... ✓
- EXPERIMENTAL DES... ✓
- ANIMAL IDENTIFICATI... ✓
- PAIN & DISTRESS CLA... ✓
- DRUGS & OTHER AGE... ✓

Submission

This **RENEWAL** application may be submitted **ONLY** by the Principal Investigator.

- If you are **not** the PI, click the **Notify PI to Submit** button to alert the PI that the **Renewal** application is ready for review and submission. Successful notification will be indicated by a gray bar across the button.
- If you are the **PI**, please go to the next step, PI certification.

As the Principal Investigator on this project, I certify that, to the best of my knowledge, the information included herein is accurate and complete. I agree to report to the IACUC any emergent problems, serious adverse reactions, or any procedural changes that may affect the status of the investigation and that no change, whether minor or major, will be made without IACUC approval, except where necessary to eliminate apparent immediate hazards. I also agree to periodic review of this project by the IACUC at intervals appropriate to assure that the project is being conducted in compliance with the IACUC's understanding and recommendation.

☒ I certify and agree **D5b**

☐ I do not certify and agree

Submit for Review

Click "Submit" for the application to be sent to the IACUC Office for review. A member of the IACUC Office staff will contact you through KR if additional information or revisions are needed. You will receive a system-generated notification after the review has been completed and a determination has been made.

Submit **D5c**

Print

END OF RENEWAL FORM

6. The **status** of the application will change to **Submitted for Review** and the **Submit** button will disappear.

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL REPORTABLE EVENTS ACTIVITY LOG

Jump to:

- Renewal Progress Rep... ✓
- INTRODUCTION ✓
- GENERAL INFORMATI... ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓
- PROJECT PERSONNEL ✓
- OTHER REGULATORY ... ✓

Version: 7 | Renewal | Submitted for Review

Protocol Information

Submission Type Renewal	Review Type --	Status Submitted for Review D6	Time in Current Status Since June 30 – a few seconds
Approval Date --	Continuing Review Date --	Expiration Date --	Initial Approval Date Jun 28, 2021

Withdraw **D6**

Print

END OF RENEWAL FORM

7. A system generated email will notify the IACUC Office of the submission.

8. The IACUC Admin will facilitate administrative and Committee review of the renewal application. Additional information or revisions may be necessary before a final determination is made. Submission of additional information or revisions will follow the same process as that for resubmission of new protocols (as described in [Section B](#)).

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E. RENEWAL & AMENDMENT

Investigators have the option to submit an amendment application concurrent with the continuing review application in Kuali. You will receive several email notifications starting 30 days before the renewal deadline.

1. Access the protocol using the link in the email notification or log into Kuali as described in [Section A](#) and click on the protocol title in the protocols table.
2. Click the **Renew & Amend** button on the right side panel. A **new version** of the protocol will be created.

The first screenshot shows the 'Manage Protocols' page for protocol #1252. The 'Version' dropdown is set to '7 | Renewed | Approved' and is highlighted with a green box labeled 'E2'. On the right-hand 'ACTIVITY LOG' panel, the 'Renew & Amend' button is highlighted with an orange box, also labeled 'E2'. The 'Protocol Information' table shows a 'Designated Member Review' with a status of 'Approved' and an expiration date of 'Jun 29, 2023'.

The second screenshot shows the same page after clicking 'Renew & Amend'. The 'Version' dropdown is now '8 | Renew/Amend | In Progress', highlighted with a green box. A red arrow points from the 'E2' label in the first screenshot to this new version. The 'Protocol Information' table now shows a 'Renew/Amend' submission type with a status of 'In Progress'.

3. The forms will display in the following order: **Renewal** > **Amendment** > **Protocol**. Complete the forms and edit the protocol as described in [Section C](#) and [Section D](#).
4. **Only the PI can submit the initial Renew & Amend application.** Follow the procedures for PI notification, certification and submission described in the previous sections. The PI certification is found in the **Amendment Form**.

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F. REPORTABLE EVENT

Study team members who become aware of any incidents or non-compliance associated with a specific IACUC-approved protocol must promptly report the incident to the IACUC using the Reportable Event Form.

1. Log into Kuali as described in [Section A](#) and click on the protocol title in the protocols table.
2. Click the **Reportable Events** tab.

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL | **REPORTABLE EVENTS** | ACTIVITY LOG

Jump to: Renewal Progress Rep. ✓, Amendment ✓, INTRODUCTION ✓, GENERAL INFORMATI... ✓, FUNDING SOURCE(S), PROJECT SCOPE ✓, PROJECT PERSONNEL ✓

Version: 9 | Renewed/Amended | Approved **F2** ☐ Show Latest Changes

Protocol Information

Review Type Designated Member Review	Status Approved	Approval Date Jul 01, 2021	Continuing Review Date Jun 30, 2022
Expiration Date Jun 27, 2021	Initial Approval Date Jun 28, 2021	Initial Review Type Full Board	

Show Less ^

Amend, Renew, Renew & Amend, Action Items Summary, Admin Notes & Files, Request Close, Print

3. Click **Report an Event**.

Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South

PROTOCOL | **REPORTABLE EVENTS** | ACTIVITY LOG **F3**

Reportable Events

Event Type	Description	Status	Event Date	Recorded Date
0 of 0 reportable events				

Load 25 at a Time

4. The **Reportable Event Form** will display. Answer all questions.

← Back Report Event for Protocol

REPORTABLE EVENT FORM

Jump to:
Event form

Introduction

All members of the LSUHSC community are obligated to report, or assure reporting of, their knowledge of any incident that potentially compromises the well-being of animals engaged in HSC-associated animal care and use activities. Incidents may include adverse events, unanticipated problems, animal welfare concerns, and instances of suspected non-compliance with laws, rules, regulations, policies and the approved protocol.

Knowledge of such incidents may be reported directly to the IACUC, Department of Animal Care, and/or the Institutional Official, or anonymously through the [LSUHSC-NO Hot Line](#) (Phone: 855-561-4099; Email: nocompliance@lsuhsc.edu).

Study team members who become aware of any incidents associated with a specific IACUC-approved protocol must promptly report the incident to:

1. DOAC veterinarians, if the incident places animals in immediate hazard; and/or
2. The IACUC using this [Reportable Event Form](#).

Report only one event per form.

Event Details

Select the event type:

✓ Save
Submit for Review
× Delete
Activity Log
View Protocol

5. Unlike the protocol applications (forms), entries are not saved automatically. Click **Save** periodically until you are ready to submit.
- Once the form is complete, click **Submit for Review**.
 - NOTE:** Any study team member with access to the protocol in *Kuali*, not just the PI, may submit a reportable event.

← Back Report Event for Protocol

Once we found dead animals, it was immediately reported to Dr. Leslie Burke on June 20th, 2021.

Jump to:
Event form

Corrective Action Plan

Please provide a corrective action plan to describe how this or similar type of event will be prevented from occurring in the future by completing the table below:

Columns

PROPOSED ACTION	COMPLETION DATE	RESPONSIBLE INDIVIDUALS	VERIFICATION METHOD
The following corrective action measures will be implemented immediately:	July 9, 2021	John Doe	Sign up sheet to be signed by lab personnel after completion of experiments each day, and daily inspection post completion of experiments.

This is the end of the Reportable Event Form.

F5 ✓ Save
F5a Submit for Review
× Delete
Activity Log
View Protocol

6. The IACUC Admin will facilitate administrative and Committee review of the event. Additional information or revisions may be necessary before the event may be resolved. Requests for, and submission of, additional information or revisions will follow the same general process as that described in previous sections of this document.

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G. CLOSURE

IACUC protocols are approved for a maximum of 3 years with intermittent (typically annual) reviews. An investigator, however, may request closure of the study prior to the 3-year expiration date.

1. Log into Kuali as described in [Section A](#) and click on the protocol title in the protocols table.
2. Click **Request Close**.

The screenshot shows the 'Manage Protocols' interface for protocol #1252, 'Understanding and Addressing Cancer Health Disparities in the Gulf South'. The left sidebar lists various protocol sections with checkmarks. The main content area displays 'Protocol Information' with fields for Review Type (Designated Member Review), Status (Approved), Approval Date (Jul 01, 2021), Continuing Review Date (Jun 30, 2022), Expiration Date (Jun 27, 2021), Initial Approval Date (Jun 28, 2021), and Initial Review Type (Full Board). On the right, a vertical menu contains options: Amend, Renew, Renew & Amend, Action Items Summary, Admin Notes & Files, **Request Close** (highlighted with an orange box and labeled 'G2'), and Print.

3. Follow instructions to complete the Closure Request Form.

The screenshot displays the 'CLOSURE REQUEST FORM' within the Kuali interface. The form is titled 'CLOSURE REQUEST FORM' in purple. It includes an 'Introduction to Form' section with text explaining the three-year expiration rule and a link to the 'Closure Request Kuali Quickguide'. Below this is the 'Close Request Questionnaire' section, which asks 'Why are you requesting closure of the study?' and provides three radio button options: 'Research project never started', 'Project to be discontinued', and 'Project completed as planned'. The left sidebar shows the 'Close Request' option selected. The right sidebar contains options: Notify PI To Submit, Admin Notes & Files, Abandon, Submit, and Print.

4. **Only the PI can submit the initial Request Close application.** Follow the procedures for PI notification, certification and submission described in the previous sections.

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