

## KUALI QUICKGUIDE

# REVIEWING IACUC PROTOCOL APPLICATIONS

This document describes procedures for accessing and reviewing different submission types of IACUC protocols in Kuali.

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

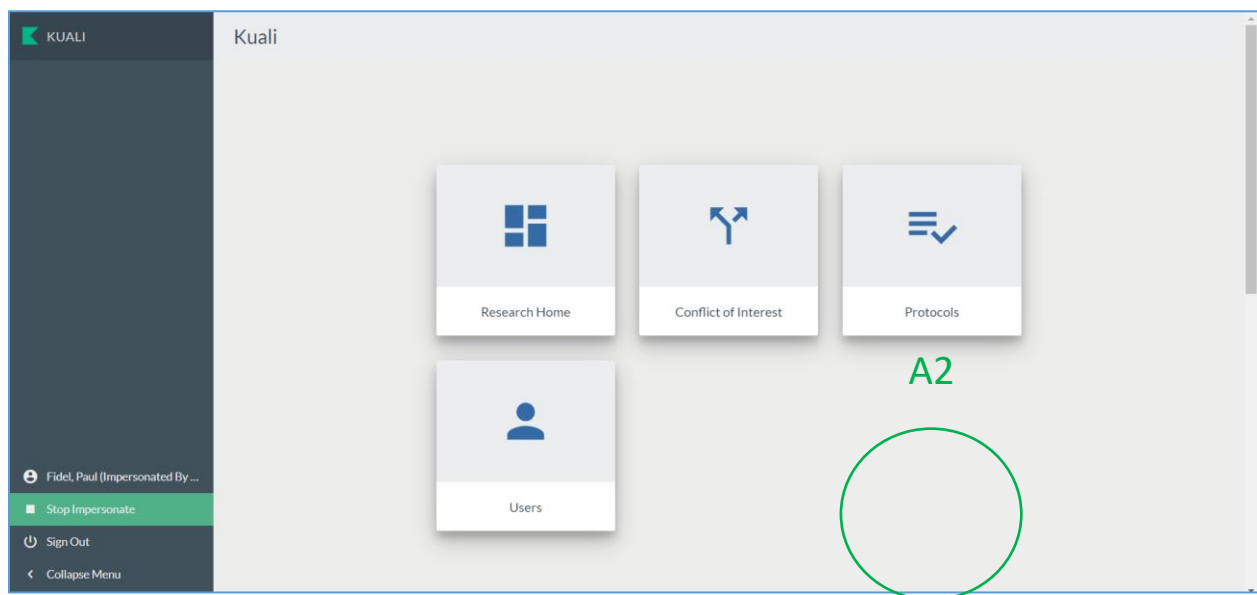
## A. ACCESSING PROTOCOLS

Each time you are assigned as a reviewer for a protocol submission by the IACUC Administrator, you will receive a system generated email notification of the assignment. *The quickest way to access the protocol is to click on the protocol link in the email notification itself.* Alternatively, follow steps 1-4 to access the protocol.

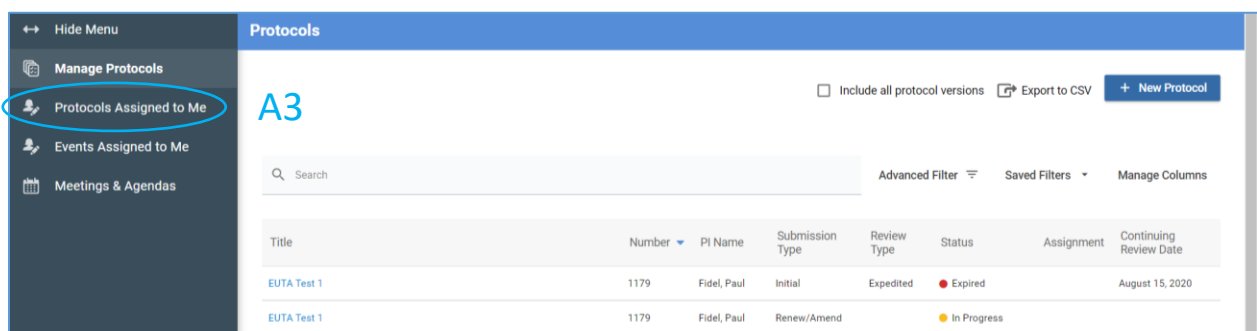
### 1. Log into Kual:

- 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](mailto:IACUCOffice@lsuhsc.edu)) if you have any problems logging into Kual.

### 2. On the landing page, click on the **Protocols** button.



### 3. You will be directed to the **Manage Protocols** page. On this page click **Protocols Assigned to Me**.



4. Click on the **title of the protocol** that you want to review.

- a) Note: The **Submission Type** will vary depending on the application submitted but the **status** will always be *Submitted for Review*.

The image displays two screenshots of a web application interface for managing protocols. Both screenshots show a sidebar menu on the left with options: 'Hide Menu', 'Manage Protocols', 'Protocols Assigned to Me', 'Events Assigned to Me', and 'Meetings & Agendas'. The main content area is titled 'Protocols' and features a search bar, a 'Saved Filters' dropdown, and a table of protocols.

**Top Screenshot:** The table lists one protocol. The title 'Understanding and Addressing Cancer Health Disparities in Louisiana' is circled in green, and a green 'A4' is placed next to it. The 'Submission Type' is 'New' and the 'Status' is 'Submitted for Review'. An orange box labeled 'A4a' highlights the 'Submission Type' column.

Title	Number	Type	PI	Submission Type	Review Type	Submitted	Status	Assignment	DMR Determination Due Date
Understanding and Addressing Cancer Health Disparities in Louisiana	252	IACUC	Ochoa, Augusto	New	Full Board	June 19, 2021	Submitted for Review	IACUC	

1 of 1 protocols

Load 25 at a Time

**Bottom Screenshot:** The table lists one protocol. The 'Submission Type' is 'Amendment' and the 'Status' is 'Submitted for Review'. Two orange boxes labeled 'A4a' highlight the 'Submission Type' and 'Status' columns.

Title	Number	Type	PI	Submission Type	Review Type	Submitted	Status	Assignment	DMR Determination Due Date
Understanding and Addressing Cancer Health Disparities in the Gulf South	1252	IACUC	Ochoa, Augusto	Amendment	Designated Member Review	June 28, 2021	Submitted for Review	IACUC	July 01, 2021

1 of 1 protocols

Load 25 at a Time

[Return to Top](#)

## B. REVIEWING INITIAL SUBMISSIONS

For initial submissions, you will be assigned either as a **Primary, Vet** (Adam and Leslie) or **Secondary Reviewer**. **Primary and Vet Reviewers** are required to enter their comments about the protocol in *Kuali* (as described below). All other Committee members are designated as **Secondary Reviewers** so they can access the protocol. **Secondary Reviewers** are **NOT** required to review the protocol or leave comments but may do so if they wish to document their evaluations. The **Primary Reviewer** is responsible for presenting the protocol at the meeting.

1. After accessing the protocol, the submitted application will be displayed.
  - a) **Basic protocol information**, including submission type, will be displayed at the top of the form.
  - b) The **left side panel** displays the individual sections of the protocol form.
  - c) The **right side panel** displays several different actions available to the reviewer.
  - d) The **Primary Reviewer** should enter their summary of the protocol in the **General Action Items** text box that appears once this button is clicked.

2. Each question or field of the protocol form is associated with an **Action Item** button. You will use these buttons to communicate your specific comments including requested modifications or clarifications.

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

PROTOCOL ACTIVITY LOG

Jump to:

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

**GENERAL INFORMATION**

Project Title: Understanding and Addressing Cancer Health Disparities in Louisiana [Action Item](#)

Principal Investigator: Ochoa, Augusto [Action Item](#) Department: Center of excellence-Cancer [Action Item](#)

Projected start date: August 2, 2021 [Action Item](#)

Estimated Duration of Project (months or years): 3 years [Action Item](#)

**B2**

Action Items Summary  
Admin Notes & Files  
Submit Review  
General Action Items  
Print

3. To leave a comment about any field entry,

- Click on the **Action Item** button associated with the field.
- A **text box** will appear on the right hand panel. Enter your comments here. *Please enter comments as if you are requesting the researcher to take an action. At this stage the comments will be visible only to the IACUC Administrator. After you submit the review, the Administrator will make comments visible to other assigned reviewers and to IACUC members during the meeting. After the meeting, the Administrator will make the comments visible to the Researcher, unless directed otherwise by you or meeting discussions.*
- Click **Post**.

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

PROTOCOL ACTIVITY LOG

Jump to:

- INTRODUCTION ✓
- GENERAL INFORMATION ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓
- PROJECT PERSONNEL ✓
- OTHER REGULATORY ... ✓
- PROGRESS REPORT ✓
- NON-SCIENTIFIC SUM... ✓
- EXPERIMENTAL DESI... ✓
- ANIMAL IDENTIFICATI... ✓
- PAIN & DISTRESS CLA... ✓

**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.

**B3a**

	SPECIES	OTHER SPECIES	STRAIN
<a href="#">Action Item</a>	Mouse		C57Bl/6
<a href="#">Action Item</a>	Mouse		FVB

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

**B3b**

**B3c**

**Number of Animals / Item 1**

**Action Items**

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.

Visibility Admins

Cancel Post

4. Your comments will be registered as indicated by **numbered orange circles** in the specific field and the relevant section of the protocol form.
  - a) You have the option to edit or delete the action item by clicking on the **ellipses**.

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

PROTOCOL

Jump to:

- INTRODUCTION ✓
- GENERAL INFORMAT... ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓
- PROJECT PERSONNEL ✓
- OTHER REGULATORY ... ✓
- PROGRESS REPORT ✓
- NON-SCIENTIFIC SUM... ✓
- EXPERIMENTAL DESI... ✓
- ANIMAL IDENTIFICATI... ✓
- PAIN & DISTRESS CLA... 1 B4**

**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

ACTION ITEMS	SPECIES	OTHER SPECIES	STRAIN
1 B4	Mouse		C57BL/6
+ Action Item	Mouse		FVB

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

Columns

ACTIVITY LOG

Number of Animals / Item 1 →

Action Items + Action Item

Fidel, Paul (impersonated by Alam, Jawed) 06/24/21 · 10:43AM 1 B4a

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

5. Continue adding comments/action items for additional fields. When completed click on the **right arrow** to hide the action items and return to the standard right side panel.

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

PROTOCOL

Jump to:

- PROJECT PERSONNEL ✓
- OTHER REGULATORY ... ✓
- PROGRESS REPORT ✓
- NON-SCIENTIFIC SUM... ✓
- EXPERIMENTAL DESI... ✓
- ANIMAL IDENTIFICATI... ✓
- PAIN & DISTRESS CLA... 1
- DRUGS & OTHER AGE... 1
- BIOLOGICAL MATERIA... ✓
- ADVERSE EFFECTS ✓
- END OF USE ANIMAL ... ✓
- NON-ANIMAL ALTERN... ✓
- SUPPORTING DOCUM... 1 B5**
- SUBMISSION INSTRU... ✓

**SUPPORTING DOCUMENTS**

Columns

ACTION ITEMS	DOCUMENT TYPE	DOCUMENT DESCRIPTION	ATTACHMENT
1 B5	SOP	Cyclophosphamide	3832 2 CYCLOPHOSPH

**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.

ACTIVITY LOG

Attachments / Item 1 → 1 B5

Action Items + Action Item

Fidel, Paul (impersonated by Alam, Jawed) 06/24/21 · 10:48AM 1 B5

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

Visibility

Admins

6. You can **view a summary** of all your comments/action items
  - a) By clicking the **Action Items Summary** tab.
  - b) You can also leave **general comments** by clicking the **General Action Items** tab.

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

PROJECT PERSONNEL ✓  
OTHER REGULATORY ... ✓  
PROGRESS REPORT ✓  
NON-SCIENTIFIC SUM... ✓  
EXPERIMENTAL DESI... ✓  
ANIMAL IDENTIFICATI... ✓  
PAIN & DISTRESS CLA... 1  
DRUGS & OTHER AGE... 1  
BIOLOGICAL MATERIA... ✓  
ADVERSE EFFECTS ✓  
END OF USE ANIMAL ... ✓  
NON-ANIMAL ALTERN... ✓  
SUPPORTING DOCUM... 1

PROTOCOL

SUPPORTING DOCUMENTS

	DOCUMENT TYPE	DOCUMENT DESCRIPTION	ATTACHMENT
Action Items: 1	SOP	Cyclophosphamide	3832 2 CYCLOPHOSPHAMIDE SOP.PDF

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.

Action Items Summary  
Admin Notes & Files  
Submit Review  
General Action Items  
Print

B6a

B6b

Action Items Summary for Protocol #1252

^ Collapse All

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

Fidel, Paul (impersonated by Alam, Jawed) 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

Fidel, Paul (impersonated by Alam, Jawed) 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

B6

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

PROJECT PERSONNEL ✓  
OTHER REGULATORY ... ✓  
PROGRESS REPORT ✓  
NON-SCIENTIFIC SUM... ✓  
EXPERIMENTAL DESI... ✓  
ANIMAL IDENTIFICATI... ✓  
PAIN & DISTRESS CLA... 1  
DRUGS & OTHER AGE... 1  
BIOLOGICAL MATERIA... ✓  
ADVERSE EFFECTS ✓  
END OF USE ANIMAL ... ✓  
NON-ANIMAL ALTERN... ✓  
SUPPORTING DOCUM... 1

PROTOCOL

NON-ANIMAL ALTERNATIVES

	SEARCH ENGINE	DUPPLICATION KEYWORDS/CRITERIA	ALTERNATIVES KEYWORDS/CRITERIA
Action Item	PubMed	TNBC Disparities MDSC	

Explain how you determined the number of animals to be used in each group (e.g., statistical variability, specific experimental needs, power analysis). Additionally, provide justification if this duplicates any previous experiment.

Using a power calculation, we will need 9mice/group to statistically evaluate a 20% difference in tumor growth under different treatment regimens. This assumes a standard deviation of 15% with 90% power and p<0.05. In order to account for mice that need to be removed from the study, we will use 10 mice/group to ensure sufficient sensitivity.

(Refine) Indicate what alternative procedures or methods/techniques, including the use of drugs, were considered to minimize pain and/or distress (e.g., modified restraint, housing modifications, less invasive procedure, early humane endpoints).

ACTIVITY LOG

General Action Items

Action Items

Fidel, Paul (impersonated by Alam, Jawed) 06/24/21 - 10:57AM

For Committee: Is "body condition score" a standard parameter or does this need further clarification?

Show less

Visibility

Admins

B6b

7. When the review is complete, click **Submit Review**. A pop-up window will display a summary of all your comments. Scroll down to view all comments. If no changes are necessary, click **Submit Review** in the pop-up window.

The screenshot shows the 'Manage Protocols' interface for IACUC #1252. The left sidebar lists various protocol sections with checkmarks. The main area displays 'SUPPORTING DOCUMENTS' with a table containing one row: 'Action Items' (1), 'SOP', 'Cyclophosphamide', and an attachment '3832 2 CYCLOPHOSPHAMIDE SOP.PDF'. Below this is the 'SUBMISSION INSTRUCTIONS' section. On the right, a sidebar contains links like 'Action Items Summary', 'Admin Notes & Files', 'Submit Review' (circled in red), 'General Action Items' (1), and 'Print'. A red 'B7' label is placed over the 'Submit Review' button.

The screenshot shows the 'Submit Review' pop-up window. It has a 'General Comment' section with a text area containing a comment from 'Fidel, Paul (impersonated by Alam, Jawed)' dated '06/24/21 - 10:57AM'. Below this is the 'PROTOCOL FORM' section with fields for 'PAIN & DISTRESS CLASSIFICATION' and 'Number of Animals'. At the bottom right, the 'Submit Review' button is circled in red. A red 'B7' label is placed over the button.

8. Once submitted, the **Submit Review** tab will disappear but, if desired, you can **print** the review for your records.

The screenshot shows the 'Manage Protocols' interface after the review has been submitted. The 'Submit Review' button is no longer present. The 'Print' button in the right sidebar is now circled in red. A red 'B8' label is placed over the 'Print' button.

9. A notification of review completion will be sent to the IACUC Office.
10. In the IACUC Office, the Administrator, in preparation for the IACUC meeting, will review all Action Items and make them visible to all **Assigned Reviewers** and to members at the **Meeting**.



← Back

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

PROTOCOL

ACTIVITY LOG

ANCILLARY REVIEW

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 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
Action Items: 1	Mouse		C57Bl/6
Action Item	Mouse		FVB

Number of Animals / Item 1

Action Items

Fidel, Paul (impersonated by Alam, Jawed) 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 Who should see this?

Assigned Reviewers Researchers Meeting

Mark as resolved

← Back

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

PROTOCOL

ACTIVITY LOG

ANCILLARY REVIEW

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 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
Action Items: 1	Mouse		C57Bl/6
Action Item	Mouse		FVB

Number of Animals / Item 1

Action Items

Fidel, Paul (impersonated by Alam, Jawed) 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 Who should see this?

Assigned Reviewers Researchers Meeting

Mark as resolved

- Based on decisions at the IACUC meeting, the IACUC Administrator may edit or delete action items and make some or all visible to the Researcher who then can appropriately revise the protocol for subsequent review.

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## C. REVIEWING A RESUBMITTED PROTOCOL

Once a revised protocol has been submitted (for instance, after a MRSA determination), the IACUC Administrator will assign the **Primary** and **Vet Reviewers** of the initial application as the reviewers of the revised application. No **Secondary Reviewers** will be assigned in this case. As a reviewer, you will receive an email notification of this assignment.

1. Access the protocol directly using the link in the notification email or as described in [Section A](#).
  - a) There now will be **another version** (2 | New | Resubmitted) of the protocol. Please make sure to review the new version.
  - b) Click on the **Show Latest Changes** checkbox. All **new text** will be highlighted in green and deletions will be highlighted in red (example shown below).
  - c) If the IACUC Administrator has left you any **notes or instructions**, they will be found in the **Admin Notes & Files** tab.

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

PROTOCOL ACTIVITY LOG

Jump to: INTRODUCTION ✓ GENERAL INFORMAT... ✓ FUNDING SOURCE(S) ✓ PROJECT SCOPE ✓ PROJECT PERSONNEL ✓ OTHER REGULATORY ... ✓ PROGRESS REPORT ✓ NON-SCIENTIFIC SUM... ✓ EXPERIMENTAL DESI... ✓

Version: 2 | New | Resubmitted

Protocol: 1 | New | Revisions Required

Submission Type: New Review Type: Full Board Status: Resubmitted Time in Current Status: Since June 24 – 44 minutes

In Kuai, 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.

Action Items Summary

Admin Notes & F... 1

Submit Review

General Action Items

Print

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

PROTOCOL ACTIVITY LOG

Jump to: INTRODUCTION ✓ GENERAL INFORMAT... ✓ FUNDING SOURCE(S) ✓ PROJECT SCOPE ✓ PROJECT PERSONNEL ✓ OTHER REGULATORY ... ✓ PROGRESS REPORT ✓

EXPERIMENTAL DESIGN

	SPECIES	OTHER SPECIES	TOTAL ANIMALS
No Action Items	Mouse		20

For each unique experiment in which live animals will be used, please provide a detailed narrative of the experiment that will allow the IACUC to understand the entire course of this project. Describe in detail all non-surgical procedures that will be conducted on animals.

Mice will be subjected to minimally invasive procedures throughout the study. These include s.c. tumor cell injection into the flank or fat pad of the animals, tumor measurements using calipers, and intraperitoneal or intragastric administration of compounds including Cyclophosphamide. At the end of the study, mice will be euthanized by CO2 and tissue (tumor, spleen, lymph nodes, prostate, liver, blood) removed for analysis of immune parameters.

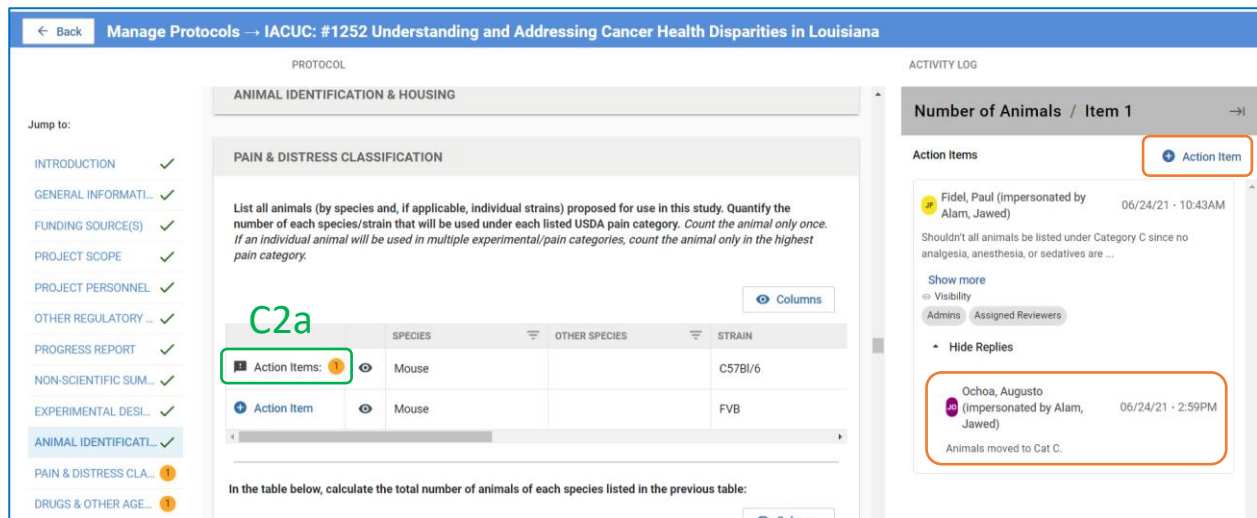
PROTOCOLS

Admin Notes & Files

File	Note	Date Added	Added By
	Please indicate if the revisions are satisfactory for protocol approval.	Jun 24, 2021 3:42 PM	Alam, Jawed

2. Next:

- Click on each **action item** to...
- Review the **investigator's response**.
- To indicate if the response is acceptable or to request further clarification or modifications, click on **Action Item** and...
- Type your comments**.
- Click **Post**.
- The new action item is only visible to the IACUC Administrator. He/She will make it visible to the researcher as appropriate.*



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

PROTOCOL

ANIMAL IDENTIFICATION & HOUSING

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.

	SPECIES	OTHER SPECIES	STRAIN
Action Items: 1	Mouse		C57Bl/6
Action Item	Mouse		FVB

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

Fidel, Paul (impersonated by Alam, Jawed) 06/24/21 - 10:43AM

Shouldn't all animals be listed under Category C since no analgesia, anesthesia, or sedatives are ...

Show more

Visibility

Admins Assigned Reviewers

Hide Replies

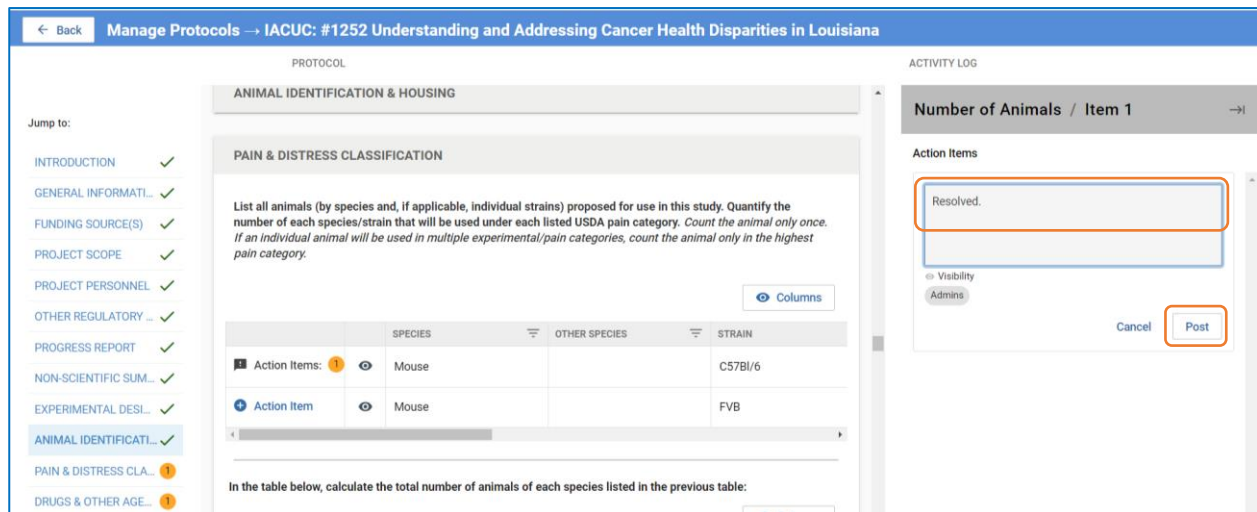
Ochoa, Augusto (impersonated by Alam, Jawed) 06/24/21 - 2:59PM

Animals moved to Cat C.

C2a

C2c

C2b



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

PROTOCOL

ANIMAL IDENTIFICATION & HOUSING

PAIN & DISTRESS CLASSIFICATION

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	SPECIES	OTHER SPECIES	STRAIN
Action Items: 1	Mouse		C57Bl/6
Action Item	Mouse		FVB

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

Resolved.

Visibility

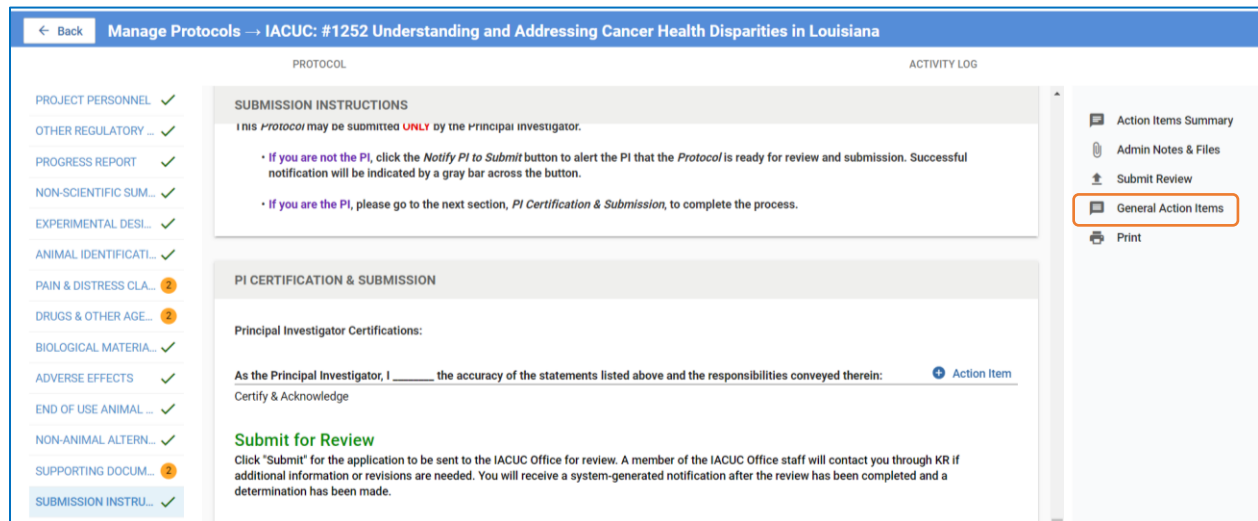
Admins

Cancel Post

C2d

C2e

3. Instead of commenting on each individual Action Item response/revision by the researcher, **especially if all the revisions are acceptable**, you may simply...
  - a. Click on the **General Action Items** tab and...
  - b. Leave **a single note** for the IACUC Admin.



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

PROJECT PERSONNEL ✓  
OTHER REGULATORY ... ✓  
PROGRESS REPORT ✓  
NON-SCIENTIFIC SUM... ✓  
EXPERIMENTAL DESI... ✓  
ANIMAL IDENTIFICATI... ✓  
PAIN & DISTRESS CLA... 2  
DRUGS & OTHER AGE... 2  
BIOLOGICAL MATERIA... ✓  
ADVERSE EFFECTS ✓  
END OF USE ANIMAL ... ✓  
NON-ANIMAL ALTERN... ✓  
SUPPORTING DOCUM... 2  
SUBMISSION INSTRU... ✓

**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:

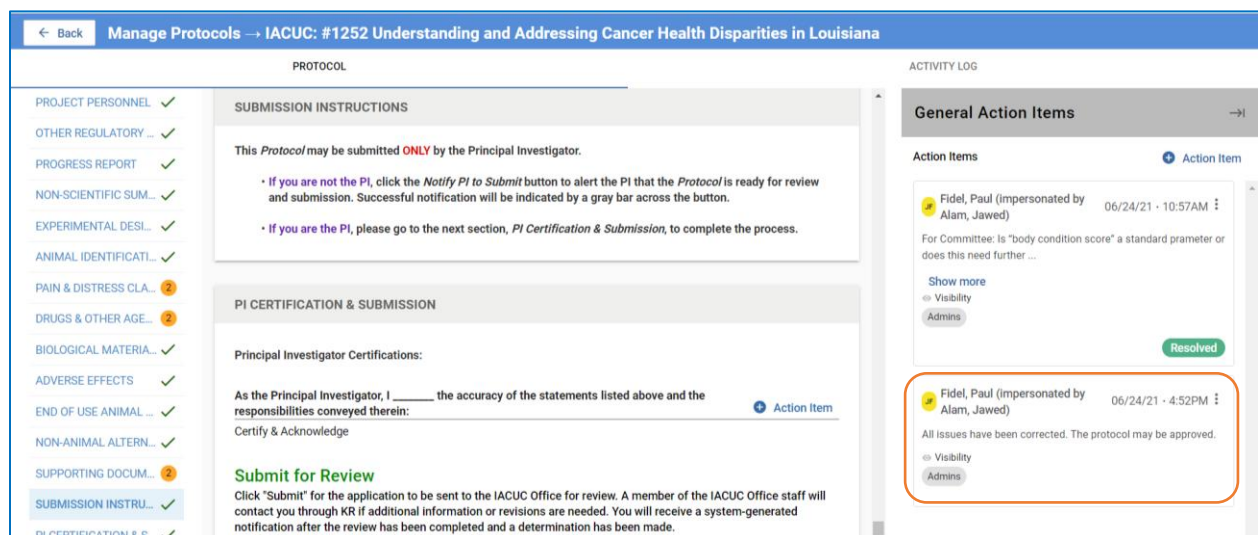
As the Principal Investigator, I \_\_\_\_\_ the accuracy of the statements listed above and the responsibilities conveyed therein: [Action Item](#)  
Certify & Acknowledge

**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.

General Action Items

C3a



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

PROJECT PERSONNEL ✓  
OTHER REGULATORY ... ✓  
PROGRESS REPORT ✓  
NON-SCIENTIFIC SUM... ✓  
EXPERIMENTAL DESI... ✓  
ANIMAL IDENTIFICATI... ✓  
PAIN & DISTRESS CLA... 2  
DRUGS & OTHER AGE... 2  
BIOLOGICAL MATERIA... ✓  
ADVERSE EFFECTS ✓  
END OF USE ANIMAL ... ✓  
NON-ANIMAL ALTERN... ✓  
SUPPORTING DOCUM... 2  
SUBMISSION INSTRU... ✓  
PI CERTIFICATION & S... ✓

**SUBMISSION INSTRUCTIONS**

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**PI CERTIFICATION & SUBMISSION**

Principal Investigator Certifications:

As the Principal Investigator, I \_\_\_\_\_ the accuracy of the statements listed above and the responsibilities conveyed therein: [Action Item](#)  
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.

**General Action Items**

Action Items [Action Item](#)

Fidel, Paul (impersonated by Alam, Jawed) 06/24/21 · 10:57AM  
For Committee: Is "body condition score" a standard parameter or does this need further ...  
Show more  
Visibility  
Admins  
**Resolved**

Fidel, Paul (impersonated by Alam, Jawed) 06/24/21 · 4:52PM  
All issues have been corrected. The protocol may be approved.  
Visibility  
Admins

C3b

- When finished, **submit the review** then click the **Submit Review** in the pop-up window.

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

PROJECT PERSONNEL ✓  
OTHER REGULATORY ... ✓  
PROGRESS REPORT ✓  
NON-SCIENTIFIC SUM... ✓  
EXPERIMENTAL DESI... ✓  
ANIMAL IDENTIFICATI... ✓  
PAIN & DISTRESS CLA... 2  
DRUGS & OTHER AGE... 2  
BIOLOGICAL MATERIA... ✓  
ADVERSE EFFECTS ✓  
END OF USE ANIMAL... ✓

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:

As the Principal Investigator, I \_\_\_\_\_ the accuracy of the statements listed above and the responsibilities conveyed therein: Action Item

Certify & Acknowledge

Action Items Summary  
Admin Notes & F... 1  
**Submit Review**  
General Action Items 1  
Print

C4

Submit Review

General Comment

YOUR ANONYMOUS COMMENTS:

Fidel, Paul (impersonated by Alam, Jawed) 06/24/21 - 10:57AM  
For Committee: Is "body condition score" a standard parameter or does this need further clarification?  
Show less

Resolved

Fidel, Paul (impersonated by Alam, Jawed) 06/24/21 - 4:52PM  
All issues have been corrected. The protocol may be approved.

PROTOCOL FORM

PAIN & DISTRESS CLASSIFICATION

Cancel

C4

Submit Review

- Once submitted, the **Submit Review** tab will no longer be available.

PROTOCOLS

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

PROJECT PERSONNEL ✓  
OTHER REGULATORY ... ✓  
PROGRESS REPORT ✓  
NON-SCIENTIFIC SUM... ✓  
EXPERIMENTAL DESI... ✓  
ANIMAL IDENTIFICATI... ✓  
PAIN & DISTRESS CLA... 2  
DRUGS & OTHER AGE... 2

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

Action Items Summary  
Admin Notes & F... 1  
General Action Items 1  
Print

C5

- An email notification of review completion will be sent to the IACUC Office. **Please Note:** Additional cycles of resubmission and review may be necessary before a final determination is made.

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## D. REVIEWING AMENDMENTS

Investigators submit proposed modifications to an approved protocol in Kuali by a two-step process: first by completing a short Amendment Form indicating the type(s) of modification(s) requested and the rationale for each modification; and then by directly modifying (editing) relevant sections of the most recently approved version of the Protocol Form. Initially, all members of the IACUC will be assigned as **Secondary Reviewers** for an amendment (explanation provided below). As a reviewer, you will need to evaluate changes described in both the Amendment and Protocol Forms.

1. After accessing the protocol as described in [Section A](#), please note the following:
  - a. You have access to **multiple versions of the protocol**; make sure you are reviewing the appropriate version.
  - b. As with resubmitted protocols (Section C), check **Show Latest Changes** to view 'track changes' text.
  - c. Using the left side panel, you can jump to the **Amendment Form** or to different **sections of the Protocol Form**.

The screenshot displays the Kuali system interface for reviewing amendments. The top navigation bar includes a 'Back' button and the protocol title: 'Manage Protocols → IACUC: #1252 Understanding and Addressing Cancer Health Disparities in the Gulf South'. The interface is divided into three main sections: 'PROTOCOL', 'REPORTABLE EVENTS', and 'ACTIVITY LOG'. On the left, a 'Jump to:' menu (D1c) allows navigation between different parts of the protocol, with 'Amendment' selected. A green box (D1a) highlights the 'Version:' dropdown menu, which lists five versions of the amendment, with the most recent version (5) selected. A green box (D1b) highlights the 'Show Latest Changes' checkbox. The main area displays the amendment details, including submission dates and review status. The right sidebar shows 'Action Items Summary' and other navigation options.

2. Initially, all members of the IACUC will be assigned as **Secondary Reviewers** for an amendment. **Within 48 hours**, please take one or more of the following actions:
  - a. Review information in the **Amendment Form** (and changes in the **Protocol Form**) and leave comments via field-specific **Action Items** as described in [Section C2](#). Then **Submit Review**.
  - b. Leave a **general comment** such as "no FCR required" or "I recommend review by the full committee" via the **General Action Items tab** as described in [Section C3](#). Then **Submit Review**.
  - c. Take no action.



← 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 INFORMATION ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓
- PROJECT PERSONNEL ✓
- OTHER REGULATORY ... ✓
- PROGRESS REPORT ✓
- NON-SCIENTIFIC SUM... ✓
- EXPERIMENTAL DESI... ✓
- PROJECT PERSONNEL ✓
- OTHER REGULATORY ... ✓
- PROGRESS REPORT ✓
- NON-SCIENTIFIC SUM... ✓
- EXPERIMENTAL DESI... ✓
- ANIMAL IDENTIFICATI... ✓
- PAIN & DISTRESS CLA... ✓

### Amendment Questionnaire

Please select the option that best describes the application you are preparing: [+ Action Item](#)  
 Amend alone **New**

Which modifications are being proposed for this study (select all that apply)? [+ Action Item](#)  
 Change of protocol title Change in animal type or number **New**

Is the project funded by a federal agency? [+ Action Item](#)  
 Yes **New**

Does this amendment constitute a reportable change in scope? [+ Action Item](#)  
 No **New**

### Rationale/Justification

Please provide the reason for changing the protocol title: [+ Action Item](#)  
 To match the title with the title of the grant award **New**

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: [+ Action Item](#)  
 Availability of new KO mice **New**

Action Items Summary  
 Admin Notes & Files  
 Submit Review  
 General Action Items  
 Print

D2a

← 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 INFORMATION ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓

### GENERAL INFORMATION

Project Title: [+ Action Item](#)  
 Understanding and Addressing Cancer Health Disparities in Louisiana **Old** the Gulf South **New**

Principal Investigator: [+ Action Item](#) Department: [+ Action Item](#)  
 Ochoa, Augusto Center of excellence-Cancer

Action Items Summary  
 Admin Notes & Files  
 Submit Review  
 General Action Items  
 Print

D2a

← 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 INFORMATION ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓

### GENERAL INFORMATION

Project Title: [+ Action Item](#)  
 Understanding and Addressing Cancer Health Disparities in Louisiana **Old** the Gulf South **New**

Principal Investigator: [+ Action Item](#) Department: [+ Action Item](#)  
 Ochoa, Augusto Center of excellence-Cancer

### General Action Items

Action Items [+ Action Item](#)

Fidel, Paul (impersonated by Alam, Jawed) 06/29/21 - 12:54PM  
 I recommend review by the full committee.  
 Visibility Admins

Action Items Summary  
 Admin Notes & Files  
 Submit Review  
 General Action Items

D2b

← 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 INFORMATION ✓
- FUNDING SOURCE(S) ✓
- PROJECT SCOPE ✓
- PROJECT PERSONNEL ✓
- OTHER REGULATORY ... ✓
- PROGRESS REPORT ✓
- NON-SCIENTIFIC SUM... ✓

### Submit Review

#### General Comment

YOUR ANONYMOUS COMMENTS:

Fidel, Paul (impersonated by Alam, Jawed) 06/29/21 - 12:54PM  
 I recommend review by the full committee.

Cancel Submit Review

Action Items Summary  
 Admin Notes & Files  
 Submit Review  
 General Action Items

D2a,b

3. After 48 hours, the IACUC Admin will do one of the following:
  - a. Place the amendment application on the agenda for the next convened meeting (if FCR is recommended or determined); or
  - b. In consultation with the Chair, assign a member to serve as the **Designated Member Reviewer (DMR)** to fully review the amendment application (if FCR is not recommended or there is no response).
4. If DMR is selected, the assigned member will carry out a thorough review using procedures described in the previous sections.
5. **PLEASE NOTE:** *All communications between the DMR and the PI or study team for additional information or clarification should be conducted and documented in Kuali using the Action Item – Researcher Response mechanism facilitated by the IACUC Admin as described in Sections B & C above.*

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## E. REVIEWING RENEWALS

*Continuing Review (Annual Renewal) applications will be reviewed, and status determined, by the IACUC Admin in consultation with the IACUC Chair.*

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## F. REVIEWING RENEWAL & AMENDMENTS

*Investigators have the option to submit an amendment application concurrent with the continuing review application in Kulai. The Amendment and Renewal applications will be reviewed by the procedures described in Sections D and E, respectively. Annual renewal will not be granted until the amendment has been approved. If an amendment cannot be approved, the IACUC Admin will notify the PI to submit a Renewal application ONLY.*

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## G. REVIEWING REPORTABLE EVENTS

Once a reportable event has been submitted, the IACUC Administrator, in consultation with the Chair, will assign reviewers as described for Initial Submission (Section B). You will receive an email notification of this assignment.

1. You can access the reportable event in one of two ways:
  - a. Click on the protocol link in the reviewer assignment email.
    - i. On the protocol page, click **Reportable Events**.

The screenshot shows the 'Manage Protocols' interface for protocol #1252. The 'REPORTABLE EVENTS' tab is highlighted in green. The page displays protocol information including version 9, review type 'Designated Member Review', status 'Approved', approval date 'Jul 01, 2021', and continuing review date 'Jun 30, 2022'. A green box labeled 'G1ai' is overlaid on the 'REPORTABLE EVENTS' tab.

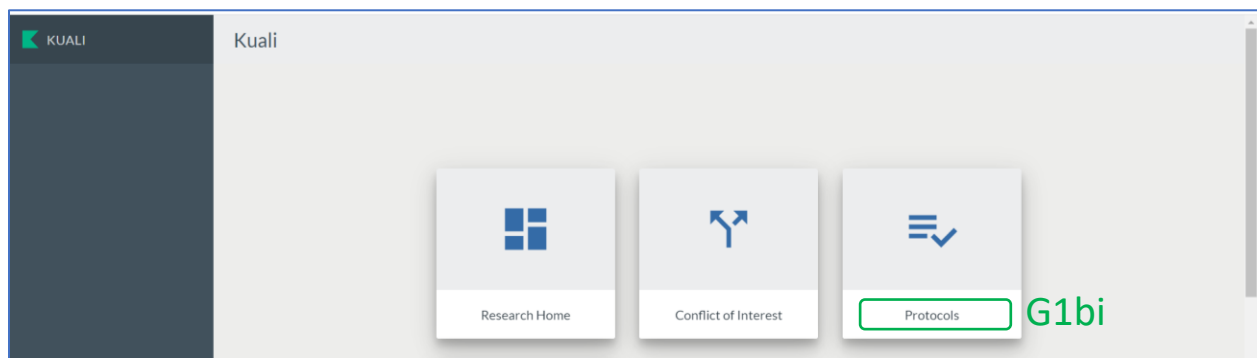
- ii. On the next page, click on the **event**.

The screenshot shows the 'Reportable Events' page. A table lists reportable events. The first event is highlighted with a green box labeled 'G1aii'.

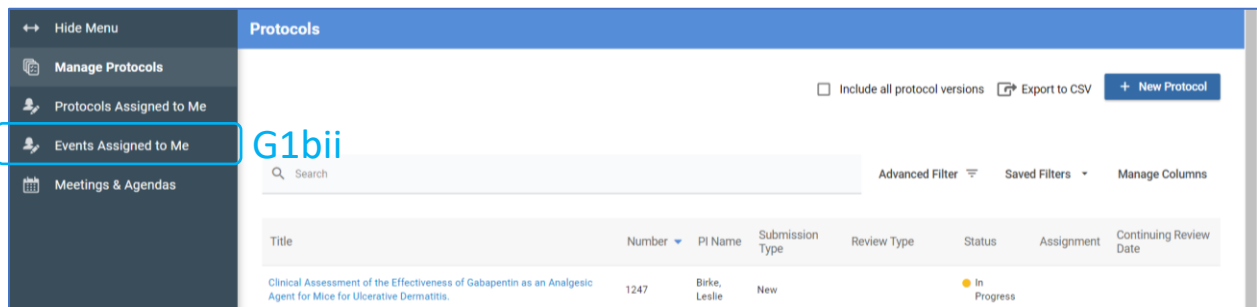
Event Type	Description	Status	Event Date	Recorded Date
Unanticipated Problem	Several CD-1 mice were found dead...	Submitted	June 30, 2021	July 01, 2021

1 of 1 reportable events

- b. Log into Kuali as described in [Section A](#).
  - i. Click on the **Protocols** button.



- ii. Click **Events Assigned to Me**.



- iii. Click the **event**.



2. The **Reportable Events Form** will display.
  - a. Review the **information provided by the researcher**.
  - b. If necessary, you may **view the protocol**.
  - c. Click **Submit Review**.

← Back Report Event for Protocol

Jump to:  
Event form

**Event Details**

Select the event type:  
Unanticipated Problem

Where did the event occur?  
LCRC, Room 908

When did the event occur?  
June 30, 2021

When did a member of the study team become aware of the event?  
June 30, 2021

**Event Description**

Please provide a detailed description of the event:  
Several CD-1 mice were found dead...

In your opinion, what is the root cause of the event, problem or non-compliance?  
The root cause of the deficiency may be misunderstanding/misinterpreting of lack of clear instructions to the students by ....

Submit Review  
Activity Log  
View Protocol

3. **NOTE:** Unlike for review of the protocol itself, review of reportable events does not provide the option for entering individual action items.
  - a. Enter all your comments, including any additional information you may require from the researcher, in the **Submit Review** text box. Click **Submit**.

← Back Report Event for Protocol

Jump to:  
Event form

**Event Description**

Please provide a detailed description of the event:  
Several CD-1 mice were found dead...

In your opinion, what is the root cause of the event, problem or non-compliance?  
The root cause of the deficiency may be misunderstanding/misinterpreting of lack of clear instructions to the students by ....

Submit Review  
Activity Log  
View Protocol

**Submit Review**

Comment  
Description of the event is provided in sufficient detail and the corrective action plan is acceptable.

Cancel Submit

4. Once the review is submitted, the IACUC Admin will facilitate any requested revisions from the researcher and also place the event on the agenda of the next IACUC meeting.

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## H. REVIEWING CLOSURES

*Closure Requests will be reviewed and approved, if appropriate, by the IACUC Admin in consultation with the IACUC Chair and DOAC.*

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