

KUALI QUICKGUIDE

CREATING AND SUBMITTING IBC PROTOCOLS IN KUALI

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

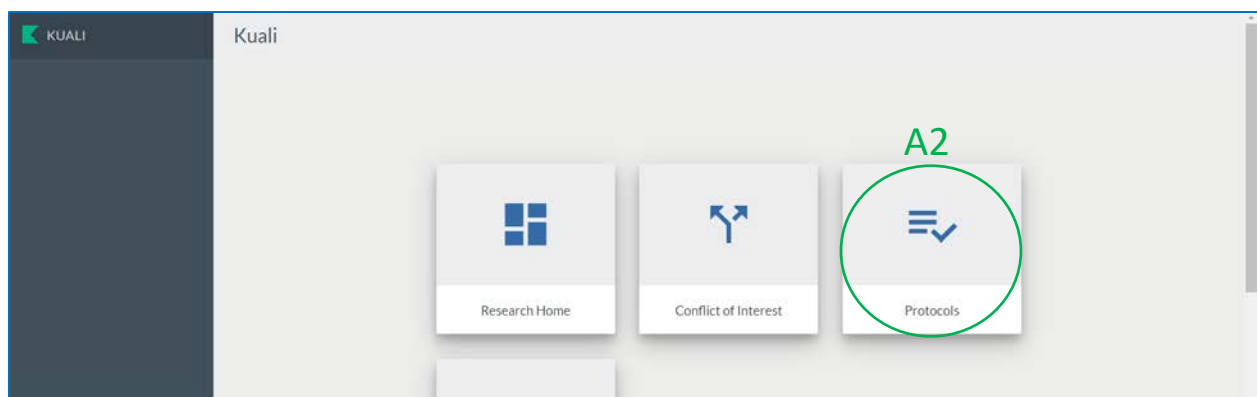
- A. [New Protocol – Initial Submission](#)
- B. [New Protocol - Resubmission](#)
- C. [Amendment](#)
- D. [Renewal](#)
- E. [Renewal & Amendment](#)
- F. [Reportable Event](#)
- G. [Closure](#)

A. NEW PROTOCOL - INITIAL SUBMISSION

1. Log into Kuali:

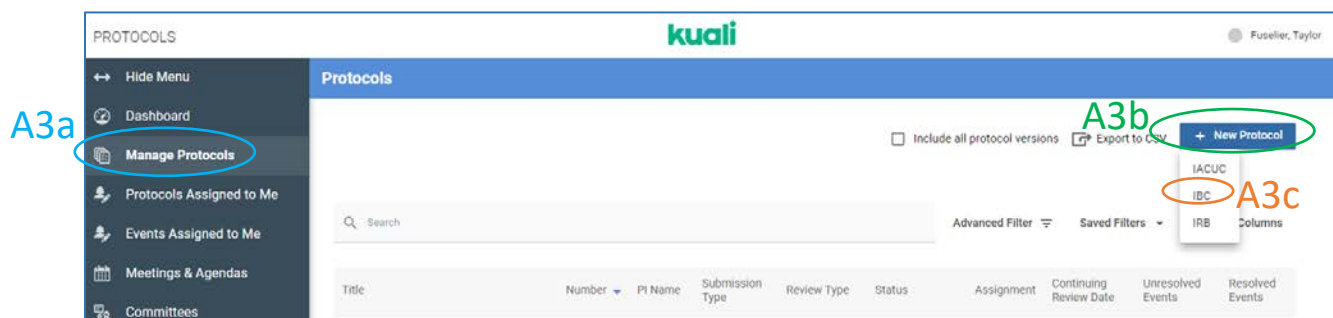
- LSUHSC Personnel (individuals **with** an active @lsuhsc.edu email address): <https://lsuhsc.kuali.co/cor/main/#/apps>.
- Non-LSUHSC Personnel (individuals **without** an active @lsuhsc.edu email address): <https://lsuhsc.kuali.co/auth/kuali>.
- Please contact the IBC Office (IBCOffice@lsuhsc.edu) 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 **IBC**.



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

IBC - General Information

A4 X Cancel
→ Next

IBC PROTOCOL FORM

In Kuali, 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 IBC for initial review. Detailed step by step instructions for completing the Protocol Form are found in this [document](#). Additional information about this Kuali module may be accessed by placing the pointer on the Help icon  below.

Please identify the proposed research by providing the following information:

Project Title:
Click Here to Add Text

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

PI's position:
-- --

5. On the next page, identify the scope of the project and then click **Next**.

A5 → Next

Please define the scope of the proposed research by answering all of the following questions.

This research project requires...

A) Review and approval by the LSUHSC-NO IACUC (i.e., involves use of live animals)

B) Review and approval by the LSUHSC-NO IRB (i.e., involves living individuals as research participants and/or use of their information or biospecimens)

C) Review and approval by the LSUHSC-NO IBC (i.e., involves the collection, isolation, preparation, manipulation or use of synthetic or recombinant nucleic acid molecules; recombinant microbes; genetically modified organisms; toxins; potentially infectious tissues, specimens or agents; or other biohazards)

A + B + C

Does this application represent an initial submission of a new project or a 5-year renewal of a previously approved project?

☒ Initial submission

☐ Renewal submission


Does this project require approval by:

- The LSUHSC-NO Radiation Safety Committee, or
- A Non-LSUHSC compliance committee or body?

☐ Yes

☒ No

This proposed research involves the use of (select all that apply):

- The CDC/USDA list of select agents and toxins is published [here](#).
- "Other Research Materials" may include experimental drugs, chemical carcinogens, animal tissues, and other potential biohazards
- The definition of Human Gene Transfer is available by placing the pointer over the Help icon .

☒ Adeno-associated viral (AAV) expression system

☐ Lentiviral (LV) expression system

☐ Other viral expression system (non-AAV, non-LNV)

6. The core **IBC Protocol Form** will be displayed including the information entered on the previous page.
- The **Type** and **Status** of the protocol will be indicated.
 - 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).
 - The **left side panel** will display the core sections of the Protocol Form.

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

8. 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 **Research Personnel** table, the status of KDS required training automatically will be displayed for the listed researcher. 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.

PRELIMINARY INFORMATION
PROJECT SCOPE
FUNDING SOURCE(S)
PERSONNEL
RESEARCH ACTIVITY LOCATION
PROJECT NARRATIVE
AAV EXPRESSION SYSTEM
LENTIVIRAL EXPRESSION
SYNTHETIC/RECOMBINANT NUCLEOTIDES
MICROORGANISMS/INFECTION
TOXINS OF BIOLOGICAL ORIGIN
HUMAN GENE TRANSFER
DILUTION & CONCENTRATION
INVENTORY & SHIPMENT
RISK ASSESSMENT/SAFETY
NIH GUIDELINES SECTION

TABLE: RESEARCH PERSONNEL
Click "Add Line" to enter a project personnel. Repeat this process until all personnel are listed.
Not all columns of a table may be visible. Click on the "Columns" button to select visibility of individual columns.

Columns + Add Line

NAME	DEGREE	AFFILIATION	PERMISSIONS	ACTIVITIES	TRAINING IN SYSTEM
Fuseller, Taylor	PhD		Full Access	experiment	Taylor Fuseller has no training courses on file.
Zea, Arnold	PhD		Full Access	pipette	KDS - CBI in Research 04/25/18 - 04/25/22 KDS - BHP High Risk 07/07/20 - 05/21/21 Expired KDS - Laboratory Safety 05/05/20 - 05/05/22 KDS - IBC Compliance 09/16/19 - 06/16/24

Submit
Print

9. Answer all questions or enter all data into fields.

- The **number of required questions remaining to be answered** in any given section will be indicated under the section title.
- Once the Protocol Form is complete, all supporting documents have been uploaded, click **Next** to go to the **Protocol Submission** page.

← Back Manage Protocols → IBC: #1326 Final Run-through

Protocol Activity Log Ancillary Review Permissions

Pages Expand Nav

IBC PROTOCOL

PRELIMINARY INFORMATION
PROJECT SCOPE
FUNDING SOURCE(S)
PERSONNEL
RESEARCH ACTIVITY LOCATION
PROJECT NARRATIVE
AAV EXPRESSION SYSTEM
LENTIVIRAL EXPRESSION
SYNTHETIC/RECOMBINANT NUCLEOTIDES
MICROORGANISMS/INFECTION
TOXINS OF BIOLOGICAL ORIGIN
HUMAN GENE TRANSFER
DILUTION & CONCENTRATION
INVENTORY & SHIPMENT
RISK ASSESSMENT/SAFETY
NIH GUIDELINES SECTION

NIH GUIDELINES SECTIONS
1 REQUIRED REMAINING
Click the "Add Line" button for additional rows.
Not all columns of a table may be visible. Click on the "Columns" button to select visibility of individual columns.

Columns + Add Line

SECTION	SUBSECTION	SUBPART	APPENDIX	EXPERIMENT/ACTIVITY
+ Add Info				

SUPPORTING DOCUMENTS
Use this table to provide required documents not previously attached to this application. You also may attach any additional documents, including any protocols or SOPs developed specific for this study, that may assist the IBC in its evaluation of the research.

TABLE: SUPPORTING DOCUMENTS
If needed, click the "Add Line" button for additional rows.

Columns + Add Line

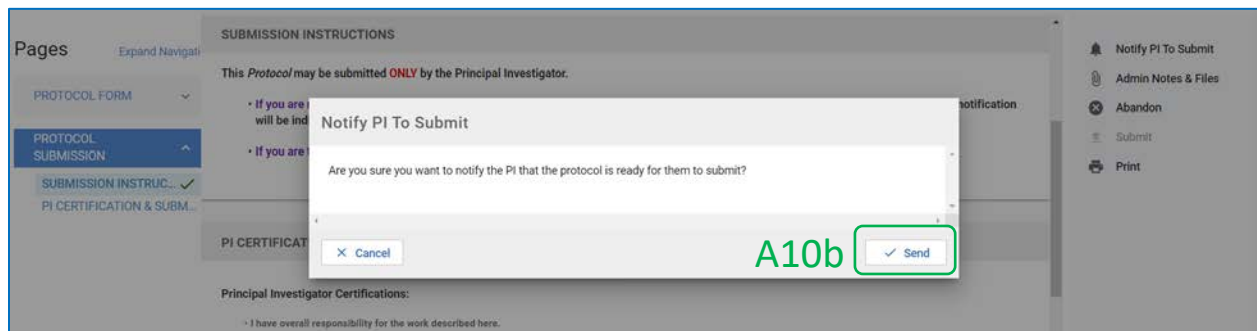
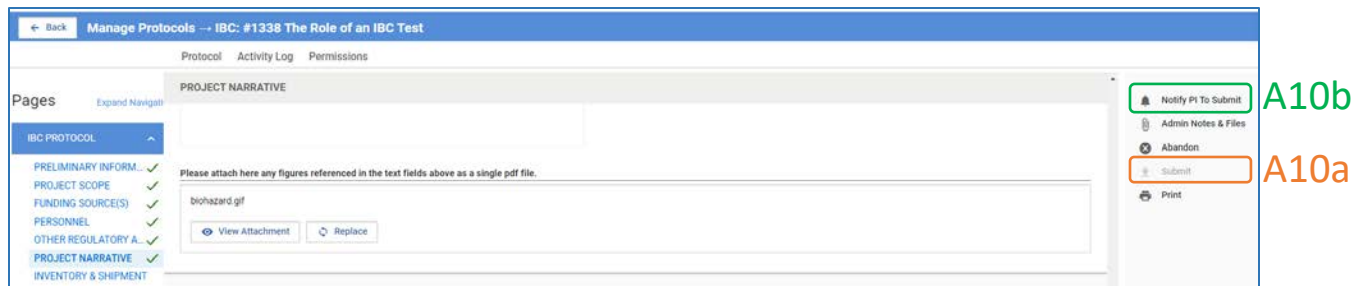
DOCUMENT TYPE	DOCUMENT DESCRIPTION	DOCUMENT UPLOAD
+ Add Info		

PROTOCOL SUBMISSION →

Notify PI To Submit
Admin Notes & Files
Abandon
Submit
Print

10. **Only the PI may submit the initial version of any protocol application.**

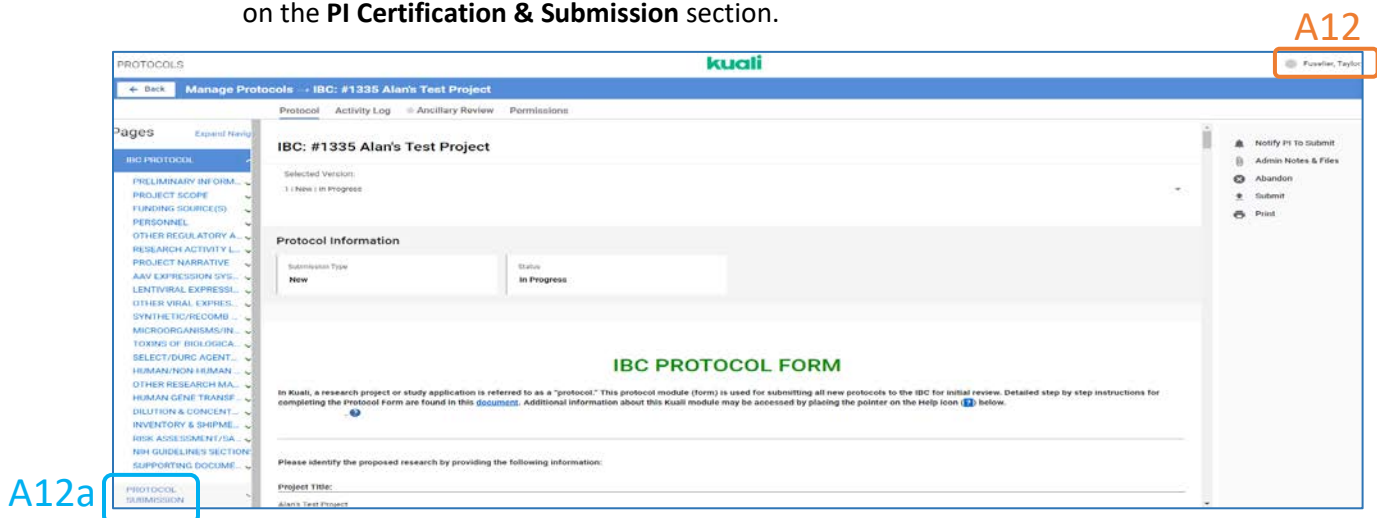
- If you are not the PI, the **Submit** button will be inactive.
- Click **Notify PI to Submit**; then click **Send** in the pop-up window.



11. 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.

12. Once the PI has opened the protocol...

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



13. The PI must:

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

SUBMISSION INSTRUCTIONS

- 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

PI Certification

As the Principal Investigator on this project, I _____ that:

- To the best of my knowledge, the information included in this application is accurate and complete;
- No research described in the application will be carried out until it has been approved by the IBC and all requirements have been met;
- All personnel will be informed of the potential risks associated with this research and will receive adequate training to perform all activities safely and proficiently;
- Once approved, the research will be carried out safely, in accordance with the approved protocol, and using practices and procedures that conform to the Biological Safety Level(s) assigned by the IBC;
- This research will be conducted in compliance with Section IV-B-7 of the NIH Guidelines: http://oba.od.nih.gov/odha/ish/guidelines_oba.html and, where applicable, with the NIH requirements pertaining to shipment and transfer of recombinant DNA materials;
- All research personnel, including myself, have a currently active annual COI disclosure. "Currently active" means the COI disclosure has been updated to reflect any COI acquired as a consequence of this specific research project; and
- No modifications to the research will be implemented without prior review and approval by the IBC.

☒ Certify
☐ Do Not Certify

Submit

14. If any required questions or data fields are empty, an **error message** will appear.

- Scroll through the application to identify fields with missing data/info.
- Entries in these fields may be made by the PI or the person who initially prepared the protocol, but only the PI will be able to submit the protocol.

HUMAN GENE TRANSFER

4 REQUIRED REMAINING

Incomplete
4 fields have validation errors.

You have indicated that this research is a first-in-human use.

Please answer the following questions.

Briefly describe the protocol design: *

Include, as appropriate, use of controls, number of arms, selection and number of subjects, number of rounds of therapy or study visits, length of follow-up, etc.

Click Here to Add Text

Required

Please describe the agent(s) being used for therapy: *

Click Here to Add Text

Required

Is this a first-in-human use? *

☐ Yes
☒ No

Submit

15. Once all required fields have entries, the error icons and message will disappear; PI clicks **Submit**.

HUMAN GENE TRANSFER

Please answer the following questions.

Briefly describe the protocol design: *

Include, as appropriate, use of controls, number of arms, selection and number of subjects, number of rounds of therapy or study visits, length of follow-up, etc.

Test

Please describe the agent(s) being used for therapy: *

Test

Is this a first-in-human use? *

☐ Yes
☒ No

Please summarize the safety profile of the agent(s) in humans, thus far: *

Test

Please provide a brief summary of the biosafety concerns related to the use of the agent(s): *

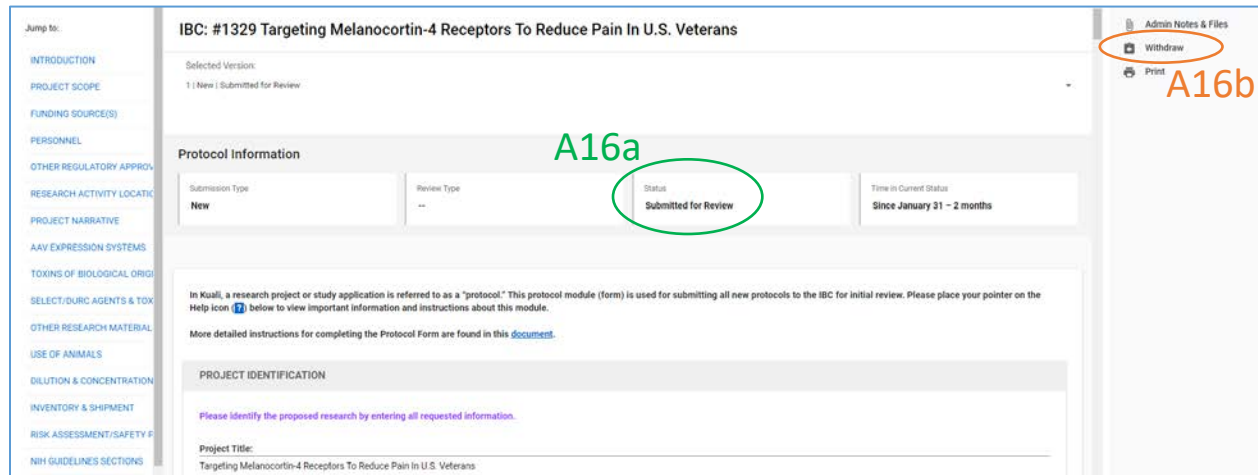
Address, as appropriate, pathogenicity, apl/iplash/aerosol/needlestick hazards, potential for transmission (horizontal or vertical), genome integration, adventitious infection and environmental implications.

Test

Submit

16. The **Status** of the protocol...

- a) Will change to **Submitted for Review** and...
- b) The applicant will have a new option: **withdrawing** the protocol.



The screenshot displays the IBC protocol submission interface for the protocol titled "IBC: #1329 Targeting Melanocortin-4 Receptors To Reduce Pain In U.S. Veterans". The left sidebar contains a "Jump to:" menu with various sections like INTRODUCTION, PROJECT SCOPE, FUNDING SOURCE(S), PERSONNEL, etc. The main content area shows the "Protocol Information" section with a table containing the following data:

Submission Type	Review Type	Status	Time in Current Status
New	--	Submitted for Review	Since January 31 - 2 months

The "Status" cell is circled in green and labeled "A16a". In the top right corner, the "Withdraw" button is circled in red and labeled "A16b". Below the table, there is a "PROJECT IDENTIFICATION" section with a prompt: "Please identify the proposed research by entering all requested information." and a "Project Title:" field containing "Targeting Melanocortin-4 Receptors To Reduce Pain In U.S. Veterans".

17. A system generated email will notify the **IBC Office** of the submission.

18. The IBC 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.*

[Return to Top](#)

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 IBC 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 Kualu 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 IBC 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. *Please disregard green checkmarks; they no longer are used in the most recent version of the Kualu template.*
 - e) On the right side panel, you can click on the **Admin Notes & Files** tab to view any additional information provided by the IBC 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 'Manage Protocols' interface for protocol #1323. The 'Protocol' tab is active, showing details for 'IBC: #1323 Test 1-26-22 for Guidelines'. The 'Selected Version' is '2 (New) Revisions in Progress' (B2a). The 'Protocol Information' section shows 'Submission Type: New' (B2d), 'Review Type: Designated Member Review', and 'Status: Revisions in Progress' (B2b). A 'Feedback' section (B2c) is highlighted in orange. The right sidebar (B2e) contains tabs for 'Action Items Summary', 'Admin Notes & Files', 'Review Assignments', 'Resubmit', 'Abandon', and 'Print'. The left sidebar shows a list of protocol sections, some with orange action item icons.

Action Items Summary for Protocol #1338

^ Collapse All

^ IBC PROTOCOL / FUNDING SOURCE(S) / Funding sources List / Item 1

Anonymous 02/03/22 · 2:55PM
Please provide grant number.

^ IBC PROTOCOL / FUNDING SOURCE(S) / Congruency check?

Anonymous 02/03/22 · 2:55PM
A check must be done.

^ IBC PROTOCOL / OTHER REGULATORY APPROVALS / Other regulatory status / Item 1

Anonymous 02/03/22 · 2:55PM
Please provide document.

^ IBC PROTOCOL / PROJECT NARRATIVE / Registration

Anonymous 02/03/22 · 2:55PM
Clarification needed.

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.

← Back Manage Protocols → IBC: #1338 The Role of an IBC Test

Protocol Activity Log Permissions

Pages Expand Navigation

IBC PROTOCOL

PRELIMINARY INFORM ✓

PROJECT SCOPE ✓

FUNDING SOURCE(S) ✓

PERSONNEL ✓

OTHER REGULATORY APPROVALS ✓

PROJECT NARRATIVE ✓

INVENTORY & SHIPMENT ✓

FUNDING SOURCE(S)

Is the funding source grant proposal available in the Kuall Research Proposal Development module?

Grant proposals are typically submitted by department business managers via the Kuall Proposal Development module to the Office of Research Services for review and approval. If you are unsure of the answer, select "No".

☐ Yes

☒ No

Please list all sources of funding supporting this project (including internal sources) in the table below.

TABLE: FUNDING DETAILS

Use the "Add Line" button to enter multiple sponsors.

Columns + Add Line

SPONSOR GRANT STATUS GRANT NUMBER AWARD PERIOD AWARD PI

1 Action Items Reward Pending 12345

Funding sources List / Item 1

Action Items

Anonymous 02/03/22 · 2:55PM

Please provide grant number...

Admins Assigned Reviewers Researchers

Reply

B3a

B3b

B3d

B3c

B3e

4. Next:

- a) Enter your response to this action item.
- b) Click **Post**.

← Back Manage Protocols → IBC: #1338 The Role of an IBC Test

Protocol Activity Log Permissions

Pages Expand Navigation

IBC PROTOCOL

PRELIMINARY INFORMATION ✓

PROJECT SCOPE ✓

FUNDING SOURCE(S) 1

PERSONNEL ✓

OTHER REGULATORY APPROVALS 1

PROJECT NARRATIVE 1

INVENTORY & SHIPMENT ✓

FUNDING SOURCE(S)

Is the funding source grant proposal available in the Kualu Research Proposal Development module?

Grant proposals are typically submitted by department business managers via the Kualu Proposal Development module to the Office of Research Services for review and approval. If you are unsure of the answer, select 'No'.

☐ Yes

☒ No

Please list all sources of funding supporting this project (including internal sources) in the table below.

TABLE: FUNDING DETAILS

Use the '+Add Line' button to enter multiple sponsors.

Columns + Add Line

Sponsor	Grant Status	Grant Number	Award Period	Award PI
Reward	Pending	12345		

Action Items: 1

Does the funding agency require a congruency check between the grant and the IBC application?

Action Items: 1

Funding sources List / Item 1

Action Items

A: Anonymous 02/03/22 - 2:55PM

Please provide grant number: ...

Visibility

Admin Assigned Reviewers Researchers

Grant Number is NCI 8675309

Cancel Post

5. Repeat this procedure for all action items left by the reviewer or IBC Admin.

- a) When you post your response to an action item, the **action item icon will disappear**.
- b) When all action items have been addressed, click **Resubmit**. *All study personnel with full access to the protocol can resubmit a protocol, not just the PI.*

Jump to: B5a

Renewal Progress Report

PRELIMINARY INFORMATION

PROJECT SCOPE

FUNDING SOURCE(S)

PERSONNEL

OTHER REGULATORY APPROVALS

PROJECT NARRATIVE

INVENTORY & SHIPMENT

OTHER REGULATORY APPROVALS

Please note: A research project may not be initiated until approved by all applicable compliance committees.

In the table below, please indicate the status of the review by other compliance committees (IACUC, IRB, etc.):

Columns

COMMITTEE	NON-LSUHSIC OVERSIGHT	STATUS	STUDY ID
No Action Items	IRB	Application in Preparation	

PROJECT NARRATIVE

Please Note: It is not possible to include illustrations in text fields. If you need to include figures in your project narrative, enter the figure reference (e.g., Fig. 1, Fig. 2, etc.) in the text field and attach the figures as a single pdf file at the end of this section.

Action Items Summary

Admin Notes & Files

Resubmit B5b

Abandon

Print

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 'IBC: #1321 Test 1-26-22 V2'. The interface includes a left sidebar with a 'Jump to:' section listing various protocol sections (Introduction, General Information, Project Scope, Funding Source(s), Personnel, Research Activity Location, Project Narrative, Inventory & Shipments, Risk Assessment(s), Supporting Documents, Submission Instructions, PI Certification & Signatures, and For Deletion?), each with a green checkmark. The main content area shows the 'Selected Version' as '2 (New / Resubmitted)' (labeled B6a). Below this, the 'Protocol Information' section displays 'Submission Type' as 'New', 'Review Type' as '--', and 'Status' as 'Resubmitted' (labeled B6b). The 'Time in Current Status' is 'Since February 4 - a few seconds'. On the right side, there is a 'Compare Versions' button and a 'Right Side Panel' (labeled B6c) containing 'Admin Notes & Files', 'Withdraw', and 'Print' options. A help icon and text are visible at the bottom of the main content area.

7. A system generated email will be sent to the IBC Administrator and PI notifying them of the resubmission.
8. The IBC 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.*

[Return to Top](#)

C. AMENDMENT

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

1. Log into Kualu 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 'IBC: #1343 Amendment and Renewal Instructional'. The left sidebar lists various sections like 'PRELIMINARY INFOR...', 'PROJECT SCOPE', 'FUNDING SOURCE(S)', 'PERSONNEL', 'OTHER REGULATORY APP...', 'RESEARCH ACTIVITY ...', 'PROJECT NARRATIVE', and 'SYNTHETIC/RECOMB ...'. The main content area shows 'Selected Version: 1 | Initial | Approved' and 'Protocol Information' with fields for 'Review Type' (Full Committee), 'Status' (Approved), 'Approval Date' (Feb 16, 2022), and 'Continuing Review Date' (Feb 16, 2023). The right-hand panel contains a list of actions: 'Amend' (highlighted with an orange box and label C2), 'Renew', 'Renew & Amend', 'Action Items Summary', 'Admin Notes & Files', 'Request Close', and 'Print'.

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 'IBC: #1343 Amendment and Renewal Instructional'. The left sidebar lists various sections like 'IBC PROTOCOL', 'PRELIMINARY INFOR...', 'PROJECT SCOPE', 'FUNDING SOURCE(S)', 'PERSONNEL', 'OTHER REGULATORY APP...', 'RESEARCH ACTIVITY ...', 'PROJECT NARRATIVE', 'SYNTHETIC/RECOMB ...', 'TOXINS OF BIOLOGICA...', 'SELECT/DURC AGENT...', 'DILUTION & CONCENT...', 'INVENTORY & SHIPME...', and 'RISK ASSESSMENT/SA...'. The main content area shows 'Selected Version: 2 | Amendment | In Progress' (highlighted with a green box and label C3a) and 'Protocol Information' (highlighted with a green box and label C3b) with fields for 'Submission Type' (Amendment), 'Status' (In Progress), 'Approval Date' (Feb 16, 2022), 'Continuing Review Date' (Feb 16, 2023), 'Expiration Date' (Feb 16, 2022), 'Initial Approval Date' (Feb 16, 2022), and 'Initial Review Type' (Full Committee). The right-hand panel contains a list of actions: 'Notify PI To Submit' (highlighted with an orange box and label C3c), 'Admin Notes & Files', 'Abandon', 'Submit' (highlighted with an orange box and label C3c), and 'Print'.

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

The screenshot shows the 'Manage Protocols' interface for IBC #1343. The 'Protocol' tab is selected. The main content area is titled 'IBC AMENDMENT FORM'. It includes an 'Introduction' section with instructions on how to use the form and a 'Please Note' section. Below the introduction is the 'Amendment Questionnaire' section. The left sidebar shows a list of pages, with 'IBC PROTOCOL' selected. The right sidebar contains action buttons: 'Notify PI To Submit', 'Admin Notes & Files', 'Abandon', 'Submit', and 'Print'.

5. In the **Amendment Questionnaire** section:
 - a. Select the type of submission being prepared; **Amend only** in this case.

The screenshot shows the 'Amendment Questionnaire' section of the IBC Amendment Form. A green box highlights the question: 'Please select the option that best describes the application you are preparing:'. Below this question are two radio button options: 'Amend ONLY' and 'Renew & Amend'. The 'Amend ONLY' option is selected. To the right of the options, the text 'C5a' is visible. Below the radio buttons is another question: 'As part of this amendment, are you requesting a change in the PI for this study?'. Below this question are two radio button options: 'Yes' and 'No'. The 'No' option is selected. The left sidebar and right sidebar are the same as in the previous screenshot.

6. Answer all remaining questions on the Amendment Form.
7. The **description** of the proposed modification and its **justification are** provided on the Amendment Form.

The screenshot shows the 'Description & Justification' section of the IBC Amendment Form. A green box highlights the text: 'Please list each proposed modification numerically. Then provide a detailed description of, and justification for, each modification.' Below this text is a large text area for input. To the right of the text area, the text 'C7' is visible. The left sidebar and right sidebar are the same as in the previous screenshots.

8. But you also must revise the actual, active protocol to reflect the proposed modification(s).
 - a. These revisions are made on the **Protocol Form that follows the Amendment Form.**
 - b. To modify the protocol, simply **edit the relevant text in a populated field** (e.g., change in the project title shown below) or add new entries into empty fields as appropriate.

The screenshot shows the IBC Protocol Form interface. At the top, there's a navigation bar with tabs: Protocol, Reportable Events, Activity Log, Ancillary Review, and Permissions. Below this, a sidebar on the left lists various sections like INTRODUCTION, GENERAL INFORMATION, PROJECT SCOPE, etc. The main content area is divided into two sections: 'END OF IBC AMENDMENT FORM' (highlighted with a green box) and 'IBC PROTOCOL FORM' (also highlighted with a green box). The 'IBC PROTOCOL FORM' section contains a 'Project Title' field with the text 'Investigating Kuaili IBC' (highlighted with a green box and labeled C8a). Other fields include 'Principal Investigator', 'PI's position', 'PI's department', and 'PI's telephone number'.

This screenshot shows the same IBC Protocol Form interface, but the 'Project Title' field now contains the text 'Testing the Amendment Application' (highlighted with a green box). A red arrow points from the 'Project Title' field in the previous screenshot to this one, labeled C8b. The rest of the form remains the same.

PLEASE NOTE: Certain modifications may activate additional questions or fields that previously were not visible. Please make sure to answer any new questions that become available.

9. Once all modifications have been made to the protocol,
 - a. If the person preparing the application is the PI, go to Step 11.
 - b. If not the PI, click **Notify PI to Submit** and then click **Send** in the pop-up window.

This screenshot shows the IBC Protocol Form interface with a 'Notify PI To Submit' pop-up window. The 'Notify PI To Submit' button in the top right corner is highlighted with an orange box and labeled C9b. The pop-up window contains the text 'Are you sure you want to notify the PI that the protocol is ready for them to submit?' and has 'Cancel' and 'Send' buttons. The 'Send' button is highlighted with a green box and labeled C9b. The background shows the 'Project Title' field with the text 'Testing the Amendment Application'.

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 in progress**.*

Protocol Name	Protocol Number	IBC	PI Name	Status	Submitted for Review	December 06, 2022	0	0
Investigating Kuali IBC	1301	IBC	Alam, Jawed	Initial	Exempt	Exempt		
Testing the Amendment Application	1301	IBC	Alam, Jawed	Amendment	In Progress		0	0
Taylor's Test V2	1297	IBC	Fuselier, Taylor	New	Abandoned			
Taylor's Test V1	1296	IBC	Fuselier, Taylor	New	In Progress (Withdrawn)			
20054-SP/INW Pathogenesis Research	1274	IBC	Zea, Arnold	New	In Progress			
Mouse model of breast cancer	1260	IBC	Ochoa, Augusto	New	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. The PI should review all the modifications and then...
 - a. Go to the last section, **Certification & Submission**, of the Amendment Form.
 - b. **Certify** to the attestations, and...
 - c. Click **Submit**.

Manage Protocols -> IBC: #1343 Amendment and Renewal Instructional

Protocol | Reportable Events | Activity Log | Permissions

Certification & Submission C11a

This Amendment (or Renewal + 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 application is ready for review, certification 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.

PI Certification

As the Principal Investigator on this project, I _____ that:

- I am responsible for the overall conduct of the research.
- To the best of my knowledge, the information included in this application is accurate and complete;
- No research described in the application will be carried out until it has been approved by the IBC and all requirements have been met;
- All personnel will be informed of the potential risks associated with this research and will receive adequate training to perform all activities safely and proficiently;
- Once approved, the research will be carried out safely, in accordance with the approved protocol, and using practices and procedures that conform to the Biological Safety Level(s) assigned by the IBC;
- This research will be conducted in compliance with Section IV-B-7 of the NIH Guidelines: http://oba.od.nih.gov/rdna/niH_guidelines_oba.html and, where applicable, with the NIH requirements pertaining to shipment and transfer of recombinant DNA materials;
- All research personnel, including myself, have a currently active annual COI disclosure. "Currently active" means the COI disclosure has been updated to reflect any COI acquired as a consequence of this specific research project; and
- No modifications to the research will be implemented without prior review and approval by the IBC.

☒ **Certify** C11b

☐ DO NOT certify

Submit C11c

Right sidebar buttons: Notify PI To Submit, Admin Notes & Files, Abandon, Submit, Print.

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

13. Correct all errors until the error message disappears, and then click **Submit** again.

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

15. A system-generated email will be sent notifying the IBC Office of the submission.
16. The IBC Admin will facilitate administrative and Chairperson/Committee review of the amendment application.
17. 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](#)).

[Return to Top](#)

D. RENEWAL

IBC protocols are approved for five (5) years. 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 Kuali 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 'IBC: #1343 Amendment and Renewal Instructional'. The 'Selected Version' is '3 | Amended | Approved' (D1). The 'Protocol Information' table shows: Review Type: Full Committee, Status: Approved, Approval Date: Feb 16, 2022, Continuing Review Date: Feb 16, 2023, Expiration Date: Feb 16, 2027, Initial Approval Date: Feb 16, 2022, Initial Review Type: Full Committee. On the right sidebar, the 'Renew' button is highlighted with a red box and labeled 'D1'.

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 'IBC: #1343 Amendment and Renewal Instructional'. The 'Selected Version' is '4 | Renewal | In Progress' (D2). The 'Protocol Information' table shows: Submission Type: Renewal, Status: In Progress, Approval Date: --, Continuing Review Date: --, Expiration Date: --, Initial Approval Date: --, Initial Review Type: --. On the right sidebar, the 'Notify PI to Submit' button is highlighted with a red box and labeled 'D2a', and the 'Submit' button is highlighted with a red box and labeled 'D2a'.


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

D3a IBC ANNUAL RENEWAL FORM

Introduction

Please complete this **RENEWAL FORM** to request annual re-approval of research previously approved by the IBC. If you are submitting a **Renew + Amend** application, please also complete the **AMENDMENT FORM** that follows the **RENEWAL FORM**.

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).

Instructions for completing this form are available in the Kuala QuickGuide, *Creating & Submitting IBC Protocols in Kuala*, located at the [IBC website](#). Where available, please click on the help icon, , for important guidance.

D3b

Which post-approval application are you submitting?

☒ Renew ONLY

☐ Renew & Amend

Are you aware of any incidents or events (which may have compromised the biosafety status of experiments or the study) that have occurred during the current annual approval period but have **NOT** been reported to the IBC?

☐ Yes

☒ No

During the current annual approval period, did you make any modifications to the research (change in personnel, addition of research materials, etc.) **WITHOUT** first submitting an amendment application to the IBC for review and approval?

☐ Yes

☒ No

Have all biological and laboratory activities been completed?

☐ Yes

☒ No

D3c Notify PI To Submit

D3c

Notify PI To Submit

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

4. The PI will receive an email notification to submit the Renewal application.
5. After opening the protocol, the PI should...
 - a. Review the entries on the form,
 - b. **Certify and agree** to the attestations, and

- c. **Submit** the application.

Manage Protocols → IBC: #1343 Amendment and Renewal Instructional

Protocol Reportable Events Activity Log Permissions

Jump to:

- Renewal Progress Rep... ✓
- PRELIMINARY INFOR... ✓
- PROJECT SCOPE ✓
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY APP... ✓
- RESEARCH ACTIVITY... ✓
- PROJECT NARRATIVE ✓
- SYNTHETIC/RECOMB... ✓
- TOXINS OF BIOLOGIC... ✓
- SELECT/DURC AGENT... ✓
- DILUTION & CONCENT... ✓
- INVENTORY & SHIPM... ✓

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. An email will be sent notifying the PI that the **Renewal** application is ready for review and submission.
- If you are the PI, please go to the next step, PI certification.

PI Certification

As the Principal Investigator on this project, I _____ that:

- To the best of my knowledge, the information included in this application is accurate and complete.
- No research described in the application will be carried out until it has been approved by the IBC and all requirements have been met.
- All personnel will be informed of the potential risks associated with this research and will receive adequate training to perform all activities safely and proficiently.
- Once approved, the research will be carried out safely, in accordance with the approved protocol, and using practices and procedures that conform to the Biological Safety Level(s) assigned by the IBC.
- No modifications to the research will be implemented without prior review and approval by the IBC.

☒ Certify **D5b**

☐ Do not certify

Submit for Review

Click "Submit" for the application to be sent to the IBC Office for review. A member of the IBC Office staff will contact you through KR if additional

Notify PI To Submit

Admin Notes & Files

Abandon

Submit **D5c**

Print

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

Manage Protocols → IBC: #1343 Amendment and Renewal Instructional

Protocol Reportable Events Activity Log Permissions

Jump to:

- Renewal Progress Rep... ✓
- PRELIMINARY INFOR... ✓
- PROJECT SCOPE ✓
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY APP... ✓
- RESEARCH ACTIVITY... ✓
- PROJECT NARRATIVE ✓
- SYNTHETIC/RECOMB... ✓
- TOXINS OF BIOLOGIC... ✓
- SELECT/DURC AGENT... ✓
- DILUTION & CONCENT... ✓
- INVENTORY & SHIPM... ✓

IBC: #1343 Amendment and Renewal Instructional

Selected Version: **4 | Renewal | Submitted for Review** **D6**

Protocol Information **D6**

Submission Type Renewal	Review Type --	Status Submitted for Review	Time in Current Status Since February 16 ~ a few seconds
Approval Date --	Continuing Review Date --	Expiration Date --	Initial Approval Date Feb 16, 2022
Initial Review Type Full Committee			

Admin Notes & Files

Withdraw **D6**

Print

7. A system generated email will notify the IBC Office of the submission.
8. The IBC Admin will facilitate administrative and Chairperson/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](#)).

[Return to Top](#)

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. After opening the **most recently approved version** of the protocol, click the **Renew & Amend** button on the right side panel. A **new version** of the protocol will be created.

Manage Protocols → IBC: #1343 Amendment and Renewal Instructional

Protocol | Reportable Events | Activity Log | Permissions

Jump to:

- Renewal Progress Rep... ✓
- PRELIMINARY INFOR... ✓
- PROJECT SCOPE ✓
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY APP... ✓
- RESEARCH ACTIVITY... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB... ✓
- TOXINS OF BIOLOGIC... ✓

Selected Version: 4 | Renewed | Approved E2

Compare Versions

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

Protocol Information

Review Type	Status	Approval Date	Continuing Review Date
Full Committee	Approved	Feb 16, 2022	--
Expiration Date	Initial Approval Date	Initial Review Type	
--	Feb 16, 2022	Full Committee	

Manage Protocols → IBC: #1343 Amendment and Renewal Instructional

Protocol | Reportable Events | Activity Log | Ancillary Review | Permissions

Pages

- IBC PROTOCOL
- PRELIMINARY INFORMATION
- PROJECT SCOPE
- FUNDING SOURCE(S)
- PERSONNEL
- OTHER REGULATORY APP...
- RESEARCH ACTIVITY LOG
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB NUC
- TOXINS OF BIOLOGICAL OR
- SELECT/DURC AGENTS & T
- DILUTION & CONCENTRAT
- INVENTORY & SHIPMENT
- RISK ASSESSMENT/SAFET
- NIH GUIDELINES SECTION
- SUPPORTING DOCUMENTS

Selected Version: 6 | Renew/Amend | In Progress E2

Protocol Information

Submission Type	Status	Approval Date	Continuing Review Date
Renew/Amend	In Progress	--	--
Expiration Date	Initial Approval Date	Initial Review Type	
--	Feb 16, 2022	Full Committee	

IBC ANNUAL RENEWAL FORM

Introduction

Please complete this **RENEWAL FORM** to request annual re-approval of research previously approved by the IBC. If you are submitting a **Renew + Amend** application, please also complete the **AMENDMENT FORM** that follows the **RENEWAL FORM**.

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).

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](#).

The diagram illustrates the workflow for submitting protocols in the Manage Protocols system. It consists of three screenshots of the interface, connected by a vertical red dotted line with downward-pointing arrows.

Top Screenshot: IBC ANNUAL RENEWAL FORM E3

- Header:** Manage Protocols → IBC: #1343 Amendment and Renewal Instructional
- Navigation:** Protocol, Reportable Events, Activity Log, Permissions
- Left Panel (Pages):** IBC PROTOCOL (expanded), PRELIMINARY INFORM., PROJECT SCOPE, FUNDING SOURCE(S), PERSONNEL, OTHER REGULATORY APP., RESEARCH ACTIVITY L., PROJECT NARRATIVE, SYNTHETIC/RECOMB., TOXINS OF BIOLOGICAL, SELECT/DURC AGENT, DILUTION & CONCENT., INVENTORY & SHIPME., RISK ASSESSMENT/SA., NIH GUIDELINES SECTI., SUPPORTING DOCUME., PROTOCOL SUBMISSION.
- Main Content:**
 - Introduction:** Please complete this **RENEWAL FORM** to request annual re-approval of research previously approved by the IBC. If you are submitting a **Renew + Amend** application, please also complete the **AMENDMENT FORM** that follows the **RENEWAL FORM**.
 - Which post-approval application are you submitting?**
 - ☐ Renew ONLY
 - ☐ Renew & Amend
- Right Panel:** Notify PI To Submit, Admin Notes & Files, Abandon, Submit, Print.

Middle Screenshot: IBC AMENDMENT FORM E3

- Header:** Manage Protocols → IBC: #1343 Amendment and Renewal Instructional
- Navigation:** Protocol, Reportable Events, Activity Log, Permissions
- Left Panel (Pages):** IBC PROTOCOL (expanded), PRELIMINARY INFORM., PROJECT SCOPE, FUNDING SOURCE(S), PERSONNEL, OTHER REGULATORY APP., RESEARCH ACTIVITY L., PROJECT NARRATIVE, SYNTHETIC/RECOMB., TOXINS OF BIOLOGICAL, SELECT/DURC AGENT, DILUTION & CONCENT., INVENTORY & SHIPME., RISK ASSESSMENT/SA., NIH GUIDELINES SECTI., SUPPORTING DOCUME., PROTOCOL SUBMISSION.
- Main Content:**
 - Please select the option that best describes the application you are preparing:**
 - ☐ Amend ONLY
 - ☐ Renew & Amend
 - As part of this amendment, are you requesting a change in the PI for this study?**
 - ☐ Yes
 - ☐ No
- Right Panel:** Notify PI To Submit, Admin Notes & Files, Abandon, Submit, Print.

Bottom Screenshot: IBC PROTOCOL FORM E3

- Header:** Manage Protocols → IBC: #1343 Amendment and Renewal Instructional
- Navigation:** Protocol, Reportable Events, Activity Log, Permissions
- Left Panel (Pages):** IBC PROTOCOL (expanded), PRELIMINARY INFORM., PROJECT SCOPE, FUNDING SOURCE(S), PERSONNEL, OTHER REGULATORY APP., RESEARCH ACTIVITY L., PROJECT NARRATIVE, SYNTHETIC/RECOMB., TOXINS OF BIOLOGICAL, SELECT/DURC AGENT, DILUTION & CONCENT., INVENTORY & SHIPME., RISK ASSESSMENT/SA., NIH GUIDELINES SECTI., SUPPORTING DOCUME., PROTOCOL SUBMISSION.
- Main Content:**
 - Please identify the proposed research by providing the following information:**
 - Project Title:**
- Right Panel:** Notify PI To Submit, Admin Notes & Files, Abandon, Submit, Print.

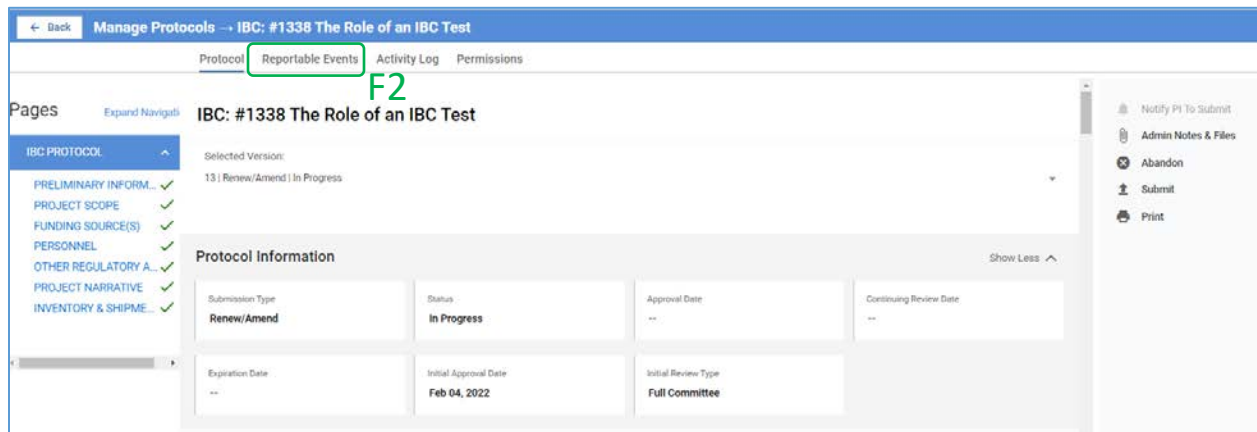
- Only the PI can submit the initial **Renew & Amend** application. Follow the procedures for PI notification, certification and submission described in the previous sections. The PI certification is found in the **Amendment Form**.

[Return to Top](#)

F. REPORTABLE EVENT

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



← Back Manage Protocols → IBC: #1338 The Role of an IBC Test

Protocol **Reportable Events** Activity Log Permissions

Pages Expand Navigation IBC: #1338 The Role of an IBC Test

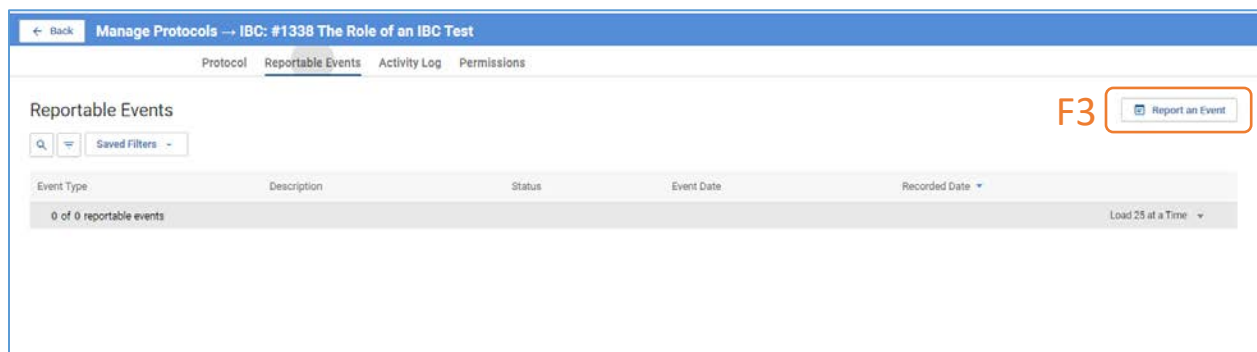
Selected Version: 13 | Renew/Amend | In Progress

Protocol Information

Submission Type Renew/Amend	Status In Progress	Approval Date ---	Continuing Review Date ---
Expiration Date ---	Initial Approval Date Feb 04, 2022	Initial Review Type Full Committee	

Notify PI To Submit
Admin Notes & Files
Abandon
Submit
Print

3. Click **Report an Event**.



← Back Manage Protocols → IBC: #1338 The Role of an IBC Test

Protocol **Reportable Events** Activity Log Permissions

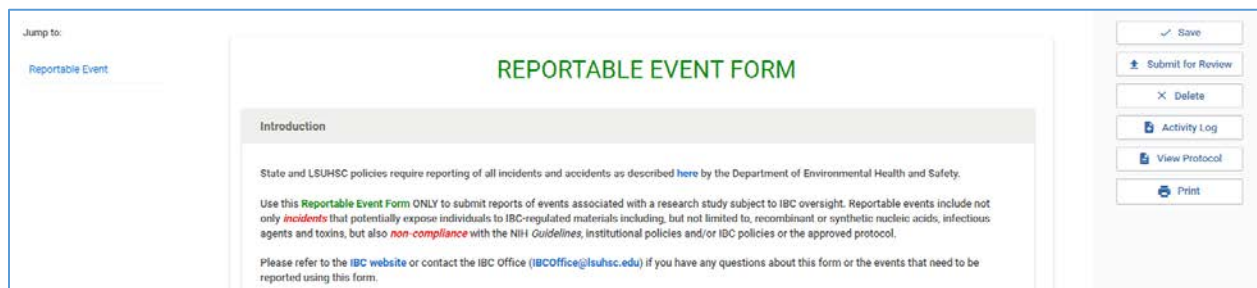
Reportable Events

0 of 0 reportable events

Load 25 at a Time

F3 Report an Event

4. The **Reportable Event Form** will display. Follow directions and answer all questions.



Jump to:
Reportable Event

REPORTABLE EVENT FORM

Introduction

State and LSUHSC policies require reporting of all incidents and accidents as described [here](#) by the Department of Environmental Health and Safety.

Use this **Reportable Event Form** ONLY to submit reports of events associated with a research study subject to IBC oversight. Reportable events include not only **incidents** that potentially expose individuals to IBC-regulated materials including, but not limited to, recombinant or synthetic nucleic acids, infectious agents and toxins, but also **non-compliance** with the NIH Guidelines, institutional policies and/or IBC policies or the approved protocol.

Please refer to the [IBC website](#) or contact the IBC Office (IBCOffice@lsuhsc.edu) if you have any questions about this form or the events that need to be reported using this form.

Save
Submit for Review
Delete
Activity Log
View Protocol
Print

5. Unlike the protocol applications (forms), entries are not saved automatically. Click **Save** periodically until you are ready to submit.
 - a. Once the form is complete, click **Submit for Review**.

← Back Report Event for Protocol

Jump to:
Reportable Event

REPORTABLE EVENT FORM

Introduction

State and LSUHSC policies require reporting of all incidents and accidents as described [here](#) by the Department of Environmental Health and Safety.

Use this **Reportable Event Form** ONLY to submit reports of events associated with a research study subject to IBC oversight. Reportable events include not only **incidents** that potentially expose individuals to IBC-regulated materials including, but not limited to, recombinant or synthetic nucleic acids, infectious agents and toxins, but also **non-compliance** with the NIH Guidelines, institutional policies and/or IBC policies or the approved protocol.

Please refer to the [IBC website](#) or contact the IBC Office (IBCOffice@lsuhsc.edu) if you have any questions about this form or the events that need to be reported using this form.

F5 Save
F5a Submit for Review
X Delete
Activity Log
View Protocol
Print

b. NOTE: Any study team member with access to the protocol in Kuali, not just the PI, may submit a reportable event.

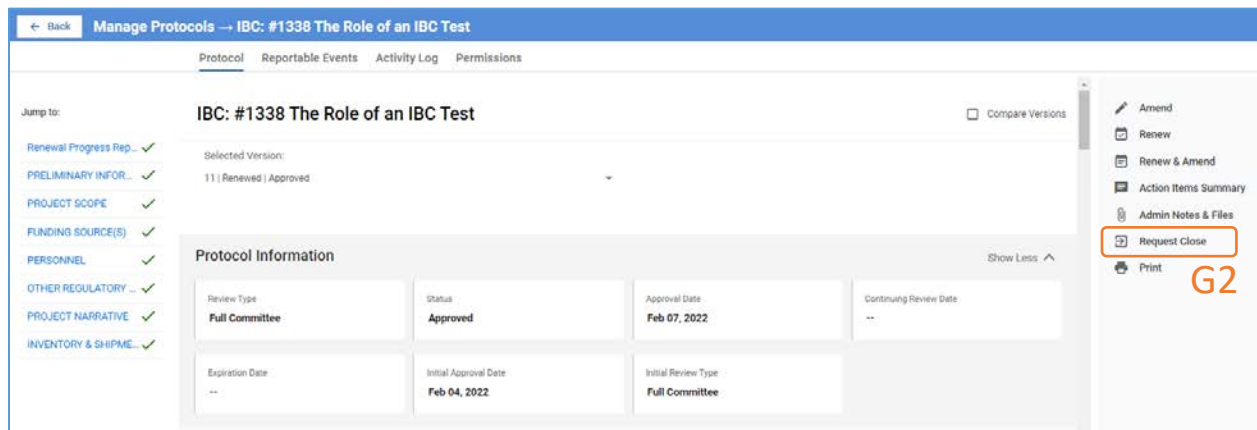
6. The IBC Admin will facilitate administrative and Committee review of the event. Additional information or revisions may be necessary before the event may be resolved. Requests for, and submission of, additional information or revisions will follow the same general process as that described in previous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

[Return to Top](#)

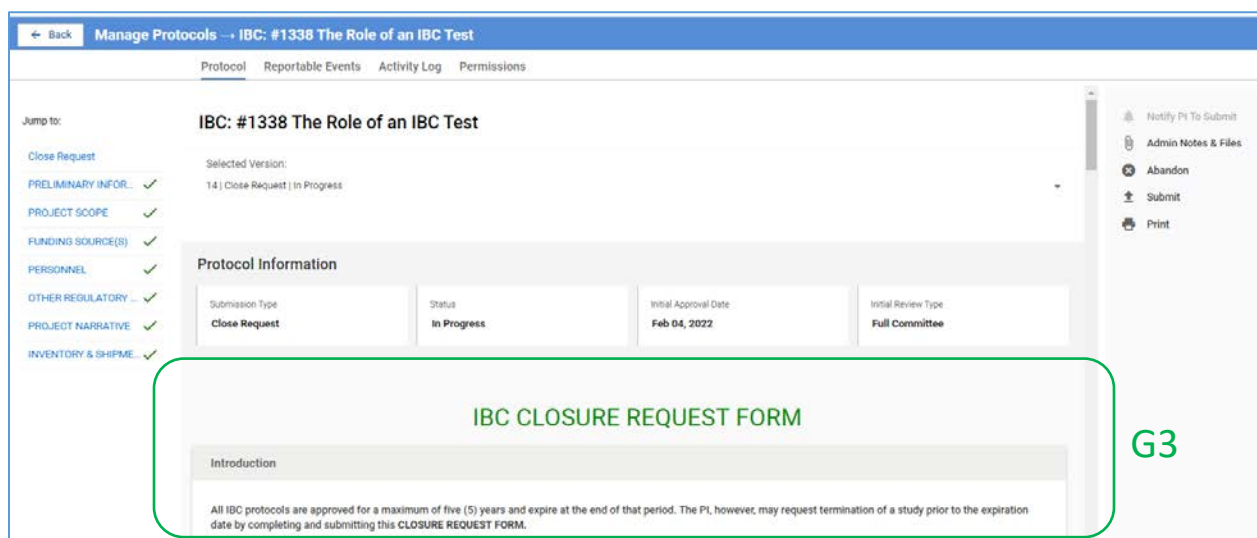
G. CLOSURE

IBC protocols are approved for a maximum of 5 years with intermittent (typically annual) reviews. An investigator, however, may request closure of the study prior to the 5-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**.



3. Follow instructions to complete the **Closure Request Form**.



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.

[Return to Top](#)