

## KUALI QUICKGUIDE

# REVIEWING IBC PROTOCOL APPLICATIONS

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

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

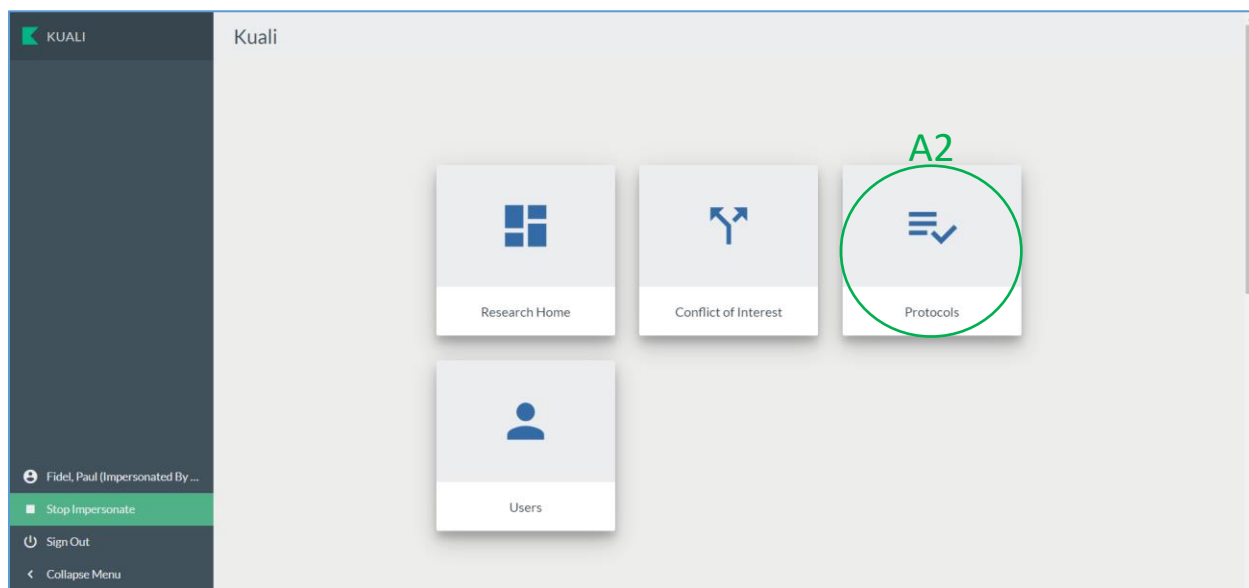
## A. ACCESSING PROTOCOLS

Each time you are assigned as a reviewer for a protocol submission by the IBC 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.

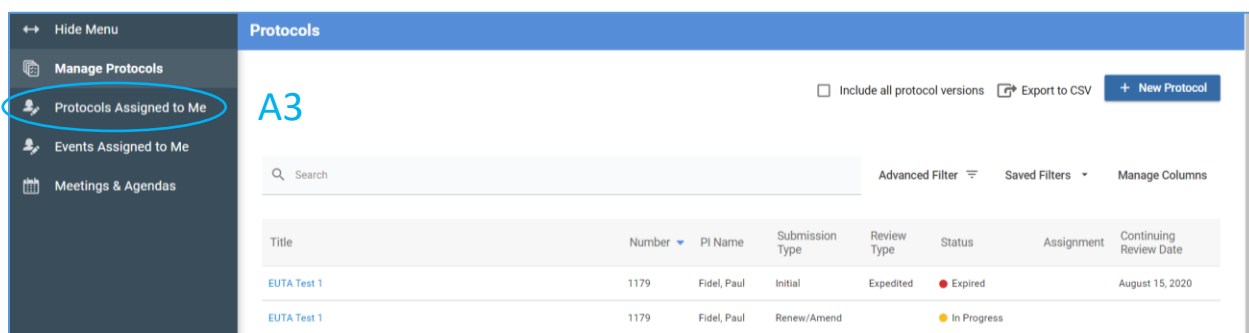
### 1. Log into Kuali:

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

### 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 table with columns: Title, Number, Type, PI, Submission Type, Review Type, Submitted, Status, Assignment, and DMR Determination Due Date.

**Top Screenshot:** The table contains one protocol entry: "Testing a Review" (Number 1340, Type IBC, PI Smith, Alison). The "Submission Type" is "New" and the "Status" is "Submitted for Review". A green circle highlights the "Title" column (labeled A4), and two orange boxes highlight the "Submission Type" and "Status" columns (labeled A4a).

**Bottom Screenshot:** The table contains two protocol entries: "Testing a Review" (Number 1340, Type IBC, PI Smith, Alison) and "The Role of an IBC Test" (Number 1338, Type IBC, PI Smith, Alison). Both have "Submission Type" as "Amendment" and "Status" as "Submitted for Review". Orange boxes highlight the "Submission Type" and "Status" columns (labeled A4a).

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## B. REVIEWING INITIAL SUBMISSIONS

For initial submissions, you will be assigned either as a **Primary** or **Secondary Reviewer**. **Primary 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. *Please note that the green checkmarks are no longer exist in the new Kuali IBC template.*
  - 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.

The screenshot displays the 'Manage Protocols' interface for 'IBC: #1340 Testing a Review'. The interface is divided into three main sections:

- B1b (Left Side Panel):** A vertical list of protocol sections, each with a green checkmark indicating completion. The sections are: PRELIMINARY INFOR..., PROJECT SCOPE, FUNDING SOURCE(S), PERSONNEL, OTHER REGULATORY..., RESEARCH ACTIVITY..., PROJECT NARRATIVE, SYNTHETIC/RECOMB..., MICROORGANISMS/L..., DILUTION & CONCENT..., INVENTORY & SHIPM..., RISK ASSESSMENT/S..., and IBC GUIDELINES SECT.
- B1a (Protocol Information):** A central area containing a table with the following data:

| Submission Type | Review Type    | Status               | Time in Current Status      |
|-----------------|----------------|----------------------|-----------------------------|
| New             | Full Committee | Submitted for Review | Since February 11 - an hour |
- B1c,d (Right Side Panel):** A vertical list of actions available to the reviewer: Action Items Summary, Admin Notes & Files, Submit Review, General Action Items, and Print.

Below the Protocol Information section, the heading 'IBC PROTOCOL FORM' is displayed. A note at the bottom states: '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.'

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.

The screenshot shows the 'Manage Protocols' interface for 'IBC: #1340 Testing a Review'. The 'PROJECT SCOPE' section is active, displaying several questions and their corresponding 'Action Item' buttons. A green circle labeled 'B2' highlights these buttons on the right side of the form.

3. To leave a comment regarding any field entry,
  - a) Click on the **Action Item** button associated with the field.
  - b) 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 IBC Administrator. After you submit the review, the Administrator will make comments visible to other assigned reviewers and to IBC 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.*
  - c) Click **Post**.

The screenshot shows the 'Manage Protocols' interface for 'IBC: #1340 Testing a Review'. The 'PROJECT SCOPE' section is active. A green circle labeled 'B3a' highlights an 'Action Item' button. An orange circle labeled 'B3b' highlights the 'Use of?' dropdown menu. An orange circle labeled 'B3c' highlights the 'Post' button.

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**.

← Back Manage Protocols → IBC: #1340 Testing & Review

Protocol Activity Log

Jump to:

PRELIMINARY INFOR... ✓

**PROJECT SCOPE** ①

FUNDING SOURCE(S) ✓

PERSONNEL ✓

OTHER REGULATORY ... ✓

RESEARCH ACTIVITY ... ✓

PROJECT NARRATIVE

SYNTHETIC/RECOMB ... ✓

MICROORGANISMS/IN ... ✓

DILUTION & CONCEN... ✓

INVENTORY & SHIPME... ✓

RISK ASSESSMENT/S... ✓

NIH GUIDELINES SECT... ✓

PROJECT SCOPE

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

This research project requires...

C only

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

Initial submission

Does this project require approval by:

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

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 ①

Synthetic or recombinant (S/R) nucleic acids (other than those used in viral expression systems)

Microorganisms (other than viruses generated using the viral expression systems listed above)

Use of?

Action Items

Zea, Arnold (impersonated by Fuseller, Taylor) 02/11/22 · 3:29 PM ⓘ

Please clarify what the LD50 is for the agent listed...

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.

← Back Manage Protocols → IBC: #1340 Testing & Review

Protocol Activity Log

Jump to:

PRELIMINARY INFOR... ✓

PROJECT SCOPE ①

FUNDING SOURCE(S) ✓

PERSONNEL ✓

OTHER REGULATORY ... ✓

RESEARCH ACTIVITY ... ✓

PROJECT NARRATIVE

SYNTHETIC/RECOMB ... ✓

MICROORGANISMS/IN ... ①

**DILUTION & CONCEN...** ①

INVENTORY & SHIPME... ①

DILUTION & CONCENTRATION

Will any listed research materials that are toxins or pathogens be diluted for storage or use?

No

Does this project involve culturing and/or concentration of cells, viruses or other microorganisms?

No

INVENTORY & SHIPMENT

Research material, including clinical samples, used or stored in a LSUHSC-NO laboratory must be listed and managed in the EH&S On-Site BioInventory.

Enter the date when your inventory was last verified.

4/21/22

Inventory verification date

Action Items

Zea, Arnold (impersonated by Fuseller, Taylor) 02/11/22 · 3:31 PM ⓘ

Please clarify...

Visibility Admins

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

← Back Manage Protocols → IBC: #1340 Testing a Review

Protocol Activity Log

Jump to:

- PRELIMINARY INFOR... ✓
- PROJECT SCOPE 1
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY ... ✓
- RESEARCH ACTIVITY ... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB ... ✓
- MICROORGANISMS/IN ... 1
- DILUTION & CONCENT... ✓
- INVENTORY & SHIPME... 1
- RISK ASSESSMENT/S... ✓

**DILUTION & CONCENTRATION**

No

Does this project involve culturing and/or concentration of cells, viruses or other microorganisms? Action Item

No

**INVENTORY & SHIPMENT**

Research material, including clinical samples, used or stored in a LSUHSC-NO laboratory must be listed and managed in the EH&S On-Site Bioinventory. Enter the date when your inventory was last verified. Action Items: 1

4/21/22

Do you anticipate transporting and/or shipping research materials or specimens to external sites? Action Item

No

**B6a**

**B6b**

Action Items Summary for Protocol #1340

^ Collapse All

^ IBC PROTOCOL / PROJECT SCOPE / Regular App / Use of?

Ze, Arnold (Impersonated by Fuseller, Taylor) 02/11/22 - 3:29PM

Please clarify what the LD50 is for the agent listed.

^ IBC PROTOCOL / MICROORGANISMS/INFECTIOUS AGENTS / Select agents (microbes)?

Ze, Arnold (Impersonated by Fuseller, Taylor) 02/11/22 - 3:31PM

Please clarify.

^ IBC PROTOCOL / INVENTORY & SHIPMENT / Inventory verification date

Ze, Arnold (Impersonated by Fuseller, Taylor) 02/11/22 - 3:31PM

Please clarify.

**B6**

← Back Manage Protocols → IBC: #1340 Testing a Review

Protocol Activity Log

Jump to:

- PRELIMINARY INFOR... ✓
- PROJECT SCOPE 1
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY ... ✓
- RESEARCH ACTIVITY ... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB ... ✓
- MICROORGANISMS/IN ... 1
- DILUTION & CONCENT... ✓

**DILUTION & CONCENTRATION**

Will any listed research materials that are toxins or pathogens be diluted for storage or use? Action Item

No

Does this project involve culturing and/or concentration of cells, viruses or other microorganisms? Action Item

No

**INVENTORY & SHIPMENT**

Research material, including clinical samples, used or stored in a LSUHSC-NO laboratory must be listed and managed in the EH&S On-Site Bioinventory. Enter the date when your inventory was last verified. Action Items: 1

**B6b**

**General Action Items**

Action Items

For Committee: What is the current BSL2+ conditions for Covid-19 research?

Visibility Admins

Cancel Post

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.

← Back Manage Protocols → IBC: #1340 Testing a Review

Protocol Activity Log

Jump to:

- PRELIMINARY INFOR... ✓
- PROJECT SCOPE 1
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY... ✓
- RESEARCH ACTIVITY... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB ✓
- MICROORGANISMS/I... 1

**MICROORGANISMS/INFECTIOUS AGENTS**

In the table below, please identify and describe microorganisms to be employed in the proposed research:  
*Please include all bacteria, fungus, parasites, prions and viruses except those viruses generated using the viral expression systems, if any, described in previous sections.*

Columns

|             | NAME        | VENDOR/SOURCE | NIH RISK GROUP | INFECTIOUS HOST RANGE | TRANSMISSION | ADMINISTERED TO |
|-------------|-------------|---------------|----------------|-----------------------|--------------|-----------------|
| Action Item | E.coli K-12 | ATCC          | RG-1           | Humans                | Ingestion    | mice            |

Are any of the microorganisms listed in the table above on the CDC/USDA list of select agents and toxins?  
No

Action Items: 1

Right sidebar: Action Items Summary, Admin Notes & Files, **Submit Review** (circled), General Action Items 1, Print.

← Back Manage Protocols → IBC: #1340 Testing a Review

Protocol Activity Log

Jump to:

- PRELIMINARY INFOR... ✓
- PROJECT SCOPE 1
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY... ✓
- RESEARCH ACTIVITY... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB ✓
- MICROORGANISMS/I... 1
- DILUTION & CONCENT...
- INVENTORY & SHIPME...
- RISK ASSESSMENT/S...
- NIH GUIDELINES SECT...
- SUPPORTING DOCUM...
- SUBMISSION INSTRU...
- PI CERTIFICATION & S...

**General Comment**

YOUR ANONYMOUS COMMENTS:

1 Zea, Arnold (impersonated by Fuselier, Taylor) 02/11/22 - 3:36PM  
For Committee: What is the current BSL2+ conditions for Covid-19 research?

**IBC PROTOCOL**

**PROJECT SCOPE**

**Regular App**

**Use of?**

Synthetic or recombinant (S/R) nucleic acids (other than those used in viral expression systems)  
Microorganisms (other than viruses generated using the viral expression systems listed above)

YOUR ANONYMOUS COMMENTS:

1 Zea, Arnold (impersonated by Fuselier, Taylor) 02/11/22 - 3:29PM  
Please clarify what the LD50 is for the agent listed.

**MICROORGANISMS/INFECTIOUS AGENTS**

Cancel

Right sidebar: Action Items Summary, Admin Notes & Files, General Action Items 1, Print.

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

← Back Manage Protocols → IBC: #1340 Testing a Review

Protocol Activity Log

Jump to:

- PRELIMINARY INFOR... ✓
- PROJECT SCOPE 1
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY... ✓
- RESEARCH ACTIVITY... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB ✓
- MICROORGANISMS/I... 1
- DILUTION & CONCENT...
- INVENTORY & SHIPME...

**MICROORGANISMS/INFECTIOUS AGENTS**

In the table below, please identify and describe microorganisms to be employed in the proposed research:  
*Please include all bacteria, fungus, parasites, prions and viruses except those viruses generated using the viral expression systems, if any, described in previous sections.*

Columns

|                 | NAME        | VENDOR/SOURCE | NIH RISK GROUP | INFECTIOUS HOST RANGE | TRANSMISSION | ADMINISTERED TO |
|-----------------|-------------|---------------|----------------|-----------------------|--------------|-----------------|
| No Action Items | E.coli K-12 | ATCC          | RG-1           | Humans                | Ingestion    | mice            |

Are any of the microorganisms listed in the table above on the CDC/USDA list of select agents and toxins?  
No

Action Items: 1

**DILUTION & CONCENTRATION**

Right sidebar: Action Items Summary, Admin Notes & Files, General Action Items 1, **Print** (circled).



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

The image displays two screenshots of a web application interface titled 'Manage Protocols -> IBC: #1340 Testing a Review'. The interface is divided into several sections:

- Left Sidebar (Jump to):** Contains links to various sections: PRELIMINARY INFOR... (checked), PROJECT SCOPE (selected, with a yellow circle icon), FUNDING SOURCE(S) (checked), PERSONNEL (checked), OTHER REGULATORY... (checked), RESEARCH ACTIVITY... (checked), PROJECT NARRATIVE, SYNTHETIC/RECOMB... (checked), and MICROORGANISMS/IN... (with a yellow circle icon).
- Main Content Area:** Titled 'PROJECT SCOPE', it contains a form with the following questions and options:
  - 'Please define the scope of the proposed research by answering all of the following questions.'
  - 'This research project requires...' with a dropdown menu showing 'C only' and an 'Action Item' button.
  - 'Does this application represent an initial submission of a new project or a 5-year renewal of a previously approved project?' with a dropdown menu showing 'Initial submission' and an 'Action Item' button.
  - 'Does this project require approval by:' with a list of options: 'The LSUHSC-NO Radiation Safety Committee, or' and 'A Non-LSUHSC compliance committee or body?'. The 'No' option is selected, and there is an 'Action Item' button.
- Right Sidebar (Use of?):** Titled 'Action Items', it shows a list of items. The first item is 'Zea, Arnold (impersonated by Fuseller, Taylor)' dated '02/11/22 - 3:29PM'. Below the item, it says 'Please clarify what the LD50 is for the agent listed...'. There is a 'Visibility' dropdown menu showing 'Who should see this?'. Below this, there are three buttons: 'Assigned Reviewers' (highlighted with an orange box), 'Researchers', and 'Meeting'. A red dotted arrow points from the 'Assigned Reviewers' button in the top screenshot to the same button in the bottom screenshot. Below the buttons, there is a 'Mark as resolved' checkbox.

11. Based on decisions at the IBC meeting, the IBC 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 IBC Administrator will assign the **Primary Reviewers** of the initial application as the reviewer 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** of the protocol. Please make sure to review the correct version.
  - b) Click on the **Compare Versions** checkbox. All new text will be highlighted in green and deletions will be highlighted in red (example shown below).
  - c) If the IBC Administrator has left you any notes or instructions, they will be found in the **Admin Notes & Files** tab.

The screenshot displays the 'Manage Protocols' interface for 'IBC: #1340 Testing a Review'. The interface is divided into three main sections:

- Left Sidebar (C1a):** A vertical list of navigation links including 'PRELIMINARY INFOR...', 'PROJECT SCOPE', 'FUNDING SOURCE(S)', 'PERSONNEL', 'OTHER REGULATORY ...', 'RESEARCH ACTIVITY ...', 'PROJECT NARRATIVE', 'SYNTHETIC/RECOMB...', and 'MICROBIOPLASMA...'. Each link has a status indicator (checkmark or exclamation mark).
- Main Content Area:**
  - Protocol Information:** A table showing submission details.

| Submission Type | Review Type    | Status      | Time in Current Status        |
|-----------------|----------------|-------------|-------------------------------|
| New             | Full Committee | Resubmitted | Since February 11 - 2 minutes |
  - Compare Versions:** A section with a 'Compare Versions' checkbox (checked) and a dropdown menu showing '3 | New | Revisions Required'.
- Right Sidebar (C1c):** A vertical list of action items including 'Action Items Summary', 'Admin Notes & F...', 'Submit Review', 'General Action Items', and 'Print'. The 'Admin Notes & F...' item is highlighted with a red box and a green circle, indicating it is the current selection.

## 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** in the text box.
- Click **Post**, which will become active once text is entered in the text box.
- The new action item only will be visible to the IBC Administrator. He/She will make it visible to the researcher as appropriate.*

The screenshot shows the 'Manage Protocols' interface for 'IBC: #1340 Testing a Review'. The left sidebar lists various sections like 'PRELIMINARY INFOR...', 'PROJECT SCOPE', 'FUNDING SOURCE(S)', 'PERSONNEL', 'OTHER REGULATORY', 'RESEARCH ACTIVITY', 'PROJECT NARRATIVE', 'SYNTHETIC/RECOMB...', 'MICROORGANISMS/I...', 'DILUTION & CONCENT...', 'INVENTORY & SHIPM...', and 'RISK ASSESSMENT/S...'. The main content area is titled 'PROJECT NARRATIVE' and contains a section for 'SYNTHETIC/RECOMB NUCLEIC ACIDS'. Below this is a table with columns: NA NAME, NA TYPE, GROUP, PRODUCT/TARGET, and SOURCE SPECIES. The table contains one row with 'pc' as the NA NAME, 'Plasmid (recombinant)' as the NA TYPE, 'Control' as the GROUP, 'Receptor' as the PRODUCT/TARGET, and 'Human' as the SOURCE SPECIES. To the right of the table is a question: 'Does any s/rNA (including viral expression plasmids) used in this study encode for an oncoprotein or otherwise produce a product that may be toxic to cells, animals, or humans?' with a 'No' response. An 'Action Items' button is highlighted with a green box and labeled 'C2a'. On the far right, there is a panel titled 'Oncogenic/toxic?' with an 'Action Item' button highlighted with an orange box and labeled 'C2b'.

This screenshot is similar to the previous one, showing the same interface. The 'Action Item' button in the 'Oncogenic/toxic?' panel is highlighted with an orange box and labeled 'C2c'.

This screenshot shows the 'Oncogenic/toxic?' panel with a text input field for adding a comment, highlighted with an orange box and labeled 'C2d'. Below the input field are 'Cancel' and 'Post' buttons, with the 'Post' button highlighted by an orange box and labeled '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 IBC Admin.

← Back Manage Protocols → IBC: #1340 Testing a Review

Protocol Activity Log

Jump to:

- PRELIMINARY INFOR... ✓
- PROJECT SCOPE ✓
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY... ✓
- RESEARCH ACTIVITY... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB... ⚠
- MICROORGANISMS/L... ✓
- DILUTION & CONCENT... ✓

**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.):

|             | COMMITTEE | NON-LSUHSC OVERSIGHT | STATUS                     | STUDY ID | CERTIFICATE OF APPROVAL  |
|-------------|-----------|----------------------|----------------------------|----------|--------------------------|
| Action Item | IACUC     |                      | Application in Preparation |          | <input type="checkbox"/> |

Columns

**RESEARCH ACTIVITY LOCATIONS**

In the table below, enter all LSUHSC-NO and external locations where research activities will be conducted and/or research materials stored.

Columns

General Action Items

Action Items Summary

Admin Notes & F... 1

Submit Review

General Action Items

Print

**C3a**

← Back Manage Protocols → IBC: #1340 Testing a Review

Protocol Activity Log

Jump to:

- PRELIMINARY INFOR... ✓
- PROJECT SCOPE ✓
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY... ✓
- RESEARCH ACTIVITY... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB... ⚠
- MICROORGANISMS/L... ✓
- DILUTION & CONCENT... ✓
- INVENTORY & SHIPM... ✓
- RISK ASSESSMENT/S... ✓
- NIH GUIDELINES SECT... ✓

**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.):

|             | COMMITTEE | NON-LSUHSC OVERSIGHT | STATUS                     | STUDY ID | CERTIFICATE OF APPROVAL  |
|-------------|-----------|----------------------|----------------------------|----------|--------------------------|
| Action Item | IACUC     |                      | Application in Preparation |          | <input type="checkbox"/> |

Columns

**RESEARCH ACTIVITY LOCATIONS**

In the table below, enter all LSUHSC-NO and external locations where research activities will be conducted and/or research materials stored.

Columns

**General Action Items**

Action Items

Action Item

Zea, Arnold (impersonated by Fuselier, Taylor) 02/11/22 - 3:36PM

For Committee: What is the current BSL2+ conditions for Covid-19 research? ...

Visibility Admins

Resolved

Zea, Arnold (impersonated by Fuselier, Taylor) 02/11/22 - 4:30PM

All issues have been corrected. Please approve the application.

Visibility Admins

**C3b**

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

Protocol Activity Log

Jump to:

- PRELIMINARY INFOR... ✓
- PROJECT SCOPE ✓
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY ... ✓
- RESEARCH ACTIVITY ... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB ... ⚠
- MICROORGANISMS/I... ✓
- DILUTION & CONCENT... ✓

**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.):

| Action Item | COMMITTEE | NON-LSUHS OVERSIGHT | STATUS                     | STUDY ID | CERTIFICATE OF APPROVAL  |
|-------------|-----------|---------------------|----------------------------|----------|--------------------------|
| +           | IACUC     |                     | Application in Preparation |          | <input type="checkbox"/> |

RESEARCH ACTIVITY LOCATIONS

Right Sidebar:

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

Protocol Activity Log

Jump to:

- PRELIMINARY INFOR... ✓
- PROJECT SCOPE ✓
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY ... ✓
- RESEARCH ACTIVITY ... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB ... ⚠
- MICROORGANISMS/I... ✓
- DILUTION & CONCENT... ✓
- INVENTORY & SHIPM...
- RISK ASSESSMENT/S...
- NIH GUIDELINES SECT...
- SUPPORTING DOCUM...
- SUBMISSION INSTRU...
- PI CERTIFICATION & S...

**SYNTHETIC/RECOMB NUCLEIC ACIDS**

Oncogenic/toxic?

No

YOUR ANONYMOUS COMMENTS:

⚠ Zea, Arnold (impersonated by Fuseller, Taylor) 02/11/22 · 4:15PM  
Please add a plasmid map.

Show Replies (1 replies)

⚠ Zea, Arnold (impersonated by Fuseller, Taylor) 02/11/22 · 4:28PM  
This was addressed.

**MICROORGANISMS/INFECTIOUS AGENTS**

Select agents (microbes)?

No

YOUR ANONYMOUS COMMENTS:

⚠ Zea, Arnold (impersonated by Fuseller, Taylor) 02/11/22 · 3:31PM

Buttons: Cancel, Submit Review

Right Sidebar:

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

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

Protocol Activity Log

Jump to:

- PRELIMINARY INFOR... ✓
- PROJECT SCOPE ✓
- FUNDING SOURCE(S) ✓
- PERSONNEL ✓
- OTHER REGULATORY ... ✓
- RESEARCH ACTIVITY ... ✓
- PROJECT NARRATIVE
- SYNTHETIC/RECOMB ... ⚠

**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.):

| No Action Items | COMMITTEE | NON-LSUHS OVERSIGHT | STATUS                     | STUDY ID | CERTIFICATE OF APPROVAL  |
|-----------------|-----------|---------------------|----------------------------|----------|--------------------------|
|                 | IACUC     |                     | Application in Preparation |          | <input type="checkbox"/> |

Right Sidebar:

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

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

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*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. As a reviewer, you will need to evaluate changes described in both the Amendment and Protocol Forms.*

- D1c

2. Scroll through both the Amendment Form and the Protocol Form to identify modifications
  - a. New text will be in green font; original text, if any, will be in red font and crossed out.

← Back

Manage Protocols → IBC: #1354 test 3.2.22 amended title

Protocol

Reportable Events

Activity Log

Jump to:

Amendment

PRELIMINARY INFORMATION

PROJECT SCOPE

FUNDING SOURCE(S)

PERSONNEL

Description & Justification

Please list each proposed modification numerically. Then provide a **detailed** description of, and justification for, each modification.

test v3 Testing Amend function in protocol template with required fields v4

Protocol Form Instructions

Action Items Summary

Admin Notes & Files

Submit Review

General Action Items

Print

3. The review process for amendments is similar to that of full protocols. **Follow the instructions outlined in sections B2 – B11.**
4. One key difference is that, unlike full protocols, amendments typically are not sent to the full committee for review. Rather, decisions on amendments are made by the IBC Chair taking into consideration comments by the reviewer and the IBC Administrator.

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## E. REVIEWING RENEWALS

*Continuing Review (Annual Renewal) applications will be reviewed, and status determined, by the IBC Admin in consultation with the IBC 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 Kualu. 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 IBC 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 IBC 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 or b below):

- a. Click on the protocol link in the reviewer assignment email.
  - i. On the protocol page, click **Reportable Events**.

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

Protocol **Reportable Events** Activity Log Permissions

Jump to: IBC: #1338 The Role of an IBC Test

Renewal Progress Rep... ✓  
PRELIMINARY INFOR... ✓  
PROJECT SCOPE ✓  
FUNDING SOURCE(S) ✓  
PERSONNEL ✓  
OTHER REGULATORY... ✓  
PROJECT NARRATIVE ✓  
INVENTORY & SHIPM... ✓

Selected Version: 11 | Renewed | Approved

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 07, 2022        | --                     |
| Expiration Date | Initial Approval Date | Initial Review Type |                        |
| --              | Feb 04, 2022          | Full Committee      |                        |

Show Less ^

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

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

Protocol **Reportable Events** Activity Log Permissions

Reportable Events

Report an Event

Search Saved Filters

| Event Type | Description         | Status    | Event Date | Recorded Date     |
|------------|---------------------|-----------|------------|-------------------|
| None       | A problem occurred. | Submitted |            | February 14, 2022 |

1 of 1 reportable events Load 25 at a Time

b. Log into Kuali as described in [Section A](#).

- i. Click on the **Protocols** button.

Research Home Conflict of Interest **Protocols**

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

Protocols

Include all protocol versions Export to CSV + New Protocol

Search

Advanced Filter Saved Filters Manage Columns

| Title   | Number | PI Name       | Submission Type | Review Type | Status      | Assignment | Continuing Review Date |
|---|--------|---------------|-----------------|-------------|-------------|------------|------------------------|
| Clinical Assessment of the Effectiveness of Gabapentin as an Analgesic Agent for Mice for Ulcerative Dermatitis | 1247   | Birke, Leslie | New             |             | In Progress |            |                        |

iii. Click the **event**.

Protocols

Search Saved Filters

| Event Type | Description        | Status    | Event Date | Recorded Date     |
|------------|--------------------|-----------|------------|-------------------|
| None       | A problem occurred | Submitted |            | February 14, 2022 |

1 of 1 protocols Load 25 at a time

2. The **Reportable Events Form** will display.

- Review the **information provided by the researcher**.
- If necessary, you may **view the protocol**.
- Click **Submit Review**.

Report Event for Protocol

Jump to: Reportable Event

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.

Event Identification

Please identify the event by completing the table below:

| DATE             | LOCATION      | EVENT TYPE         | AGENT TYPE                        | SPECIFIC AGENT       |
|------------------|---------------|--------------------|-----------------------------------|----------------------|
| February 1, 2022 | Lions Eye 489 | Personnel exposure | Infectious agent Biological toxin | Ricin and Adenovirus |

Event Description

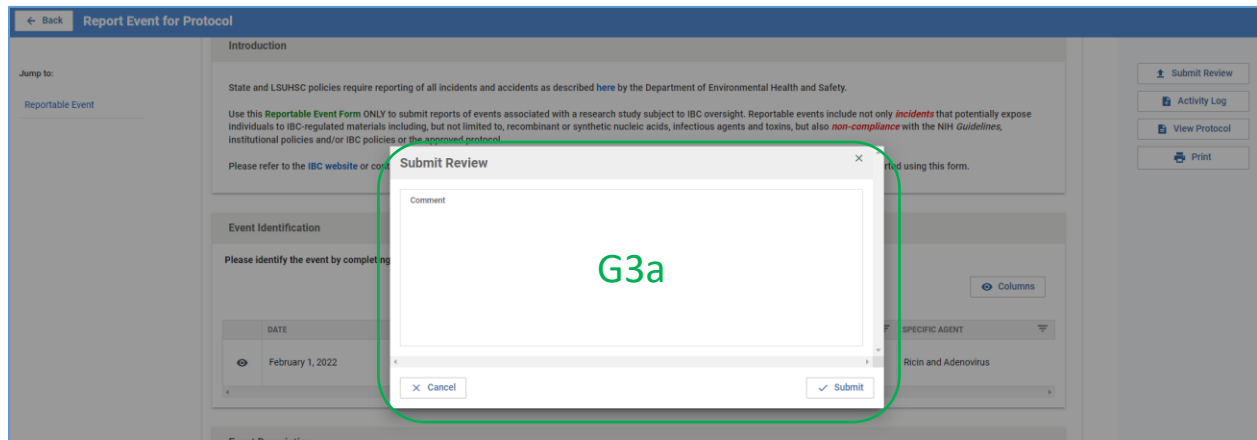
In this section, you will provide a brief overview/summary of the event and then answer specific follow-up questions. The summary and responses to the subsequent questions should be sufficiently detailed to allow the IBC to fully comprehend the nature and consequences of the event.

All fields must have text entries. If a question is not applicable to the event please enter "N/A" or "None" before proceeding to the next question.

Submit Review Activity Log View Protocol Print

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 that appears after Step 2c. Once you have entered all your comments, click **Submit** on the pop-up box.



The screenshot shows a web application titled "Report Event for Protocol". The main form is partially visible, showing sections for "Introduction", "Event Identification", and "Event Description". A "Submit Review" pop-up box is overlaid on the form, containing a text area for "Comment" and "G3a" entered. The pop-up box has "Cancel" and "Submit" buttons. The background form includes a "Jump to:" section with a "Reportable Event" link, a "State and LSUHSC policies" section, and a "Please identify the event by completing" section with a "DATE" field showing "February 1, 2022".

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

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## H. REVIEWING CLOSURES

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

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