KUALI QUICKGUIDE

CREATING AND SUBMITTING IACUC PROTOCOLS IN KUALI

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

A. New Protocol – Initial Submission

B. New Protocol - Resubmission

C. Amendment

D. Renewal

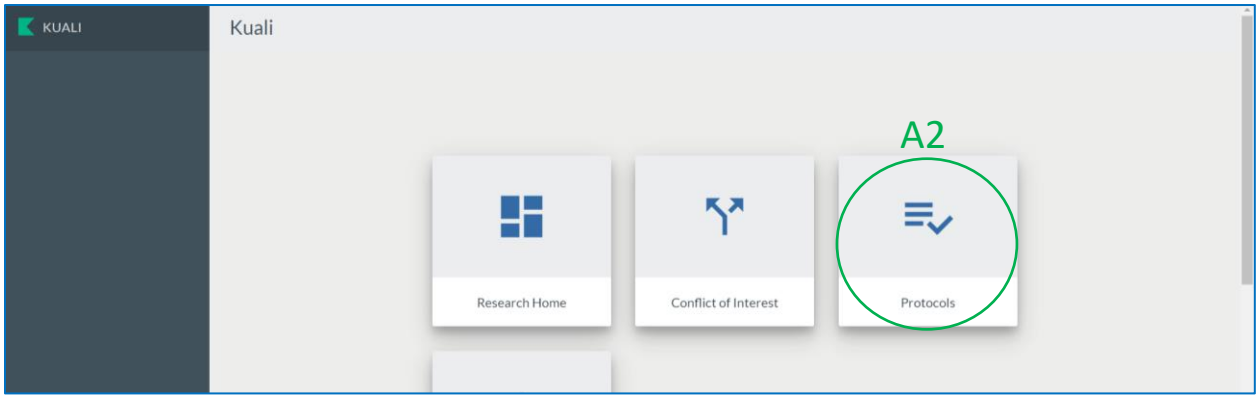
E. Renewal & Amendment

F. Reportable Event

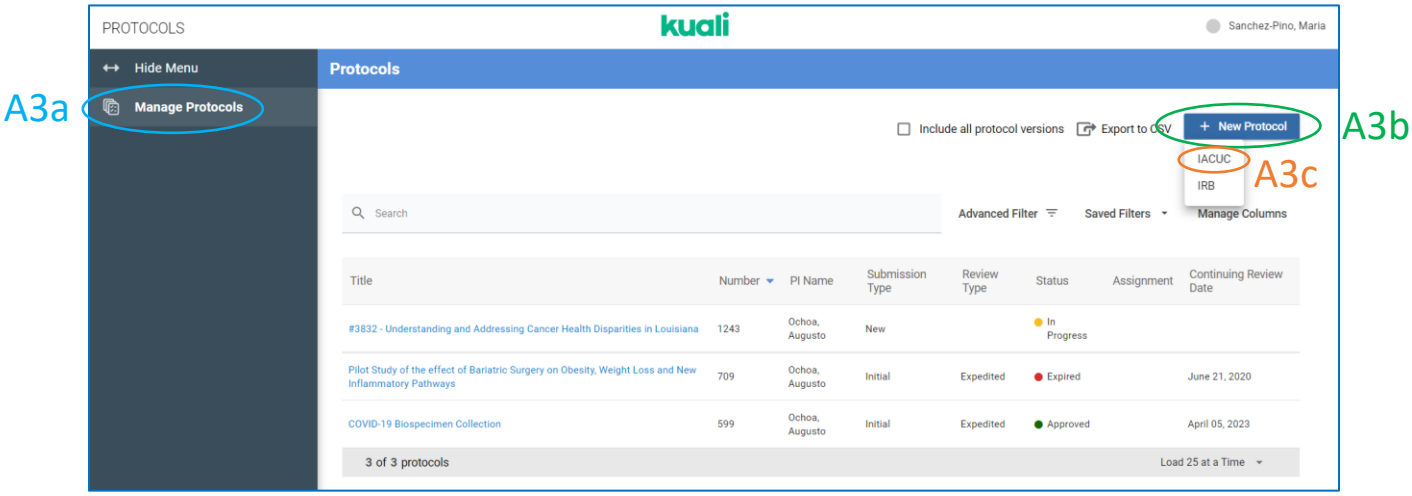
G. Closure

A. New Protocol - Initial Submission

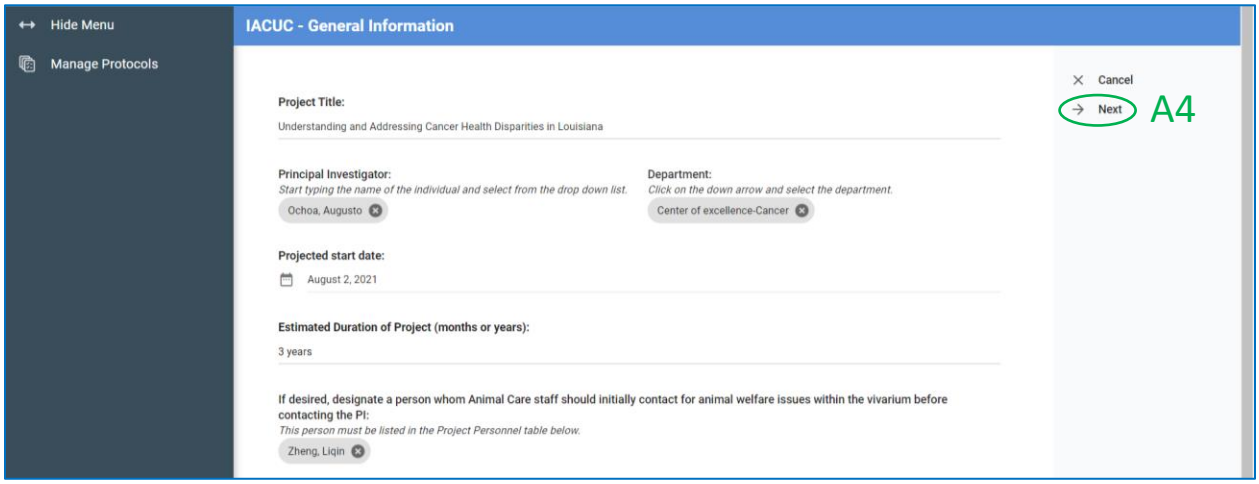
1. Log into Kuali:
   a) LSUHSC Personnel (individuals **with** an active @lsuhsc.edu email address): https://lsuhsc.kuali.co/cor/main/#/apps.
   b) Non-LSUHSC Personnel (individuals **without** an active @lsuhsc.edu email address): https://lsuhsc.kuali.co/auth/kuali.
   c) Please contact the IACUC Office (IACUCOffice@lsuhsc.edu) if you have any problems logging into Kuali.
2. Click on the **Protocols** button.



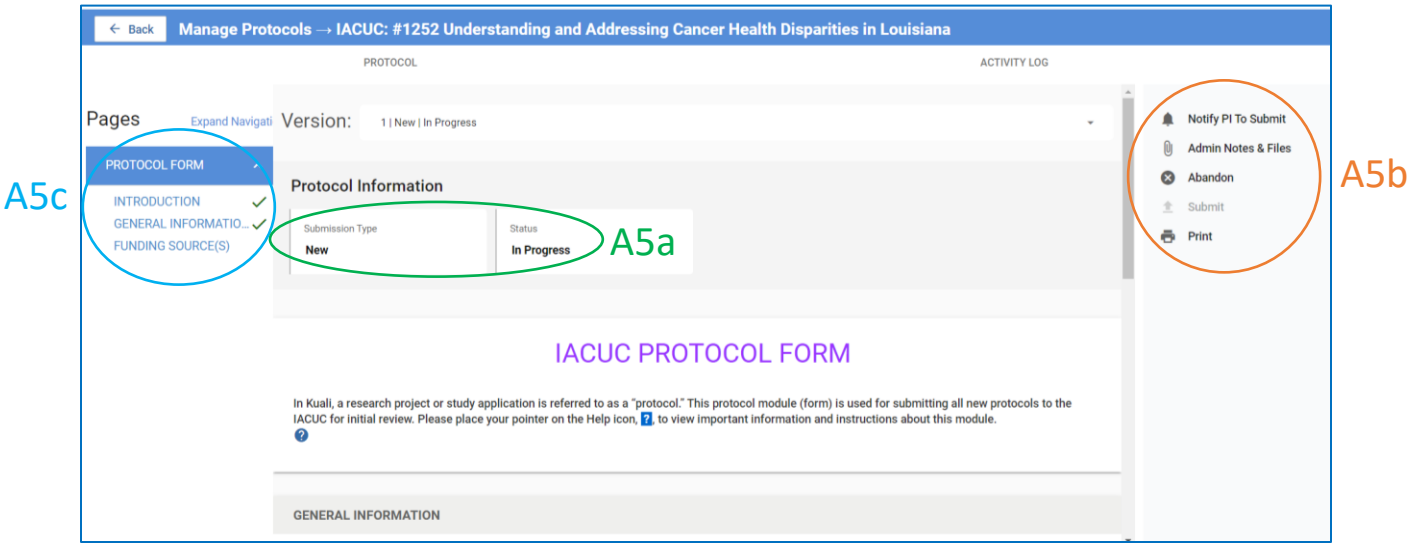
3. Next:
   a) On the **Manage Protocols** page;
   b) Click the **+ New Protocol** button; and
   c) Select **IACUC**.



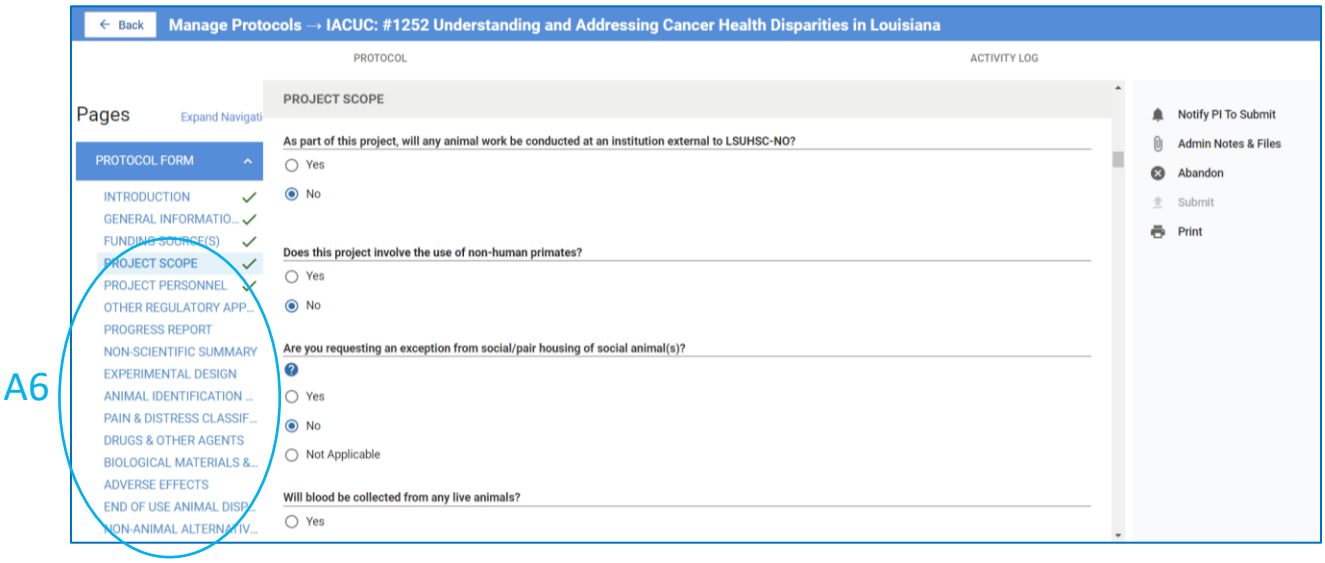
4. You will arrive at the **General Information** page of the IACUC Protocol Form. Provide the requested information and then click **Next**.



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

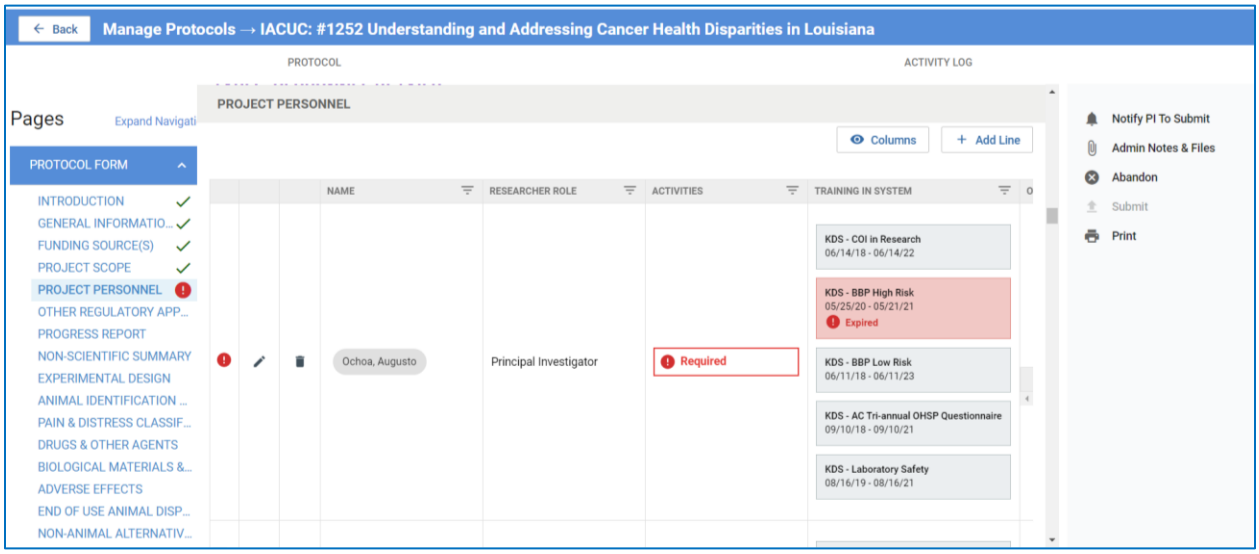


6. Scroll down the Protocol Form and answer the displayed questions. Additional sections of the form will appear as questions are answered.



7. Some questions require an answer while others do not. In some, but not all, sections an error message will display if a required field is left empty.

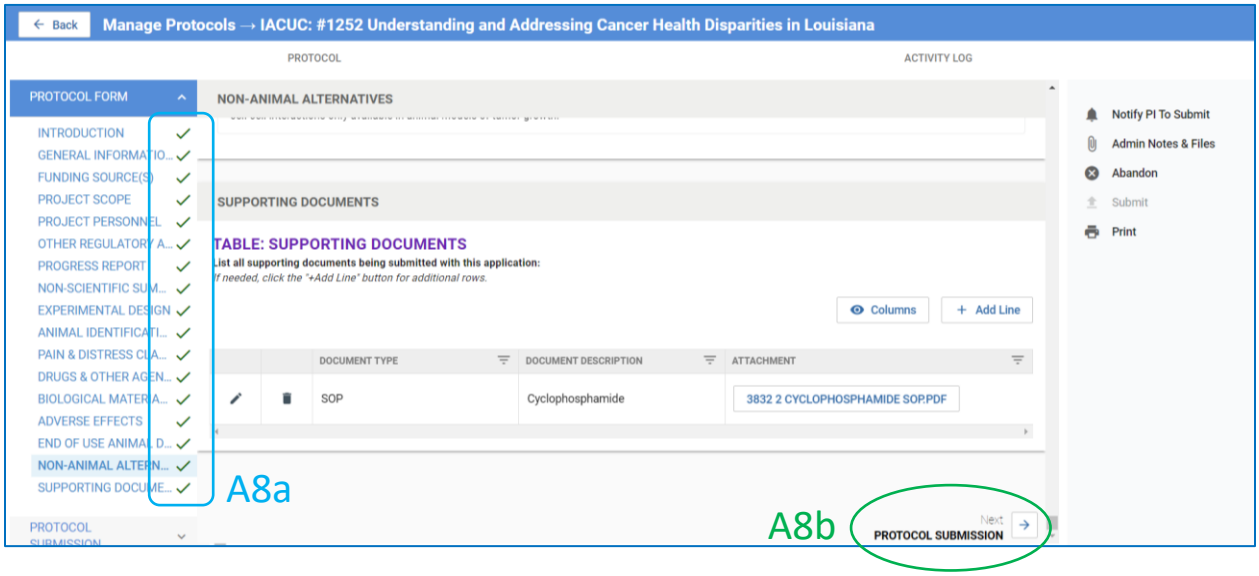
   a) **NOTE:** In the **Project Personnel** section, the status of KDS and CITI required training automatically will be displayed for the listed researcher. You will have to provide information about other training such as DOAC courses conducted in classrooms. If training is missing but the submission is otherwise complete, the protocol will move forward for review. However, all required training must be complete prior to approval of the protocol.



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

   a) **Green checkmarks** next to section names indicate completion.

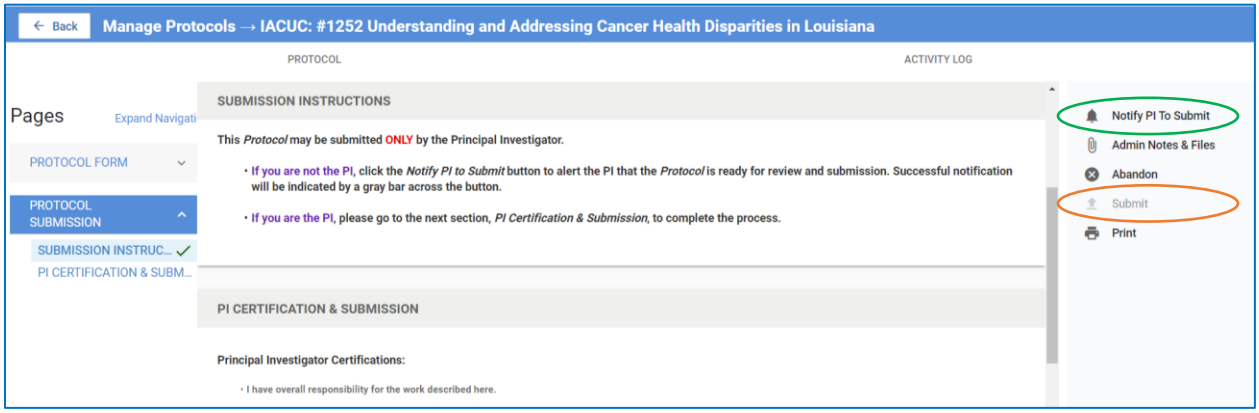
   b) Once the Protocol Form is complete, click **Next** to go to the **Protocol Submission** page.

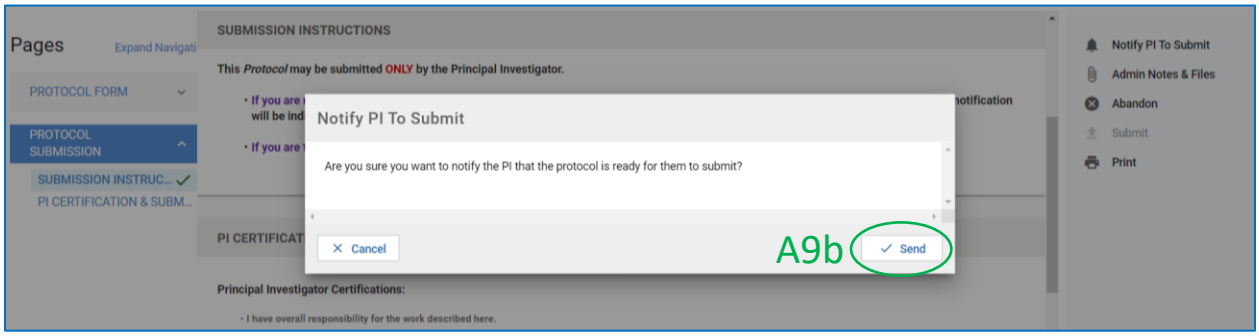


9. **Only the PI may submit the initial version of the protocol**.

   a) If you are not the PI, the **Submit** button will be inactive.

   b) Click **Notify PI to Submit**; then click **Send** in the pop-up window.

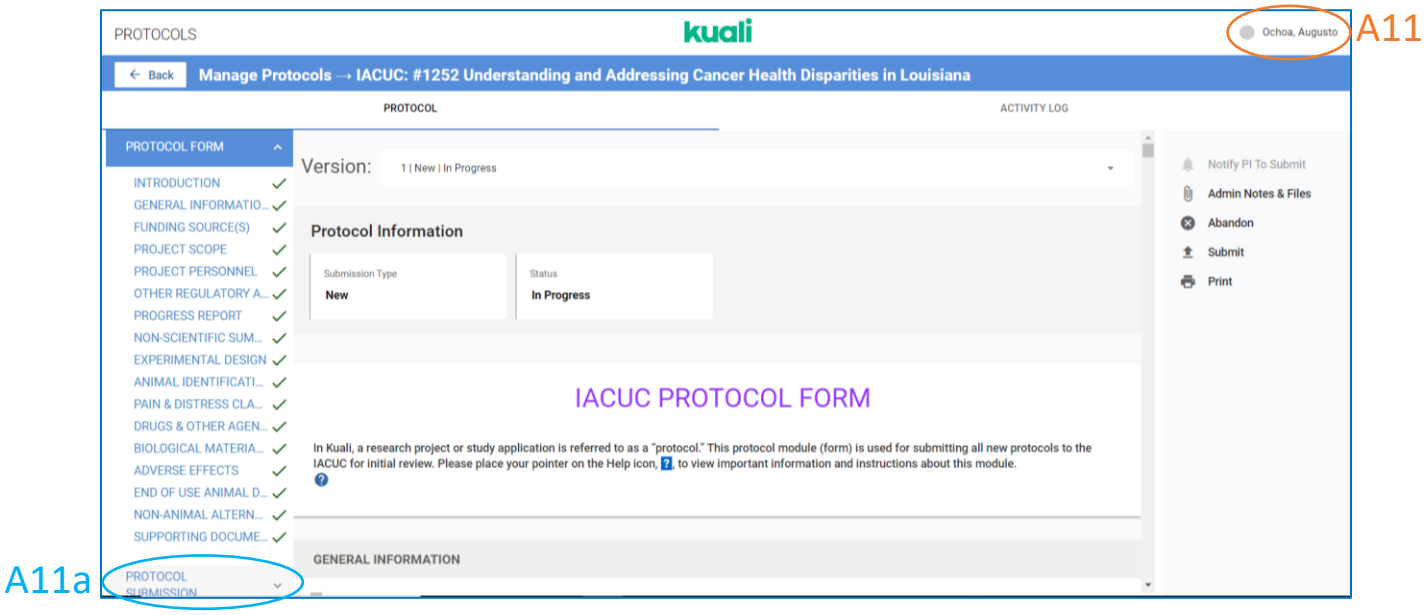




10. The PI will receive an email notification that the protocol is ready for submission. The PI can access the protocol directly from a link in the email.

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

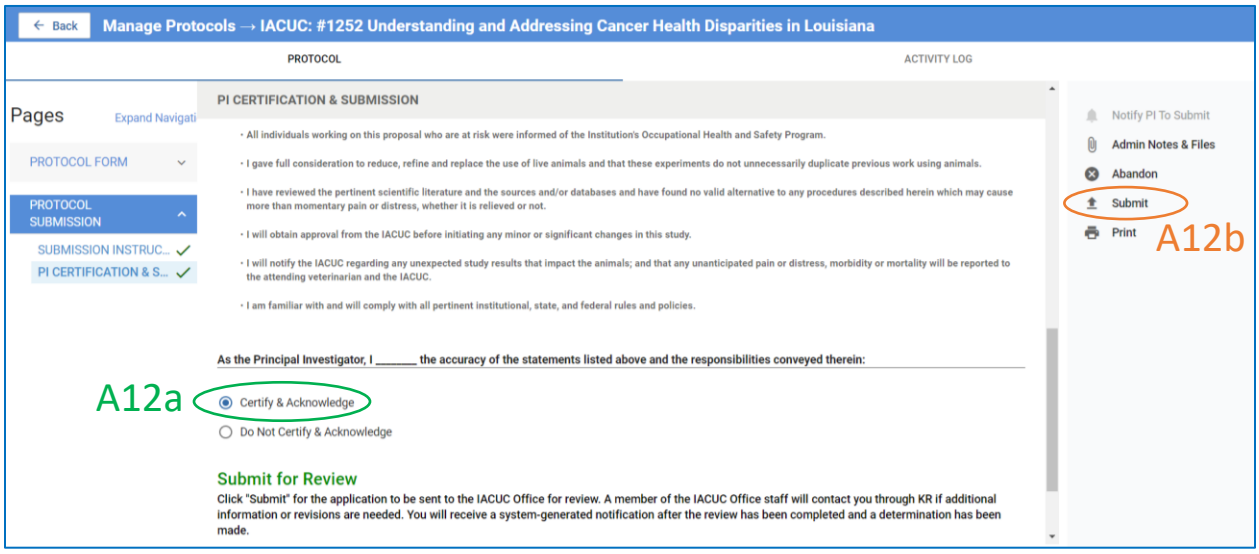
    a) He/She should click on the **down arrow** on the **Protocol Submission** tab and then click on the **PI Certification & Submission** section.



12. The PI must:

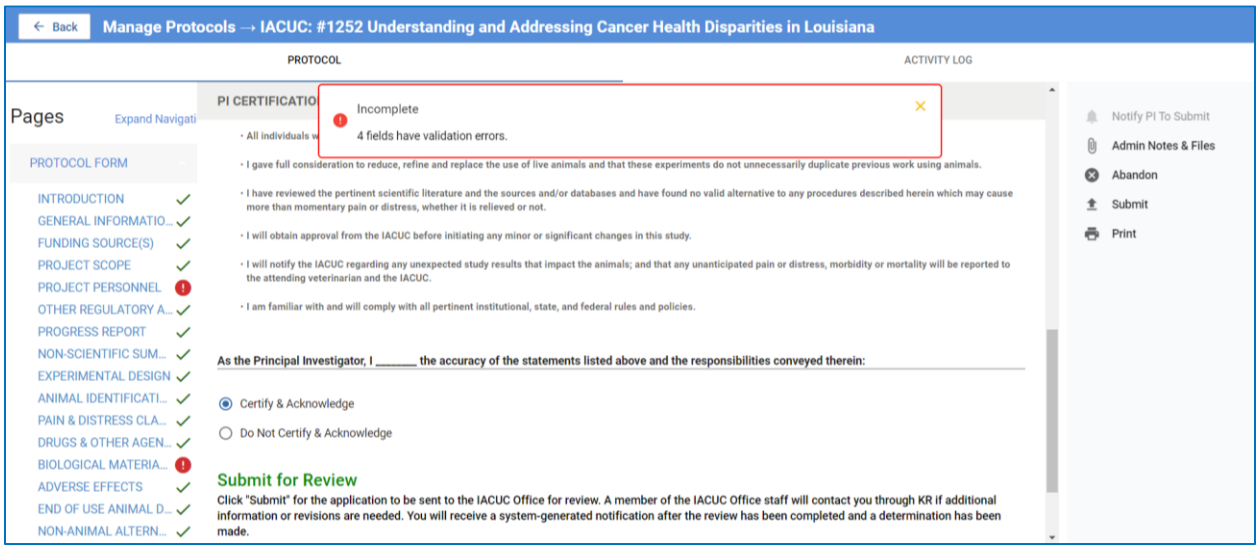
    a) **Certify & Acknowledge** the attestations and then …

    b) **Submit** the protocol for review.

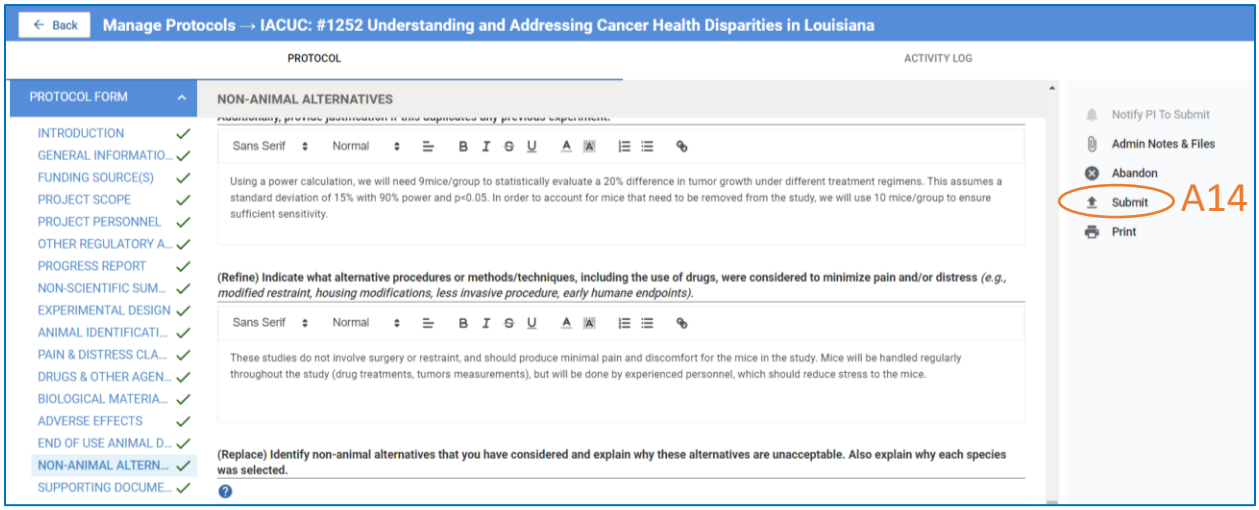


13. If any required questions or data fields are incomplete, an **error message** will appear. **Sections requiring attention** will also be indicated by **error icons**.

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

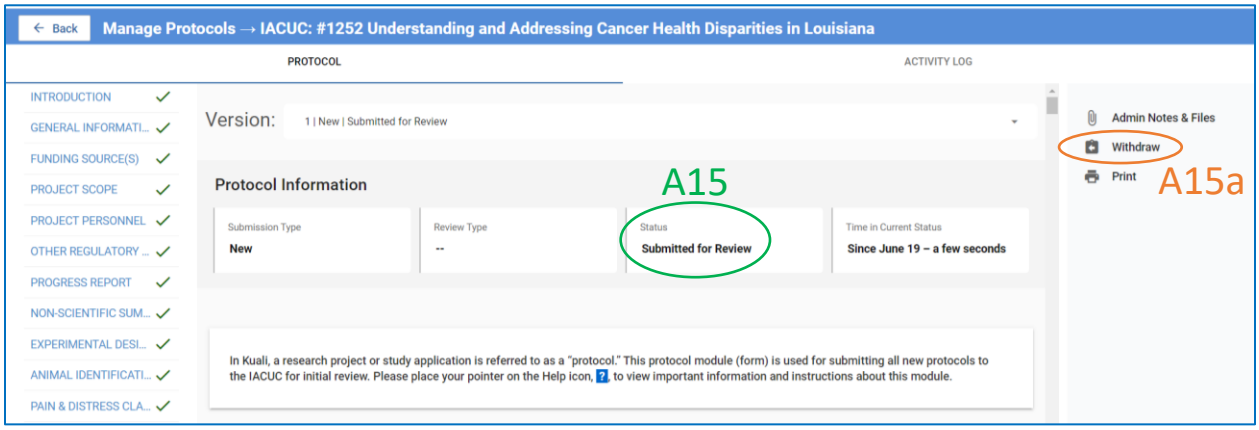


14. Once all corrections have been fixed, the error icons and message will disappear; PI clicks **Submit**.



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

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



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

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

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

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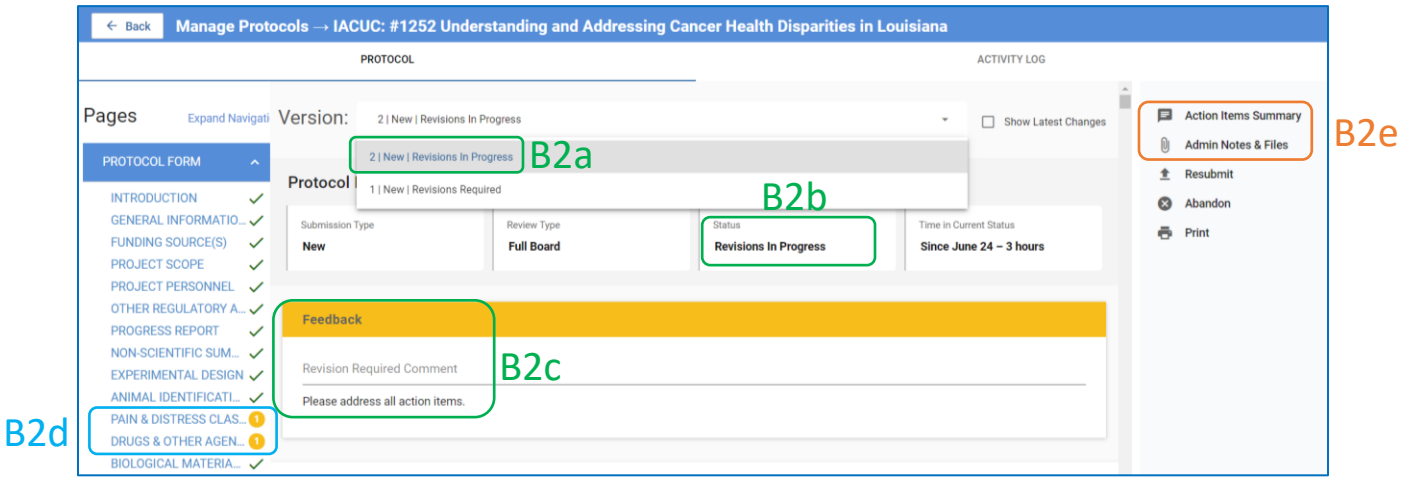
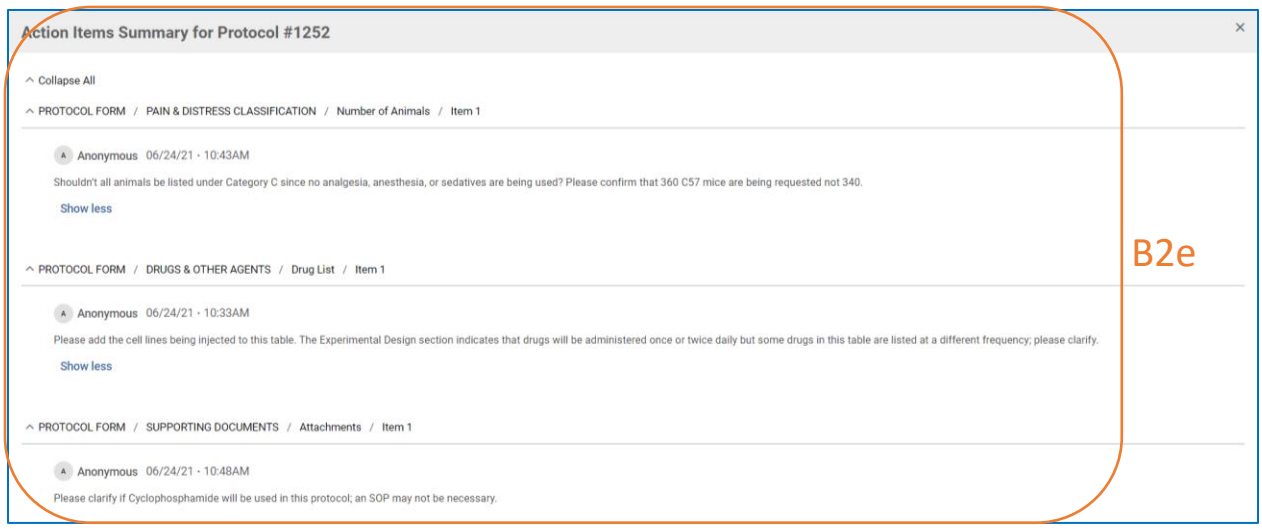
B. New Protocol - Resubmission

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

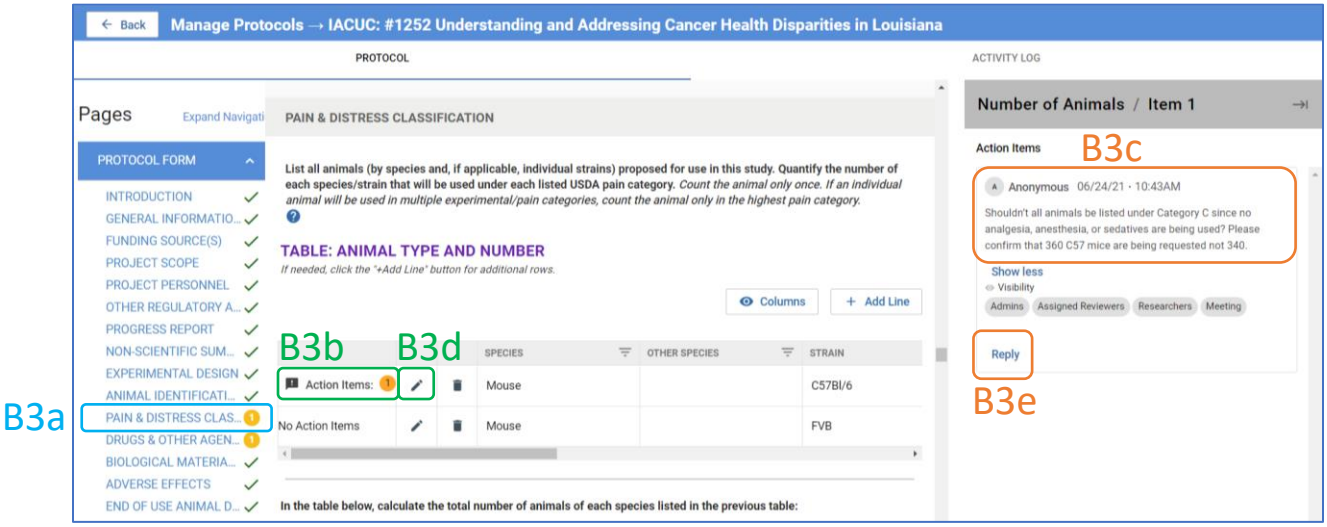
1. Access the protocol using the link in the email notification or log into Kuali as described in Section A and click on the appropriate protocol in the protocols table.

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





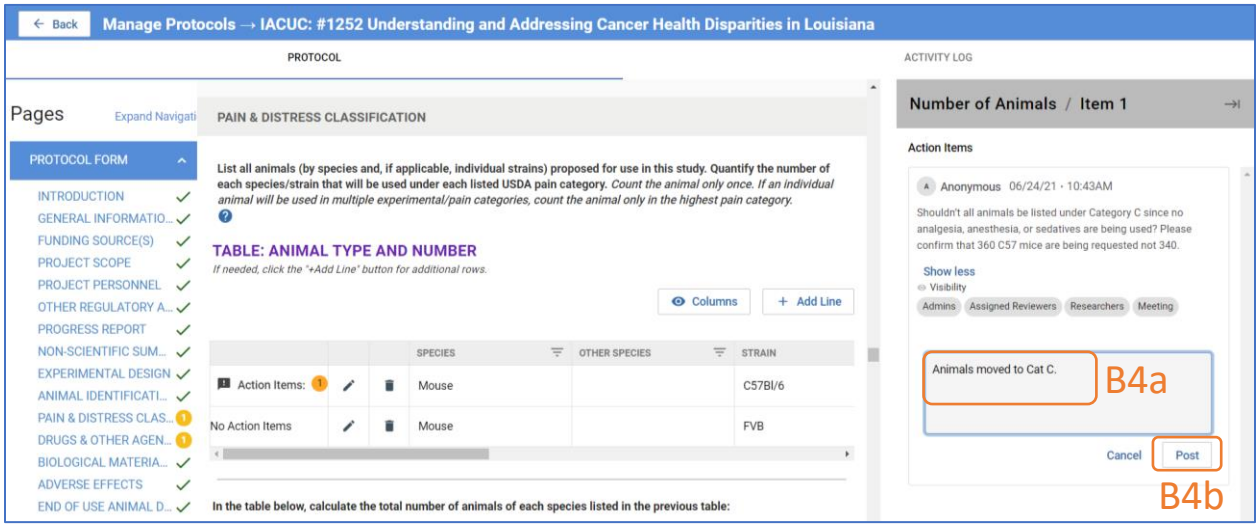
3. To view and address the action items:
    a) Click on the **section with an action item** to go to that section of the form.
    b) Click **Action Item**.
    c) The right side panel will display the **comments from the reviewer**.
    d) If edits are warranted, **edit the field** or text, as applicable.
    e) Click **Reply** on the right side panel.



4. Next:

   a) **Summarize your response** to this action item.

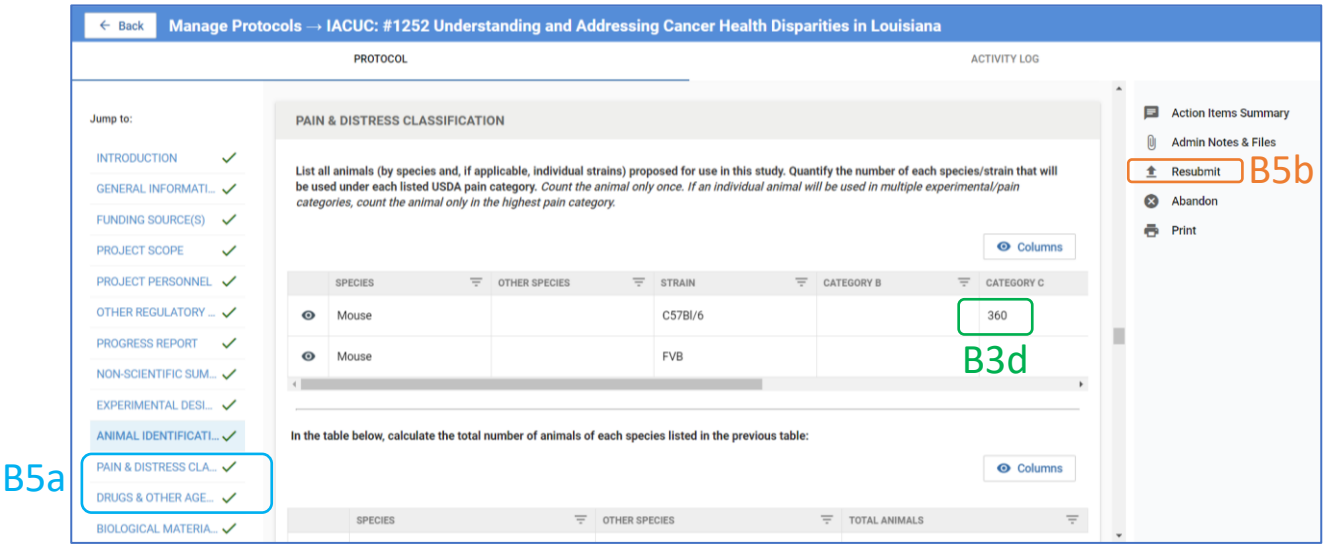
   b) Click **Post**.



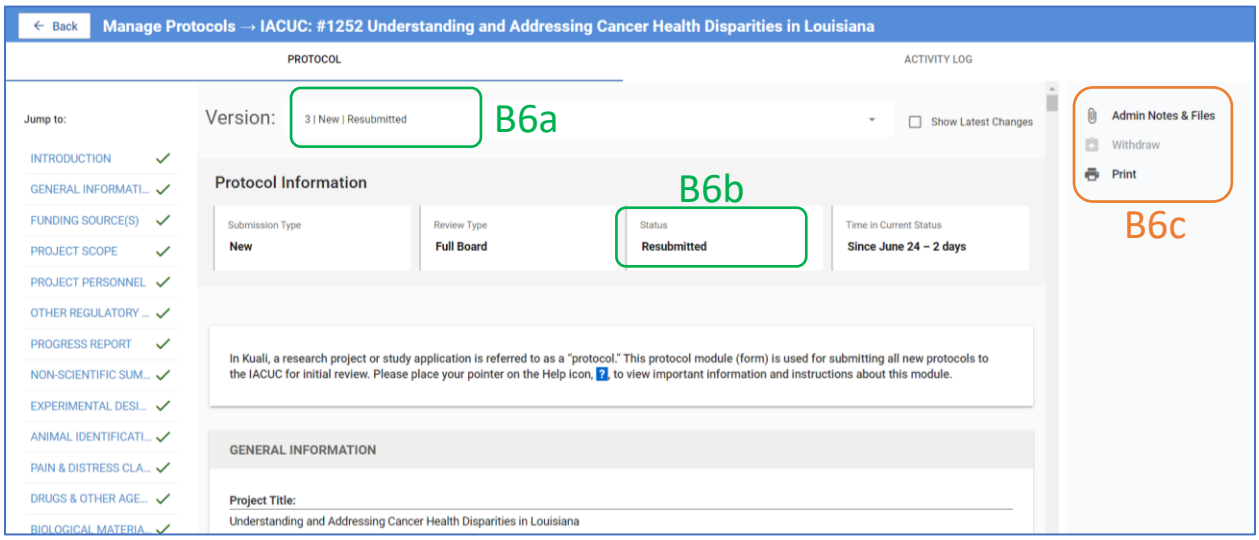
5. Repeat this procedure for all action items left by the reviewer or IACUC Admin.

   a) When you post your response to an action item, the **action item icon will disappear**.

   b) Click **Resubmit**. *All study personnel with full access to the protocol can resubmit a protocol, not just the PI.*



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.



7. A system generated email will be sent to the IACUC Administrator and PI notifying them of the resubmission.

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

9. **NOTE:** *Multiple resubmission-review cycles may be necessary before a final determination is made*.

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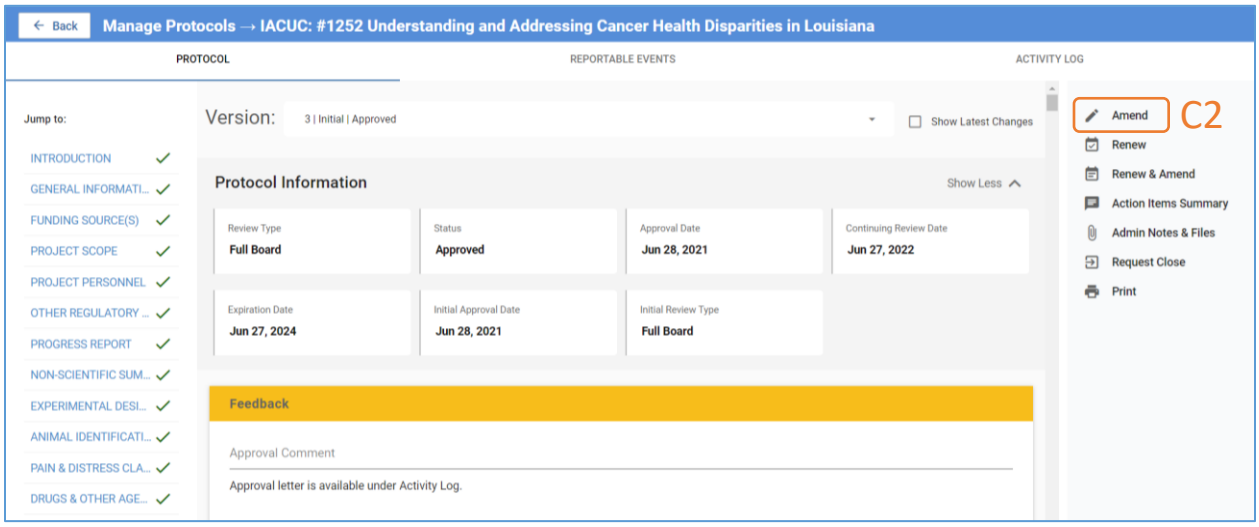
C. AMENDMENT

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

1. Log into Kuali as described in Section A and click on the protocol in the protocols table.

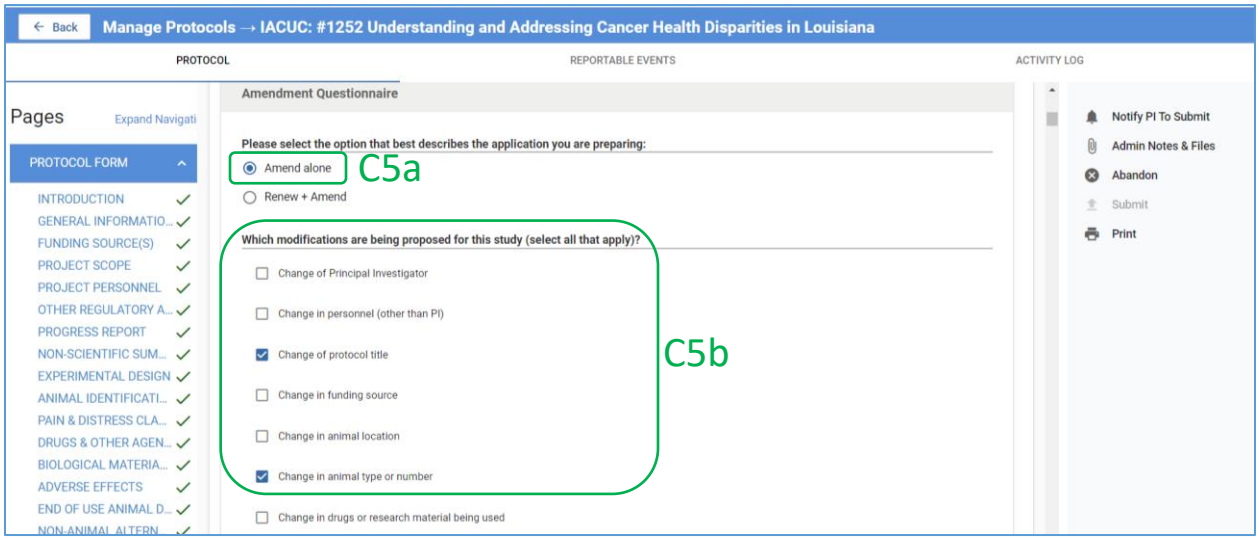
2. Click the **Amend** button on the right side panel.



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.

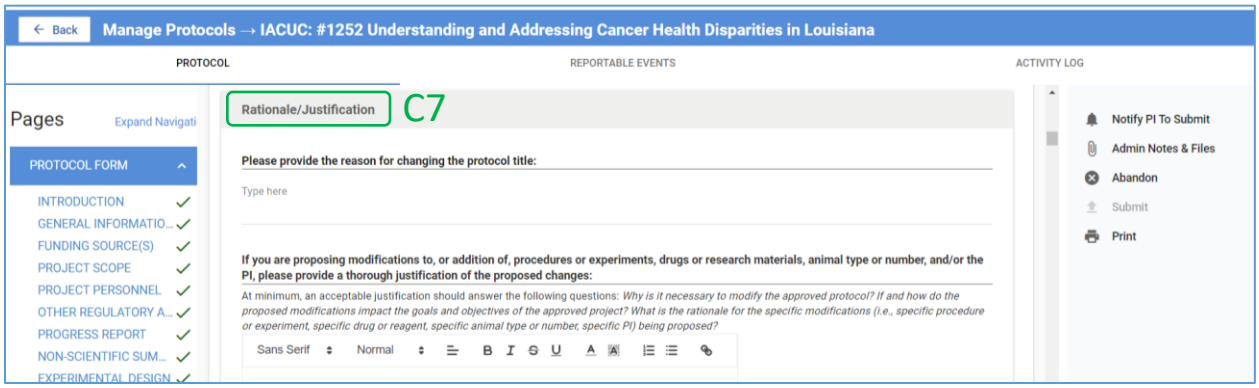
4. The **Amendment Form** will appear right below the Protocol Information section. Please read and follow the instructions.

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

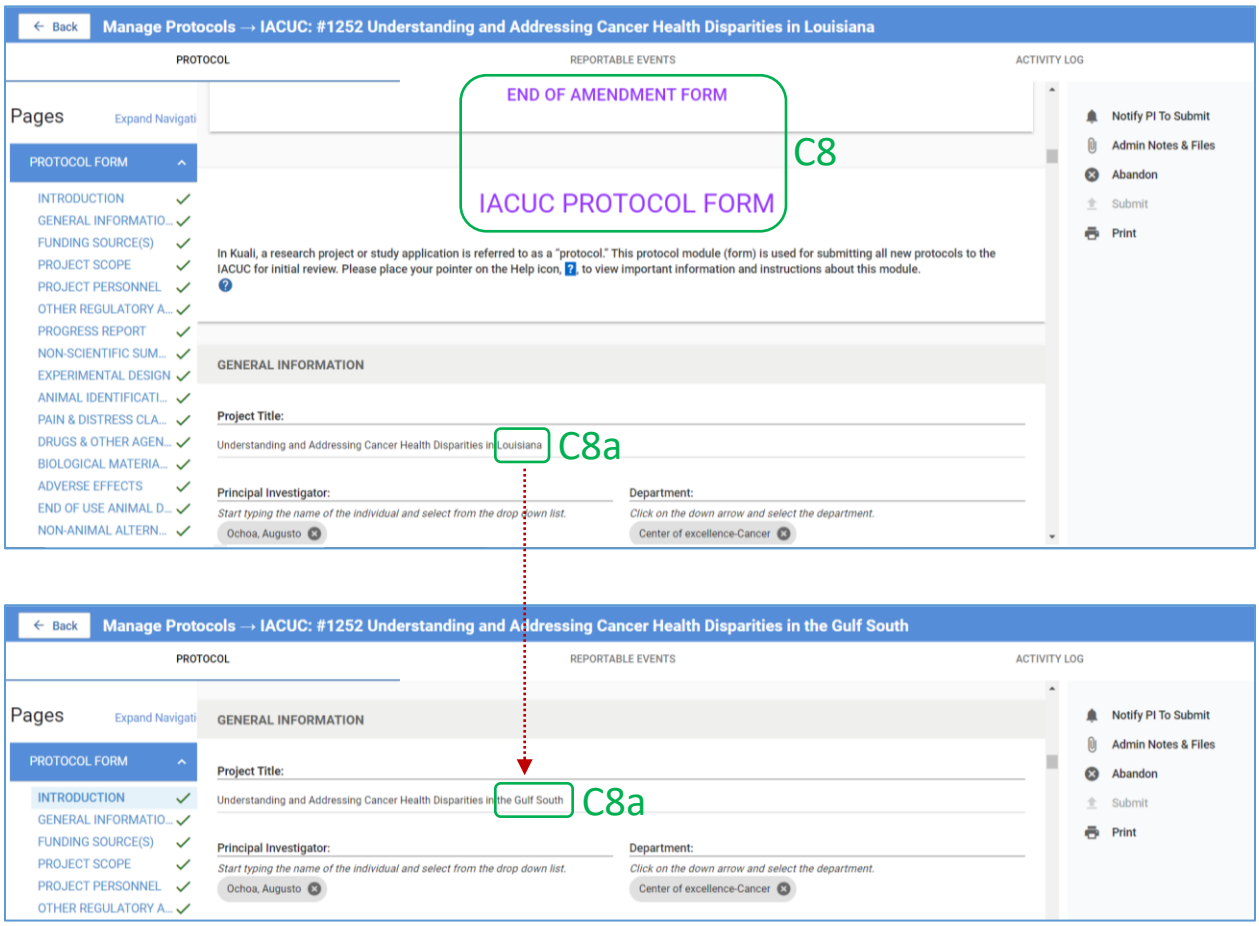


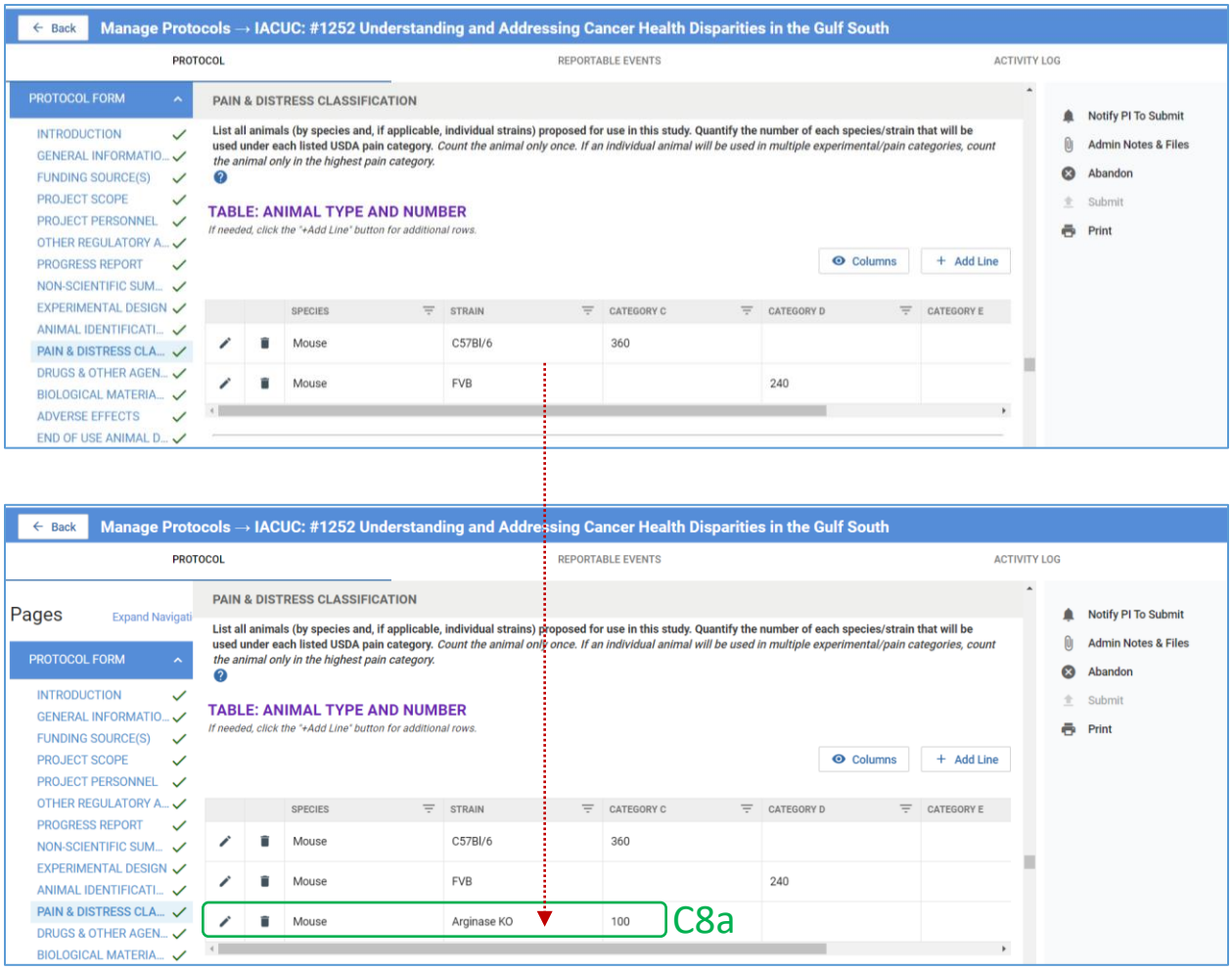
6. Answer all questions on the Amendment Form.

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

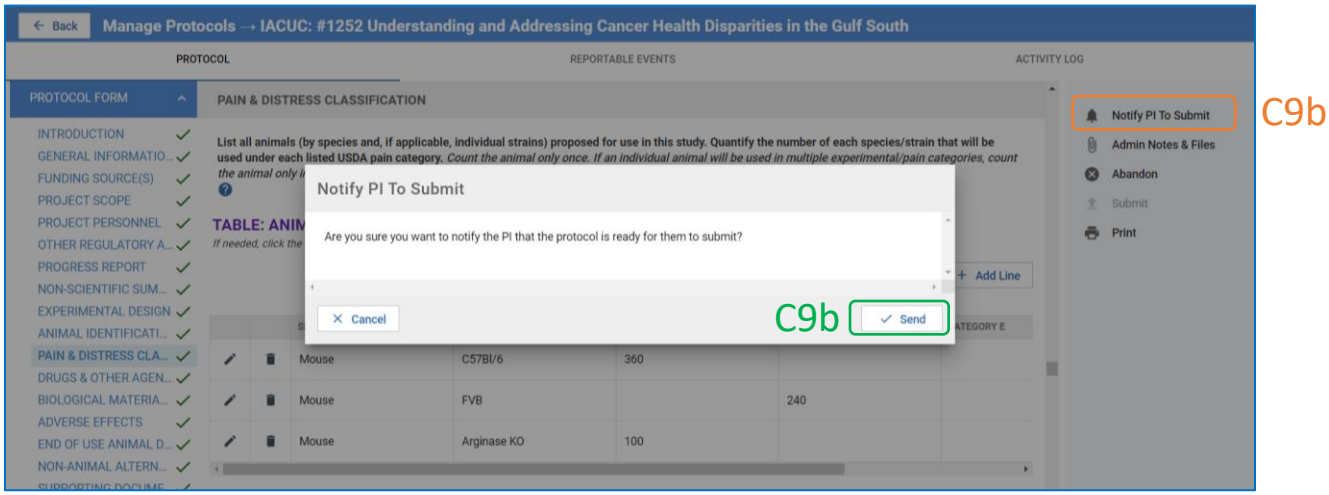


8. But the actual modifications to the protocol are made on the **Protocol Form that follows the Amendment Form**.
    a. To modify the protocol, simply **edit the text or field** as desired (examples shown below).

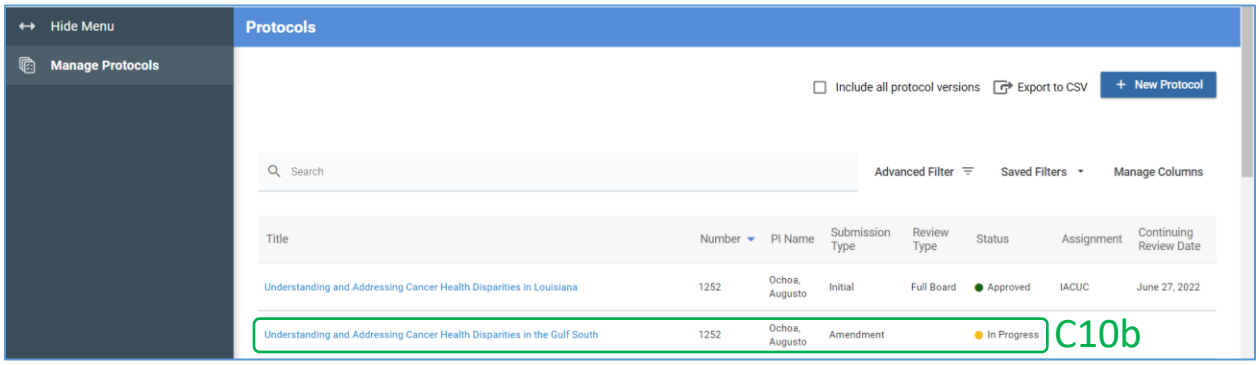




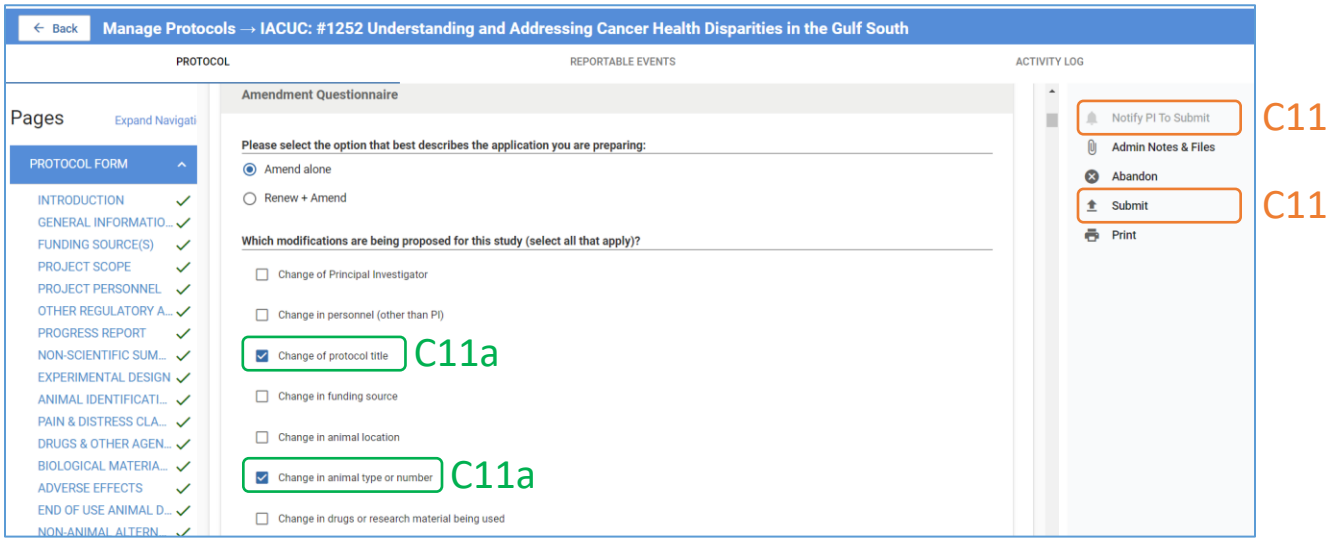
9. Once all modifications have been made to the protocol,
    a. If the person preparing the application is the PI, go to Step 10.
    b. If not the PI, click **Notify PI to Submit** and then click **Send** in the pop-up window.



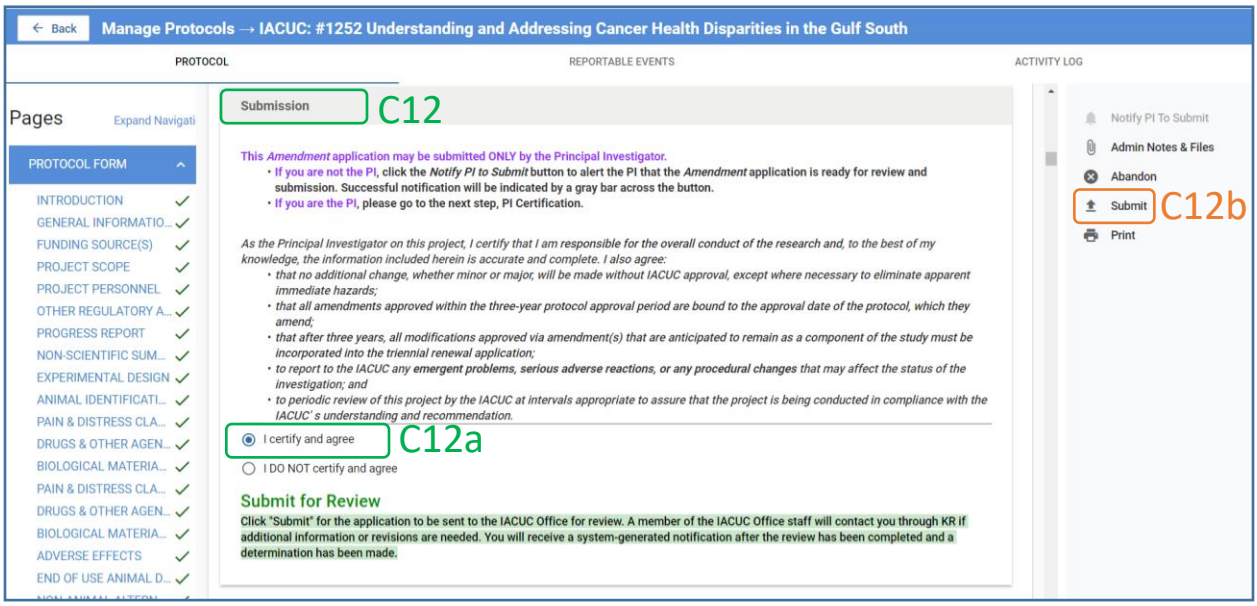
10. An email notification will be sent to the PI to review, certify and submit the amendment application.
    a. The quickest way for the PI to access the amendment application is through the protocol link in the email itself.
    b. Alternatively, the PI can log into Kuali as described in Section A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



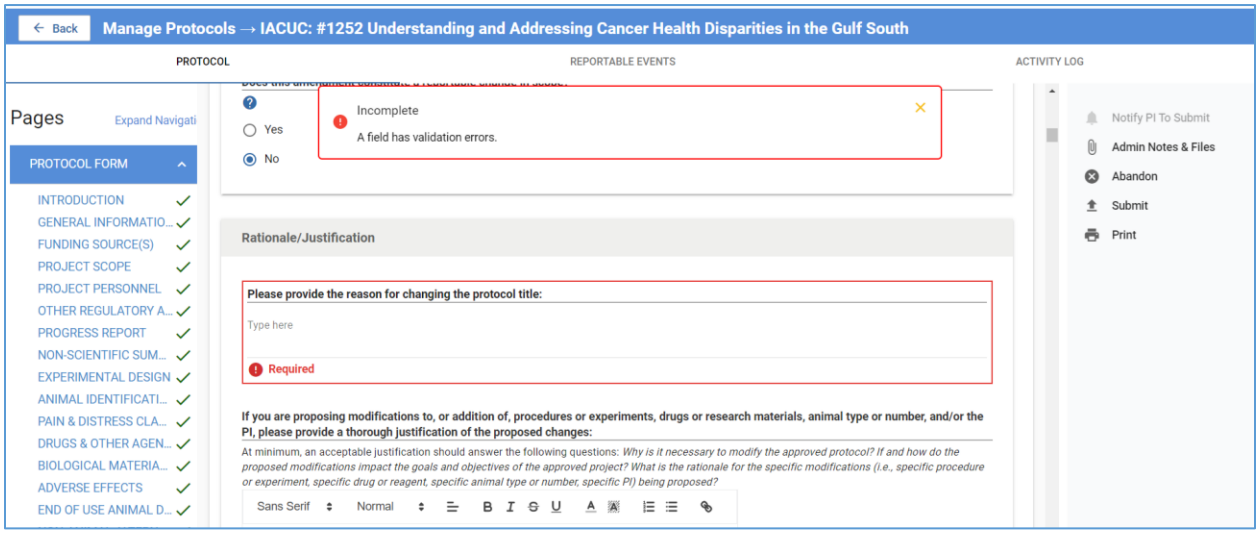
11. Because the PI has opened the protocol, the **Notify PI to Submit** button will be grayed out and the **Submit** button will be active.
    a. The PI should review **all the modifications** and then….



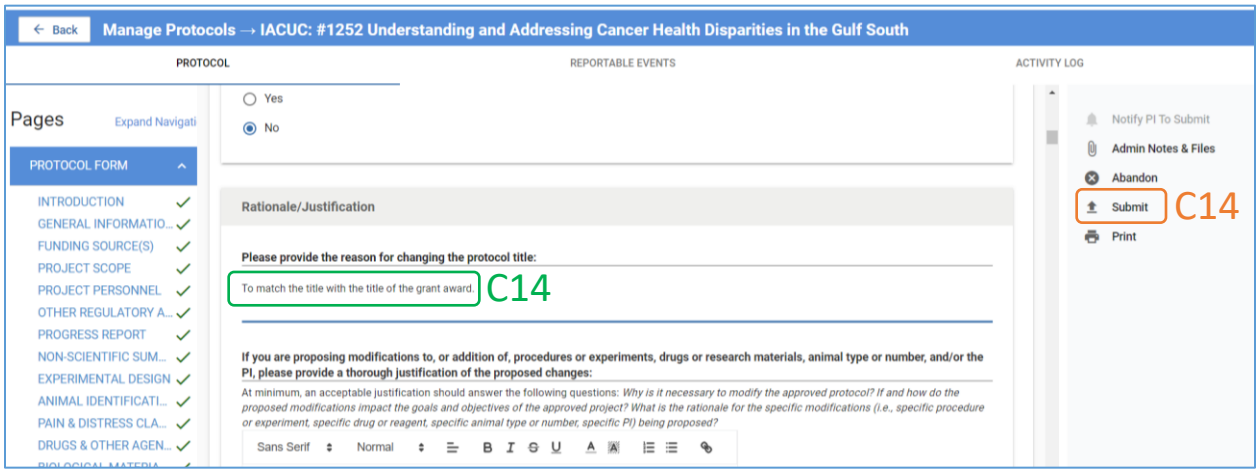
12. Go to the last section, **Submission**, of the Amendment Form.
    a. **Certify** to the attestations, and…
    b. Click **Submit**.



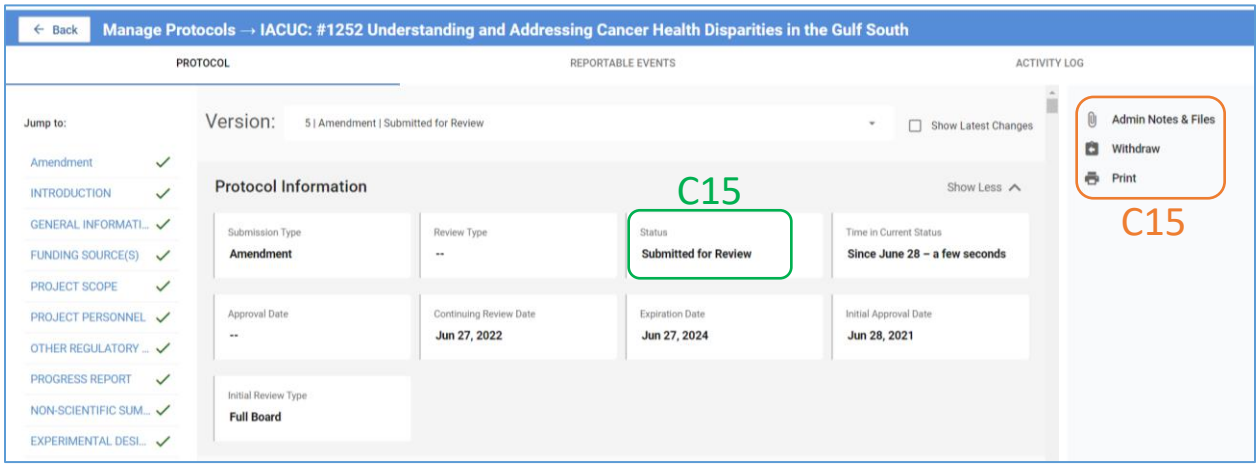
13. If any fields are incomplete, an error message will appear.



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



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



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

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

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

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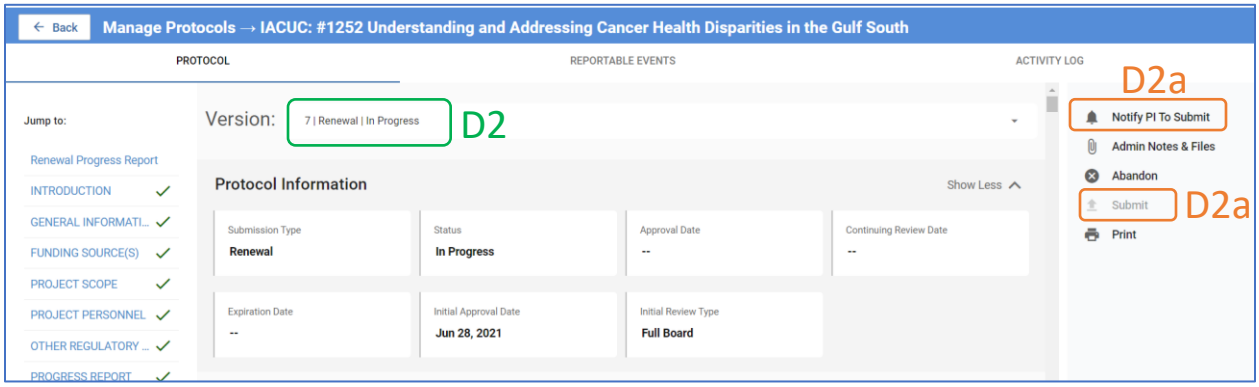
D. Renewal

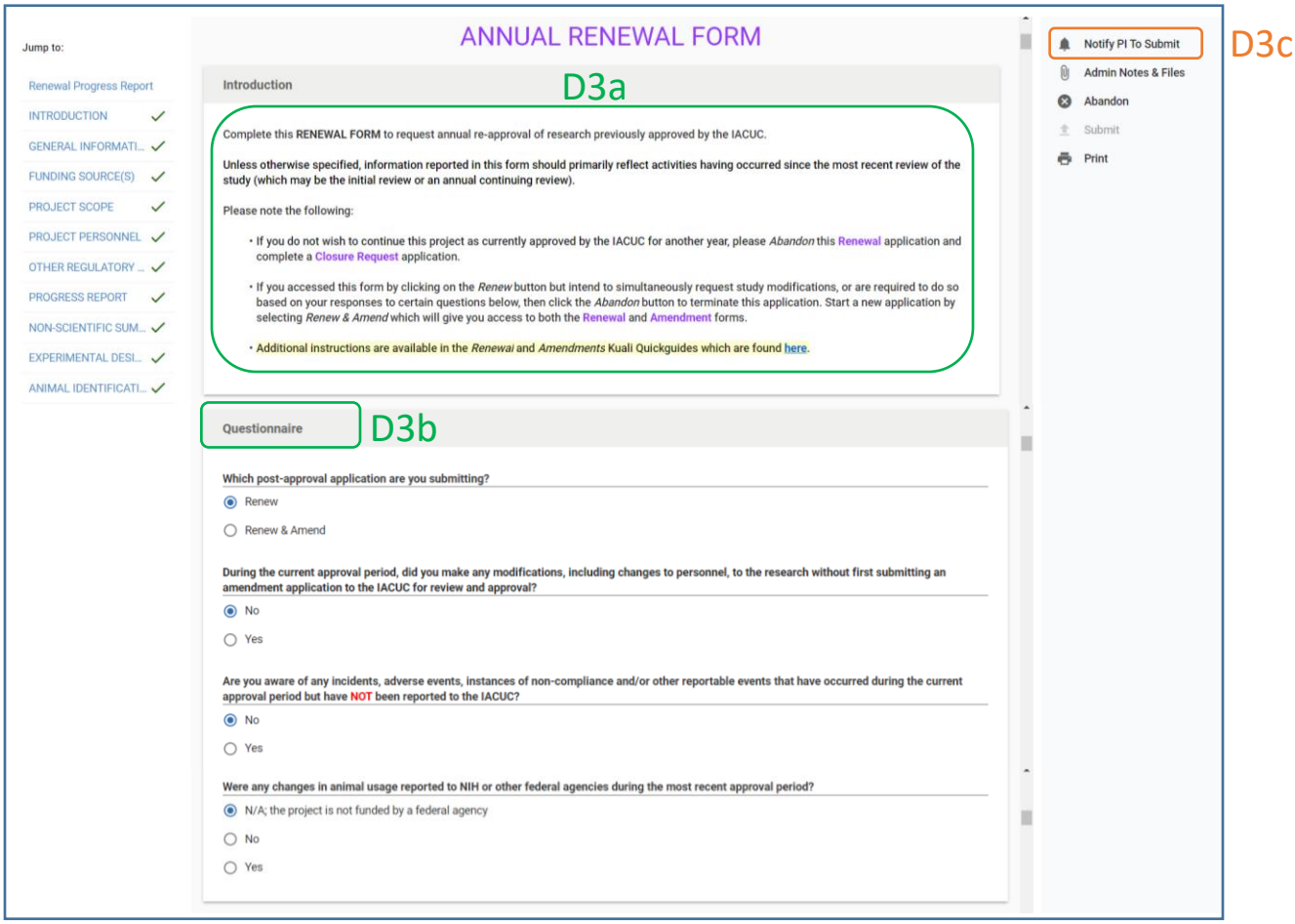
IACUC protocols are approved for three (3) years. Federal regulations and institutional policy, however, requires continuing review of approved protocols on at least an annual basis. Use the Renewal Form to submit protocols for continuing review. You will receive several email notifications starting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

1. Access the protocol using the link in the email notification or log into 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**.

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.



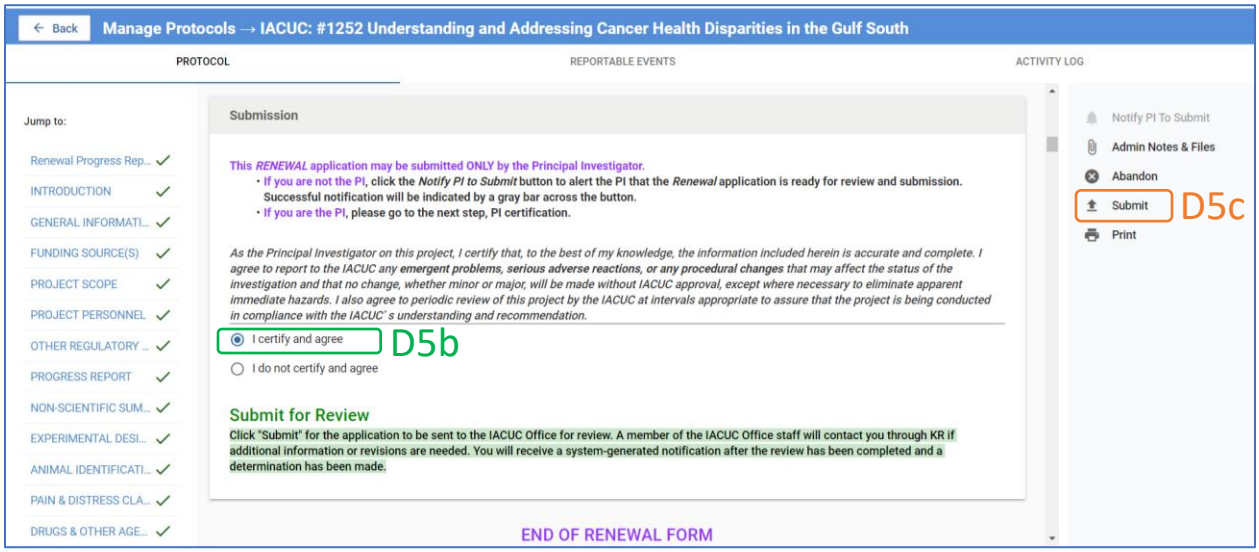
3. Scroll down to the **Renewal Form**; then…
    a. Read the **instructions**,
    b. Complete the **questionnaire**, and
    c. Click **Notify PI to Submit**.



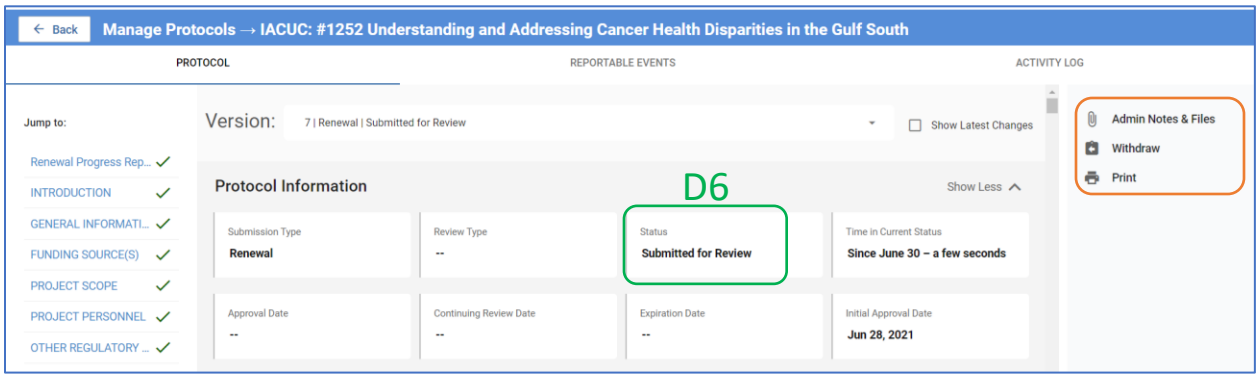
4. The PI will receive an email notification to submit the Renewal application.

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.



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



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

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

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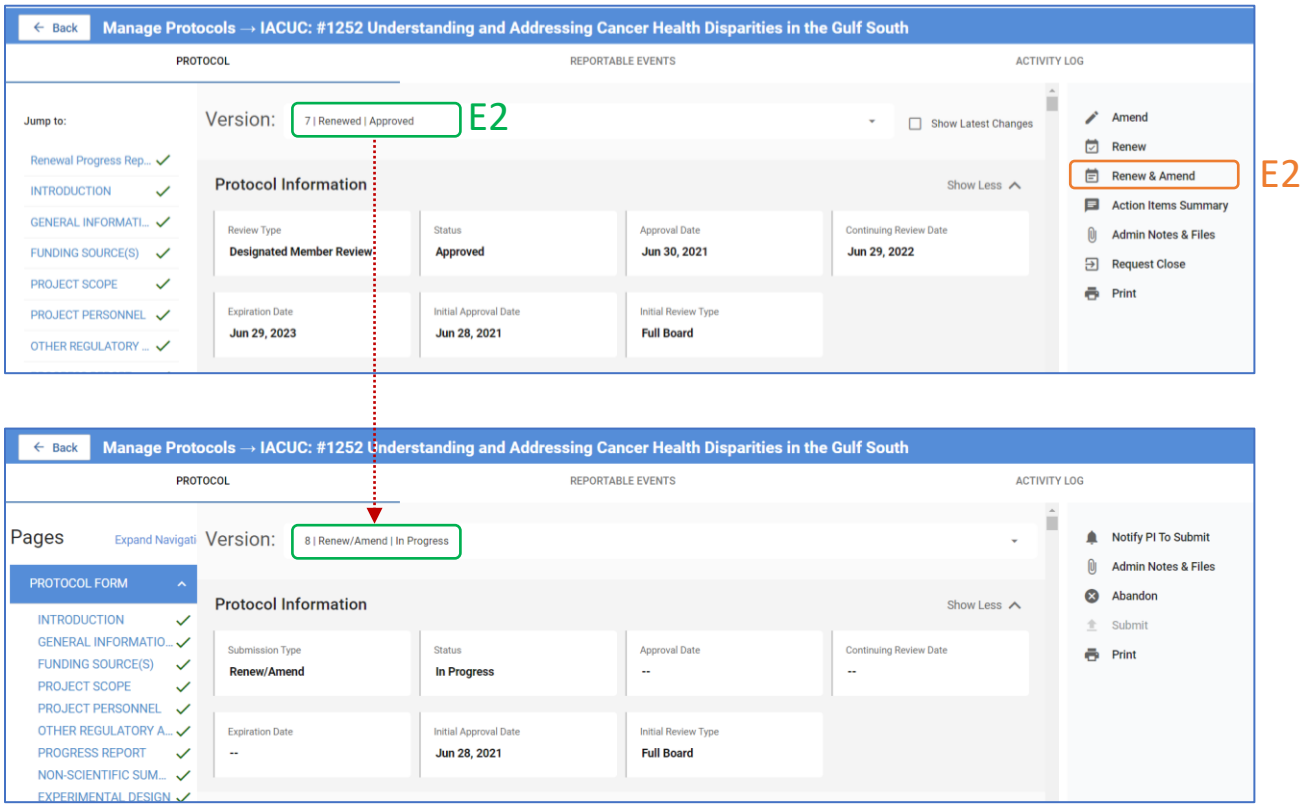
E. Renewal & Amendment

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

1. Access the protocol using the link in the email notification or log into Kuali as described in Section A and click on the protocol title in the protocols table.

2. Click the **Renew & Amend** button on the right side panel. A **new version** of the protocol will be created.



3. The forms will display in the following order: **Renewal** > **Amendment** > **Protocol**. Complete the forms and edit the protocol as described in Section C and Section D.

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

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F. Reportable Event

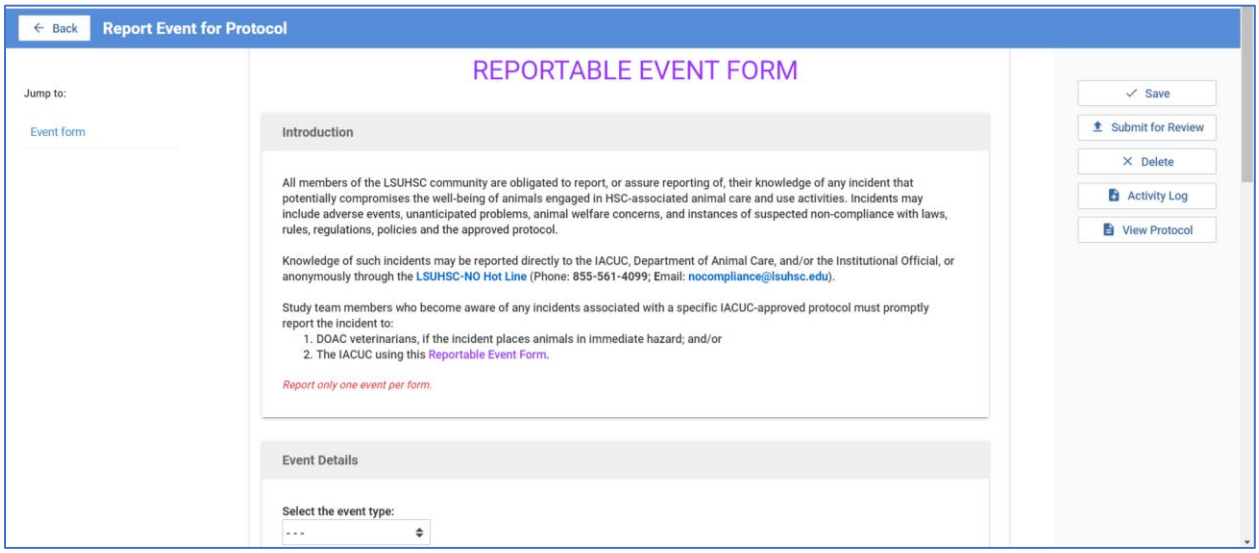
Study team members who become aware of any incidents or non-compliance associated with a specific IACUC-approved protocol must promptly report the incident to the IACUC using the Reportable Event Form.

1. Log into Kuali as described in Section A and click on the protocol title in the protocols table.

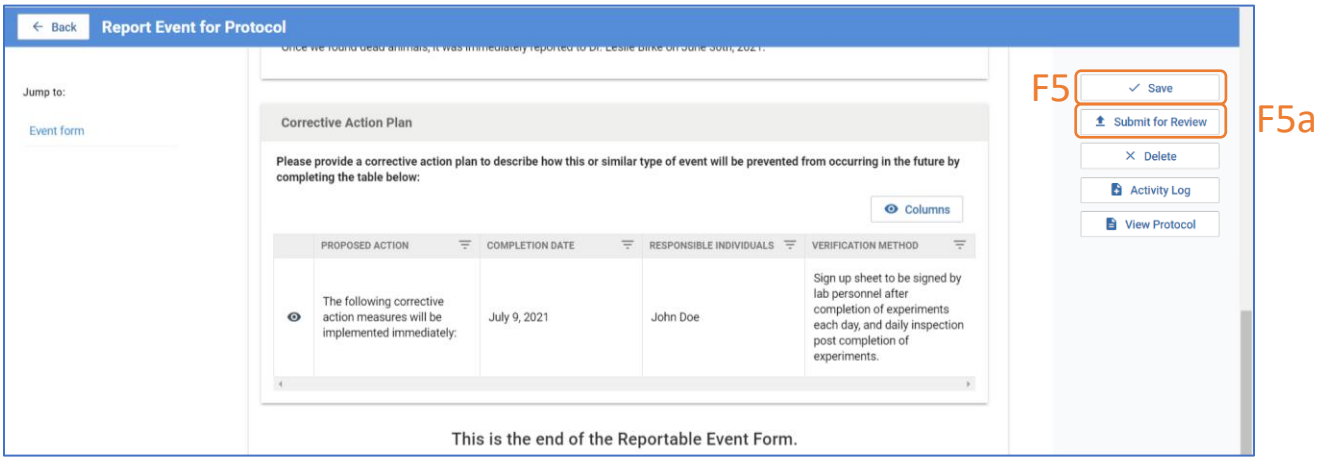
2. Click the **Reportable Events** tab.

3. Click **Report an Event**.

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



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



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

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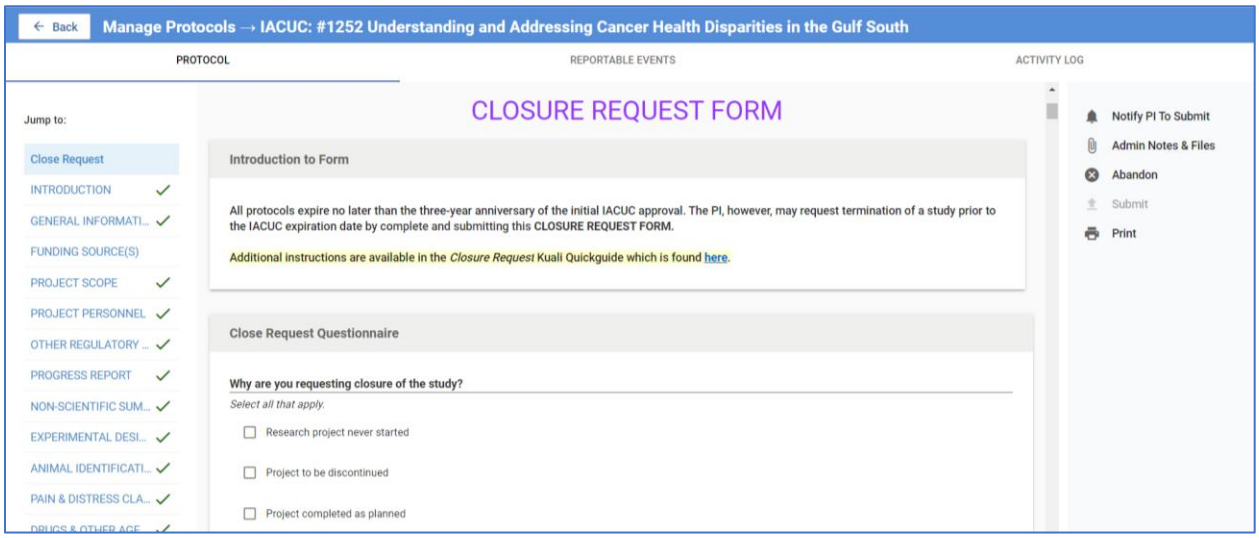
G. CLOSURE

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

1. Log into Kuali as described in Section A and click on the protocol title in the protocols table.

2. Click **Request Close**.

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.

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