Drexel University DragonSPOT Lab Animals (IACUC) Module User Manual

Office of Research and Innovation
Spring 2021

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Introduction

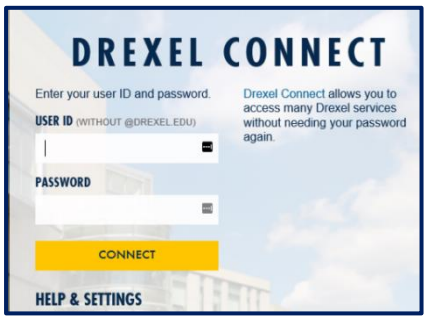
The DragonSPOT IACUC Module is a streamlined way to create, submit, and revise your protocol for Drexel's IACUC approval. Once you have submitted your protocol by following the guidance below, it will pass through the review stage at which point you can make any requested changes and revise for further approval. The application is reviewed by a subset of the IACUC Committee, usually consisting of a primary and a secondary reviewer, statistician, outside member, and by the veterinarian. Once your protocol and corresponding revisions are pre-approved, it will be voted on for final approval at the monthly IACUC Meeting.

This guide is intended for researchers and PIs who are submitting an IACUC protocol. Training materials for other users and modules can be found at https://drexel.edu/research/proposal/electronic-research-administration. If any IACUC-specific questions arise throughout your protocol submission process, please reach out to iacuc@drexel.edu. For technical questions, please contact DragonSPOT-help@drexel.edu.

Accessing Drexel's DragonSPOT portal

- Log into Drexel's DragonSPOT at https://dragonspot.drexel.edu/. Click the link under **Drexel Connect Users**: "Click here to use Drexel Connect to login with your Drexel User ID *(abc123)*."
    - ✔ *Note: You can access DragonSPOT on any of these browsers – Safari, Firefox, Chrome, or Microsoft Edge.*

- You will then be taken to the Drexel Connect page where you can log in with your Drexel user ID (abc123) and password.



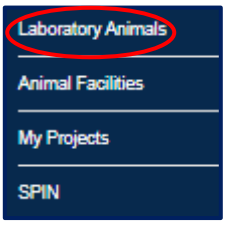
Navigating the DragonSPOT Homepage

- Once you are logged in, you will see your personalized DragonSPOT homepage.
    - ✔ *Note: Your homepage is customizable and you can add widgets that are most helpful to you. To configure your homepage, press the **Portal Configurations** button in the top right corner.*

*Once you configure your homepage, your settings will be saved for the future. Please see the **Portal Configuration Quick Guide** for more information on portal features and customizing your homepage.*

Creating and Submitting your IACUC Protocol

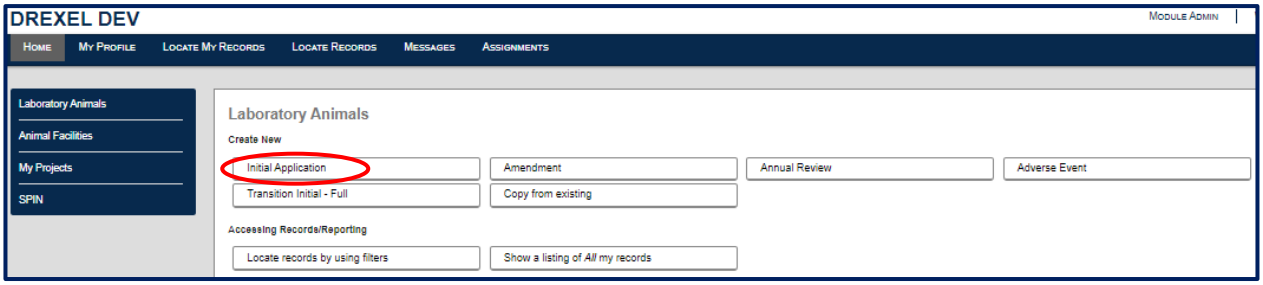
- In the left sidebar of your home screen you will see the different DragonSPOT modules available. To begin your IACUC protocol, please click on the **Laboratory Animals** button.
    - ✔ *Note: For guides on using the other modules, please visit the training website at https://drexel.edu/research/proposal/electronic-research-administration.*



Creating an Initial Application

- You will now see the menu for the **Laboratory Animals** module.
  For future reference, this is where you can also create an Amendment, an Annual Review, an Adverse Event, or Copy from an existing protocol.

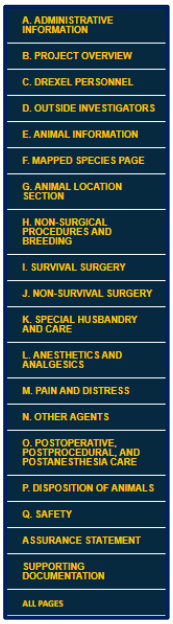
- Click on **Initial Application** under the **Create New** header.



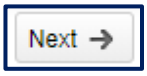
- A new window will open and you can begin your protocol.

Navigating the eForm

- When the eForm window opens, please take notice of the left-hand sidebar, which indicates the different sections of the protocol. Clicking on the tabs will jump you to the different pieces of the submission form or you can remain on the main page to navigate through one long form that is not broken out into separately paged sections. You can also view the entire form by clicking on the **All Pages** tab at the very bottom of the sidebar.
    - ✔ *Note: The asterisk symbol will appear next to mandatory questions on the form.*



    - ✔ *Note: If you choose to use the sidebar to access each section individually, clicking the **Next** button at the bottom of each page will take you to the next section and save your data as you go.*

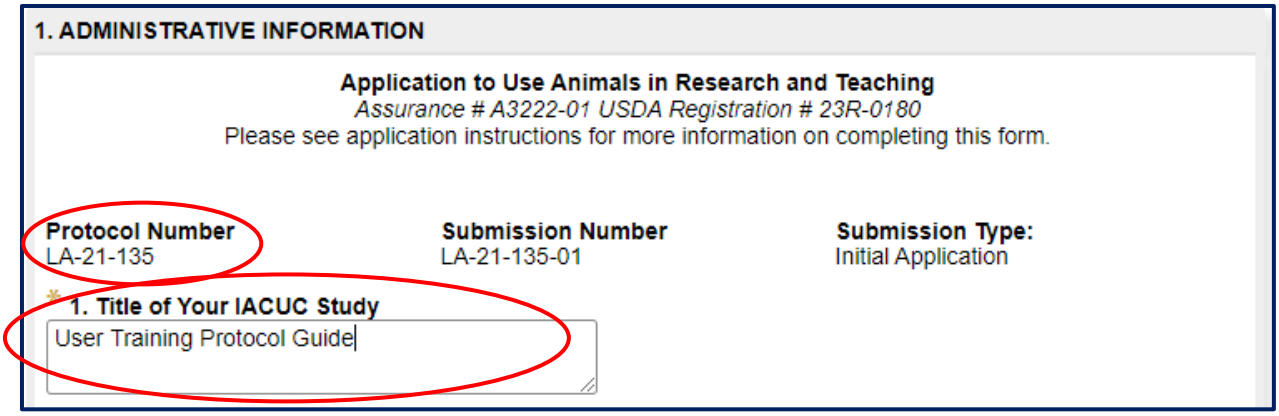


Saving While You Work

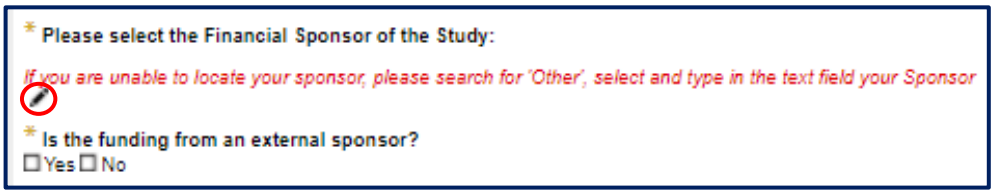
- Please make note of the top bar menu, where you will be able to **Save** your protocol, in addition to the other options, such **as Finalize Form, Validate, and Submit**. The **Menu** button will allow you to print and view history as well. More details on the functionality of these headers can be *found below in the **Finalization, Validation, and Submission** section of this manual.*
    - ✔ *Note: Pressing the **Validate** button will tell you if you missed any mandatory fields throughout the protocol. More information can be found on the **Finalization, Validation, and Submission** section of this manual.*
- **Important!**: Be sure to **Save** as you go. Once you've entered data in a field, an autosave function will occur once you attempt to enter data in the subsequent field. It will not save until you attempt to answer the next question. As a best practice, please manually click the save button throughout completing your record. You will find reminders throughout this manual.

Administrative Information Section

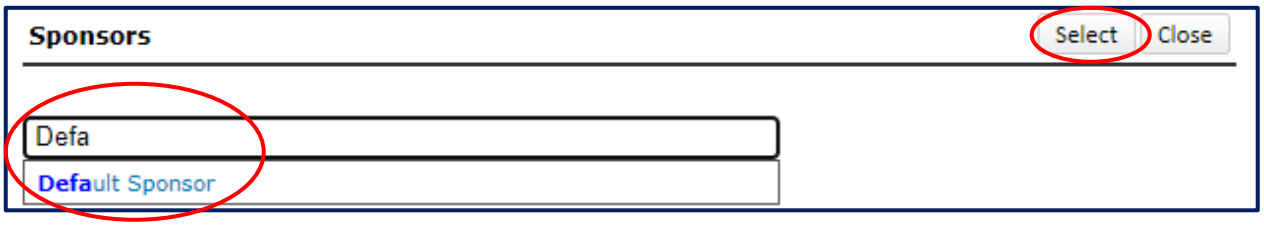
- The form begins with the **Administrative Information** section. Please fill out the title of your study in box #1.
    - ✶*Be aware that this section is mandatory.*
- **Important!**: Please make note of your Protocol Number. This will help you search for your record in the event you need to exit and return to it later.



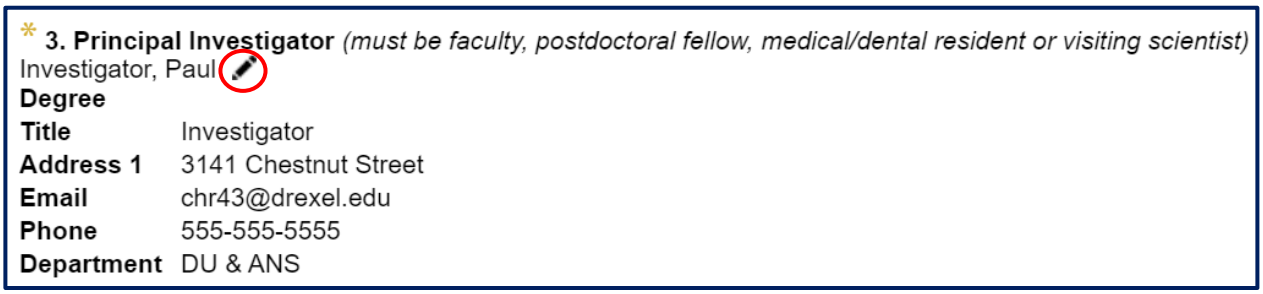
- Beneath the title, you will have to enter the **Financial Sponsor** of the Study.
- Please click the **pencil icon** to search for your Sponsor.



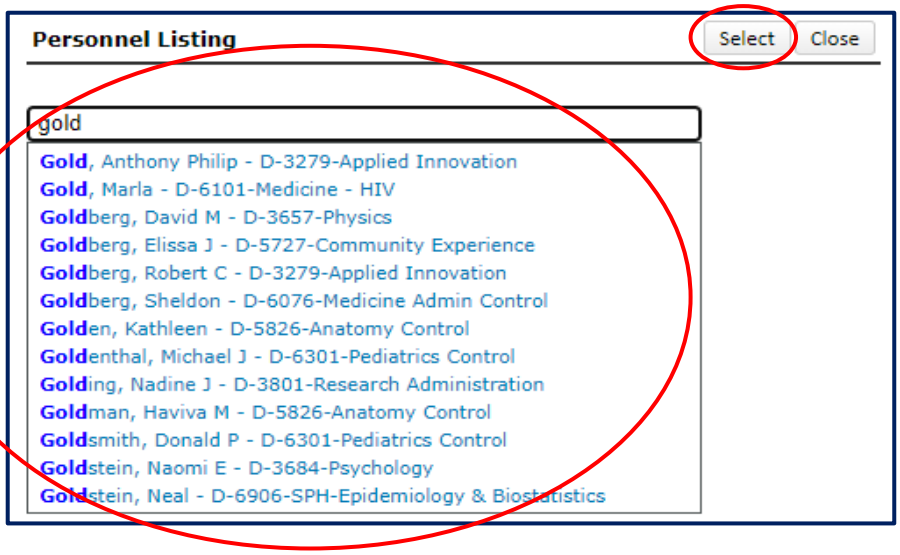
- A new window will pop up and you will be able to search for your Sponsor's name. As you start typing, suggestions will appear. When your Sponsor's name appears, please click on it. If your Sponsor is not listed, type **Other**. Once you click on the Sponsor name, click the **Select** button to add this sponsor to your form.
    - ✔ *Note: The **Close** button will close the box without saving your selection so be sure to click the **Select** button.*



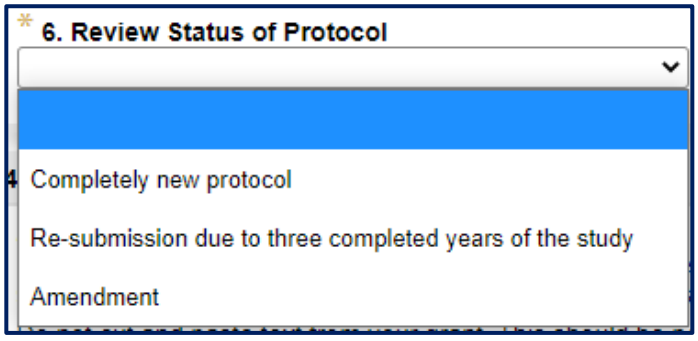
- Follow the same steps for using the **pencil icon** as Question 3 to add your **Principal Investigator**. By default, you will be the Principal Investigator listed on the record. To change this, click on the **pencil icon** to the right of your name.



- A new window will pop up and you will be able to search for the PI's name. As you start typing, suggestions will appear. When the PI's name appears, please click on it. Once you click on the PI's name, click the **Select** button to add this PI to your form.
  - ✔ *Note: The **Close** button will close the box without saving your selection so be sure to click the **Select** button…*



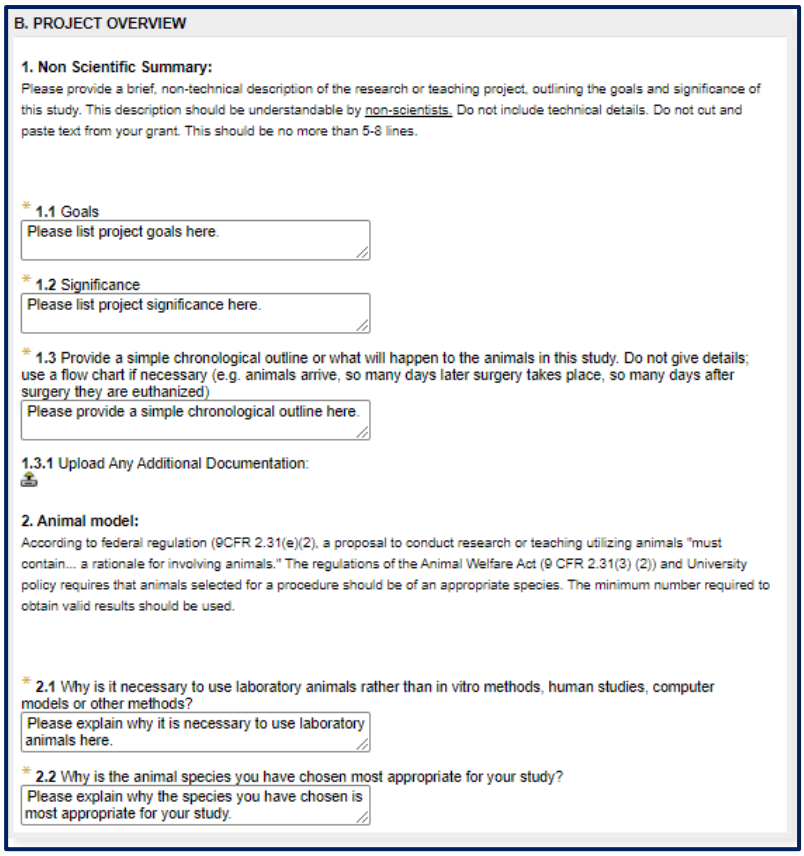
- To complete this section, please select the Review Status of the Protocol from the drop down:



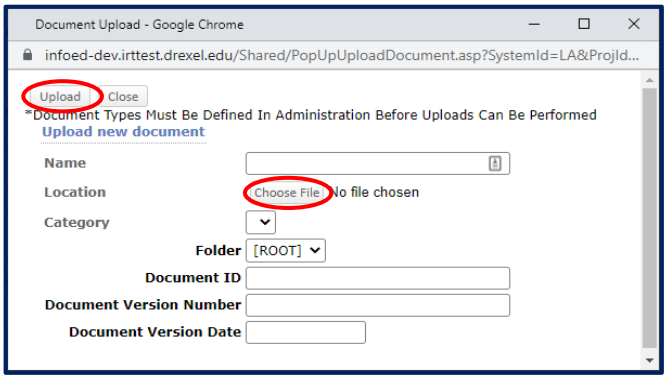
  - ✔ *Remember: Be sure to save as you go!*

Project Overview section

- Continue to fill out the form sections in the boxes indicated below.
  - ✶*Be aware that pieces of this section are mandatory.*



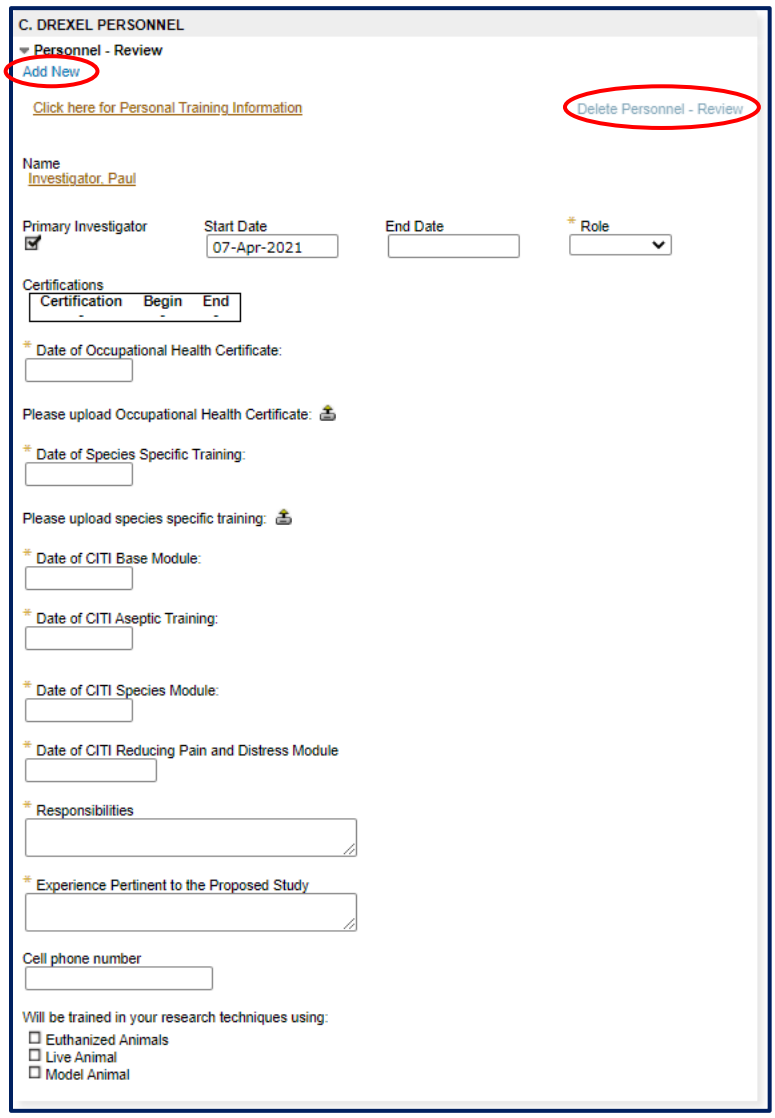
  - ✔*Note:* The icon indicates a field where you can upload supporting files.
  - Clicking this button will open a new window. Use the **Choose File** button to add a specific file from your computer. When you are done, please click on the **Upload** button.



  - ✔*Remember: Be sure to save as you go!*

Drexel Personnel Section

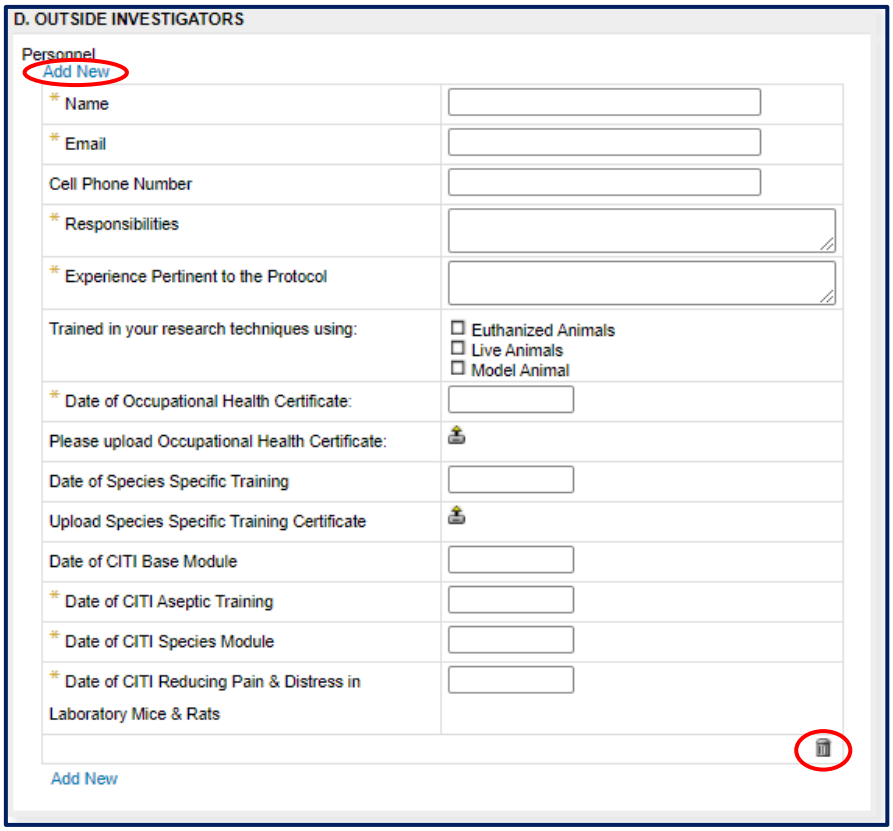
- The next section is the **Personnel** section. You can add additional internal personnel in this section by using the **Add New** button. This **Add New** button follows the same instructions as the PI search section explained above. Use the **Add New** button to search for additional personnel, which will be added underneath you're the PI information. You can remove personnel by clicking the **Delete Personnel** button. You may add multiple personnel here.
    - Please remember to make sure the person selected as the **Principal Investigator** on the **Drexel Personnel** page matches with the **Principal Investigator** identified on the **Adminsitrative Information** page.
    - ✶*Be aware that pieces of this section are mandatory.*



    - ✔*Remember: Be sure to save as you go!*

Outside Investigator Section

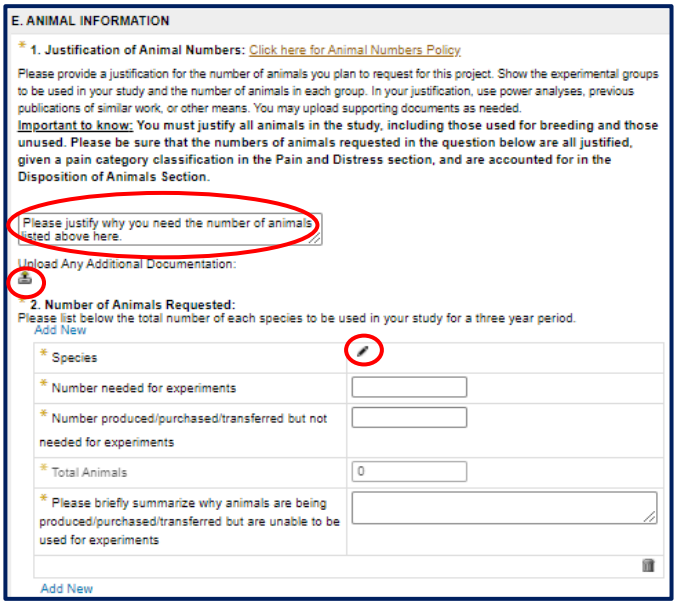
- The Outside Investigators section allows you to add information for personnel external to Drexel. You may add multiple personnel here by clicking the **Add New** button or press the **trash can** icon to remove personnel. Use the **upload icons** to attach files.
    - ✶*Be aware that pieces of this section are mandatory.*



    - ✔*Remember: Be sure to save as you go!*

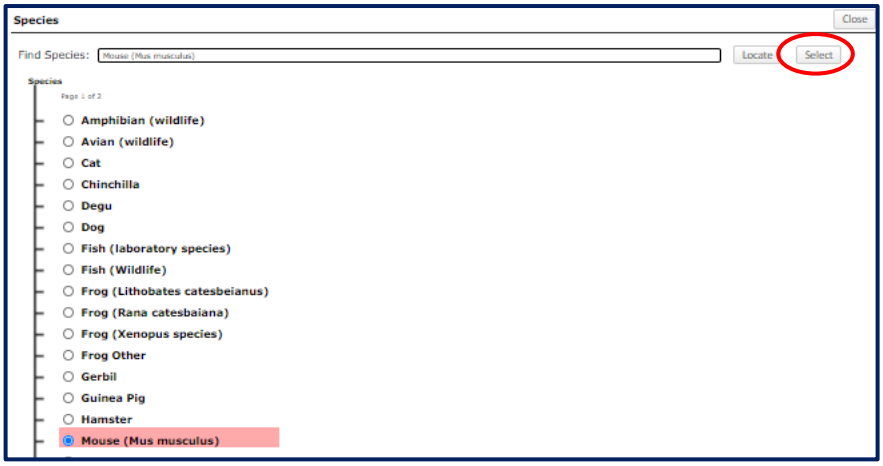
Animal Information Section

- In the Animal Information section, begin to fill out the form and upload any additional documentation, if necessary.
    - ✶*Be aware that this section is mandatory.*
- The second part of the Animal Information section prompts you to add your species. click the **pencil icon** to add your species select the **Species Name.** Please click the **pencil icon** to search for your species.



- Upon clicking the **pencil icon** next to species, a pop-up window will appear where you can select your species from a list, or search for the species in the search box to find it more easily in the list.

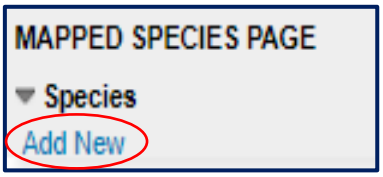
- Be sure to click on the radio button next to your species and then press the **Select** box to save your choice.



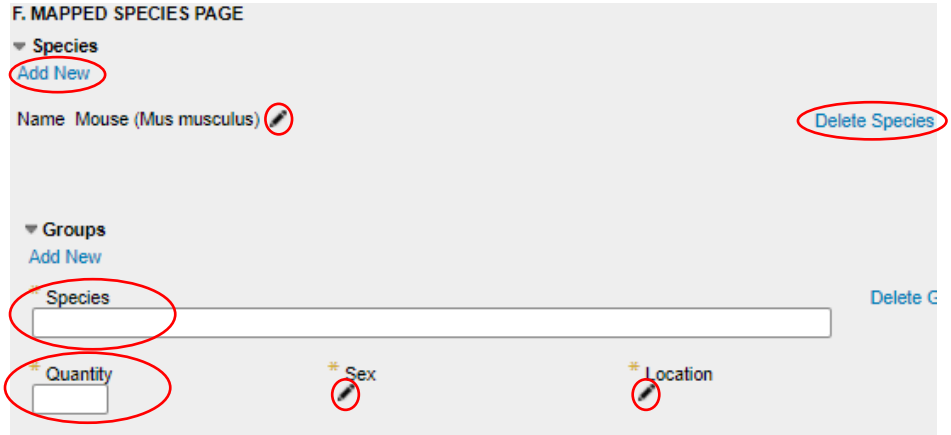
- ✔ *Note: Remember that you can click **Add New** again to add additional species or press the **trash can** icon to remove species.*
- ✔ *Remember: Be sure to save as you go!*

Mapped Species Section

- You will need to enter the species type one more time, along with some additional details regarding the species, as this section ensures your species information connects to the Animal Facilities module in DragonSPOT and is also needed for reporting data. Click on the **Add New** button under the **Mapped Species** section of your protocol.



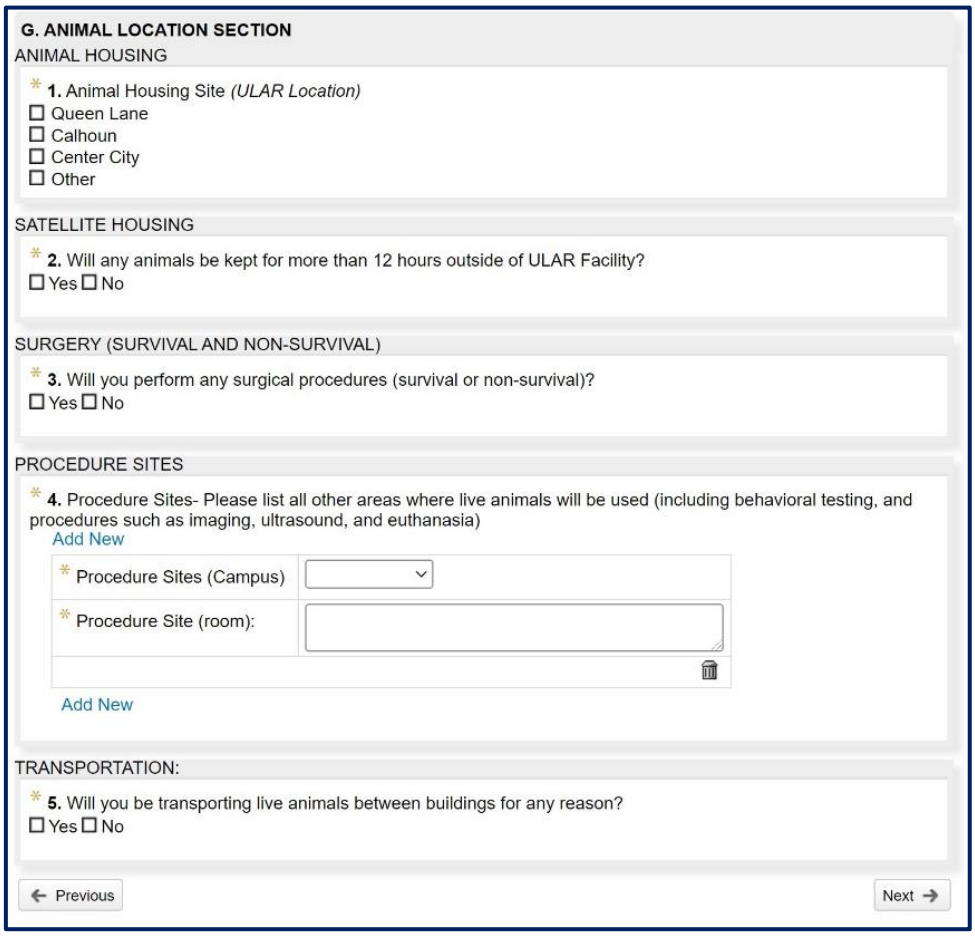
- The same species selection screen as the one above will appear – please select your species. After you click your species from the list and press the **Select** button, you will be prompted to enter additional information about the species. Please use the **Add New**, **Delete**, and **pencil Icon** to make any changes needed.
- Underneath the **Groups** header, please manually enter the **SPECIES** (ex: Rat, Mouse).
  - Please make sure to enter type in the **species** to match exactly with the species from the picklist
    - Please **do not** enter the strain, subspecies, or experimental group
- In **Quantity**, please re-enter **the total number of animals from question 2 in the Animal Information Section**. Please complete the other corresponding fields. Use the **pencil icon** to search for appropriate responses.
  - ✔ *Note: You can click **Add New** or **Delete Groups** as needed in this section as well.*
- ✔ *Note:* If you are using more than one sex for each species, please select "Both or Either". Please **do not** make a separate group entry for each sex.
- ✔ *Note:* If you are using more than one location, please select "Drexel University". Please **do not** make a separate group entry for each location.



  - ✔ *Remember: Be sure to save as you go!*

Animal Location Section

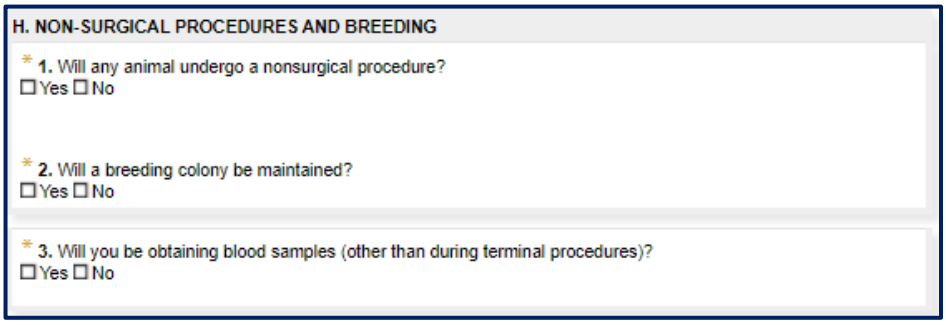
- Continue filling out the checkboxes in the remaining sections. Note that responding **Yes** to some of the questions will result in expanding fields which require additional information. Please use the **Add New** button and **trash can** icon to manage edits.
- Remember that the **Add New** button will typically add a new section for you to fill out within the page or allow you to search for your answer in a list of responses. Additionally, the **pencil icon** will also allow you to search for possible choices.
- ✶*Be aware that this section is mandatory.*



- ✔ *Remember: Be sure to save as you go!*

Non-Surgical Procedures and Breeding Section

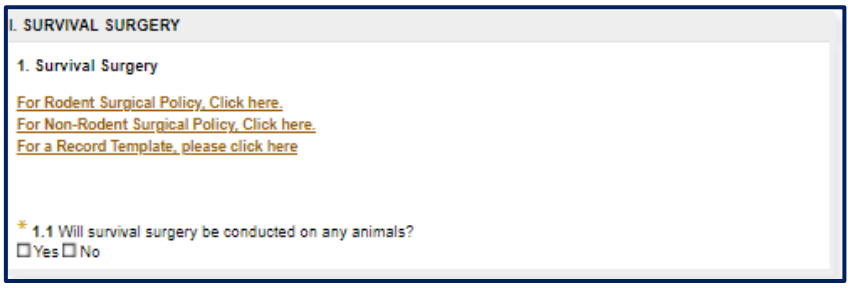
- Continue filling out the checkboxes in the remaining sections. Note that responding **Yes** to some of the questions will result in expanding fields which require additional information. Please use the **Add New** button and **trash can** icon to manage edits.
- Remember that the **Add New** button will typically add a new section for you to fill out within the page or allow you to search for your answer in a list of responses.
- ✶*Be aware that this section is mandatory.*



  - ✔ *Remember: Be sure to save as you go!*

Survival Surgery Section

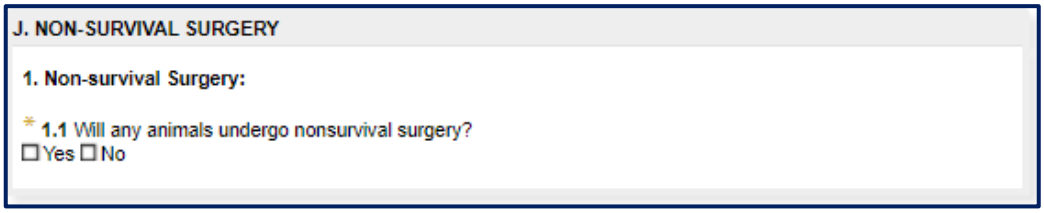
- Continue filling out the checkboxes in the remaining sections. Note that responding **Yes** to some of the questions will result in expanding fields which require additional information. Please use the **Add New** button and **trash can** icon to manage edits.
- Remember that the **Add New** button will typically add a new section for you to fill out within the page or allow you to search for your answer in a list of responses.
- ✶*Be aware that this section is mandatory*



  - ✔ *Remember: Be sure to save as you go!*

Non-Survival Surgery Section

- Continue filling out the checkboxes in the remaining sections. Note that responding **Yes** to some of the questions will result in expanding fields which require additional information. Please use the **Add New** button and **trash can** icon to manage edits.
- Remember that the **Add New** button will typically add a new section for you to fill out within the page or allow you to search for your answer in a list of responses.
- ✶*Be aware that this section is mandatory*


J. NON-SURVIVAL SURGERY

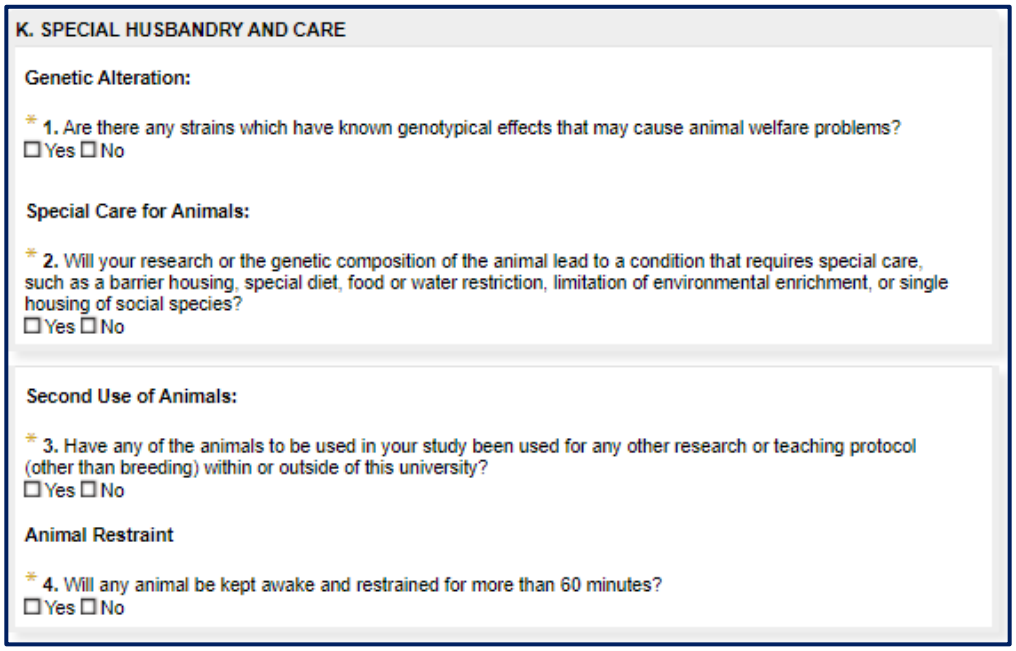
1. Non-survival Surgery:

* 1.1 Will any animals undergo nonsurvival surgery?
☐ Yes ☐ No

  - ✔ *Remember: Be sure to save as you go!*

Special Husbandry and Care Section

- Continue filling out the checkboxes in the remaining sections. Note that responding **Yes** to some of the questions will result in expanding fields which require additional information. Please use the **Add New** button and **trash can** icon to manage edits.
- Remember that the **Add New** button will typically add a new section for you to fill out within the page or allow you to search for your answer in a list of responses.
- ✶*Be aware that this section is mandatory*


K. SPECIAL HUSBANDRY AND CARE

Genetic Alteration:

* 1. Are there any strains which have known genotypical effects that may cause animal welfare problems?
☐ Yes ☐ No

Special Care for Animals:

* 2. Will your research or the genetic composition of the animal lead to a condition that requires special care, such as a barrier housing, special diet, food or water restriction, limitation of environmental enrichment, or single housing of social species?
☐ Yes ☐ No

Second Use of Animals:

* 3. Have any of the animals to be used in your study been used for any other research or teaching protocol (other than breeding) within or outside of this university?
☐ Yes ☐ No

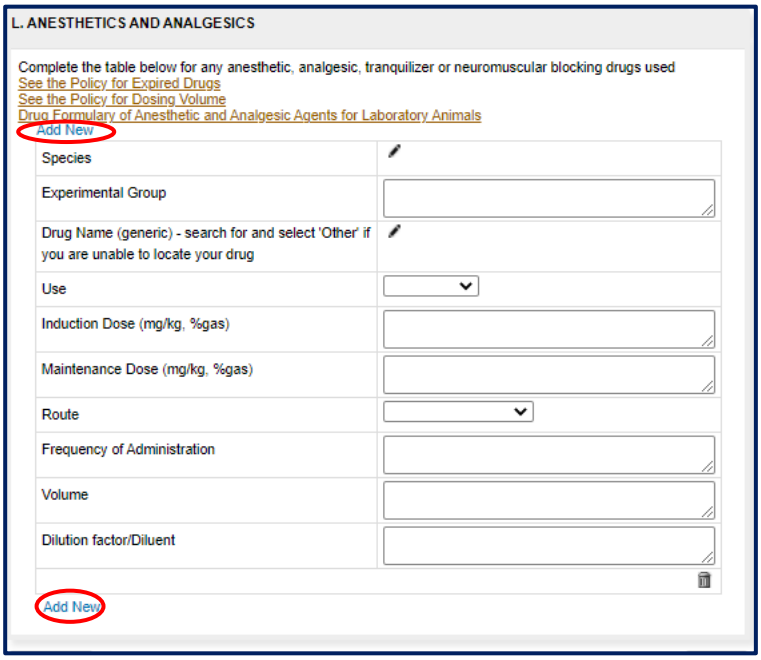
Animal Restraint

* 4. Will any animal be kept awake and restrained for more than 60 minutes?
☐ Yes ☐ No

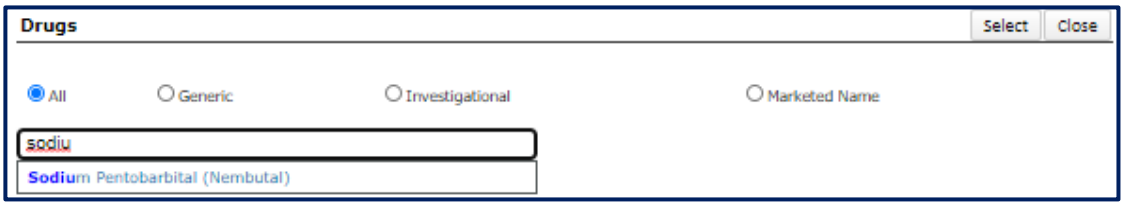
  - ✔ *Remember: Be sure to save as you go!*

Anesthetics and Analgesics Section

- The section will now list your medications and you can enter additional information.



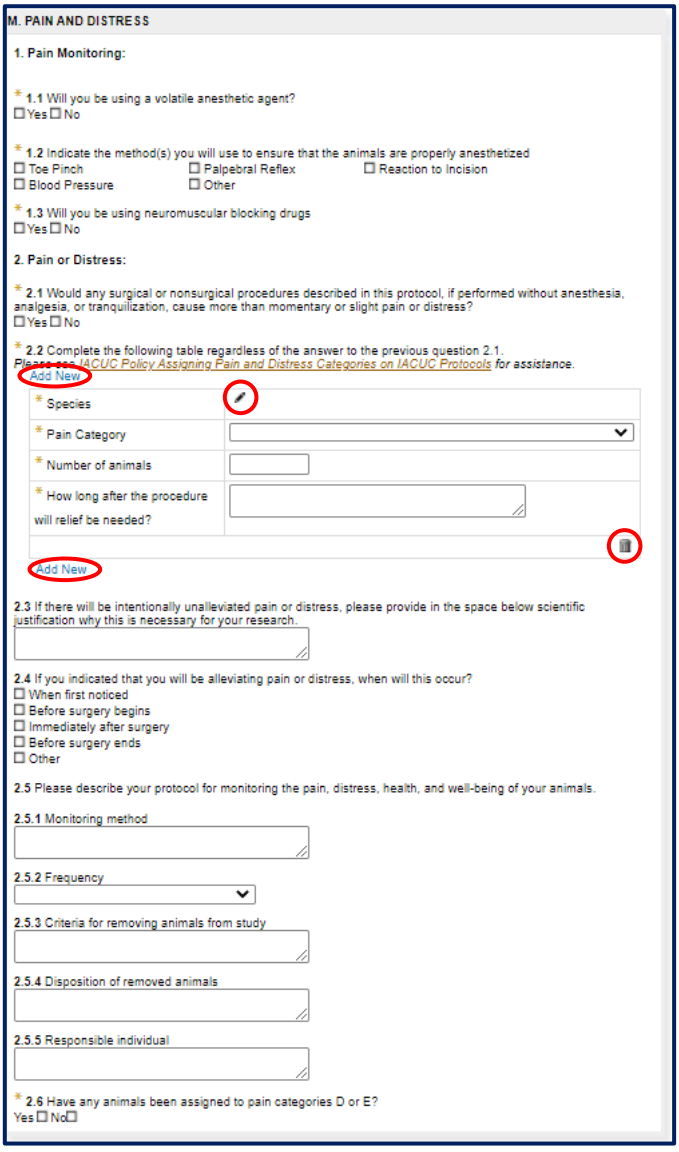
- Remember that the **Add New** button allow you to add a medication and the **trash can** icon will delete the medication. Additionally, the **pencil icon** will also allow you to search for possible choices.
- Click the **pencil icon** next to Drug Name for a pop-up window of Drugs to appear for you to choose from. Begin typing the drug and click on the correct on as it appears.
    - ✔ *Note: You can use the radio buttons above the search bar to filter by **All**, **Generic**, **Investigational**, or **Marketed Name**.*
- When you are done, click on your drug and press **Select** to save your choice.



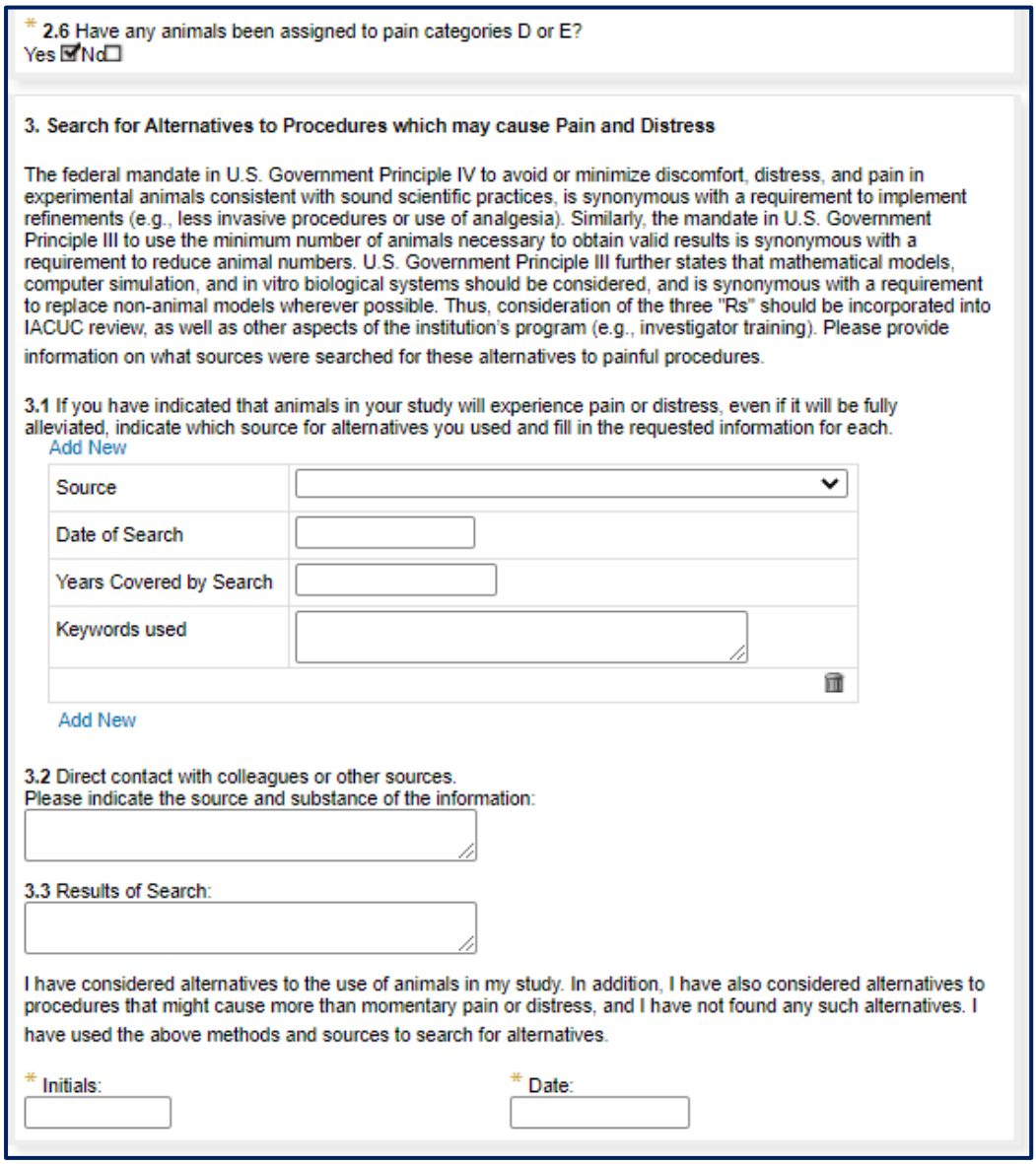
    - ✔ *Remember: Be sure to save as you go!*

Pain & Distress Section

- Continue filling out the checkboxes in the remaining sections. Note that responding **Yes** to some of the questions will result in expanding fields which require additional information. Please use the **Add New** button and **trash can** icon to manage edits.
- Remember that the **Add New** button will typically add a new section for you to fill out within the page or allow you to search for your answer in a list of responses. Additionally, the **pencil icon** will also allow you to search for possible choices.
- ✶*Be aware that pieces of this section are mandatory.*



- Please note if you indicate you are using animals in Category D or E by selecting “Yes” to question 2.6, you will have to complete, initial, and date question #3 to confirm that you have considered alternatives to the use of animals in your study.
- ✶*Be aware that this section is mandatory.*



* **2.6** Have any animals been assigned to pain categories D or E?
Yes ☑ No ☐

3. Search for Alternatives to Procedures which may cause Pain and Distress

The federal mandate in U.S. Government Principle IV to avoid or minimize discomfort, distress, and pain in experimental animals consistent with sound scientific practices, is synonymous with a requirement to implement refinements (e.g., less invasive procedures or use of analgesia). Similarly, the mandate in U.S. Government Principle III to use the minimum number of animals necessary to obtain valid results is synonymous with a requirement to reduce animal numbers. U.S. Government Principle III further states that mathematical models, computer simulation, and in vitro biological systems should be considered, and is synonymous with a requirement to replace non-animal models wherever possible. Thus, consideration of the three "Rs" should be incorporated into IACUC review, as well as other aspects of the institution's program (e.g., investigator training). Please provide information on what sources were searched for these alternatives to painful procedures.

3.1 If you have indicated that animals in your study will experience pain or distress, even if it will be fully alleviated, indicate which source for alternatives you used and fill in the requested information for each.

Add New

Source	
Date of Search	
Years Covered by Search	
Keywords used	

Add New

3.2 Direct contact with colleagues or other sources.
Please indicate the source and substance of the information:

3.3 Results of Search:

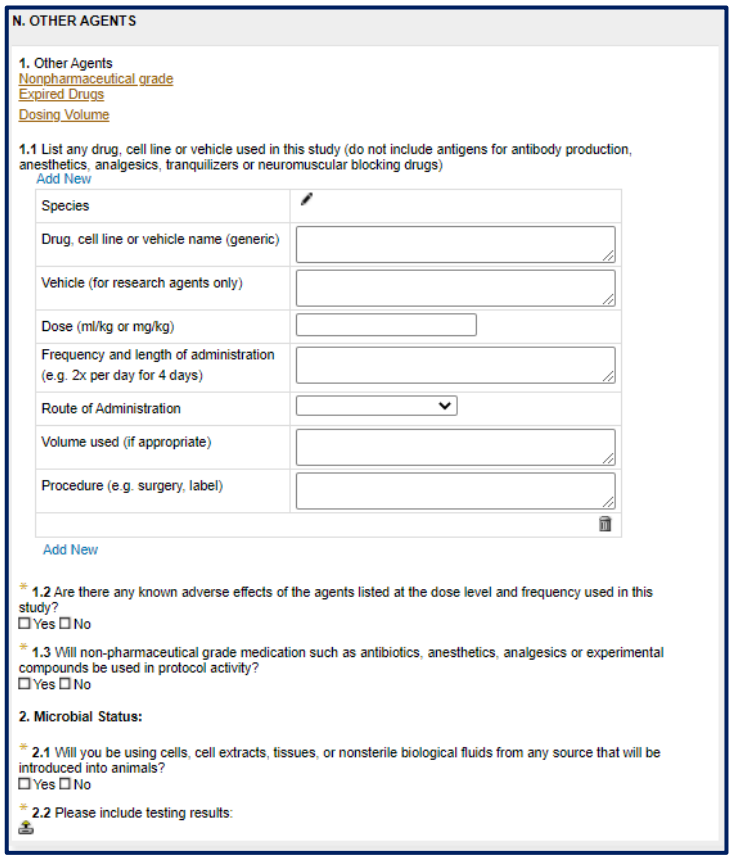
I have considered alternatives to the use of animals in my study. In addition, I have also considered alternatives to procedures that might cause more than momentary pain or distress, and I have not found any such alternatives. I have used the above methods and sources to search for alternatives.

* Initials: * Date:

- ✔ *Remember: Be sure to save as you go!*

Other Agents Section

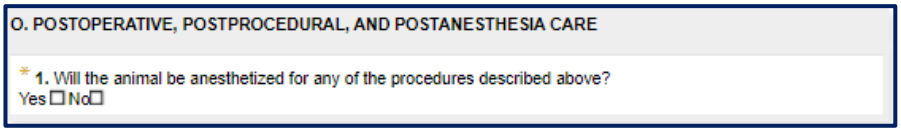
- Continue filling out the checkboxes in the remaining sections. Note that responding **Yes** to some of the questions will result in expanding fields which require additional information. Please use the **Add New** button and **trash can** icon to manage edits.
- Remember that the **Add New** button will typically add a new section for you to fill out within the page or allow you to search for your answer in a list of responses.
- ✶*Be aware that pieces of this section are mandatory.*



  - ✔ *Remember: Be sure to save as you go!*

Postoperative, Postprocedural, and Postanesthesia Care Section

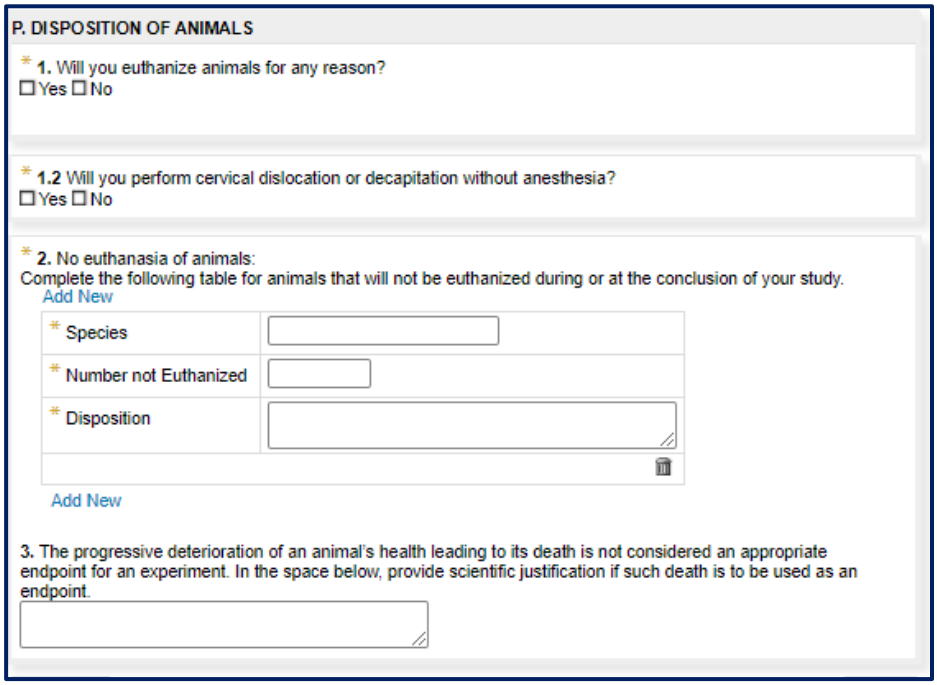
- Continue filling out the checkboxes in the remaining sections. Note that responding **Yes** to the questions will result in expanding fields which require additional information. Additionally, remember that the **pencil icon** will also allow you to search for possible choices.
- ✶*Be aware that this section is mandatory.*



  - ✔ *Remember: Be sure to save as you go!*

Diposition of Animals Section

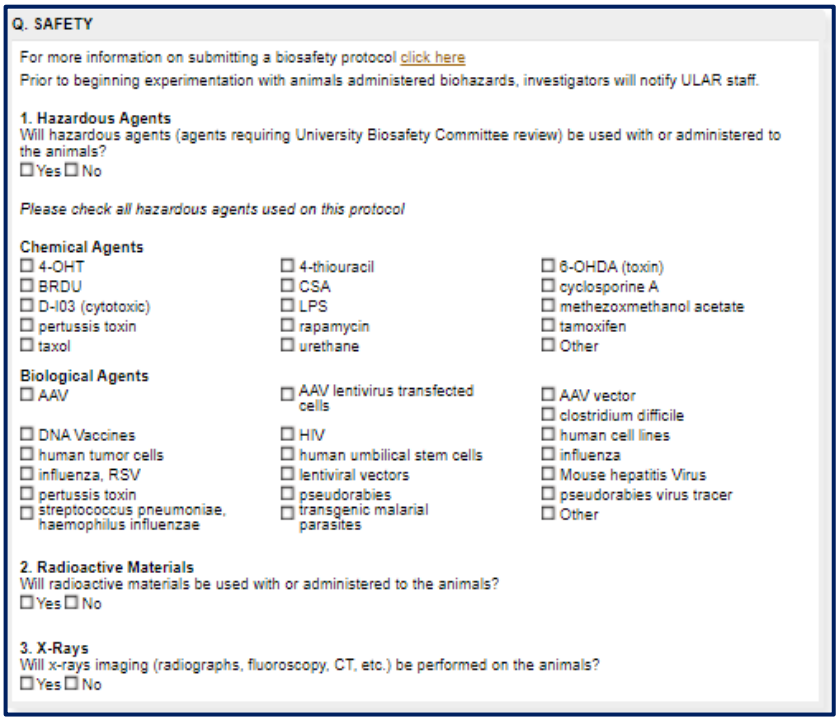
- Continue filling out the checkboxes in the remaining sections. Note that responding **Yes** to some of the questions will result in expanding fields which require additional information. Please use the **Add New** button and **trash can** icon to manage edits.
- ✶*Be aware that pieces of this section are mandatory.*



  - ✔ *Remember: Be sure to save as you go!*

Safety Section

- Continue filling out the checkboxes in the remaining sections. Note that responding **Yes** to the questions will result in expanding fields which require additional information.



Q. SAFETY

For more information on submitting a biosafety protocol click here

Prior to beginning experimentation with animals administered biohazards, investigators will notify ULAR staff.

1. Hazardous Agents
Will hazardous agents (agents requiring University Biosafety Committee review) be used with or administered to the animals?
☐ Yes ☐ No

Please check all hazardous agents used on this protocol

Chemical Agents

☐ 4-OHT	☐ 4-thiouracil	☐ 6-OHDA (toxin)
☐ BRDU	☐ CSA	☐ cyclosporine A
☐ D-I03 (cytotoxic)	☐ LPS	☐ methezoxmethanol acetate
☐ pertussis toxin	☐ rapamycin	☐ tamoxifen
☐ taxol	☐ urethane	☐ Other

Biological Agents

☐ AAV	☐ AAV lentivirus transfected cells	☐ AAV vector
		☐ clostridium difficile
☐ DNA Vaccines	☐ HIV	☐ human cell lines
☐ human tumor cells	☐ human umbilical stem cells	☐ influenza
☐ influenza, RSV	☐ lentiviral vectors	☐ Mouse hepatitis Virus
☐ pertussis toxin	☐ pseudorabies	☐ pseudorabies virus tracer
☐ streptococcus pneumoniae, haemophilus influenzae	☐ transgenic malarial parasites	☐ Other

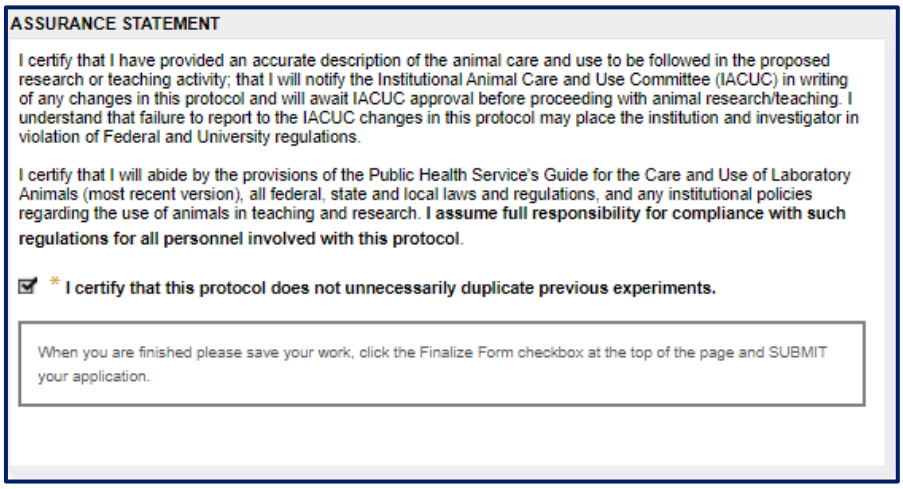
2. Radioactive Materials
Will radioactive materials be used with or administered to the animals?
☐ Yes ☐ No

3. X-Rays
Will x-rays imaging (radiographs, fluoroscopy, CT, etc.) be performed on the animals?
☐ Yes ☐ No

- ✔ *Remember: Be sure to save as you go!*

Assurance Statement

- Lastly, before submitting, be sure to check the assurance statement, certifying that your protocol does not unnecessarily duplicate previous experiments.
- ✶*Be aware that this section is mandatory.*



ASSURANCE STATEMENT

I certify that I have provided an accurate description of the animal care and use to be followed in the proposed research or teaching activity; that I will notify the Institutional Animal Care and Use Committee (IACUC) in writing of any changes in this protocol and will await IACUC approval before proceeding with animal research/teaching. I understand that failure to report to the IACUC changes in this protocol may place the institution and investigator in violation of Federal and University regulations.

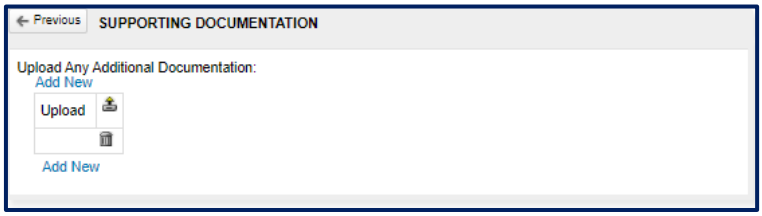
I certify that I will abide by the provisions of the Public Health Service's Guide for the Care and Use of Laboratory Animals (most recent version), all federal, state and local laws and regulations, and any institutional policies regarding the use of animals in teaching and research. **I assume full responsibility for compliance with such regulations for all personnel involved with this protocol.**

☑ * **I certify that this protocol does not unnecessarily duplicate previous experiments.**

When you are finished please save your work, click the Finalize Form checkbox at the top of the page and SUBMIT your application.

Supporting Documentation Section

- Here you can upload any additional supporting documentation. Click the **Add New** button if you need to upload more than one file.



Finalization, Validation, and Submission

- **Important!**: When you are ready to submit, select the **Finalize Form** checkbox to confirm that you have finished completing the record and are ready to finalize.
    - **Important!**: If you do not click **Finalize Form,** your record will not properly finish its submission.

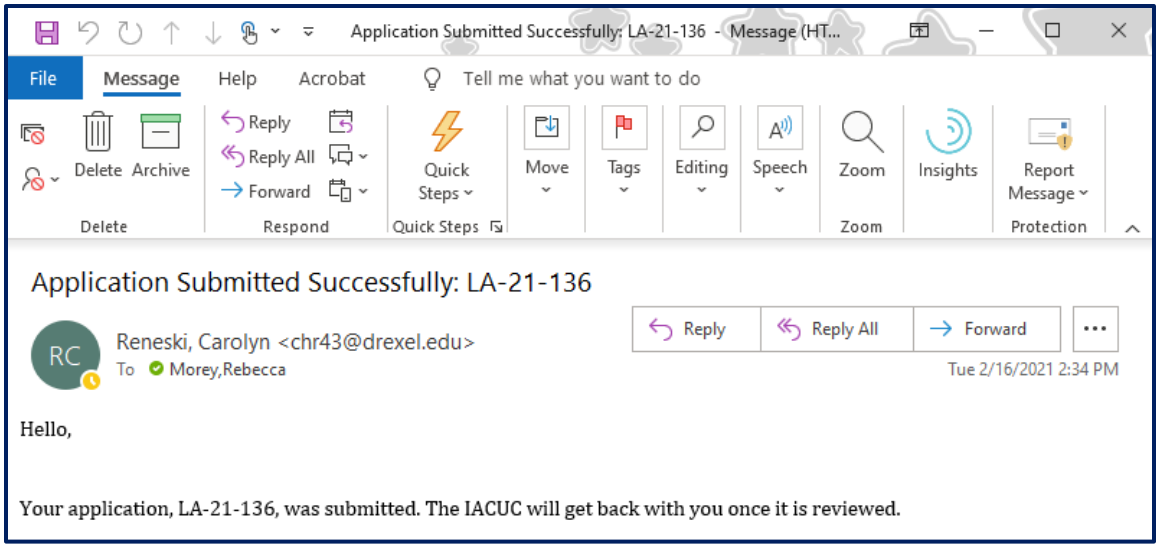
- If you missed any mandatory fields throughout the protocol, a popup box will appear stating **Incomplete mandatory field(s) found** – press OK.
    - ✔ *Note: Pressing the **Validate** button will also display any incomplete mandatory field(s). You will still need to check off the Finalize Form box to submit yoru protocol.*

- A listing of what you have not completed will appear:

- You can click on each line to jump to the corresponding section to make edits. Once you have completed the missing sections, click the **Finalize Form** checkbox again. If there are no errors, you are ready to submit! Press the **Submit** button.

    - **Important!**: Remember, if you do not click **Finalize Form,** your record will not properly finish its submission.

- You will receive a confirmation email similar to the one below which will confirm your submission



Review Process

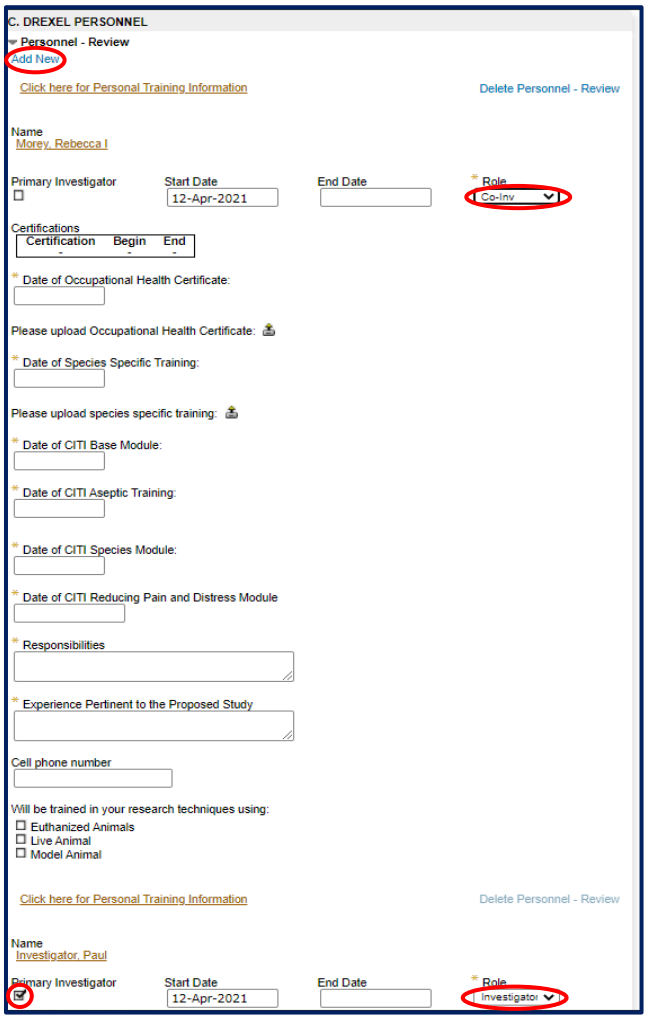
Once you submit your protocol, it then enters the review process which takes approximately one month but may take longer if modifications are necessary. For more information, please visit the IACUC website. The review process is as follows:

- The Principal Investigator must submit the application forms to IACUC at least 15 working days before IACUC Meeting. Please see the Submission Calendar for new protocol submission deadlines.
- The application is reviewed prior to the meeting (pre-reviewed) by two or more reviewers.
- Pre-review comments are provided to the principal investigator at least nine working days before IACUC meeting.
- The Principal Investigator submits revised application along with a letter summarizing responses to pre-reviewers comments at least seven working days before the meeting.
- The IACUC will review the protocol at the subsequent meeting. Based on the deliberations, the IACUC will make one of the following decisions: approve, approve pending conditions, tabled, or withhold approval.

Protocols Created by Personnel Other Than the Principal Investigator

Personnel who are not the PI can create and complete protocols as well as continuations, renewals, and amendments on behalf of the PI. However, **only the Principal Investigator can submit the protocol to the IACUC**. This is to ensure authenticity of the information and to ensure that the Principal Investigator has reviewed the application prior to submission. The process to create a protocol by personnel other than the PI is as follows:

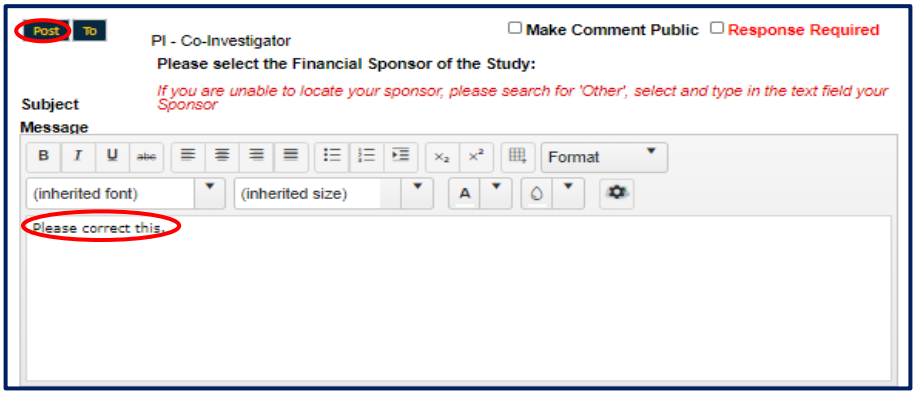
- The personnel representative creating the protocol should create their new initial application following the instructions **at the beginning of this document****.**
- By default, the person creating the application will be listed as the PI. To change this please complete the following steps:
    - Under the section C, **Drexel Personnel**, change your role to **Co-Investigator** in the **Role** dropdown box.
    - Click **Add New** under **Personnel – Review** and search for the PI to add to the protocol. Their information will appear below where your information is listed on the page.
    - Click the checkbox next to **Principal Investigator** under the name of the PI and select the role of **Principal Investigator** under the **Role** dropdown box. The Primary Investigator checkbox next to your name will automatically disappear upon selecting the actual PI checkbox.
    - If the personnel completing the application is not the Principal Investigator, please remember to update the PI information in section A, the Administrative Information section.



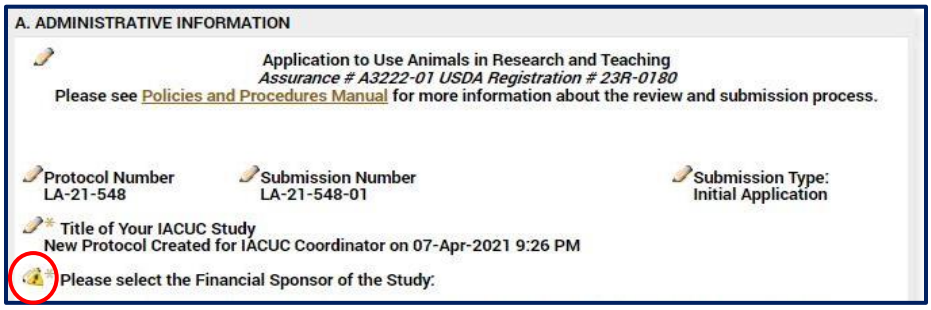
- Once the rest of the protocol form is complete, the representative should select **Finalize Form** and **Submit** at the top of the form.
    - ✔ *Note: Only the person listed as PI can fully submit a protocol to the IACUC office. By clicking submit, the representative is submitting the protocol to the PI, not the IACUC office.*
- Upon submission to the PI, the PI will see the protocol appear in their **Assignments** tab on the homepage. The PI can click the protocol name to review the protocol.

PI Review of the Protocol and Commenting

- The PI should review each section by clicking through the tabs in the left-hand sidebar.
    - ✔ *Note: The PI can make revisions directly by unchecking the* **Finalize Form** *box at the top of the page and making edits directly to the form.*
- The PI can communicate to the representative directly though the protocol form:
    - Click on the **pencil icon** next to any question to open the message box.
        - ✔ *Note: The pencil icon* *is where you can add your comments regarding any section throughout the protocol.*
    - Once you click on the **pencil icon**, please communicate your comment or requested change by writing in the message box that opens. These comments will only be visible to the PI and PI representative.
        - ✔ *Note: By default, this message will be sent to the Co-I.*
    - Click the **Post** button to send your message. You will then see your sent comment and can close the message box.
    - The comments panel is only visible between **PI, Investigator** and **Co-Investigator**. IACUC reviewers **will not** be able to see any comments made using the pencil icons.

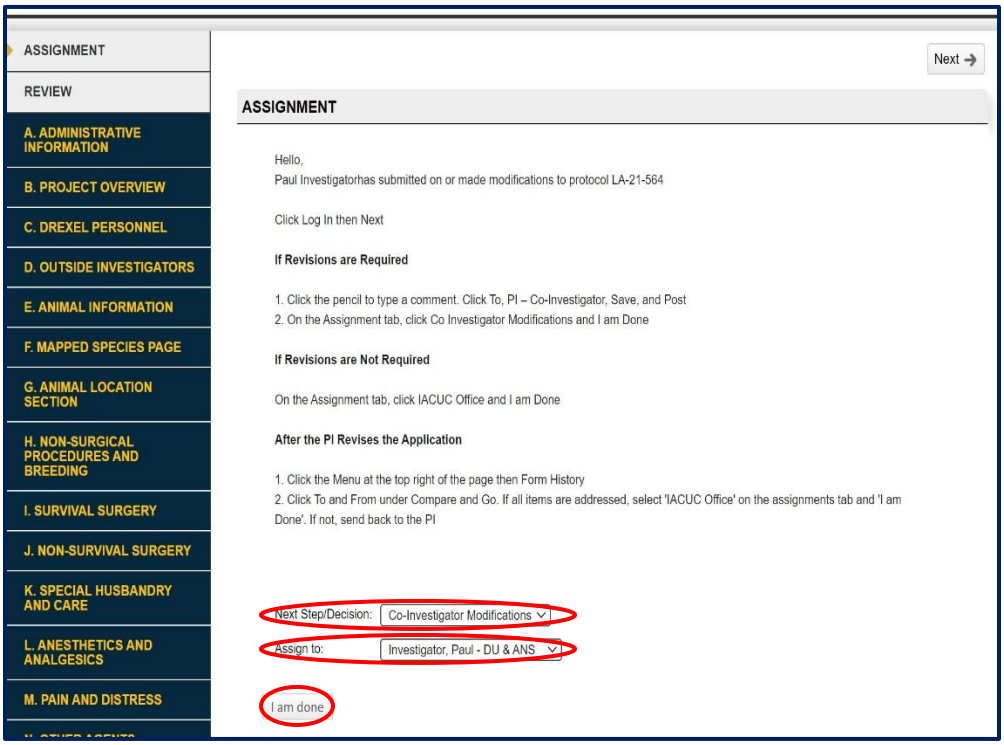


- ✔ *Note: A yellow triangle icon with an exclamation point* *will appear where the pencil icon had been, which reflects that a comment has been made in that spot.*

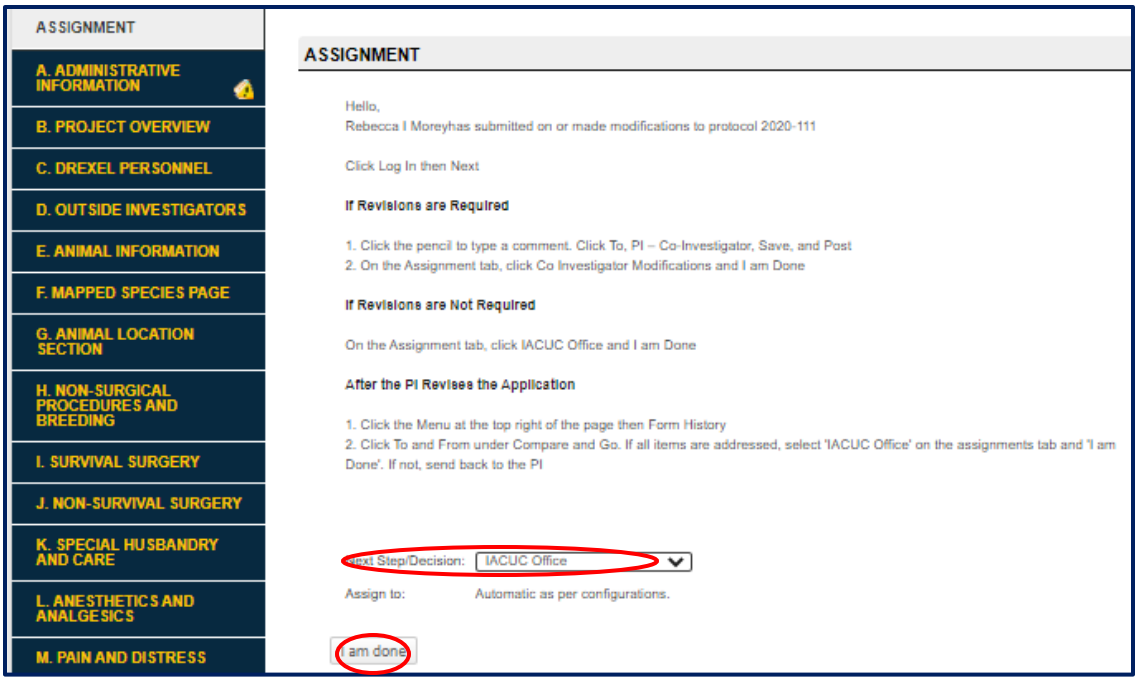


Once the review is complete by the PI

- If revisions are required:
  - Navigate to the **Assignment** tab at the top at the top of the record.
  - Under the **Next Step/Decision** dropdown, please select **Co-Investigator Modifications.**
  - The **Assign to** field will automatically default to the representative who submitted the protocol.
  - Click the **I am done** button.
  - ✔ *Note: The PI can also make revisions directly by unchecking "finalize form" and making edits directly to the form.*

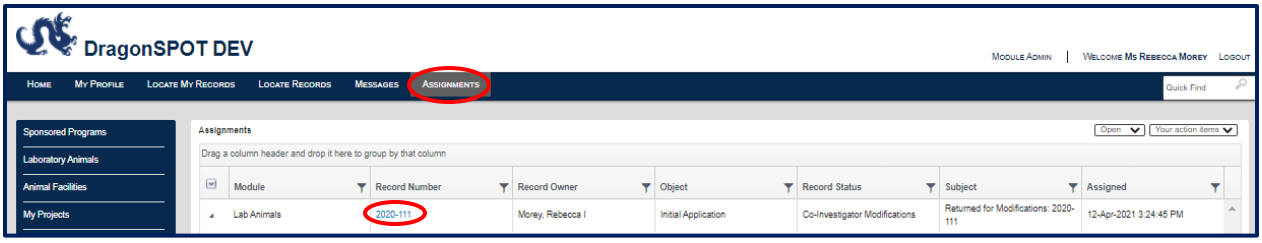


- If revisions aren't required or revisions have been completed, the protocol is ready for submission to the IACUC office:
    - Navigate to the **Assignment** tab at the top at the top of the record.
    - Under the **Next Step/Decision** dropdown, please select **IACUC Office**.
    - Click the **I am done** button.

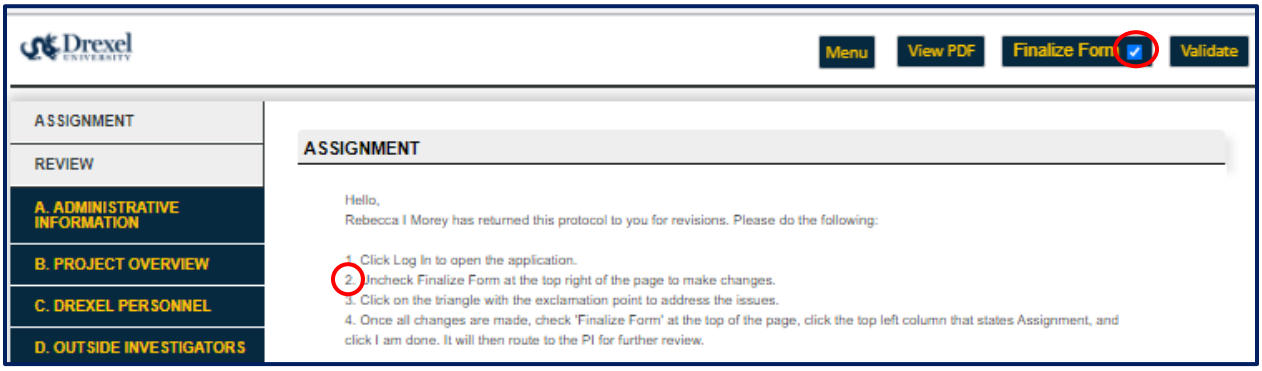


Making Requested Changes to the Protocol (Representative)

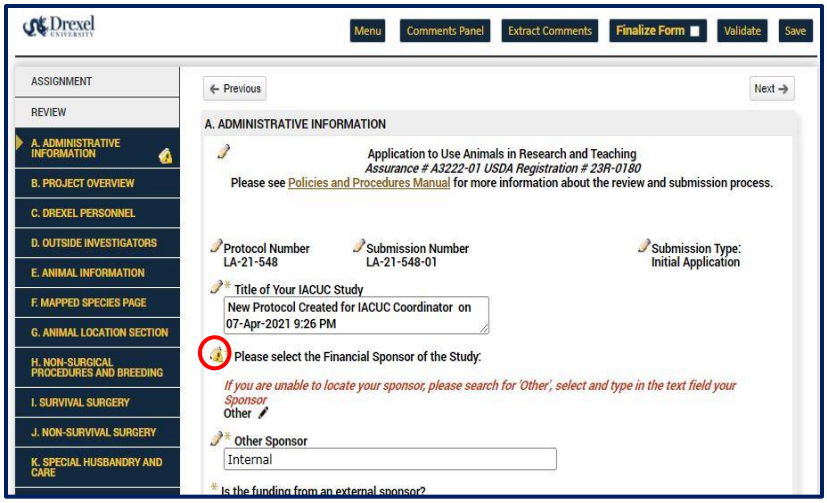
- If the PI requires changes prior to submission to the IACUC office, they may submit the protocol back to the representative for changes (please see the **PI Review and Commenting** section of this manual).
- The representative should click on the **Assignments** tab on their homepage and locate the record and then click on the **Record Number** to open the protocol.



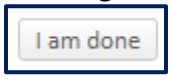
- To edit the protocol, uncheck the **Finalize Form** box at the top of the protocol, as indicated in the instructions under the Assignment tab of the record itself. The protocol is now able to be edited and modifications can be made.



  - If the PI has used the commenting feature:
    - A yellow triangle icon with an exclamation point will appear where the pencil icon had been, which reflects that a comment has been made in that spot.
    - In this example, the yellow triangle icon next to the Study Sponsor, which indicates the PI left a comment there.



    - By clicking on the icon, you will see that the PI noted that the representative should change the project sponsor to NIH. At this point you can make any relevant changes.
- Once all changes are complete, recheck the **Finalize Form** box and then **click I am Done** back under the initial instructions at the top of the **Assignments** section.



  - **Important!**: If you do not recheck **Finalize Form,** your record will not properly finish its submission.

- The protocol will now appear in the PI's assignments. The PI should repeat the steps outlined in PI Review of the Protocol and Commenting section above until the protocol has been submitted by the PI to the IACUC office.
    - ✔ *Note: The entire process will need to be repeated as necessary throughout the review process.*

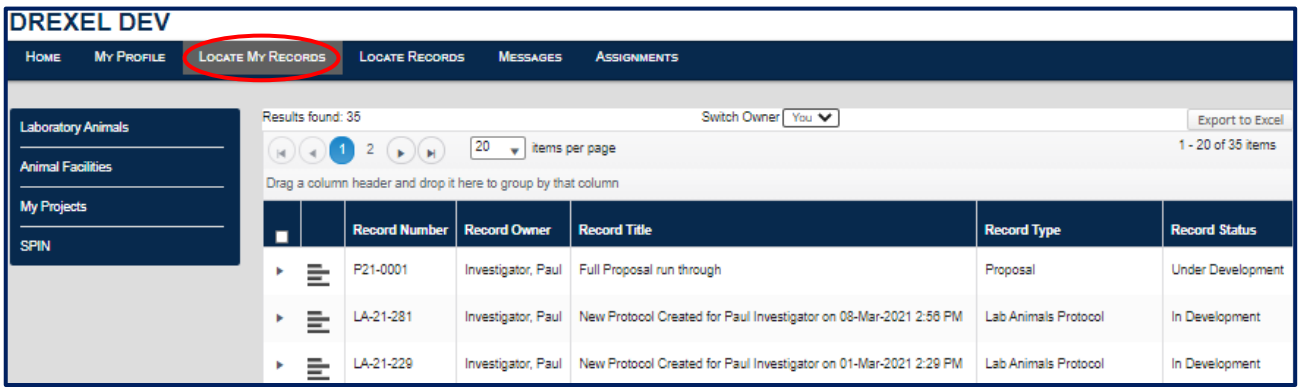
Protocol Review after Submission to the IACUC Office

Once you submit your protocol, it then enters the review process which takes approximately one month but may take longer if modifications are necessary. For more information, please visit the IACUC website. The review process is as follows:

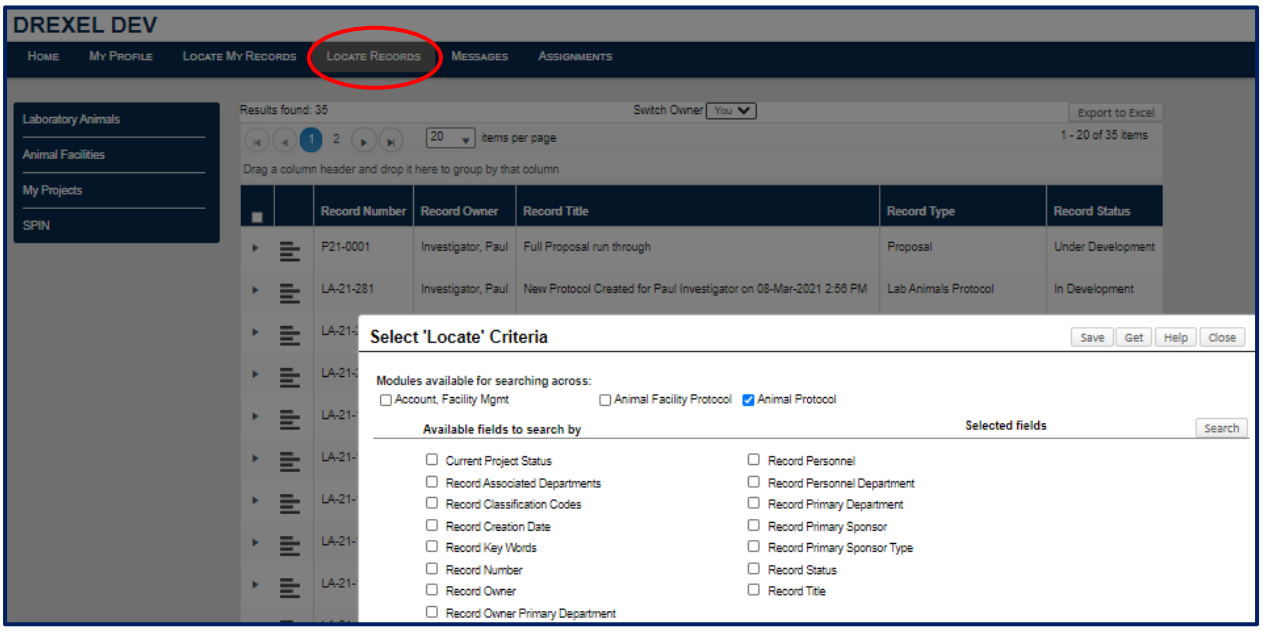
- The Principal Investigator must submit the application forms to IACUC at least 15 working days before IACUC Meeting. Please see the Submission Calendar for new protocol submission deadlines.
- The application is reviewed prior to the meeting (pre-reviewed) by two or more reviewers.
- Pre-review comments are provided to the principal investigator at least nine working days before IACUC meeting.
- The Principal Investigator submits revised application along with a letter summarizing responses to pre-reviewers comments at least seven working days before the meeting.
- The IACUC will review the protocol at the subsequent meeting. Based on the deliberations, the IACUC will make one of the following decisions: approve, approve pending conditions, tabled, or withhold approval.

Checking the Status of Your Protocol

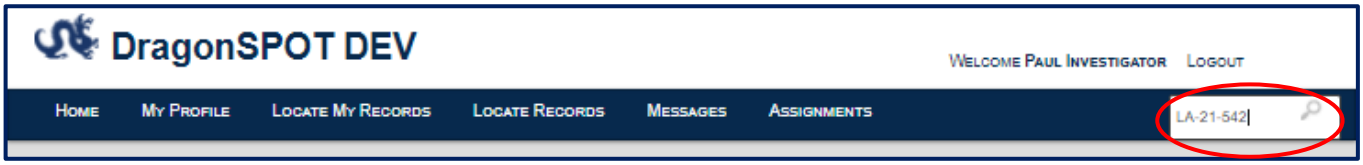
- You can check the status of your protocol submission at any time by clicking the **Locate My Records** tab on your DragonSPOT homepage.



- Alternatively, you can search for different records you have access to by clicking the **Locate Records** tab on your DragonSPOT homepage and using the various fields to navigate.

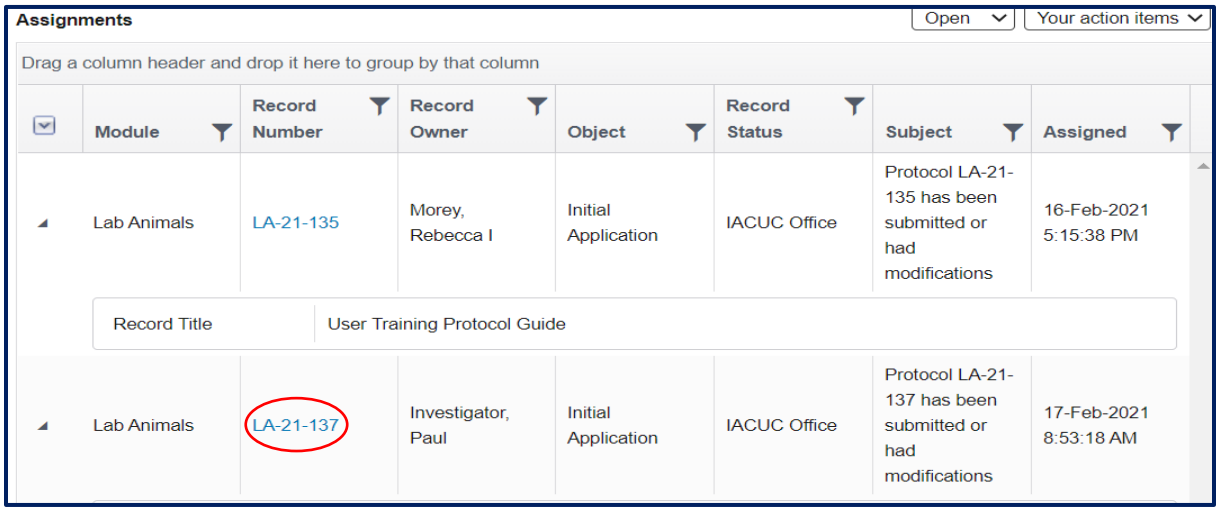


- You can also use the Quick Find box on your homepage to search for a record number directly.

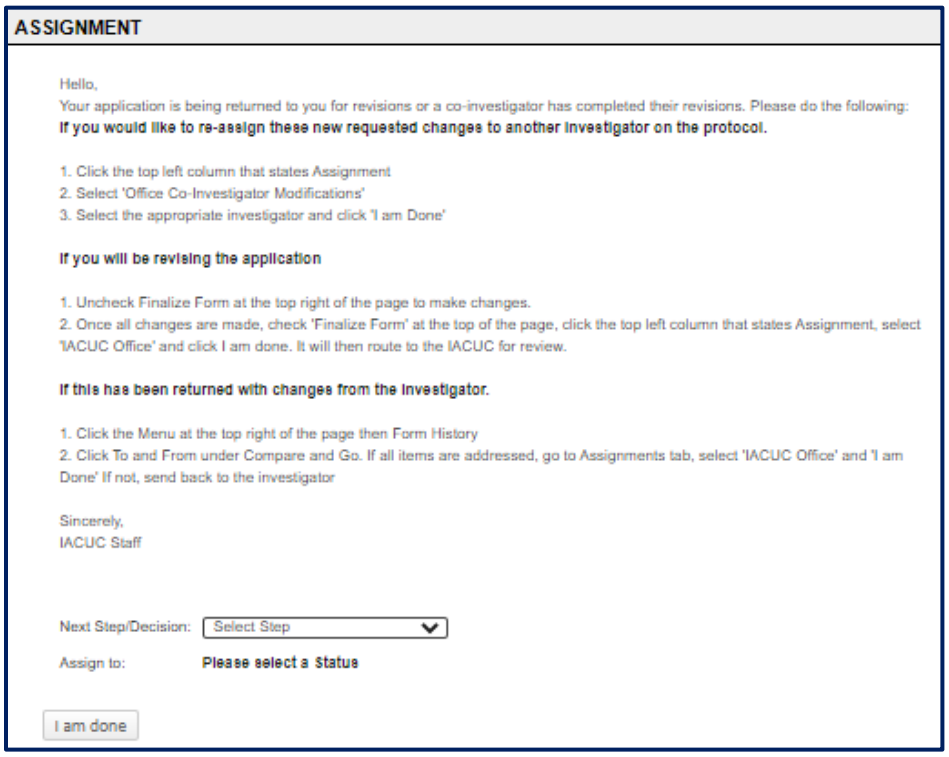


Making Requested Changes to Your Protocol (IACUC Review)

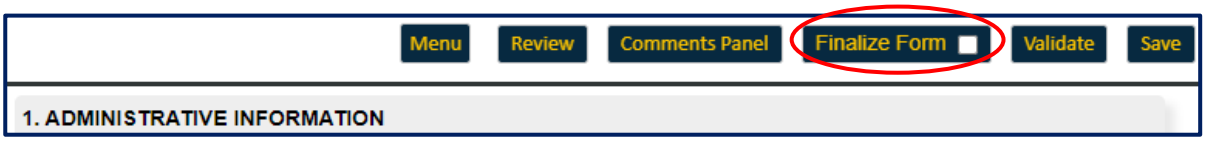
- After the IACUC Office's review, you may receive a list of requested modification to your protocol form. To edit the form in order to make the requested changes:
    - Click on the **Assignments** tab and locate your record and then click on the **Record Number** to open your protocol.



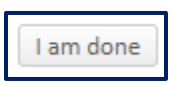
- Once you open your record, you will see an Assignment at the top that explains the process to you.



- Uncheck the **Finalize Form** box, as indicated in the instructions in the Assignment section above, which will now allow you to edit the protocol as requested.
- Make the appropriating changes to your protocol using the **list of modification requests** sent to you from the IACUC coordinator after the IACUC review.
- Please include a cover letter with a point-by point response to the requested modification and upload it into the **supporting documents** section.
- Please remember that the comments panel is only visible between **PI, Investigator** and **Co-Investigator**. IACUC reviewers **will not** be able to see any comments made using the pencil icons.



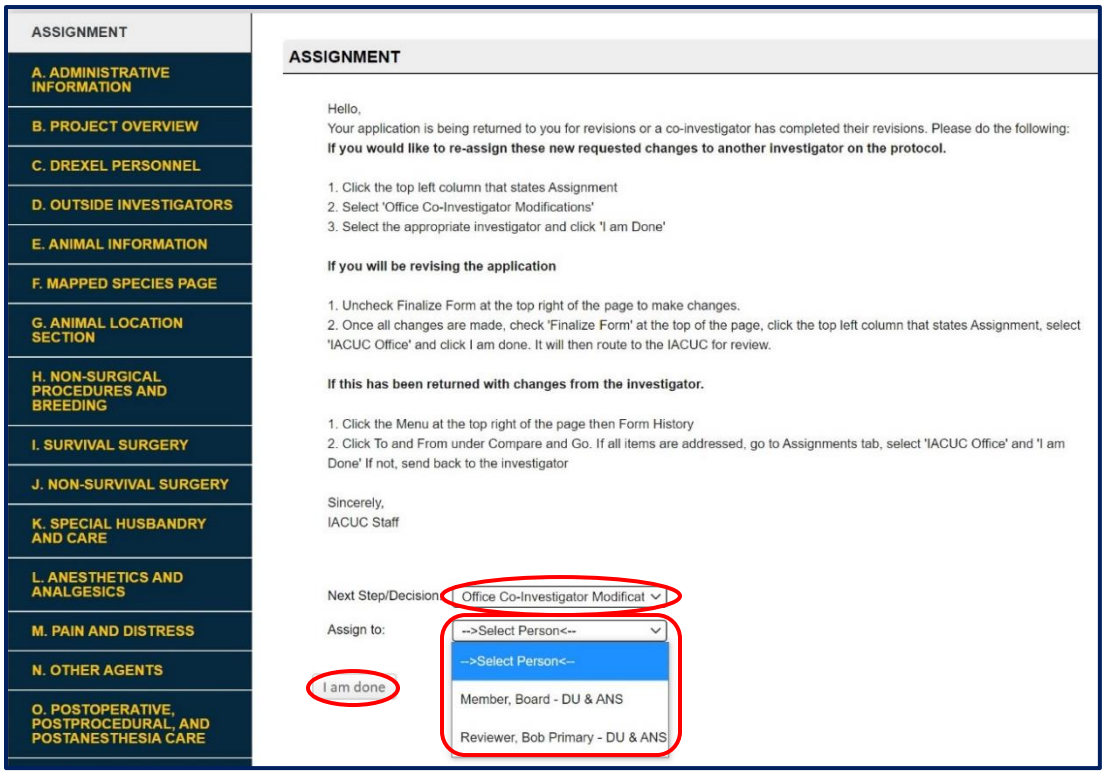
- Lastly, recheck the **Finalize Form** box and then click I am Done back under the initial instructions at the top of the **Assignments** tab.
    - **Important!**: If you do not click **Finalize Form,** your record will not properly finish its submission.



- ✔ *Note: Process will need to be repeated as necessary throughout review process.*

Designating a Representative to Make Modifications to your Protocol

- If a protocol needs modification after an IACUC review, the protocol and list of modifications will always be returned directly to the PI. The PI has the option of assigning a representative to modify the protocol on their behalf. The representative must be listed in the Drexel Personnel tab for them to make modifications.
    - ✔ *Note: If the PI would like to assign personnel that will not be working on the protocol (i.e. only in an administrative role), please contact DragonSPOT-help@drexel.edu to have the person added as a delegate. This person will then have access to complete and edit protocols, but will not need to be listed as personnel.*
- To open a protocol that requires modification, please follow the directions above in the **Making Requested Changes** section.
- Click on the **Assignments** tab and locate your record and then click on the **Record Number** to open your protocol.
- Navigate to the **Assignment** section at the top of your protocol.
    - Under the **Next Step/Decision** dropdown, please select **Office Co Investigator Modifications**.
    - Under the **Assign To** dropdown, please select the representative you wish you assign.
    - Click "I am Done".
        - ✔ *Note: You can choose any person you have listed under the Drexel Personnel tab to make modifications to the protocol*
        - ✔ *Note: You can use the pencil tab to communicate with the representative. Please see the **PI Review of the Protocol and Commenting** section of this manual for instructions.*



- The protocol will now appear in the representative's **Assignments** page.
    - The representative should complete the steps outlined in the **Making Requested Changes to Your Protocol** section of this manual to make the necessary modifications.
    - Once the representative is ready to submit the protocol, navigate to the **Assignments** tab of the protocol. Under the **Next Step/Decision** dropdown, select the PI's name.
    - Click the **I am Done** button.
- Once the protocol has been submitted, the PI should follow the instructions outlined in the **Protocols created by personnel other than the Principal Investigator- PI Review of the Protocol and Commenting** section of this manual.