Create and Submit an IACUC Protocol

Contents

Log in to Endeavor

Welcome to the IACUC in Endeavor system! This document will walk you through the entire process of creating and submitting your IACUC protocol, from creating your Research Team, to submitting the Protocol for review.

To begin, please navigate to Endeavor through AU Access, Endeavor Card or **https://endeavor.auburn.edu** and choose the IACUC tab from the dark blue modules bar. If you do not immediately see the IACUC tab, please click the three dots (···) at the left end of the dark blue modules bar. This will open up a drop-down list, and you can choose IACUC from there.
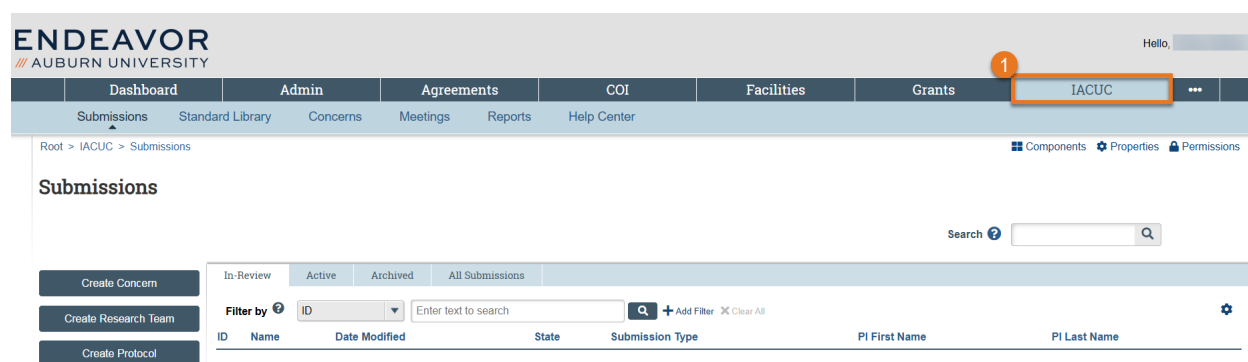
Overview

Now that you are in the IACUC module, we can create a protocol. This process requires several steps: first, we will create the Research Team, and populate Substances and Procedures for the Team to use. Once these components are in place, we will use them to create the Protocol, which will be submitted to the IACUC office for review.

So, the process will look like this:

> 1. **Create Research Team → 2. Create Substances Team will use → 3. Create Procedures for the research → Create Protocol**

Important Note: Once the research team, substances, and procedures are created, they can be reused for future protocols.

Anything you enter into the Endeavor system will become part of the permanent record for the protocol, so that everyone with viewing or editing permissions will be able to access it. This facilitates collaboration and transparency, as well as ensuring that all records are complete.

In addition to this guide, remember that you can always check the help text, by clicking on the blue ❓ icon beside a question for helpful tips, instructions and definitions.

Create a Research Team

Our first step is to create a Research Team. The Research (i.e., Protocol) Team outlines the PI and everyone else who will be working on the protocol. A Research Team may have more than one protocol created under it. Every protocol in Endeavor, whether or not it is considered a research protocol, must be created under a Research Team . Endeavor also saves Procedures, Substances, and if desired, Species that a team works with, to facilitate easy set-up of future projects.

1. Clicking on the IACUC tab opens up the **Submissions** landing page. From here, there are three buttons on the left side of the screen – please choose **Create Research Team.**

Research Team Information Page

2. Question 1**.** asks you to give your **Research Team a name.** All teams must have a unique name in the system. This can be something like "Dr. Jone's Fish Research Team" or "Poultry Disease Research Lab Team". The name should be short, descriptive, and not generic (i.e., Research Team 626). This will make it easier to find the team in the system later.

3. Next, you need to list the **Principal Investigator (PI).** You may either click the button with the three dots (···) under Question 2, or simply start typing the name in the search bar. If you do not find the person you are looking for, first please try to find them using the **wildcard feature (%).** If this still yields no results, please submit at ticket at https://aub.ie/endeavorsupport and the ERA team will be glad to add them to the system for you.

4. Now it is time to add the rest of the **Team Members**. Use the ＋Add button, under Question 3 to find and add all other members of the Research Team .Please note that only Auburn employees are listed in the Endeavor system, so if you have a student who is not also an employee as part of your research team, please submit a ticket at https://aub.ie/endeavorsupport so that they can be added to Endeavor. For each team

member, you will be asked if the person has an animal handling role, and if they are authorized to order animals. Please check the appropriate box. You will also need to specify their role(s) for the protocol, on this screen. Once you have entered a team member's information, click **OK and Add Another** if you have more people to add, or **OK** if you are finished adding people.

5. Finally, Question 4 asks you to choose a **Default Species** for your team. This is optional, but adding a default species can make setting up other portions of the protocol easier, as it will auto-populate for some questions. Don't worry, if you need to change the species for any particular **Procedure,** you can always change it at the individual question level. If your protocol team works with more than one species, it is recommended to leave the **Default Species** line blank.

6. Now all that is left is to click **Finish** at the lower left of the screen. Endeavor will return you to the workspace for the Research Team you just created.

Create a Substance

Now we will create any substances that will be used in the Protocol. Some substances may already be included in the Standard Library and should not be recreated for each protocol*. You can check to see if the substance you intend to use already exists by choosing **Substances** (Point 1) from the light blue control bar that appears beneath the Research Team name. You have the option to search for a particular substance using the search bar (Point 2), or you can view the list immediately below it.

*The Standard Library will grow with more options as the system is used and populated.

When searching for a substance, please use the wildcard feature (%) and short portions of the name you need to find to make sure you're finding all iterations of it in the system. If any of the substances you will need for your protocol are not listed, please follow the instructions below to create them.

1. On the left side of the Research Team workspace screen, there are four blue buttons with available actions. Click the bottom button, **Create Substance** (Point 3) to open the substance creation screen.
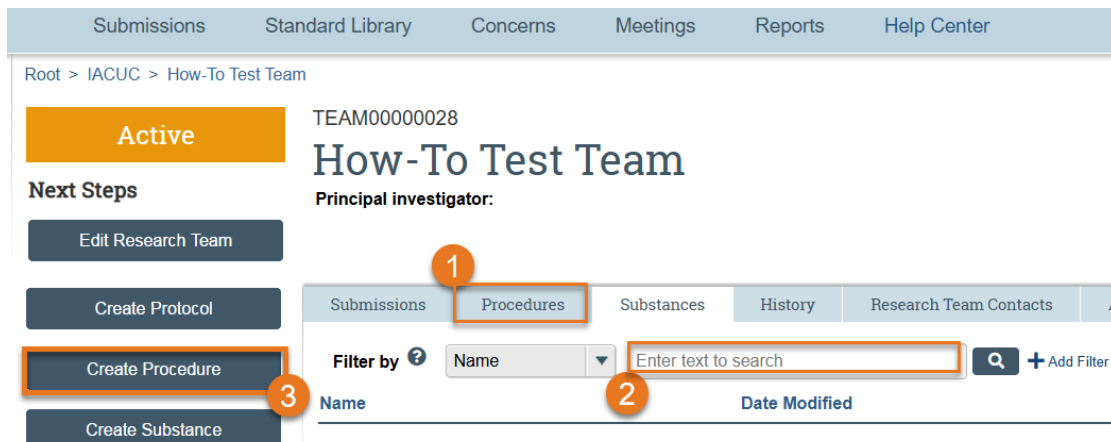
Substance Information Page

2. Enter a name for the substance. This could be the chemical name, the name the manufacturer uses for the substance, or an indicator that includes the concentration.

3. Select what type(s) of substance this is. Some substances may qualify as more than one category; please check all that apply. If you have questions about how to classify a substance, please click on the blue ❓ icon beside the question for helpful definitions.

4. Indicate whether this is a hazardous agent. A hazardous agent is defined as "any substance or compound that has the capability of producing adverse effects on the health and safety of humans or animals."

5. Finally, upload any supporting documents for the substance. These could include Safety Data Sheets, manufacturer's inserts, instructions for administering the substance, or other information and documentation. Anything you upload here will be available to view on the substance's page.

6. Click **Finish** at the bottom right corner of the screen. You will be returned to the Research Team workspace.

Create a Procedure

Now it's time to create the procedures your protocol will use. As with substances, if a procedure is** already listed in the Standard Library and should not be recreated for each individual protocol.

You can check to see if the procedure you intend to use already exists by choosing **Procedures** (Point 1) from the light blue control bar that appears beneath the Research Team name. You have the option to search for a procedure using the search bar (Point 2), or you can view the list immediately below it. When searching for a procedure, you can use the **wildcard feature (%)** to make sure you're finding all iterations of it in the system. If any of the procedures you will need for your protocol are not listed, please follow the instructions below to create them.

1. From the left side of the screen in the Research Team workspace, click the third blue button, **Create Procedure** (Point 3).

Procedure Identification Page

2. Give your procedure a **short name**. This can be descriptive or technical.

3. Select the **procedure type**. Each type selected here brings up a different set of questions regarding the specifics of the procedure, on the next page.

4. Indicate which **species** you will be working with. If you designated a default species for your research team, it will pre-populate here. If you did not designate a default species, or need to change the species for this procedure, you can do so by using the search bar (if there is a pre-populated species, click the X beside it to switch to the search bar) or by clicking the button with three dots (...) which will open the species search screen.

   **The Standard Library will grow with more options as the system is used and populated

   As with other areas of the Endeavor system, we recommend using the wildcard feature (%) to search for the species you need. If the species you are looking for is not available, please submit a ticket at **https://aub.ie/endeavorsupport** and the ERA team can add it for you.

5. Indicate whether the procedure will cause more than momentary pain or distress. If you answered "Yes", you must answer the next two questions by typing a full response in the text boxes. As a guideline, a painful procedure is defined as "any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure is applied, that is, pain in excess of that caused by injections or other minor procedures" (AWR 9 CFR § 1.1) warrants a "Yes" answer to this question.

6. Click **Continue** in the bottom right-hand corner of the page.

7. The following pages are determined by your selection under Question 2 on page 1. All pages have text boxes asking you to describe the procedure. The more thoroughly the questions are answered, the less likely the IACUC will request clarification.

8. Click **Continue** in the bottom right-hand corner of the page.

Procedure Documents Page

9. On this page, you can upload any **supporting documents** for your procedure. These could include pictures or diagrams of the planned procedure, a detailed set of step-by-step instructions, or any other relevant documentation. These documents will be available on the **Documents** tab of the procedure workspace.

10. From the upper left-hand side of the screen, click **Validate.** If there are no errors or omissions, the sidebar will list each page of the procedure creation SmartForm with a green check mark ✅ beside it. If there is something missing, there will instead be a red circle ⛔ with a negative sign in it. You can click on each page marked with a red circle to find and fix any issues.
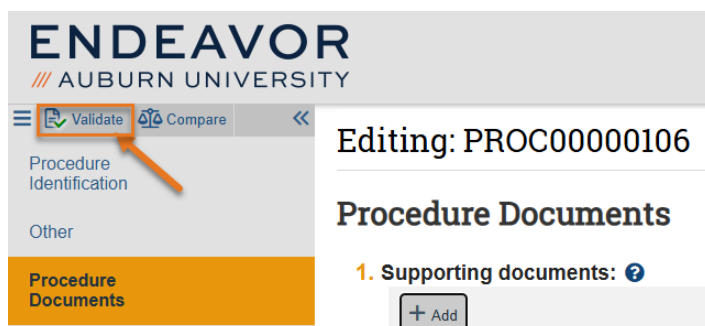

11. Once all issues have been resolved, click **Finish** in the bottom right corner of the screen. You will be returned to the Research Team workspace.

Create a Protocol

Now that you have set up your Research (i.e., Protocol) Team and made sure that all of the substances and procedures you will use are in place, we can get to the exciting part – creating your protocol!

1. From the side bar at the right-hand side of the Research Team workspace, click the blue **Create Protocol** button.
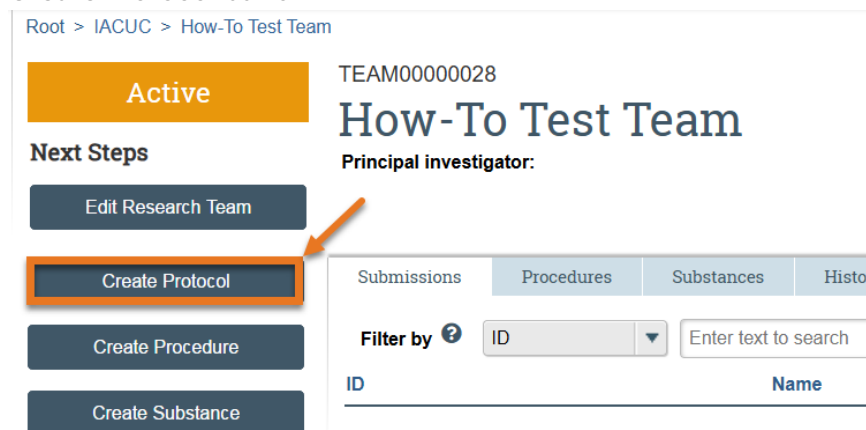
Basic Information and Funding Page

2. Question 1 asks you to select the **Protocol Team**. If you are only on one Research Team, it will appear here, preselected. If you are on multiple teams, you will need to select the team that will be completing this protocol.

3. In the next box, type the full **title of your protocol**. The following question (Question 3) asks you to give your protocol a short title. This should be a unique, easily identifiable title, as it will be used to track the protocol throughout the IACUC system and Endeavor.

4. For Question 4, please type a brief **overview of your project**. Think of this like an abstract and use terms that a lay-person would reasonably be expected to understand.

5. Indicate the **Principal Investigator**. This will have auto-populated based on the PI listed for your Research Team, but you can change it by clicking the box with three dots (···) and searching for another PI, if needed.

6. Indicate the intention of your animal protocol. If you need assistance deciding which **type of protocol** this is, the help text – accessed by clicking the blue ❓ icon beside the question, has some helpful pointers regarding classification.

7. Click **Continue**

8. On this page, you will list all the people involved with the protocol. Members of your **Research Team** will auto-populate, but you can use the button beside any name to remove it, or click the ➕ Add button at the top left of the list to add any additional people. People who are NOT part of the Auburn system should be added under Question 2 **External team member information.** To add external team members, please upload a file regarding them by either dragging and dropping said files into the grey box, or clicking the ➕ Add button and using the **Submit a Document** screen to upload them. When you have added everyone, click **Continue.**

9. Add all **sources of funding** for this protocol. You can click the ➕ Add button at the upper left of the list to search for funding organizations, as well as provide ID numbers from either the sponsor or the Grants office. If you do not see the funding organization you are looking for, first please attempt to locate it using the wildcard feature (%). If the organization still cannot be found, please submit a ticket at https://aub.ie/endeavorsupport so that the ERA team may add the organization.

10. Select all team members who have a **financial interest** in this project. For help in deciding who should be selected here, click the blue ❓ icon to view the help text. Click **Continue.**

Experimental Design Page

11. On this page, you will be asked to describe the **scientific aims**, as well as the **significance and benefits**, of the protocol. Goals and objectives of the protocol should be stated here. What are the goals you hope to achieve with this research? How does the knowledge it will produce fit into and augment the body of information already available? How will this research help? Once you have answered these questions in the two text boxes provided, click

Continue. For Holding protocols, please skip to Item 29, **Animal Housing and Use.** For all other protocols, continue with Item 12, below.

12. Now we're on the Experiments page; this is where you will use all those procedures you created earlier! Under **Define the experiments to be used in this protocol** click the [+ Add] button. This will open up the **Add Experiment** screen.
    a. First, indicate the Display Order. This means the order that the experiment will be used in the protocol.
    b. Name this experiment. As elsewhere, the name should be short, unique, and easily recognizable.
    c. Indicate the species to be used. If your Research Team has a default species, it will auto-populate here, but you can change it by clicking the button with three dots (···) beside the species name. This will bring up the species search screen.
    d. Describe the experiment. Remember, the more detail, the better.
    e. Define humane endpoints for this experiment. What will trigger an animal to be removed from the activity/procedure? Things to consider might include weight, condition, evidence of continued pain, or recovery status.
    f. Justify the purpose of this experiment. Why is this experiment necessary, and how will it help advance your goals?
    g. Select **Procedures.** These are the procedures you created earlier, or which were already included in the Standard Library. You can either begin typing a name in the search box, of click on the three dots (···) at the end of the search box to open up the procedures list and search screen. As always, you can use the wildcard feature (%) to help find a particular procedure.
    h. If there are any variations to how the procedures you've chosen are to be used in this protocol, please explain in this text box.
    i. For **Procedure Timing** please specify which order the procedures will be performed in. Be sure to include how long you will wait between each procedure.
    j. Enter the number of animals to be used for this particular experiment.
    k. Provide justification of unrelieved pain/distress. If no animals will experience unrelieved pain or distress, please state N/A or Not Applicable here.
    l. Identify how many animals fall into which pain category. To see definitions of pain categories, click the blue ❓ icon located beside this Question. The total number of animals listed must match the sum total of animals by pain category.
    m. If you will be making any exceptions to the standard husbandry expectations, please list them here by clicking the [+ Add] button.
    n. Upload any supporting documents. These may include justifications for particular procedures or husbandry exceptions, schedules, monitoring criteria, etc.
    o. Click **OK** if this is the last experiment you need to add, or **OK and Add Another** if you have additional experiments to add to the protocol.

13. Indicate if any single animal will undergo more than one survival surgery. This includes surgeries performed on the animal before they were moved to this protocol. If you answer

"yes", three additional questions about the surgical procedures will appear. All three questions are required and can be answered in the text boxes.

14. Click **Continue.**

15. On this page, you can assign **specific personnel to each procedure**. By default, all personnel are listed for each procedure. To change this, simply click the **Edit** button ✏️ at the end of any line you need to change. You can now check or uncheck the name of individual people for each procedure. Below the personnel assignment list, you can view the training that all team members have on-file. If you need to view a specific team member's training, you can find them in the list using the search bar. When you have assigned personnel to all procedures, click **Continue.**

16. You can use this screen to identify any specific **strain of animal** you are using for the protocol. You can open the **Add Background Strain** screen by clicking the ➕ Add button at the upper left corner of the strains list.

    a. Indicate the strain you will use. You can use the search bar to find it by name, or click the three dots (⋯) at the end of the search bar to open the strains list. If you cannot find the strain you are looking for, first please attempt to find it using the wildcard (%) feature. If this does not yield results, please submit a ticket at https://aub.ie/endeavorsupport

    b. Please indicate whether or not this is a genetically modified strain. Genetically modified strains are animals "that have induced mutations that are human-made alterations in their genetic code. This includes both transgenic and targeted mutations that are created to study the expression, overexpression or underexpression of a specific gene."

    c. Indicate the phenotype, and the percentage of animals that will show that phenotype.

    d. If the phenotype may create welfare issues, explain your plans for addressing and managing them.

    e. Click **OK** if this is the last strain you need to add, or **OK and Add Another** if you have additional strains for this protocol.

Animal Justification Page

17. Click **Continue** to go to the Animal Justification screen. Question 1 asks you to adjust the number of animals to accurately reflect the actual numbers used in the protocol. Adjustments may be needed due to animals being used as the control for more than one experiment, or because of other scenarios. For additional guidance here, see the help text, accessed by clicking the blue ❓ icon to the right of the question. Use the following text box to explain why adjustment was needed.

18. Explain why this protocol requires the use of animals.

19. Justify how many animals the protocol will use.

20. Explain why the species you are using was chosen.

21. Indicate where animals will be sourced from; this information should be as specific as possible and include IACUC protocol numbers, if they are being transferred from another protocol.

22. Explain how you are ensuring that your protocol activities adhere to the 3Rs (Reduce, Refine, Replace). For more information about the 3Rs, see the help text, accessed by clicking the blue ❓ icon to the right of the question.

23. If you are transferring animals from another protocol, affirm that their well-being has not been negatively impacted by previous activities. Include an explanation of how you determined their well-being and suitability for transfer.

24. Click **Continue**

25. Here you will enter all **searches** you have done to ensure that the research you are doing has not already been performed elsewhere and that it is justifiable. Click the ➕ Add button under Question 1 to open the **Add Procedure Search Details** screen. For each procedure that will cause pain or distress in Category D or E:
    a. Find the name in the search box. You can click the three dots (⋯) to open the procedure list, or simply start typing the name in the search bar.
    b. Enter the date you performed the search relevant to the procedure
    c. Check all databases you used to search.
    d. List the keywords you used
    e. Use the text box to give a brief explanation of measures you have taken to find an alternative procedure.
    f. Enter the start and end date of the time period your search covers.
    g. Click **OK** if this is the last procedure you need to add search details for, or **OK and Add Another** if you have additional procedures which will cause pain or distress

26. If you have references other than the databases you've used to find alternatives to painful procedures, list them in the text box in Question 2.

27. In questions 3 and 4, please affirm that your proposed research doesn't unnecessarily duplicate previous studies or activities.

28. Question 5 asks you to explain why continuation is necessary, if this project is a continuation of a previous project. If it is not a continuation, please indicate that or type "Not applicable" in the text box. Click **Continue.**

Animal Housing and Use Page

29. If this is a holding protocol, this page will ask you to indicate which species are being held. **If your protocol does not include holding, you may skip to 30.** Click the ＋ Add button to open the **Add Animal Count** screen. Here, you can select a species, and indicate the total number of animals you will be holding. Click **OK** if you are done adding animals, or **OK and Add Another** if you have additional species to add. Question 2 has a text box where you are asked to indicate how long and for what reasons you will be holding the animals.

30. If your protocol includes breeding, Endeavor will now ask questions about your breeding plans. **If the protocol does not include breeding, you may skip to 31**. Questions on this page are all answered in text boxes and ask you to describe why you will need to breed animals, how you will keep track of the offspring, and what your schedule/method etc. for breeding will be. If your breeding scheme will supply animals to any other protocols, you will also be asked to identify them here. Breeding tables/charts can be added to the protocol under the Supporting Documents tab. Once you've filled out the questions, click **Continue.**

31. **If your protocol involves field research, please skip to 33**. Please identify both vivarium and non-vivarium locations where animals will be housed or used. Locations, such as procedure rooms, where animal activities occur need to be listed in this section. To see how IACUC defines a vivarium or non-vivarium location, you can open the help text by clicking the blue ❓ icon beside the two questions. To add a location, choose the ＋ Add button under the appropriate list.

    a. Search for a location using the search bar, or click the three dots (⋯) at the end of the search bar to open the location list. If, after using the **wildcard function (%)** you are unable to find a particular location, please submit a ticket at https://aub.ie/endeavorsupport so that the ERA team may assist you. When submitting a ticket to have a location added, please ensure that you include the official name of the location you need.

    b. Indicate what species will be used or housed at this location

    c. Indicate how long the animals will be kept

    d. Explain how the location will be used

    e. For NON-VIVARIUM LOCATIONS, explain why the animals must be removed from the vivarium.

    f. Explain how animals will be transported to and from the location.

    g. Click **OK** or **OK and Add Another**, if you need to add additional locations.

32. Explain the enrichment options available to the animals you are using. For a classification of different types of enrichment, click the blue ❓ icon to view the help text. If you will not be providing any enrichment, please use the text box under question 4 to explain why not. Click **Continue**

33. **For Field Research protocols only.** Please list locations your research will take place and describe your planned procedure should any of the animals you are handling be injured during your research. List any required permits for the research; it is the responsibility of the PI to obtain and maintain state/federal permits for field research. Copies of these permits

should be uploaded under **Supporting Documents.** Explain what potential impact(s) your research could have on the wild animal population you are studying. Indicate any way the study could compromise the animals' health. Click **Continue.**

34. Indicate what will happen to the animals when the protocol ends. All animals assigned to the protocol must be included here. If you will be doing something other than one of the listed options with the animals involved, please explain under Question 2. Click **Continue.**

For Holding Protocols Only

35. You will be taken to the **Custom Pages** section, with a page that asks you to select any procedures you will be performing on the animals while they are part of the holding protocol. These could include routine vaccinations, health assessments, etc. You can search for procedures using the search bar, or click the three dots (···) at the end of it to open the list of available procedures.

Supporting Documents Page

36. Use the ➕ Add button to upload all **supporting documents** for the protocol. These could include permits, graphics, flowcharts outlining the order of procedures/research, related clinical trials documents, or anything else that is relevant to the protocol. These documents will be available on the **Documents** tab of the protocol workspace.

37. From the upper left of the screen click **Validate.**

If there are no errors or omissions, the sidebar will list each page of the protocol creation SmartForm with a green check mark ✔ beside it. If there is something missing, there will instead by a red circle with a negative sign in it ⛔. You can click on each page marked with a red circle to find and fix any issues.

38. Once all issues are resolved, you can click **Finish.** You will be returned to the protocol workspace, and the protocol status (in the orange bar on the left side of the screen) will show as **Pre-Submission.**

Congratulations! You've created an entire protocol! Now what? Now your protocol must be submitted to the IACUC for review and approval. The next section of this guide will walk you through that process.

I Finished Creating My Protocol, What Now?

Once you click the **Finish** button, you will be returned to the Protocol workspace, and the protocol will be in the **Pre-Submission** state. At this point, you can still click the blue **Edit Protocol** button to make any changes, or you can use the **Printer Version** button immediately below it if you need a hard copy of your protocol. If you are the PI, there are 12 other options on the lefthand task bar; if you are not the PI, only some of these options will be available to you. Let's look at the steps that must be taken to submit your protocol.

Add Ancillary Reviewers

The **Ancillary Reviews** screen allows you to assign additional individuals or organizations to review your protocol**. At a minimum, your department head or person in the equivalent leadership position should be added here**. Use the ＋ Add button to add anyone you need to list. From the **Add Ancillary Review** screen, you will be given the option to add reviewers as organizations or persons; **please use the Person** search box to assign a reviewer. Use the radial buttons to indicate whether or not a response is required. Click **OK** if you are done adding reviewers, or **OK and Add Another** if you have more reviewers to add. Once you have added all reviewers, you can also add any comments or supporting documents on this screen. Click **OK.**

Manage Related Safety Protocols:

Any safety protocols you have created in the **IBC Module** will appear in the list that opens when you click this button. If one or more of them are for the same project as the IACUC protocol you are creating, you can indicate that here by checking the box beside the relevant safety protocol. You can also add any comments or supporting documents, before clicking **OK** to save.

Submit protocol for Review

Once you hit this (and complete the certification screen it opens up), your protocol will be sent to IACUC for **Pre-Review.**

Other features

Let's look at other options you may want to utilize, before submitting.

Request Pre-Submission Assistance: You can use this option to request help with specific things in your protocol. Clicking the button will bring up a screen that asks you to choose whether you need to ask for assistance from the IACUC team, or the Veterinary team. There is also a textbox where you can explain what help you need. Please be as specific as possible here, and include which pages/questions your questions are referencing. You can also add any documents that you think may help elucidate your query. When you have filled out all of the information, click **OK** to submit it to the appropriate team.

Assign Primary Contact: Use this option to assign or change the person who should be the primary contact for your protocol team. This person will be responsible for helping get the protocol through the review process and will receive all communications from the IACUC. Use the search bar or the three dots (⋯) to find the person you want to assign this role, add any helpful comments, such as reasons for the change in primary contact, upload any documents you would like to include, and click **OK.**

Manage Guest List: The **Guest List** lets you allow people who aren't on the protocol team to view the protocol. Use the search bar or the three dots (⋯) to list anyone you want to give read-only rights. Click **OK** to submit the changes.

Manage Ancillary Reviews:

Add Comment: This button allows you to add comments or supporting documents regarding the protocol, that don't fall under any of the other categories. This is the best and quickest way to

contact the IACUC with any questions regarding your submission. You can also choose who needs an **email notification** about the comment you've added. You can choose any combination of **PI/PI Proxies/Primary Contact**, **Protocol Team Members**, or **IACUC Coordinator** by checking the box beside each group that you would like to notify. Click **OK** to save.

Discard: Clicking this button and confirming on the subsequent screen will discard your entire protocol. Please be sure this is the action you wish to take, before discarding; remember, the deletion is permanent, and your protocol will no longer be available to edit or resubmit.

Copy Submission: If you need to create an additional protocol which is exactly like or highly similar to the current one, you can use this button to do so. You will be asked to give the new protocol a unique name, and to indicate which research team will be working on it. If the research team will not be changing from the current protocol, you can leave the question blank. Click **OK** to proceed with copying. Please note that due to the size of many protocols, it may take some time for the new copy to appear in the research team workspace.

What's Next? Review Process

Now that you have completed and submitted your protocol, it must go through the IACUC review and approval process. There are three main phases to the review process.

Pre-Review when you submit your protocol, it enters the **Pre-Review** state. You can easily see where a protocol is in the creation and approval process by checking the workflow diagram located in the protocol workspace. The current step will be filled in orange.


In the **Pre-Review** phase, an IACUC coordinator will review the protocol for any immediately apparent concerns or issues. They may use the Endeavor system to ask you to clarify or make changes to the protocol. (See below, **Responding to Requests for Clarification**) This process may repeat multiple times. Once any changes have been made, an IACUC coordinator will place the protocol on the schedule for committee review.

**Responding to Requests for Clarification**

1. When clarification is requested, you will receive an email from Endeavor. You can view the clarification request by clicking on the link in the email. You can also go directly to the submission, either in My Inbox or from the IACUC workspace. Under the **History** tab, you can see the clarification request listed. Click on it to read the comments left by the

reviewer.
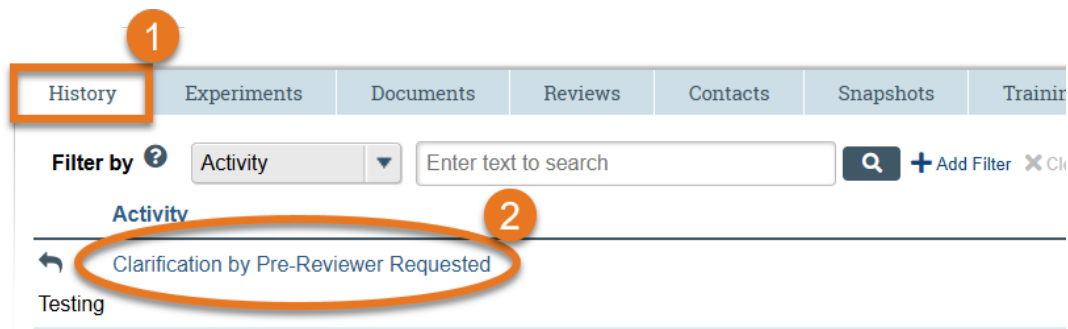
2. Once you open the clarification request screen, you will see a note from the reviewer detailing what needs to be changed or clarified. Reviewers also have the option to add supporting documents, which will appear on this screen.

3. If you were asked to make changes, you can do this by clicking the blue **Edit Protocol** button on the left side of the Protocol workspace, and editing the relevant pages. If the reviewer has asked for more information or clarification, you can use the **Submit Response** option on the left hand menu.
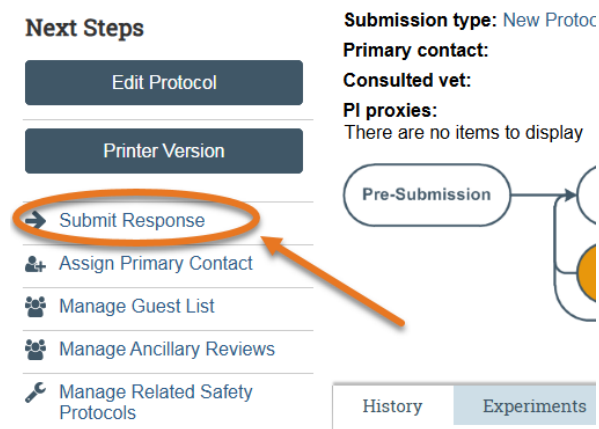
4. Once you open the **Submit Response** screen, you will have the option to both leave comments and upload supporting documents. Please note that anything submitted through this screen does not become part of the actual protocol, but rather will be found in the submission history, under the **History** tab.

5. Click **OK.** The protocol, with your additional clarification, edits, and documentation, will be returned for further review.

IACUC Review when the protocol is scheduled for committee review, the status in the workspace will change to **IACUC Review. The protocol is sent to the IACUC for review.**

Post-Review the committee will make one of three determinations – Approved, Modifications Required (to secure approval), or Withhold Approval. An IACUC coordinator will send you a letter indicating which determination was made, and outlining any next steps. **If modifications are required, the PI will be able to edit the protocol to satisfy the committee's requirements.** The

committee may require the protocol to be submitted for Full Committee Review, or may only require it to be reviewed and approved by one or more designated IACUC members. A PDF copy of your determination letter can be found under the History tab in the protocol workspace.

After the Post-Review process is complete, the submission's status will change to **Review Complete.**

Support

Endeavor Support. The ERA team can assist you with issues you have with the Endeavor system. If you are having trouble finding a person, sponsor, etc. or need assistance navigating Endeavor, the ERA team can help you. They also can help address any concerns with how the system works, add people and sponsors, and otherwise assist with Endeavor itself. You can best reach them by submitting a ticket at **https://aub.ie/endeavorsupport**.

IACUC Support. The IACUC office will continue to handle all aspects of protocol creation and review that it currently does. So, if you need clarification about what is allowed, what kind of documentation is needed, etc., they can assist you. For general questions, please email iacucadmin@auburn.edu. For questions specific to a submission in Endeavor, please use the **Add Comment** feature to contact the IACUC coordinator.