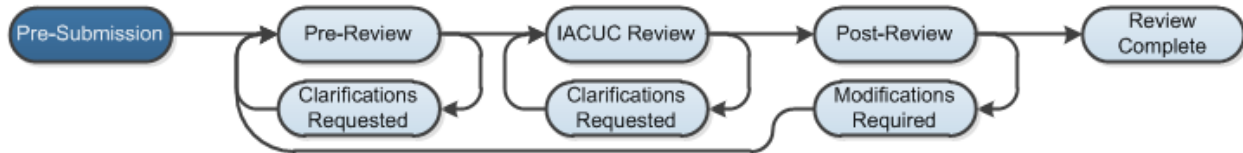




## Create and Submit a Protocol



### WORK INSTRUCTIONS:

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Any user in Click can create a protocol, but must hold the *Principal Investigator (PI)* role, or have been assigned *PI Proxy* status in order to submit the protocol for review.

1. Log into the Click Portal and click on the **IACUC** tab in the top navigation menu.
2. Select a **Research Team** from the **Research Teams** tab. The Research Team selected will become the *Study Team Members* on the protocol you create.
3. Click **Create Protocol**.

**NOTE:** Please create all of your necessary **Substances** first, and then create all **Procedures**, before you create a **Protocol**. The following work instructions are written with the assumption that all **Substances** and **Procedures** for this protocol have already been created within the system.

4. Complete each **SmartForm** page, paying special attention to the fields listed below. Click the **Continue** button to save and move through the pages.

*Required fields are marked with an asterisk (\*).*

#### Basic Information

##### Question 5: What is the intention of the animal protocol?

The **SmartForm** adds and subtracts pages and questions based on your selection here. For instance, if you select **Breeding Only**, a **Breeding** page is added to the **SmartForm**, which you will need to complete. For the remainder of this work instruction, we will focus on the five pages that are present in all variations of the **SmartForm** (the notable exception being a **Holding Protocol**).



## Protocol Team Members

**Question 1: Identify each additional person involved in the design, conduct, or reporting of the research.**

The individuals included on the **Research Team** you initially selected will automatically appear here. If additional personnel need to be added, click the **Add** button and provide their details. If personnel need to be removed, click the **Delete** button to the far right of their name.

**NOTE:** Do not add the *Principal Investigator (PI)* here. The *PI* is a protocol team member by default.

## Experiments

**Question 1: Define the experiments to be used in this protocol.**

Click **Add**. The **Edit Experiment** page opens. Complete the form, paying special attention to:

**Question 2: Species**

The default species is selected based on the **Research Team** selected, but you can change this here.

**Question 5: Select common procedures.**

These procedures are those which all animals in this experiment will undergo. Click **Add** to add common procedures.

**Question 6: Select variable procedures**

These procedures are those which only some of the animals in this experiment will undergo, or they will be applied differently across animals in the experiment. Click **Add** to add variable procedures.

**Question 11: Distribution of the total number of animals by pain category**

Click the **(?) Help Button** to view definitions of each **Pain Category**. You are going to revisit the numbers you list here on the **Animal Justification** page of the protocol.



Click **OK**, or click **OK and Add Another** if you're going to add another **Experiment**.

Alternatively, to add another **Experiment**, you can click **OK**, return to the **Experiments** page of the protocol, and click **Copy**. This copies the selected **Experiment**. You can then click on the **Name** of the copied **Experiment** and make any necessary adjustments on its **Edit Experiment** page, and then click **OK**.

### **Procedure Personnel Assignment**

**Question 1: Select the team members who will be performing each procedure**

For each **Procedure** to be performed, click **Update**, then select the team member who will be performing each **Procedure** and click **OK**.

Team Member training data is provided at the bottom of the **Procedure Personnel Assignment** page for informational purposes.

### **Animal Justification**

**Question 3: Click update to indicate the actual number of animals to be used or produced.**

For each **Pain Category** with more than 0 Animals Identified in **Experiments**, click **Update** and enter the actual number of animals which will undergo procedures in that **Pain Category** under this protocol.

**Question 4: If the number of animals in experiments do not match the actual animal count, explain the discrepancies.**

If the **Actual Animal Count** and **Animals Identified in Experiments** columns do not match in the table in Question 3, you must provide an explanation before proceeding.

For example:

- **Animals Identified in Experiments** may be greater than the **Actual Animal Count** if animals are being bred and weaned but not used experimentally, or if training animals are described on the protocol are not used experimentally.



- **Animals Identified in Experiments** may be less than the **Actual Animal Count** if you are using the same animals in more than one **Experiment**.

## Alternatives

**Question 1: Record all searches for alternatives for each procedure that causes pain or distress.**

Completion of this page is only required if you have animals that will undergo procedures in **Pain Category D** or **E**. Click the **Add** button and complete the page.

5. When the protocol form has been completed, click the **Finish** button in the footer of the last **SmartForm** page to be redirected to the Protocol workspace. At this point, your protocol will be in the **Pre-Submission** state. You may continue to return to the protocol form and make edits until the protocol is submitted by clicking **Edit Protocol**.

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*Your study has not yet been submitted for review.*

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6. Before submitting the protocol to the IACUC for review, assign any additional personnel roles as necessary:
  - **Assign PI Proxy** – assigns a user or users that will have the ability to act on behalf of the PI within the IACUC module concerning this protocol. A *PI Proxy* will have the same access to this study as the *PI* (can edit and submit the protocol, submit amendments, etc.) and will receive the same system-generated email notifications as the *PI*. The *PI Proxy* must be selected from the members of the **Research Team**.
  - **Assign Primary Contact** – assigns a user or users that will receive the same system-generated email notifications regarding this protocol the *PI* receives. The *Primary Contact* will not have the same access to the study as the *PI*.
  - **Manage Guest List** – The **Guest List** includes individuals who you would like to grant read-only access to the study and any of its follow-on submissions (i.e., amendments, annual reviews, etc.). *Guests* are not able to edit the protocol and they do not receive any system-generated emails regarding the study. *Guests* are not considered personnel on the protocol and are not permitted to work with live animals on the study. All **Research Team** members listed as personnel on the protocol will automatically have read-only access to the protocol.



7. In order to submit the protocol to the IACUC for review, the **Principal Investigator** (or **PI Proxy**) must click the **Submit** activity located under **My Current Actions** on the left side of the Protocol workspace. Read the statement, and then click **OK** to submit the study for review.
  - The system will check to ensure that all required questions have been answered on the **SmartForms**. If any items have been missed, you will be prompted to answer them.
  - If the submission is successful, the Protocol workspace will refresh and the study will transition from the **Pre-Submission** state to the **Pre-Review** state. The protocol is now with the IACUC Office for review.

