**Create and Submit a Protocol**



**Work Instructions:**

1. Log into the Click Portal and click on the **IACUC** tab in the top navigation menu.
2. Select your **Research Team** from the **Research Teams** tab.
3. Click **Create Protocol**.

**Note:** Please create **Substances**, and then the **Procedures**, before you create a **Protocol**. These work instructions are written with the assumption that the **Substances** and **Procedures** have already been created within the system.

1. Complete each **SmartForm** page, paying 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 **SmartForms**. For the remainder of this work instruction, we’ll focus on the five pages that are present in all variations of the **SmartForm** (the notable exception being a **Holding Protocol**).

**Protocol Team Members**

1. **Question 1: Identify each additional person involved in the… research**.

Add each person who will edit the protocol or perform any of the research procedures. Do not add the ***Principal Investigator (PI)*** here.

**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:
1. **Question 2: Species**The species carries over from the research team workspace, but you can change this here.
2. **Question 5: Select common procedures.**These procedures apply to all animals in the experiment.
3. **Question 6: Select variable procedures**These procedures apply to some of the animals or differently across animals in the experiment.
4. **Question 11: Distribution of the total number of animals by pain category**
Click the **(?) Help Button** to see a list of the pain categories. You are going to revisit the numbers you list here on the **Animal Justification** page.
5. Click **OK**, or click **OK and Add Another** if you’re going to add another experiment.

Alternatively, you can click **OK**, return to the **Experiments** page, then click **Copy**. This copies the experiment; make any necessary adjustments to the newly copied experiment. After completing the experiments, click **Continue**.

**Procedure Personnel Assignment**

* **Question 1: Select the team members who will be performing each procedure**Click **Update**, then select the team member for each procedure. After clicking **OK**, complete the rest of the page, then click **Continue**.

**Animal Justification**

* **Question 3: Click update to indicate the actual number of animals to be used or produced**
Click **Update**, then enter the actual number of animals for that pain category.
* **Question 4: If the number of animals in experiments do not match the actual animal count, explain the discrepancies**If the **Actual Number** column and the **Animals Identified in Experiments** columns do not match in the table in Question 3, you must provide an explanation before proceeding.

**Alternatives**

* **Question 1: Record all searches for alternatives for each procedure that causes pain or distress**
This page is required if you have animals in the ***D*** or ***E*** pain categories. Click the **Add** button and complete the page.
1. When all of the required fields have been completed, click the **Finish** button in the footer of the last **SmartForm** page to be redirected to the workspace.

Your study has not yet been submitted for review.

1. Assign any additional staff to the study, as necessary:
* **Assign PI Proxy** – assigns a user that will have the ability to act on behalf of the PI within the IACUC module. This individual will have the same access to the study as the PI, and will receive the same system-generated email notifications. The PI Proxy must be selected from the individuals that were added to the study team.
* **Assign Primary Contact** – assigns a user that will receive the same system-generated email notifications as the PI. The primary contact will not have the same access to the study as the PI.
* **Manage Guest List** – manages individuals on the Guest List; guests can read the study and any follow-on submissions, but cannot edit them. They will also not receive the same system-generated emails that a PI does.
1. The ***Principal Investigator*** (or ***PI Proxy***) must click the **Submit** activity located under **My Current Actions** on the left side of the workspace. Read the statement, and then click **OK** to submit the study for review.
* The system will check the study 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 page will refresh and the study will transition from the **Pre-Submission** state to the **Pre-Review** state.

