# Click Portal

**IACUC Module** 

Protocol Submission Guide

July 2018



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## IACUC Module - Study Submission Guide

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## What is the Click Portal?

The SUNY Pre-Award and Compliance System (PACS) is a multi-year collaboration created to support investigators and students along with compliance and research administrative staff by giving them a new administrative tool - the Click Portal.

Click will automate the submission, review, and approval processes while managing all major administrative aspects of the research and compliance lifecycle - from proposal development and submission through compliance checks, negotiations, award setup and award management, to eventual project closeout.

This system integrates the following aspects of research administration into a single system:

- Institutional Review Board (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Grants Management
- Conflicts of Interest (COI)
- Research Agreements
- Safety

Under the stewardship of UB's Office of the Vice President for Research and Economic Development, this platform will allow the University at Buffalo to achieve a new level of uniformity and efficiency, while also producing valuable data analytics that can guide future decisions.

UB is helping lead this SUNY-wide effort and was the first campus to implement the Click Portal, beginning with the IRB module in Fall 2015.

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## **IACUC Module Description**

The Institutional Animal Care and Use Committee (IACUC) must review and approve all animal use protocols in order to maintain the University's high research standards. It does so by following federal and state regulations, which reflect the professional standards of ethical conduct governing the use of animal subjects in research.

The Click IACUC module provides a streamlined way for researchers to create and submit protocols for studies involving animal subjects. It provides support for initial submissions, amendments, annual reviews, triennial renewals, and semi-annual inspections. The module also allows for the reporting of concerns involving the care and use of animals in scientific and educational activities at the institution.

## **Getting a Click Account**

Accounts have been created for all faculty and staff at the University at Buffalo in preparation for campus-wide implementation of the Click Portal. Users will log into the system using their **UBIT Name** and **Password**.

If your login attempt is unsuccessful, or you are a student participating on a research team, please follow the instructions below to request an account:

- 1. Navigate to the <u>UB Research Services: Training and Development webpage</u> at <a href="https://www.buffalo.edu/research/research-services/training.html">https://www.buffalo.edu/research/research-services/training.html</a>. Locate the Click Portal Login area on the right of the page, and click on the registration link.
- 2. Complete the **Request Account** form at the bottom of the page, and then click the **Register** button. Be sure to select the *University at Buffalo* as your **Campus Affiliation**.



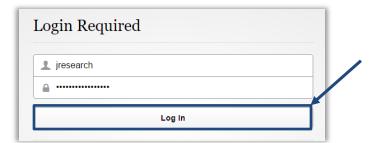
You will receive an email notification when your account has been activated.

## Logging into the Click Portal

- 1. Navigate to the <u>UB Research and Economic Development</u> page at http://www.buffalo.edu/research
- 2. Locate the Quick Links section in the center of the page.
- 3. Click on the Click Portal Login link.



4. Enter your **UBIT Name** and **Password** in the fields, and then click the **Log In** button.



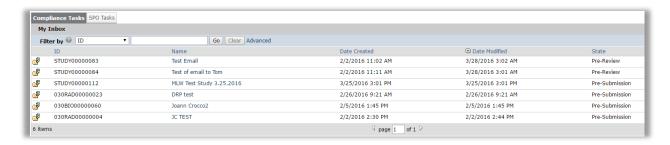
## **Basic Navigation**

## My Inbox

Each time you log into the **Click Portal**, you will be taken to your **Inbox**. This area of the portal contains a list of all submissions that currently require you to take an action.

My Inbox is divided into two tabbed pages:

- Compliance Tasks At present, this tab contains a list of your IRB, IACUC, and Safety submissions that currently require you to take an action.
- SPO Tasks At present, this tab contains a list of your Agreements and COI Disclosures that currently require you to take an action.

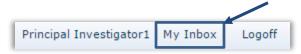


The listings within My Inbox can be sorted by using the Filter by option. This option will allow you to search by ID number, Name, Date Created, Date Modified, or State.

To determine what type of action you need to take on a submission, look at the **State** column; see the chart below for an explanation of the action required for each **State**.

IACUC Submissions in My Inbox		
State	Explanation	
Pre- Submission	The submission has been created but has <u>not yet been submitted</u> to the IACUC for review. Complete the submission as necessary and submit it to the IACUC to start the review process.	
Clarification Requested (Pre-Review)	The submission has been administratively pre-reviewed by the IACUC Office and comments must be addressed before the study can progress to Committee Review. Revise the submission form as needed, and resubmit it to the IACUC.	
Modifications Required	The submission has been reviewed by the IACUC and modifications must be made before the IACUC can approve the submission. Revise the submission form as needed and resubmit to the IACUC.	
IACUC Submissions that will NOT be in My Inbox		
<ul> <li>Submissions that are currently under review by the IACUC</li> <li>Approved submissions</li> <li>Closed submissions</li> </ul>		

- To open a submission, click on its **Name**. When you open a submission, you will be brought to its **Workspace**.
- You can return to **My Inbox** at any time by clicking the **My Inbox** link in the **Header** at the top right corner of the screen.

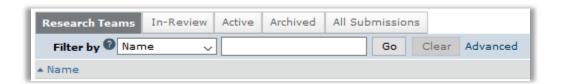


## **IACUC Submissions**

You may navigate directly to the IACUC module by clicking the IACUC tab in the navigation menu at the top of the screen.



The IACUC Submissions area is divided into five tabs:



- **Research Teams** This tab lists all of the **Research Team(s)** that you are currently a member of.
- In-Review This tab lists all of your IACUC submissions currently under IACUC review. This includes submissions in the Pre-Review, Designated Review, Committee Review, and Post-Review states.
- Active This tab lists all your currently approved IACUC submissions.
- **Archived** This tab lists all your archived/closed IACUC submissions. This includes submissions in the **Discarded** and **Closed** states.
- All Submissions This tab shows all your submissions, regardless of state.

On the left side of the screen, you will see links to **Activities** you can perform, as well as **Shortcuts** to other areas of the module.

#### **Activities:**

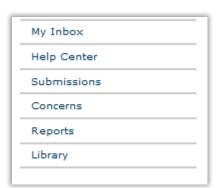
- Create Concern Create and submit an animal welfare Concern to the IACUC.
- Create Research Team Create a Research Team; a group of individuals who will be listed as team members on an animal protocol.



• **Create Protocol** - Generate a new animal research protocol, which can be completed and submitted to the IACUC for review.

#### **Shortcuts:**

- My Inbox Return to your My Inbox page.
- **Help Center** Manuals and guides to assist you in working in the IACUC module.
- **Submissions** See all **Research Teams** that you are a member of, and all of your IACUC submissions.
- Concerns See a list of all animal welfare Concerns you have submitted to the IACUC and a list of any deficiencies related to your projects.



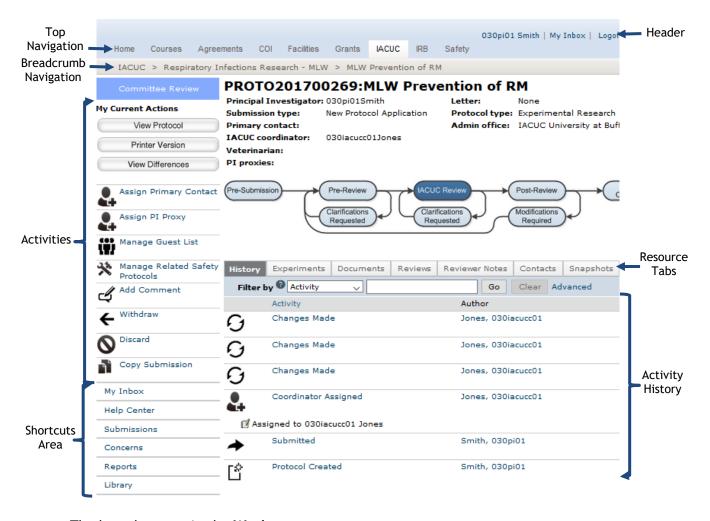
- Reports Generate Reports on any submissions that you have made to the IACUC.
- **Library** View IACUC policies, Laboratory Animal Facilities (LAF) SOP's, and download copies of template documents that may need to be uploaded to your protocol submission.

## The Workspace

Click on the **Name** of a protocol to open the study. Once you open a study, you will be taken to the **Study Workspace**.

## The **Study Workspace** allows you to:

- View the study contents and details, including all actions that have been performed on it
- Perform actions on the study



## The key elements in the **Workspace** are:

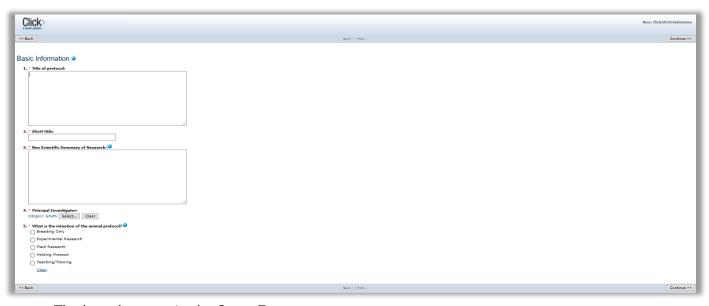
- Header Links to your profile and My Inbox, and lets you log off
- Top navigation menu Links to the different modules within the Click Portal
- **Breadcrumb navigation menu** Lists the hierarchy of pages and enables you to move quickly to a previous location
- Activities Actions that can be taken based on a submission's current State and your assigned role within the module
- Resource tabs Collected information regarding the submission
- **History** Actions taken previously on this submission
- Shortcuts Quick links to other frequently used areas of the module

## **SmartForms**

To open a protocol from its **Study Workspace**, click on the **Edit Protocol** button.

**NOTE:** This button may also be labeled **View Protocol**, dependent upon the **State** of the submission you are opening.

Protocols are comprised of several pages known as **SmartForms**. They are referred to as 'smart' because the portal will branch to add additional forms to your protocol based on your responses to questions on the pages.



The key elements in the **SmartForms** are:

- The **Continue** and **Back** buttons will move you forward or back one page in the protocol; the **Continue** button also saves your work.
- The navigation bar at the top and bottom of each page will allow you to perform the following actions:
  - Save Saves your work for the current page
  - o Exit Exits the protocol and returns you to the Workspace
  - Hide/Show Errors Performs a check on every page within the protocol to ensure that all required fields have been completed
  - Jump to: Allows you to see and navigate to all pages within the protocol
- Any item on a SmartForm that has a red asterisk (\*) next to it is a required field.
- Clicking on the blue icons ( ) next to items will open a window that will offer assistance with completing the field.

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## Filtering and Sorting Data

Many pages contain tables you can filter and sort to help you find the data you want.

- Filtering reduces the list to only the data that meets the criteria. The advanced filter lets you combine multiple filter criteria together.
- Sorting displays the data in ascending or descending order by a particular column.

## Filtering Data

1. Select the column to **Filter by** from the drop-down menu. The menu lists only the columns you can **Filter by**.



NOTE: To combine multiple filter criteria, such as *ID number*, *Name*, and *Date Created*, use the <u>Advanced Filters</u>.

2. In the next box, type the beginning characters for the items you want to find. If you do not know the beginning characters, type a % symbol as a wildcard before the characters.

#### Examples:

- 71 shows all items beginning with 71
- %71 shows all items containing 71 in any position

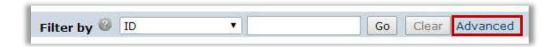




3. Click **Go** to apply the filter. The table shows only those rows that are an exact match. If you do not see the expected items in the list, click **Clear** in the **Filter by** area to remove the filter.

## **Using Advanced Filters**

1. In the **Filter by** area, click **Advanced**.



- 2. Enter filter criteria as explained in the previous section. To add criteria, click **Add Another Row**.
- 3. Click **Go** to apply the filter. The table shows only those rows that match all the filter criteria.

## **Sorting Data**

Click the column header you want to sort by. Click it a second time to reverse the sort order. The arrow indicates the column by which the data is sorted and the sort order, either ascending (up arrow) or descending (down arrow).



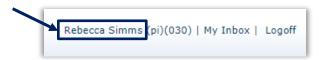
**NOTE:** If the column header is not a link, you cannot sort by that column.

## Before You Create a Protocol

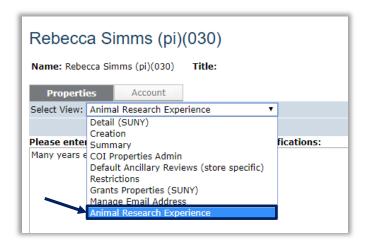
## **Update Your Animal Research Experience**

Users can save their animal research qualifications and experiences within their Click user account.

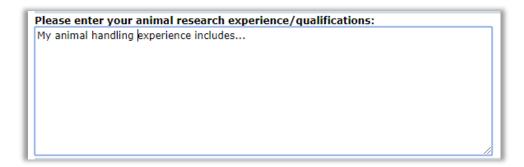
- 1. Log into the Click Portal.
- 2. Click on your name in the upper-right corner of the window.



3. From the **Select View** dropdown menu, select **Animal Research Experience**.

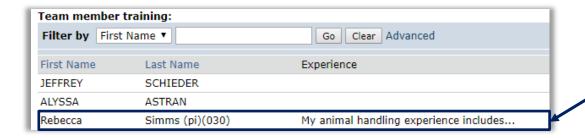


4. Enter a description of your *animal research experience/qualifications* in the text box.



## 5. Click the **Apply** button.

Your experience and qualifications will appear on the *Procedure Personnel Assignment* page within certain types of IACUC protocols in Click (e.g., Experimental Research protocols).



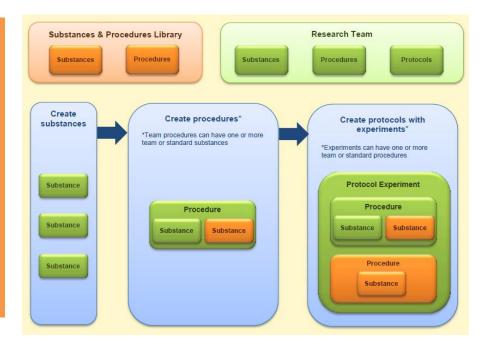
## Plan Out Your Protocol

- Consider the research (science), reasons for performing the research, and potential scientific benefits from it.
- Determine what individual researchers will need to be listed on your protocol.
- Determine the experiments you will perform and the number of animals required.
- Determine all specific substances you will administer to live animals.
- Determine all specific procedures you will perform with live animals.
- If any substances you will use will be of non-pharmaceutical grade, locate the Non-Pharmaceutical Grade Form in the IACUC Library. This form must be downloaded, completed, and uploaded to the Create Procedure SmartForm when requested.
- If the work is grant-funded, locate the **Specific Aims** and **Vertebrate Animals** sections (or their equivalents) of your grant(s). These documents must be uploaded to the **Protocol SmartForm** in the **Funding** section so that the IACUC may perform a grant congruency review.
- Locate the *Enrichment Checklist* in the IACUC Library. This form must be downloaded, completed, and uploaded to the *Protocol SmartForm* in the Supporting Documents section.

## **Understanding Building Blocks**

The diagram below shows the concept of **Building Blocks**. Once they are set up, you can create your protocol.

"Standard" Substances and "Standard" **Procedures** are those that have been pre-loaded into the library by the IACUC. These are not editable, can be seen by all users, and can be added to any protocol. In this diagram, Standard Substances and Standard **Procedures** are shaded orange.



Each Research
Team can create
their own custom
Substances and
Procedures. Only
members of the
Research Team
can edit and see
their Team
Substances and
Team Procedures.

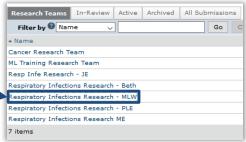
In this diagram, Team Substances and Team Procedures are shaded green.

- First, create a **Research Team**. Each **Research Team** will then have **Substances**, **Procedures**, and **Protocols** associated with it.
- Next, check the Substances tab for any pre-existing Substances required for your
  protocol experiments (see <u>Check for Existing Building Blocks</u>). If they are not in the
  library, you will need to create them.
- Then, check the **Procedures** tab for any pre-existing **Procedures** required for your protocol experiments (see <u>Check for Existing Building Blocks</u>). If they are not in the library, you will need to create them.

## **Check for Existing Building Blocks**

1. Click the IACUC tab in the navigation menu.

 On the Research Teams tab, you will find a list of all the Research Teams you are a member of. Click on the desired Research Team's Name. If you do not have a Research Team listed, please see Create a Research Team.



3. You will now be in this research team's Workspace. Click the **Procedures** tab to view all **Procedures** currently available to you. Do the same for **Substances** (on the **Substances** tab).



- 4. If the needed **Substance** or **Procedure** already exists, review its details to ensure that it is what you need. To do this:
  - a. From either the **Procedures** or **Substances** tab, click the item's **Name**.
- View Procedure

  Printer Version

  View Differences
- b. You will now be in the item's Workspace. Click **View Procedure** or **View Substance** on the top left hand side of the screen to review the item's details.
- 5. If you cannot locate pre-existing **Substances** and/or **Procedures** that meet your needs, please see the next section for information on how to <u>Create Team Substances</u> and <u>Create Team Procedures</u>.

## **Create Building Blocks**

Before you create a protocol, the **Building Blocks** for a protocol must be created in a specific order:

- 1. Create your Research Team
- 2. Create Team Substances
- 3. Create Team Procedures

If the system does not already contain the particular **Substance** or **Procedure** that you need for your protocol, you will need to create it yourself. Once created, it will be saved and can be used again in any of your **Research Team's** future protocols. It will not be viewable or available to anyone who is not on the **Research Team**.

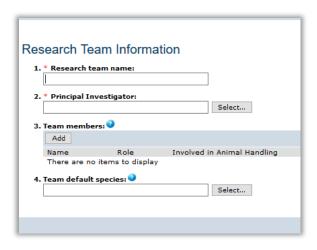
## Create a Research Team

6. Click on the IACUC tab in the top navigation menu.



- 7. Click the Create Research Team button.
- 8. Complete the **SmartForm**, paying special attention to the fields listed below.

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



- Enter a Name for the Research Team. The Name should easily identify this specific Research Team to you. The IACUC will be able to view all Research Team Names.
- Click the Select button to assign the Principal Investigator (PI). Select the PI, and then click OK.

- Click the **Add** button to select **Team Members**.
  - i. Click the **Select** button, and enter the individual's **Last Name**.
  - ii. Click the **Go** button.
  - iii. Select the appropriate person, and then click **OK**.
  - iv. Indicate whether the person has an animal handling role.
  - v. Indicate whether the person is authorized to order animals.
  - vi. Check the person's Role(s) in the research.
  - vii. Click **OK** if you are finished, or **OK** and **Add Another** to add more members.

## **Note:** You do <u>not</u> need to add the **PI** as a **Team Member**.

- Click Select to identify a Team Default Species.
  - i. Enter the **Common Name** for the species, and then click **Go**.
  - ii. Select the appropriate **Species**, and then click **OK**.
- 9. Click the **OK** button. The **Research Team** will now appear on the **Research Teams** tab.

## **Create Team Substances**

- 1. Click on the **IACUC** tab in the top navigation menu.
- 2. Select your desired **Research Team** from the **Research Teams** tab.
- 3. From the Research Team Workspace, click on the Substances tab. All Substances currently available to this **Research Team** will display.

If you need to create a **Substance** specific to your own **Research** Team, you will need to create it yourself. Substances you create will be labeled as **Team** under the **Scope** column and are only viewable and available to your specific Research Team.

4. To create a **Substance**, click the **Create Substance** button.



## Required information fields are marked with an asterisk (\*)



- Complete the SmartForm.
- When done, click Finish. You will be taken back to the Research Team
   Workspace. The new Substance you created will now be available when you create a Procedure.

## **Create Team Procedures**

- 1. Click on the IACUC tab in the top navigation menu.
- 2. Select your desired Research Team from the Research Teams tab.

3. From the Research Team Workspace, click on the **Procedures** tab. All **Procedures** available to this **Research Team** will display.

If you need to create a **Procedure** specific to your own **Research Team**, you will need to create it yourself. Procedures you create will be labeled as **Team Procedures** under the **Scope** column and are only viewable and available to your specific **Research Team**.

- If the **Procedure** you require is already listed in the procedure library, but could be made more appropriate by making a few minor changes, you can use the current **Procedure** as a template to create a new **Procedure**. Click the **Exit** button to return to the workspace and then click **Copy Procedure**.
  - Enter a new Name for the Procedure.
  - Select the applicable Research Team and click the OK button.
  - Click the IACUC tab, and then select your chosen Research
     Team from the Research Teams tab.
  - Click the Procedures tab and locate the copy by its Name.
     Click on the Name.
  - Click the Edit Procedure button, make the necessary changes, and then click Finish.
  - The new Procedure will now be available when you create your protocol.
- If the Procedure you require is not listed, proceed to Step 4.
   My Current Actions

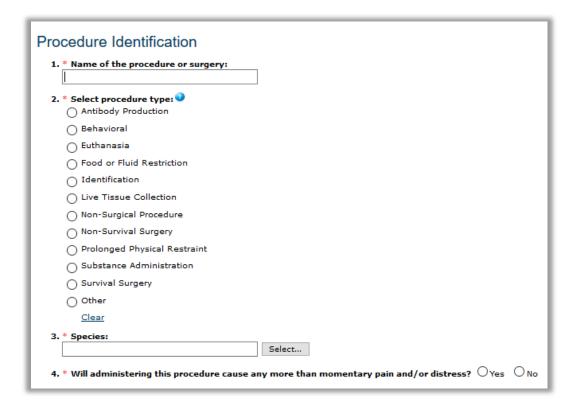
   Edit Research Team

   4. To create a Procedure, click the Create Procedure button.

   Create Procedure
   Create Procedure

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

Create Substance



- Complete the SmartForms.
  - Note that your answers may trigger other questions or pages to be added to the SmartForms for completion. For example, if for Question
     Select procedure type you select Behavioral, the Behavioral Procedures page is added to the SmartForms.
- When done, click Finish. You will be taken back to the Research Team
   Workspace. The new Procedure you created will now be available when you create a protocol.

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## Create a Protocol

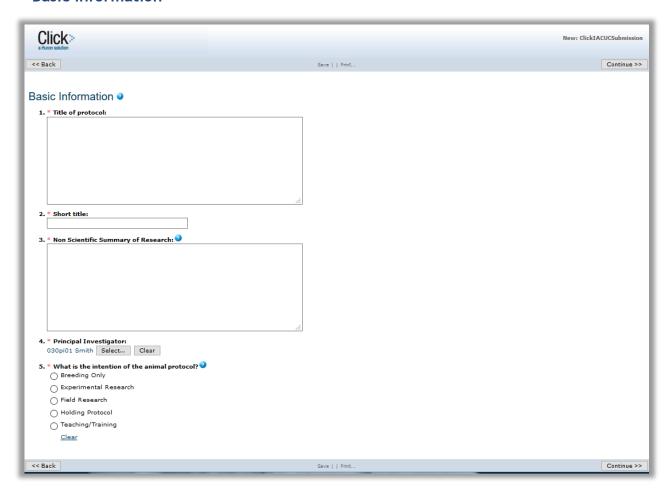
To begin the process of creating a **Protocol**, please complete the following steps:

- 1. Click the **IACUC** tab in the top navigation menu.
- 2. Select your desired **Research Team** from the **Research Teams** tab. Individuals listed in this **Research Team** will be imported into the personnel section of the **Protocol** you create.
- 3. Click the Create Protocol button.



The sections below will provide step-by-step information on some of the general **SmartForms** you may be asked to complete as part of submitting a new protocol to the IACUC for review. The directions below assume that all needed **Research Teams**, **Substances**, and **Procedures** have already been created.

## **Basic Information**



- 1. Enter a **Title** for the protocol. This will be the official **Title** of the protocol and should include the name(s) of any grants associated with the protocol.
- 2. Enter a **Short Title** for the protocol.

NOTE: The Short Title becomes the Name of the protocol in Click; be sure to make this unique across your projects.

- 3. Enter a brief **Non-Scientific Summary of Research**, for the protocol. This section must be written in layman's (non-technical) terms, such that a non-scientist would be able to understand what you are doing.
- 4. By default, the protocol creator will be listed as the *Principal Investigator (PI)*. If you are entering a study for another individual who will be serving as the *Principal Investigator*, please <u>do not</u> change this field to that person's name until you have completed all of the **SmartForms** and are ready to have the *PI* submit the protocol for review. Unless you have been previously assigned by the *PI* as a *PI Proxy* (see <u>Assign a PI Proxy</u>), you will not be able to further write or edit the protocol if you are no longer listed as *PI*.
- 5. Select the **Intention** for the protocol.

**NOTE:** Depending on the specific **Intention** you select, subsequent pages of the **SmartForms** will be added or removed.

Click the **Continue** button to save your work and move to the next page within the **SmartForms**.

## **Protocol Team Members**



The default list of personnel displayed will reflect the individuals included on the selected **Research Team**, but individuals can also be added or deleted from this page. If a required UB individual is not showing up in the search, see Getting a Click Account.

There is no need to add the **Principal Investigator** to the **Protocol Team Members** page, as the **PI** was already listed on the Basic Information page.

## **Adding Internal Team Members**

- 1. To add internal team members (UB or UB affiliates), click the Add button.
  - Begin typing the individual's last name in the Protocol team member field. If the last name is very common, you may have to type a comma followed by the first name. You can also sort through an alphabetical list by clicking the Select button.

**NOTE:** Most people with active UBIT accounts who have been employed in any capacity at UB (including graduate students on RA/GA/TA lines) will be accessible as internal personnel.

- Indicate whether or not the team member is involved in the handling of animals.
- Indicate whether or not the team member is authorized to order animals.
- Select the individual's **Role(s)** in the research. If a specific **Role** is not in the list, please select the closest match.
- Click the **OK** button. If you have additional team members to add, you may click **OK** and **Add Another** to repeat the process.

## **Adding External Team Members**

- 1. If any non-UB individuals will be involved in the work, enter them here. This is rare. To add external team members, click the **Add** button.
  - You will need to upload a separate document for each external team member, providing the same information as is provided for internal team members. Click the Choose File (or Browse) button to locate the file.
  - In the file, indicate the individual's name, their role on the study, whether or not they will be involved in animal handling, whether or not they are authorized to order animals on the protocol, their email address, and their phone number. Provide a brief synopsis of their experience and qualifications for working with live animals in relation to this study.

Collaborators who will be covered under their own institution's IACUC do not need to be added as external team members.

- Enter a **Title** for the document use the person's name as the title (e.g., John Doe).
- Click the **OK** button. If you have additional external team members to add, click **OK** and **Add Another** to repeat the process.

NOTE: External team members will need to obtain a UBIT account in order to log into Click if they need electronic access to the protocol.

These individuals will need a volunteer appointment from your department. Please contact <a href="mailto:support@research.buffalo.edu">support@research.buffalo.edu</a> for more information.

After you have finished adding team members, click the **Continue** button to save your work and move to the next page within the **SmartForms**.

## **Funding Sources**



- 1. If you anticipate funding for the study, click the **Add** button.
  - Click the Select button.
  - Enter the Name of the organization. Please do not use abbreviations (e.g., NIH); type the Name using complete words.

NOTE: If you have NIH funding, please list the specific institute (e.g., "National Institute of Allergy and Infectious Diseases," instead of just "NIH").

- Click the Go button.
- Select the **Name** of the appropriate organization.
- Click the **OK** button.

NOTE: If you cannot locate the Name of the organization using the search tool, please click the Cancel button. Then enter the Name of the organization in the Name field, and indicate its Type.

- Enter the **Sponsor's funding ID** number, if known.
- Enter the **Grants office ID** number, if known.
- For each grant, the Specific Aims and Vertebrate Animals sections (or their equivalents) should be included as attached files; click the Add button to attach them. The IACUC Office needs this information in order to perform a congruency review between the procedures as described in the protocol and the procedures as described in the grant.

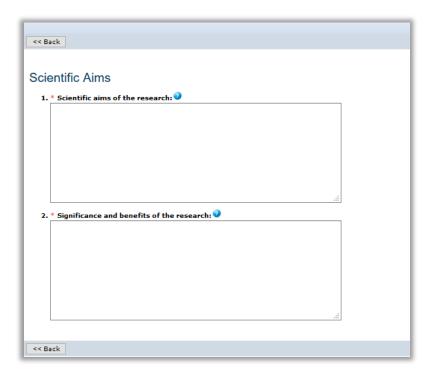
NOTE: Name the documents as you want them to appear in the approval letter.

- Click the OK button once more to close the window.
- If there are additional funding sources, please repeat the process above to add them.
- 2. Indicate if any personnel listed on the protocol have a financial interest in this research.

Financial interests in a research project usually occur where there will be a tangible product related to the research, as opposed to merely generating knowledge to be published. It also occurs when there is corporate sponsorship of a study.

Click the **Continue** button to save your work and move to the next page within the **SmartForms**.

## Scientific Aims



- 1. State the scientific aims of the research. What are the goals and objectives?
- 2. State the significance and potential human/animal health benefits of the research.

Click the **Continue** button to save your work and move to the next page within the **SmartForms**.

## **Experiments**



**Note:** All **Procedures** must have been previously created before you can assign them to the **Experiments** you create in the protocol. See <u>Create Team Procedures</u> for instructions.

#### 1. Click the **Add** button.

- Enter a Name for the Experiment.
- Click the **Select** button to choose the appropriate species for the **Experiment**, and then click **OK**. There can only be one species per **Experiment**.
- Describe the **Experiment**. What will happen to the animals? Include animal characteristics such as age, weight, and sex.
- Enter a scientific justification for the purpose of this experiment. How is it necessary to your research goals?
- Click the **Add** button to select **Common Procedures**; procedures which <u>all</u> animals in the experiment will undergo.

For example, a euthanasia procedure that all animals will undergo or a special diet all animals will receive would be considered a **Common Procedure**.

- Select the appropriate Procedure(s).
- Click OK.
- Click the **Add** button to select **Variable Procedures**; procedures which only some animals in the experiment will undergo.

For example, a surgery only performed on one group or a substance

administration procedure where the doses vary across animals would be considered a **Variable Procedure**.

- Select the appropriate Procedure(s).
- Click OK.
- List the variables of the Experiment. What items will change across groups?
   Examples include agents (substances), dosages, concentrations, routes, and frequency.
- Describe the variations applied to the procedures you added. For example, for
  a substance administration procedure where the dose (variable) will differ
  across animals, list the dose along with the number of animals that will receive
  each dose.
- Describe the timing so that the IACUC can understand the time points of the experiment. In what order will the procedures occur?
- Enter the total number of animals to be used in this experiment.
- Of the total number of animals to be used in this experiment, how many animals will be in each Pain Category? Only count each animal once, in its highest expected Pain Category.

## Pain Category B

- •Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.
- •Non-invasive observation of animals.

## Examples:

- Breeders that are not genotyped and not used experimentally
- Observation of animal behavior in the wild without manipulating the animal or its environment

## Pain Category

•Animals that are subject to research-related procedures that cause no pain or distress, or only momentary or slight pain or distress, and do not require the use of pain-relieving drugs.

#### Examples:

- Breeders that are being genotyped
- Animals receiving a peripheral injection

## Pain Category D

• Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics, tranquilizer drugs, or euthanasia.

#### Examples:

- Animals undergoing surgery (survival or non-survival)
- Retro-orbital blood collection
- •Induced infections or antibody production

## Pain Category E

•Animals subjected to potentially painful or stressful procedures that are <u>not</u> relieved with anesthetics, analgesics, tranquilizer drugs, or euthanasia. Withholding anesthesia/analgesia must be scientifically justified in writing and approved by the IACUC.

## Examples:

- Any procedures for which needed analgesics, tranquilizers, sedatives, or anesthetics must be withheld for justifiable reasons
- Research that requires continuation after clinical symptoms are evident without medical relief, or require death as an endpoint.
- Click the **Add** button to identify any husbandry exceptions you require in this experiment (e.g., no enrichment, food/water restriction, special diet, special life cycle, single housing, etc.).
  - Select an Exception Type.
  - Enter a scientific justification for the Exception.
  - Click the OK button. If you have additional Exceptions to add, click OK and Add Another to repeat the process.
- To add a supporting document, click the Add button.

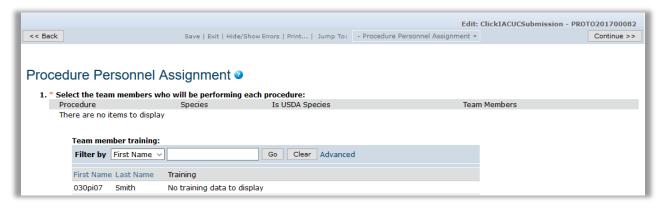
**Note:** It is not necessary to upload anything to the **Supporting Documents** section here if you do not have any additional information to provide.

- Click the Choose File (or Browse) button to locate the file.
- Enter a Name for the document.

- 35
- Select a **Category** from the drop-down menu.
- o Click the **OK** button. If you have additional forms to add, click **OK and Add Another** to repeat the process.
- 2. Click the **OK** button. If you have additional **Experiments** to add, click **OK and Add** Another to repeat the process.

Click the Continue button to save your work and move to the next page within the SmartForms.

## **Procedure Personnel Assignment**



- 1. Click the **Update** button to the left of a **Procedure**.
  - Select the Research Team Member(s) who will be performing the Procedure.
  - o Click OK.
- 2. Repeat **Steps 1-3** for any remaining **Procedures**.

**Note:** You will see a **Team Member Training** section on the bottom half of this page. There are no fields to complete in this section of the page.

> In the future, the Click Portal will automatically update training information for each Research Team Member listed on this page. This section is for informational purposes only.

Click the **Continue** button to save your work and move to the next page within the SmartForms.

# **Supporting Documents**



- 1. To add a supporting document, click the **Add** button.
  - Click the **Choose File** (or **Browse**) button to locate the file.
    - Supporting Documents that were uploaded on other pages do not need to be added again here.
    - Please upload the *Enrichment Checklist* on this page. You can locate the checklist document in the *Library*, on the *Checklists* tab. Complete the checklist concerning the animals on this protocol. When uploading the file, please name the document *Enrichment Checklist*.
    - If you are conducting a Field Research protocol, upload copies of all your required permits to the Supporting Documents section.
  - Enter a **Name** for the document. Name the document as you want it to appear in the approval letter.
  - Select a Category from the drop-down menu.
  - Click the **OK** button. If you have additional forms to add, click **OK and Add Another** to repeat the process.

After you have finished adding supporting documents, click the **Finish** button to save your work.

You have now completed your protocol! When you click the **Finish** button, you will be returned to the **Study Workspace**. If you need to further edit your protocol prior to submission, click the **Edit Protocol** button on the top left of the screen, under **My Current Actions**.

NOTE: At this point, your protocol <u>has not yet been submitted</u> to the IACUC for review.

Please see <u>Submitting a Study for Review</u>.

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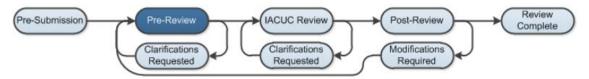
# Submitting a Study for Review

In order to submit the submission to the IACUC for review, the **Principal Investigator** (or a user designated by the **PI** as a **PI Proxy** (see **Ass**ign PI Proxy) must complete the following actions, from the **Study Workspace**:

1. To submit your study for review, click **Submit** under **My Current Actions**.

The **Click Portal** will run a brief check to ensure that all of the required fields have been completed within the **SmartForms**.

- If an error appears, click the link(s) and update any required fields that were missed. Save your changes, Exit the protocol's SmartForms, and then click the Submit button again.
- If there are no errors, a statement will appear in the window.
- 2. Read the statement and then click **OK** to submit the study for review. You do not need to include any **Comments** or **Supporting Documents** if you have no further information to provide.
- 3. After you submit, check to ensure that the following things have occurred:
  - The **Status Bar** in the upper-left corner of the **Workspace** has now changed from **Pre-Submission** to **Pre-Review**.
  - The highlighted state in the workflow image at the top of the page is now **Pre-Review**.
  - On the **History** tab, the most recent action is **Submitted**.



#### The Review Process

Congratulations - your protocol has now been submitted to the IACUC for review!

Submitting a protocol to the IACUC initiates a series of activities that will include:

- Administrative Pre-review by an IACUC Office staff member
- Review by the Full IACUC Committee and/or a Designated Reviewer

Any of these reviews may lead to a request for the study team to take further action, such as providing clarifications or modifying the study. Whenever the study team needs to act, the *PI* and any personnel the *PI* has designated as *Primary Contact* (see <u>Assign Primary Contact</u>) receives an email notification and the study appears in *My Inbox* for all study team members when they log in to the **Click Portal**.

# Clarification Requests/Modifications Required

At points during the review process, clarifications and/or modifications may be requested from the study team.

# • Clarification Requested State

If the IACUC Office has questions or requires you to change your submission prior to Committee Review, the *PI* and any user(s) the *PI* has designated as a *Primary Contact* for the protocol will receive an email notification. The protocol will also appear in My Inbox for all Research Team members. The submission will be in the Clarification Requested (Pre-Review) state, since it now requires an action.

### Modifications Required State

If the IACUC Committee has questions or requires you to change your submission prior to approval, the *PI* and any user(s) the *PI* has designated as a *Primary* Contact for the protocol will receive an email notification. The protocol will also appear in My Inbox for all Research Team members. The submission will be in the Modifications Required state, since it now requires an action.

The **PI** (or **PI Proxy**) is responsible for making any changes necessary, and for responding to the request.

#### Review the Request Details

- To respond to a request, either click on the link embedded in the email notification or navigate to My Inbox and locate the study with the status of Clarification Requested. Click on the study's Name to open it.
- 2. On the **History** tab of the submission's **Workspace**, find the **Clarification by Pre-Reviewer Requested** or **Modifications Required** activity. Clicking on this will show you the comments that need to be addressed.

Alternatively, you can navigate to the **Reviewer Notes** tab of the submission's **Workspace** to view a list of the changes requested (in Click, comments are known as **Reviewer Notes**).

#### **Respond to Reviewer Notes**

- 1. If you are on the **Reviewer Notes** tab of the submission's **Workspace**, click the **Jump To:** link to edit the submission in response to the comments. You will be brought directly to the relevant protocol page. Make the change in the SmartForm.
- 2. Then, either from the protocol page itself, or from the **Reviewer Notes** tab, click the **Click here to respond...** link in order to type a written response, if required.
- 3. Select a response based on what you did and explain your response in the text box. Your explanation may simply be "I made the change."
- 4. Click **OK**. If on a protocol page, either:

**Exit** the form when done and navigate back to the **Reviewer Notes** tab on the **Workspace** to address additional comments.

Click **Next** or **Previous** in the yellow **Reviewer Note** box at the top of the screen to move to the next comment that needs addressing. When done, **Exit** the protocol.

**NOTE:** If no actual edits/changes were needed to the study, the **PI** (or **PI Proxy**) can simply provide the written response.

#### Submit a Revised Protocol

- 1. From the Study Workspace, under My Current Actions, click Submit Response.
- 2. In the window, enter any **Notes** and then click **OK**.
- After you submit, check to ensure that the following things have occurred:
  - The **Status Bar** in the upper-left corner of the **Workspace** has changed from **Clarification Requested** or **Modifications Required** to **Pre-Review**.
  - The highlighted state in the workflow image at the top of the page is now **Pre-Review**.
  - On the History tab, the most recent action is Response Submitted.

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# Assigning Additional Roles to Personnel on a Protocol

Once the protocol has been created, additional staff and reviewer roles can be added at the discretion of the *Principal Investigator (PI)*.

# **Assign PI Proxy**

A PI Proxy can perform all of a *Principal Investigator's* duties, with the exception of assigning additional PI Proxies. The PI Proxy <u>must</u> be a member of the **Research** Team associated with the protocol.

- 1. Click the **IACUC** tab in the top navigation menu.
- 2. From the **All Submissions** tab, click on the **Name** of the desired protocol.
- 3. From the Study Workspace, click Assign PI Proxy.
- 4. Place a checkmark next to the **Name** of the person you wish to be **PI Proxy**.
- 5. You do not need to include any **Comments** or **Supporting Documents** if you have no further information to provide.
  Click the **OK** button.

# My Current Actions Edit Protocol Printer Version View Differences Submit Assign Primary Contact Assign PI Proxy Manage Guest List

# **Assign Primary Contact**

A person identified as a **Primary Contact** will receive all the system-generated email notifications that a **Principal Investigator** does. By default, the system will assign the **Primary Contact** role to whoever created the protocol in the system. Follow these steps to change the default to another person.

- 1. Click the IACUC tab in the top navigation menu.
- 2. From the **All Submissions** tab, click on the **Name** of the desired protocol.
- 3. From the **Study Workspace**, click **Assign Primary Contact**.
- 4. Click the **Select** button, and select an individual to serve as the **Primary Contact**.
- 5. Click OK.
- 6. You do not need to include any **Comments** or **Supporting Documents** if you have no further information to provide.
  Click the **OK** button.



# Manage Guest List

Those on the **Guest List** can read the protocol and any of its associated submissions, but cannot edit them.

- 1. Click the **IACUC** tab in the top navigation menu.
- 2. From the **All Submissions** tab, click on the **Name** of the desired protocol.
- 3. From the Study Workspace, click Manage Guest List.
- 4. Click the **Add** button, and select an individual to include on the **Guest List**.
- 5. Click OK.
- 7. You do not need to include any **Comments** or **Supporting Documents** if you have no further information to provide.
  Click the **OK** button.



# Follow-On Submissions

The term "Follow-On Submissions" refers to submissions that may be created only <u>after</u> the protocol has been approved.

#### This includes:

- Amendments
- Annual Reviews
- Triennial (*de novo*) Reviews

The sections below will provide step-by-step information on the general **SmartForms** you will be asked to complete as part of submitting a **Follow-On Submission** to the IACUC for review.

# **Creating an Amendment**

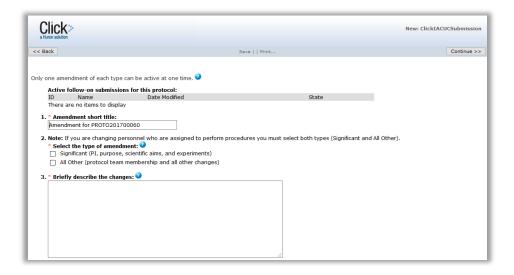
- 1. Log into the Click Portal.
- 2. Click the IACUC tab in the top navigation menu.



- 3. From the **Active** tab, which lists all of your currently approved protocols, click on the **Name** of the desired protocol.
- 4. Under My Current Actions, click on the Create Amendment button. You will be brought to the amendment's SmartForm.



#### **Amendment SmartForm**



1. By default, a **Short Title** for the **Amendment** will populate. For example, **Amendment** for **{Protocol number}**.

Delete the existing title, and then enter a short title for the **Amendment**, such as "Personnel Change" or "Add Animals," as applicable to your changes. The chosen title will become the amendment's Name in Click.

- 2. Indicate which type of amendment this will be:
  - **Significant Amendment** A change in PI, purpose, scientific aims, or experiments
  - All Other Amendment A change in protocol team membership or all other changes
- 3. Provide a brief description of the amendment. You will make direct changes to the protocol form itself in subsequent pages of the **SmartForm**.
- 4. Provide a brief description of the rationale for these changes.
- 5. Click the **Continue** button to save your work. You will be taken directly to the protocol's **SmartForms**.

#### **Editing the Protocol**

1. Make any changes you need to make directly to the protocol's **SmartForms**. You can use the **Continue** and **Back** buttons to move through the protocol form or use

- the **Jump To:** drop down links at the top of the page to move directly to any page within the protocol.
- 2. Once you have made your changes, click **Exit** at the top or bottom of any page within the **SmartForms**.
- You will be brought to the amendment's Workspace. You can continue to edit your amendment by clicking Edit Amendment on the top left of the amendment's Workspace, under My Current Actions.

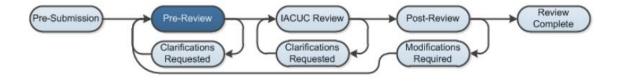
NOTE: At this point, your Amendment has not yet been submitted to the IACUC for review.

# **Submitting the Amendment for Review**

1. To submit your **Amendment** for review, from the **Study Workspace**, click **Submit** under **My Current Actions**.

The **Click Portal** will run a brief check to ensure that all of the required fields have been completed within the **SmartForms**.

- If an error appears, click the link(s) and update any required fields that were missed. Save your changes, Exit the protocol's SmartForms, and then click the Submit button again.
- If there are no errors, a statement will appear in the window.
- 2. Read the statement and then click **OK** to submit the study for review. You do not need to include any **Comments** or **Supporting Documents** if you have no further information to provide.
- 3. After you submit, check to ensure that the following things have occurred:
  - The **Status Bar** in the upper-left corner of the **Workspace** has changed from **Pre-Submission** to **Pre-Review**.
  - The highlighted state in the workflow image at the top of the page is now Pre-Review.
  - On the History tab, the most recent action is Submitted.



# **Creating an Annual Review**

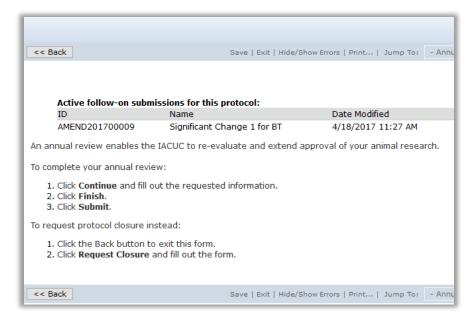
- 1. Log into the Click Portal.
- 2. Click the IACUC tab in the top navigation menu.



- 3. From the **Active** tab, which lists all of your currently approved protocols, click on the **Name** of the desired protocol.
- 4. Under My Current Actions, click on the Create Annual Review button. You will be brought to the annual review's SmartForm.



#### **Annual Review SmartForms**



- 1. Read the initial page of the **SmartForms**, and then click the **Continue** button.
- 2. Describe the progress you have made on the protocol over the last year. Include the number of animals you have used and/or generated to date.
- 3. Describe any unanticipated results involving animal health and well-being during the last year. Indicate whether or not the LAF clinical veterinary staff was notified. If none occurred, indicate so.
- 4. Click the **Finish** button.
- 5. You will be brought to the annual review's **Workspace**. You can continue to edit your annual review by clicking **Edit Annual Review** on the top left of the amendment's **Workspace**, under **My Current Actions**.

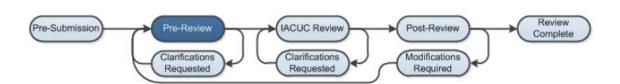
NOTE: At this point, your **Annual Review** has **not yet been submitted** to the IACUC for review.

#### **Submitting the Annual Review**

1. To submit your **Annual Review**, from the Annual Review **Workspace**, click **Submit** under **My Current Actions**.

The **Click Portal** will run a brief check to ensure that all of the required fields have been completed within the **SmartForms**.

- If an error appears, click the link(s) and update any required fields that were missed. Save your changes, Exit the SmartForms, and then click the Submit button again.
- If there are no errors, a statement will appear in the window.
- 2. Read the statement and then click **OK** to submit the **Annual Review**. You do not need to include any **Comments** or **Supporting Documents** if you have no further information to provide.
- 3. After submitting, check to ensure that the following things have occurred:
  - The **Status Bar** in the upper-left corner of the **Workspace** has changed from **Pre-Submission** to **Pre-Review**.
  - The highlighted state in the workflow image at the top of the page is now **Pre-Review**.
  - On the **History** tab, the most recent action is **Submitted**.

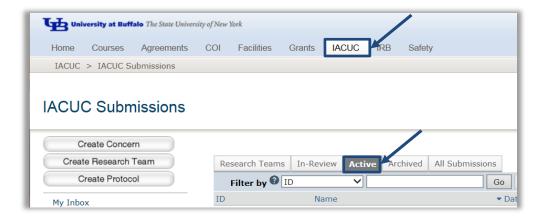


# Creating a Triennial (de novo) Review

Protocols are approved by the IACUC for a maximum of 3 years. Well ahead of the expiration date, the protocol will need to be submitted to the IACUC again for a full review and re-approval if you would like to continue your approval. The *PI* and any user(s) designated by the PI as a *Primary Contact* for the study will receive a system-generated email reminder 90, 60, and 30 days prior to the protocol's expiration date. If you will no longer pursue approval for the study, please see Requesting Protocol Closure below.

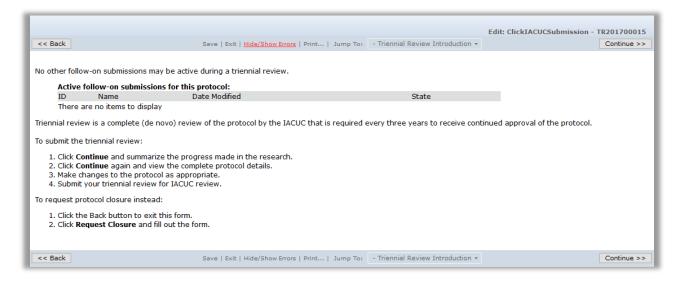
Note: It is highly recommended you submit your renewal as soon as possible in order to prevent a lapse in approval. Currently the IACUC meets <u>once per month</u> to review triennial renewal submissions. You should plan to submit your renewal well in advance of its expiration date, to allow enough time for the IACUC to review and approve the submission prior to its expiration date.

- 1. Log into the Click Portal.
- 2. Click the IACUC tab in the top navigation menu.



- 3. From the **Active** tab, which lists all of your currently approved protocols, click on the **Name** of the desired protocol.
- 4. Under My Current Actions, click on the Create Triennial Review button. You will be brought to the triennial review's SmartForm.

#### Triennial Review SmartForms



Note: No other Follow-On Submissions (e.g., Amendment, Annual Review) may be active during a protocol's Triennial Review. Please plan accordingly.

If you need to amend your protocol at the same time as your Triennial Review, simply incorporate your Amendment revisions into your Triennial Review.

- 1. Read the initial page of the **SmartForms**, and then click the **Continue** button.
- 2. Describe the progress you have made on this protocol over the past 3 years. Include the number of animals used and/or generated to date.
- 3. Describe any unanticipated results involving animal health and well-being during the last 3 years. Indicate if the LAF clinical veterinary staff was notified. If none occurred, indicate so.
- 4. Click the **Continue** button to save your work. You will be taken directly to the protocol's **SmartForms**.

#### **Editing the Protocol**

- Make any changes you need to make directly to the protocol's SmartForms. You
  can use the Continue and Back buttons to move through the protocol form or use
  the Jump To: drop down links at the top of the page to move directly to any page
  within the protocol.
- 2. Once you have made your changes, click **Exit** at the top or bottom of any page within the **SmartForms**.

3. You will be brought to the triennial review's **Workspace**. You can continue to edit your triennial review by clicking **Edit Triennial Review** on the top left of the triennial review's **Workspace**, under **My Current Actions**.

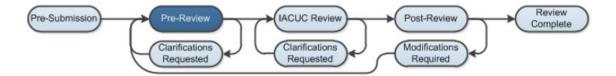
NOTE: At this point, your Triennial Review has <u>not yet been submitted</u> to the IACUC for review.

#### Submitting the Triennial Review

1. To submit your **Triennial Review** for review, from the Triennial Review **Workspace**, click **Submit** under **My Current Actions**.

The **Click Portal** will run a brief check to ensure that all of the required fields have been completed within the **SmartForms**.

- If an error appears, click the link(s) and update any required fields that were missed. Save your changes, Exit the protocol's SmartForms, and then click the Submit button again.
- If there are no errors, a statement will appear in the window.
- 2. Read the statement and then click **OK** to submit the study for review. You do not need to include any **Comments** or **Supporting Documents** if you have no further information to provide.
- 3. After submitting, check to ensure that the following things have occurred:
  - The **Status Bar** in the upper-left corner of the **Workspace** w has changed from **Pre-Submission** to **Pre-Review**.
  - The highlighted state in the workflow image at the top of the page is now Pre-Review.
  - On the History tab, the most recent action is Submitted.



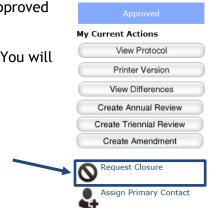
# **Requesting Protocol Closure**

If you would like to request closure of a currently approved protocol, follow the steps below.

- 1. Log into the Click Portal.
- 2. Click the IACUC tab in the top navigation menu.



- 3. From the **Active** tab, which lists all of your currently approved protocols, click on the **Name** of the desired protocol.
- 4. Under **My Current Actions**, click on **Request Closure**. You will be brought to the Request Closure **SmartForm**.



**NOTE:** You must ensure that <u>no</u> animals currently remain at UB under this protocol and that you have communicated to all personnel that this protocol is being closed and live animal work must stop.

If there are animals currently under this protocol, you cannot close the protocol. If you would like to close the protocol and animals remain, please make arrangements for their disposition (e.g., euthanasia, transfer to a different protocol) prior to requesting closure.

#### **Request Closure Form**

Request Closure
You are formally requesting closure of this protocol. You must ensure the following:
<ul> <li>No animals remain at the institution under this protocol number. If animals remain, make arrangements for the disposition of those animals (either euthanize the animals or transfer them to a holding protocol) prior to executing this activity.</li> <li>You have communicated to all protocol personnel that this protocol is being closed and all animal work must stop.</li> </ul>
1. * I agree that the above items are true: O Yes O No Clear
2. * Reason for closure:
3. * Describe the progress made toward achieving the goals of the research:
guille resourcing

- 1. Indicate that all animal work on the protocol has ceased, and that all animals used in the protocol have been properly disposed.
- 2. Enter a brief explanation for why you wish to close this protocol, such as "The study has been completed."
- 3. Describe in brief the progress made toward achieving the goals of the research.
- 4. Update the number of animals you actually used on this protocol. The IACUC module will automatically pull the animal numbers you requested in the **Experiments** section of the protocol into the **Animals Identified in Experiments** column.
  - Click the **Update** button next to each **Pain Category** that contains more than 0 **Animals Identified in Experiments** to indicate how many animals were <u>actually</u> used in each **Pain Category**.
- 5. Describe any unanticipated results involving animal health on this protocol. Indicate if the LAF clinical veterinary staff was notified. If none occurred, indicate so.
- 6. You do not need to add any **Comments** or **Supporting Documents** if you have no further information to provide.

- 2. Click **OK** to submit the request. You do not need to include any **Comments** or **Supporting Documents** if you have no further information to provide.
- 3. After submitting, check to ensure that the following things have occurred:
  - The **Status Bar** in the upper-left corner of the **Workspace** has changed from **Approved** to **Closure Requested**.
  - On the **History** tab, the most recent action is **Closure Requested**.



# Institutional Animal Care and Use Committee (IACUC)

Clinical and Translational Research Center 875 Ellicott Street, Room 5018 Buffalo, NY 14203 716.829.3977 iacuc@research.buffalo.edu

# **Electronic Research Administration (eRA)**

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support@research.buffalo.edu