



Instructions to Complete a New or Triennial Protocol Application

**If you read no further!
Substances and procedures should be created first before starting a new or triennial protocol application.**

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First Steps – before you enter any information into eIACUC

*****How to assign a PI proxy (Do this in the parent protocol before starting the triennial protocol)**

1. From the IACUC tab, click on your Research Team name (PI proxy must be listed in research team and on approved protocol).
2. Click the protocol name.
3. Click Assign PI proxy on the left-hand side.
4. Enter the PI proxy(s) in #1 and click OK.
5. Repeat for all protocols in which you would like to assign a PI proxy.
6. If you already started your triennial protocol and would like to add a PI proxy, contact the IACUC office for assistance. You will not see the Assign PI Proxy button in the menu.

What constitutes an Experiment, and what is a Procedure?

An **experiment** is a stand alone study, usually with several steps. An example:

Subcutaneous tumor model. There are several steps in this experiment –

1. Injection of tumor cells
2. Allow time for tumor growth e.g. 3-4 weeks
3. When tumor reaches a specified size, start treating with potential anti-tumor compounds, or alternatively do a survival surgery to remove the tumor.
4. Experimental endpoint – could be after a defined number of treatments, or when the humane endpoint is reached (tumor size exceeds the limit as per the Rutgers Policy, or tumor ulcerates etc.)

Procedures: As part of this experiment you will perform a number of procedures. These might be:

1. Tumor cell injection
2. Substance administration – drug, or drugs that you will administer
3. Survival surgery – tumor removal
4. Euthanasia. Carbon dioxide asphyxiation etc. If you will perfuse animals, then perfusion is a non-survival surgery procedure.

How to start?

Creating a **new protocol**: write out a narrative of your objectives and aims and list the various experiments you plan on doing. This will not be wasted time, you can cut and paste when you start entering the information into the form.

For **triennial renewals**: read through the narrative of your currently approved protocol and make note of the following:

Individual experiments – try to break down to manageable sections, with step by step procedures. Within each experiment:

1. Make a list of all the **substances** (including anesthetics and analgesics) you will administer in all experiments and surgeries. These are categorized in eIACUC in the Substance tab of your research team. Many of the compounds and drugs that were included in protocols in the past are already in the database so when you are entering your specific compounds first search the Substance library. Note – special diets should be added as substances.
2. Make a list of the different **procedures** and attempt to categorize them - substance administration, blood and tissue collection, survival/nonsurvival surgeries, behavioral, imaging etc. Once you create a procedure you can choose the category from a menu.
3. Create an Anesthetic administration procedure and a separate Analgesia procedure. Then you can reference these in all procedures where anesthesia and/or analgesia is required. This is especially helpful if you have several different surgical procedures.
4. Create substance administration procedures for each route of administration and then add **ALL** the compounds/drugs etc. that you will give by that route. For example – for intraperitoneal injections – list all the drugs given via that route. If you will administer both pharmaceutical grade drugs and non-pharmaceutical, create separate procedures for each group e.g. “IP Pharmaceutical grade drugs”, and a separate “IP Non-pharmaceutical grade drugs”. If you are unsure if a compound/drug is available as a pharmaceutical grade substance, refer to the FDA’s “Orange Book” <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>.
5. Examples of other activities that will require a procedure are: special diets (include the specific name of the diet, the relevant dietary content e.g. high fat, alcohol etc.); food and/or fluid regulation or restriction e.g. fasting before a blood collection for blood glucose determination. Fasting prior to surgery doesn’t need a procedure unless it will be longer than the accepted period for that species.

Use of standard procedures

There is a library of standard procedures and procedure templates to assist you in creating your protocol. The library is not inclusive, and you need to exercise caution when using a standard procedure for your protocol. Standard procedures and procedure templates have been written to help you with some information already populated in the form. However for most, you will need to copy and create as a team procedure so you can edit to include the specifics for your protocol. Suitable procedures to retain in the Standard format are some of the euthanasia procedures.

An example of a procedure that will need editing is one for blood or tissue collection– remove the standard wording and replace with the number of bleeds you will do, the amount of blood removed and the bleeding interval if you will do multiple bleeds.

How to copy a standard procedure to create a team procedure

1. Go to <https://eiacuc.rutgers.edu/>.
2. Click on the Research Team tab in gray in the middle of the page.
3. Click on your research team.
4. Click on the Procedure tab in gray in the middle of the page to view the list of standard procedures/substances.
5. Click on the procedure you wish to use.
6. On the left hand side, click on the ‘Copy Procedure’ button.
7. Type in New Procedure Name and select the New Research Team. Click OK.
8. Go back into your research team and click on the Procedure to locate the item renamed above.
9. Open the newly created procedure and click Edit Procedure to make changes.

How to edit a procedure that was previously used in an approved protocol

1. Go to <https://eiacuc.rutgers.edu/>.
2. Locate the name of the procedure you would like to copy.
3. To copy, click on the arrow next to "Action-Copy" button under 'Execute Activity'. Type in New Procedure Name and select the Research Team. Click OK.
4. Alternatively, click "Copy Procedure" from the menu on the left hand side of the page.
5. Open the newly created procedure and click Edit Procedure/Substance to make changes.

How to edit a procedure so that it populates in the 'Alternatives' section

In order to have the alternatives section populate procedures that are Pain Category D and E, the experiments used in the protocol need to indicate that there is more than momentary pain/distress. To edit this, please follow the instructions below:

1. Go to <https://eiacuc.rutgers.edu/>.
2. Click the IACUC tab
3. Click your Research Team
4. Click the Procedures tab
5. Open the procedure
6. Click Edit Procedure on the left
7. On page 1, question 4, please change the response to "yes" and respond to i. and ii. (*Note, once you have updated the procedure, it will appear in the drop down menu under the Alternatives section*).

How to create a triennial renewal application

*** If you would like a research team member to be able to edit the protocol, click Assign PI Proxy. Enter the protocol team member name and click OK. You can assign multiple PI proxies per protocol. All other research team members will only be able to view protocols***

1. Go to <https://eiacuc.rutgers.edu/>.
2. Click on the 'All Submissions' tab located in the middle of the page.
3. Click on the protocol you wish to renew.
4. On the left hand side of the protocol home page, click on the 'Create Triennial Review' tab.
5. Complete the required fields (*) and click Continue to move to the next page.
6. Note: For #1 Protocol Title - remove the old protocol number (if that is what is showing as the title) and replace with an appropriate title for the protocol, #2 Short Title: Use an abbreviated title, not the old protocol number.

New and Triennial protocols

Read every question before you answer, if you don't understand the question or are unsure of how to respond, contact the IACUC office for clarification.

Please ensure you answer every question in each section!

7. For the **Protocol Team Members**, include each person who will perform work under this protocol. Do not include the PI here, your name will automatically populate.
8. For the **Experiments**, select the procedures that apply to all animals (common procedures) and those that apply to some animals or are used differently across animals (variable procedures). In each experiment add the total number of animals to be used.
To select a **pain category** – read the Help instructions to determine the best category. In general, if a procedure will cause only momentary pain or distress, place the number in C; if there will be more than momentary pain/distress but it will be relieved through the use of anesthetics and analgesics, place the number in D. Any procedure where animals will experience unrelieved pain/distress (unavoidable pain, behavior tests that will cause distress e.g. forced swim test, infectious models where animals may die etc.) place those numbers in E.
9. Enter all **husbandry exceptions** e.g. single housing of social species e.g. male mice used for breeding, post surgery etc., food/fluid restriction, light cycle changes, metabolism cages, wire bottom cages etc. There is a list of exceptions for you to choose those that apply to your protocol.
10. On the final page, click Finish.
11. On the application home page, click on the 'Submit' button located on the left hand side of the page.

Writing an amendment

Go to <https://eiacuc.rutgers.edu/>.

How to create and submit an amendment in eIACUC (for protocols already entered in eIACUC smartforms)

1. From the **IACUC** tab, click your research team.
2. Select the name of the approved protocol.
3. On the left, click the “**Create Amendment**” button.
4. Answer questions 1-3 on the Amendment Summary page.
5. Click **Continue** to move to the next page. Edit any sections of the protocol necessary.
6. When done, click **Save** and **Exit**.
7. Click **Submit**.
8. Click **OK** to agree to the statement and submit for review.

How to Create an Amendment Using an Attached Amendment Form

*****Note:** This can only be done until your triennial review is due. You must create your triennial review in eIACUC at that point.

1. From the **IACUC** tab, click your research team.
2. Select the name of the approved protocol.
3. On the left, click the “**Create Amendment**” button.
4. Answer questions 1-3 on the Amendment Summary page.
5. Continue to the **Protocol Team Members** page. Click **Add** to add personnel. *****Note:** Students must log into eIACUC once to register their accounts prior to a PI adding them as protocol personnel. Once the student is registered, their name will appear in the pick list.
6. Continue to the **Supporting Documents** section. ***Do not edit any shell data that is already entered in the system. The only section you are allowed to edit is the Protocol Team Member section.**
7. Add the amendment form as an attachment. Click **Finish**.
 1. For Newark- This is an unlocked version of your approved protocol with changes incorporated.
 2. For Legacy Rutgers- This is your protocol with changes highlighted and a cover letter.
 3. For RWJMS- This is a cover letter or memo.
8. Click **Submit**.
9. Click **OK** to agree to the statement and submit for review.

For #1 Protocol Title remove the old protocol number (if that is what is showing) and replace with an appropriate title for the protocol #2 Short Title: Use an abbreviated title, not the old protocol number.