Topaz Electronic Protocol Development Information on Filling out the UConn Health IACUC Protocol Forms

UCONN HEALTH

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

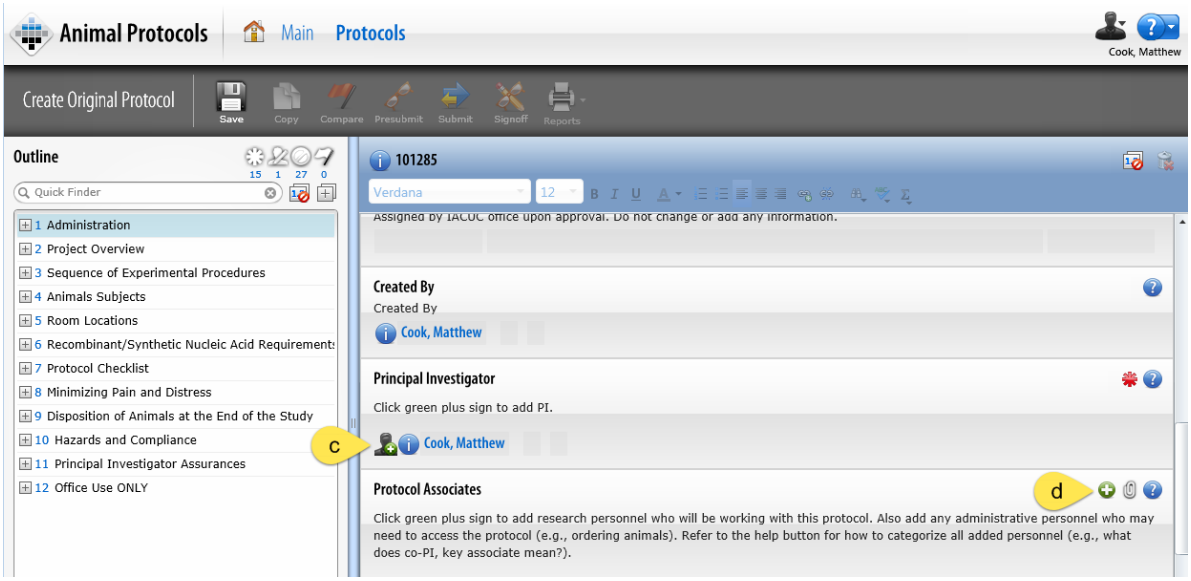
Topaz Electronic Protocol Development
Information on Filling out the UConn Health Protocol Form

Companion Document to "Topaz Electronic Protocol Development Instructions for Researchers"

****

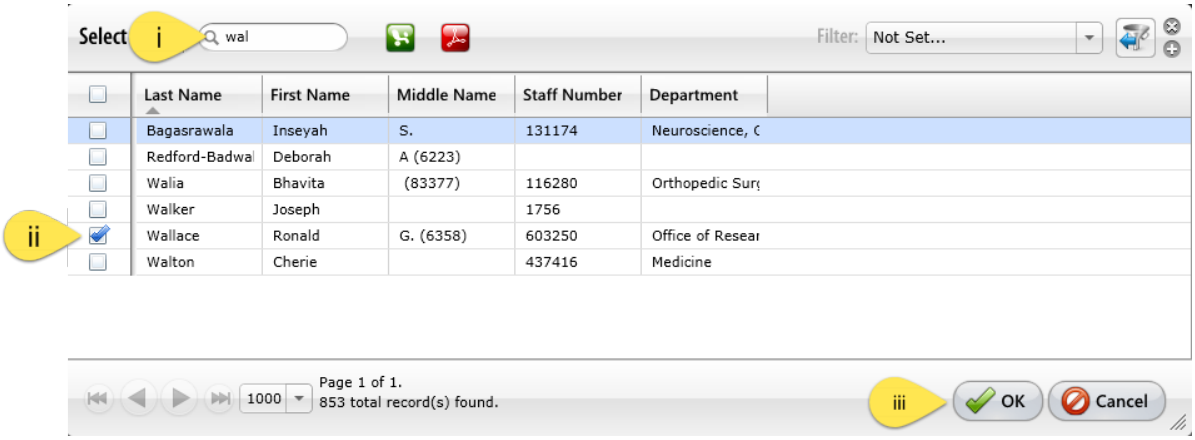
THE IACUC ANIMAL CARE AND USE PROTOCOL FORM

1. Administration Section
   - **a. Title (Required)**
     Enter the title of your protocol. Do not use the enter button when you are finished. Use the TAB key or click on the save button instead.
   - **b. Protocol renewal information (Required)**
     Select if this submission is a new protocol or a 3 year renewal. If it is a 3 year renewal, place the old IACUC number in the field provided.
   - **c. Principal Investigator (Required)**
     If you are **NOT** the PI, select the PI now. Click on the type in the last name of the PI in the Quick Finder search box Quick Finder. Click on the row of that person to select him/her.
   - **d. Protocol Associates**
     One of the first items you will come to is entering personnel. To add personnel, click .

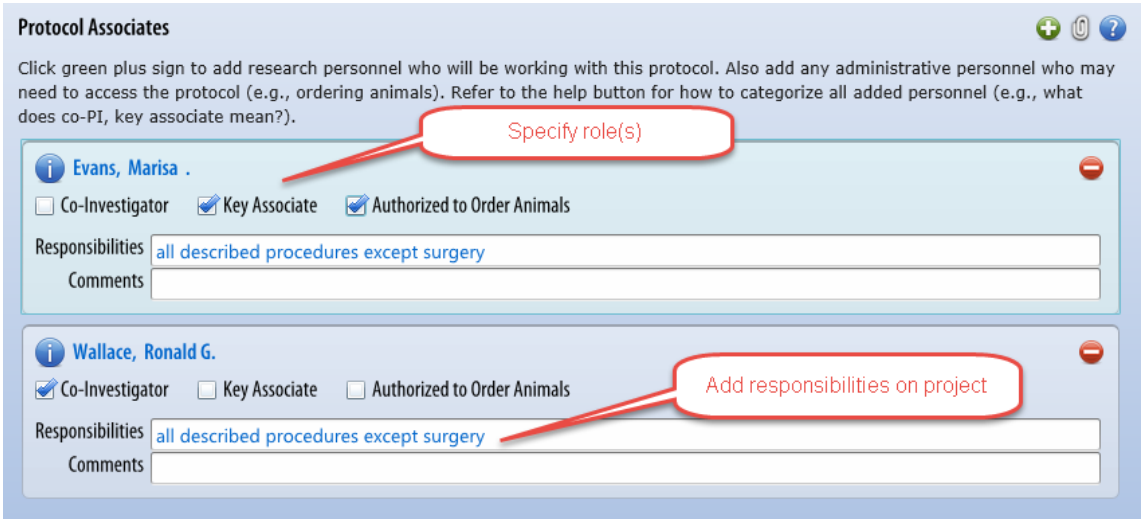


A Select Staff grid dialogue box appears.

i. Entering the person's name (first or last) in the Quick Finder box.
ii. Select the individual by checking the box to the left of their name. **DO NOT DOUBLE CLICK ON THE PERSON'S NAME**.
iii. Repeat steps i and ii.
iv. When you have selected everyone you need, click the OK button OK.



The individuals will then be added as Protocol Associates. For each protocol associate, indicate their role and responsibilities. Individuals can be designated in a co-investigators, key personnel, and/or authorized to order animals, if desired. These roles gives them different rights to the specific protocol.



Co-investigators- will have the same rights as a PI. They will be able to create and edit protocols, *if they have been authorized by the IACUC Office*. Simply making them co-PIs on your protocol form is not enough. However, if they do have the Research Protocol Writer Access or PI rights to create protocols, they will NOT be able to edit your protocol unless you check the co-investigator box.

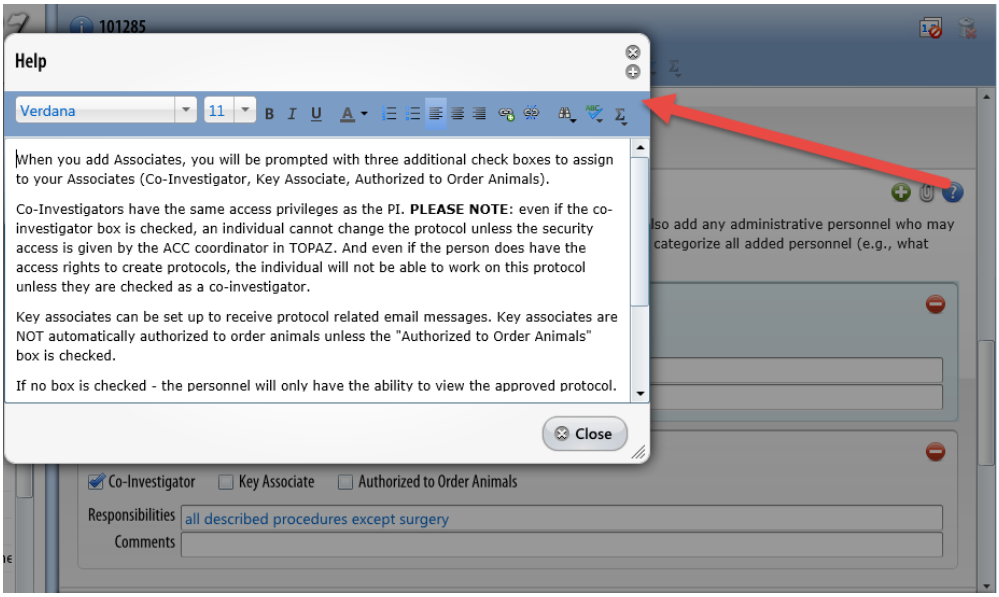
Key personnel- will be sent all associated emails generated by the system along with the PI.

If neither Co-investigator nor Key personnel is checked - individual will be able to view approved protocols on which they are listed. Topaz calls this other personnel.

Authorized to Order Animals – individual can order animals on the PI's behalf on this approved protocol. This can include departmental administrators and other research personnel.

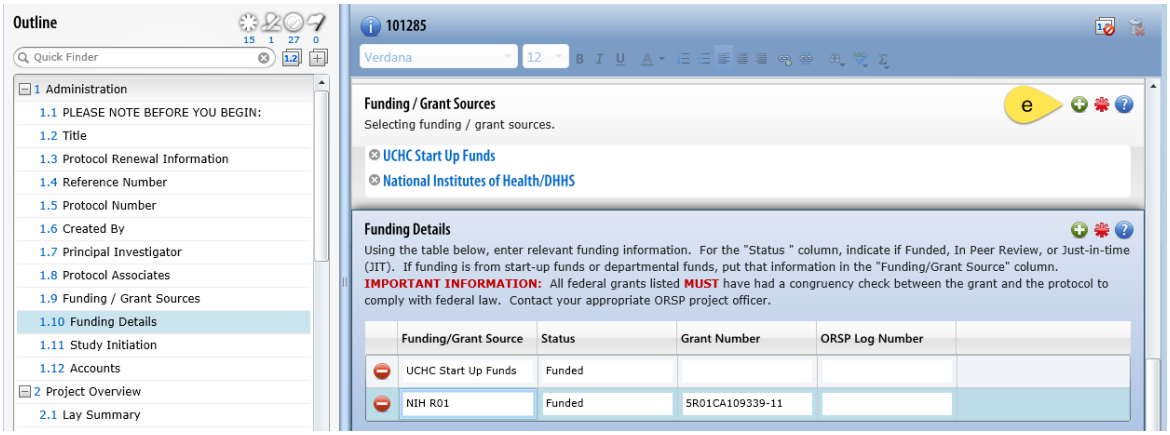
Also, put their responsibilities on the project especially the activities they will be performing on live animals. If their only role is ordering animals, you do not need to put in additional responsibilities if they are not handling or using live animals.

If you forget this, not to worry. If you see a in a question box, that means additional information regarding that question is available for you to look at. A help window will generate (show below) with the information.

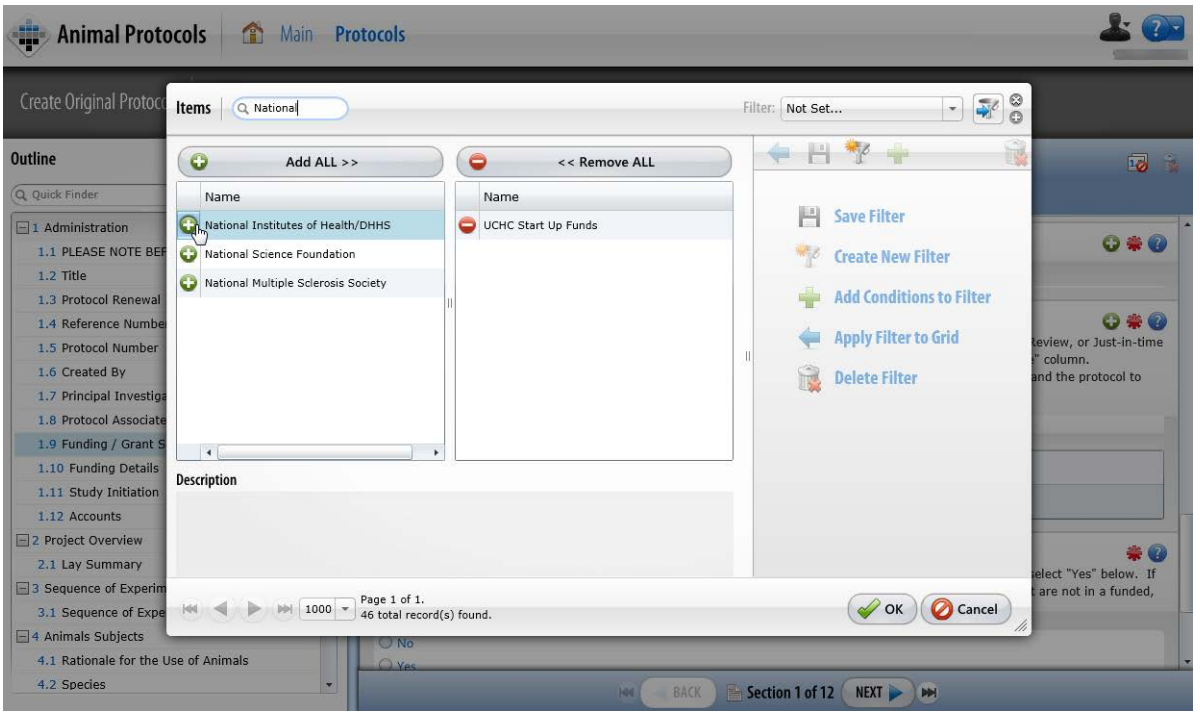


e. Funding/Grant Source (Required)

You will need to select the funding source. Click  .

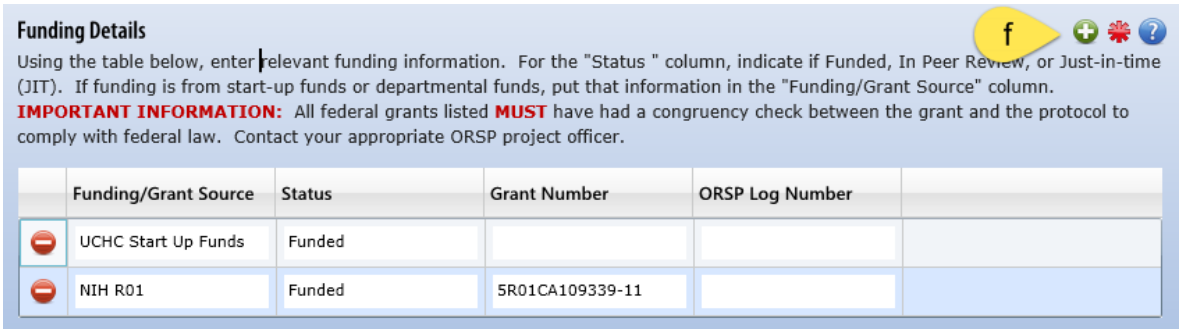


This will generate a list from which to choose. Clicking on the Name box will sort them in ascending or descending order. It is best to enter a few letters or words in the Quick Finder box to locate items. Select your funding source(s) by clicking on the green circle with the plus sign to move the source into the right column. Repeat for other sources. Use  to remove a source. Click the OK button after selecting all sources. If you don't see your selection, you can call the IACUC office (679-3429) and ask to have the source added to the list or you can select "other".



f. Funding Details (Required)

Click to add a row. Click to remove a row.



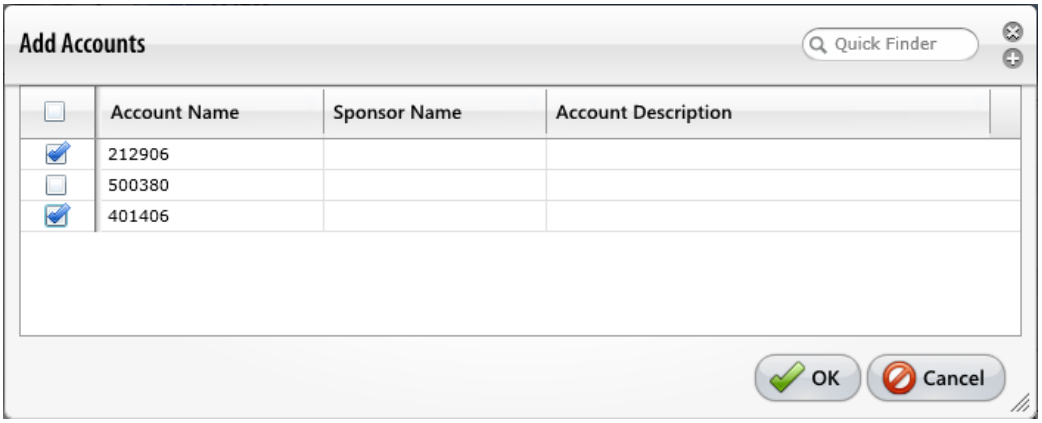
In each row, put the name of the funding source that you entered in section (f) above and include the status, grant number and ORSP/SPS Log Number. For the "Status" column, indicate if Funded, In Peer Review, or Just-in-time (JIT). If funding is from start-up funds or departmental funds, put that information in the "Funding/Grant Source" column. Note you **MUST** enter either the Grant Number or the ORSP/SPS Log number in the table.

g. Study Initiation

You need to inform the committee if any animal work will be done prior to peer review. If you are going to start your work before you have funding, you need to select **YES** and then provide the name of a potential scientific reviewer not associated with the protocol. If you are not going to start your work before you have funding, you need to select **NO**. If you are obtaining funding from an agency that does not perform peer review (e.g., departmental funds, pharmaceutical companies, etc.) you need to select **YES** and then provide the name of a potential scientific merit reviewer not associated with the protocol.

h. Accounts

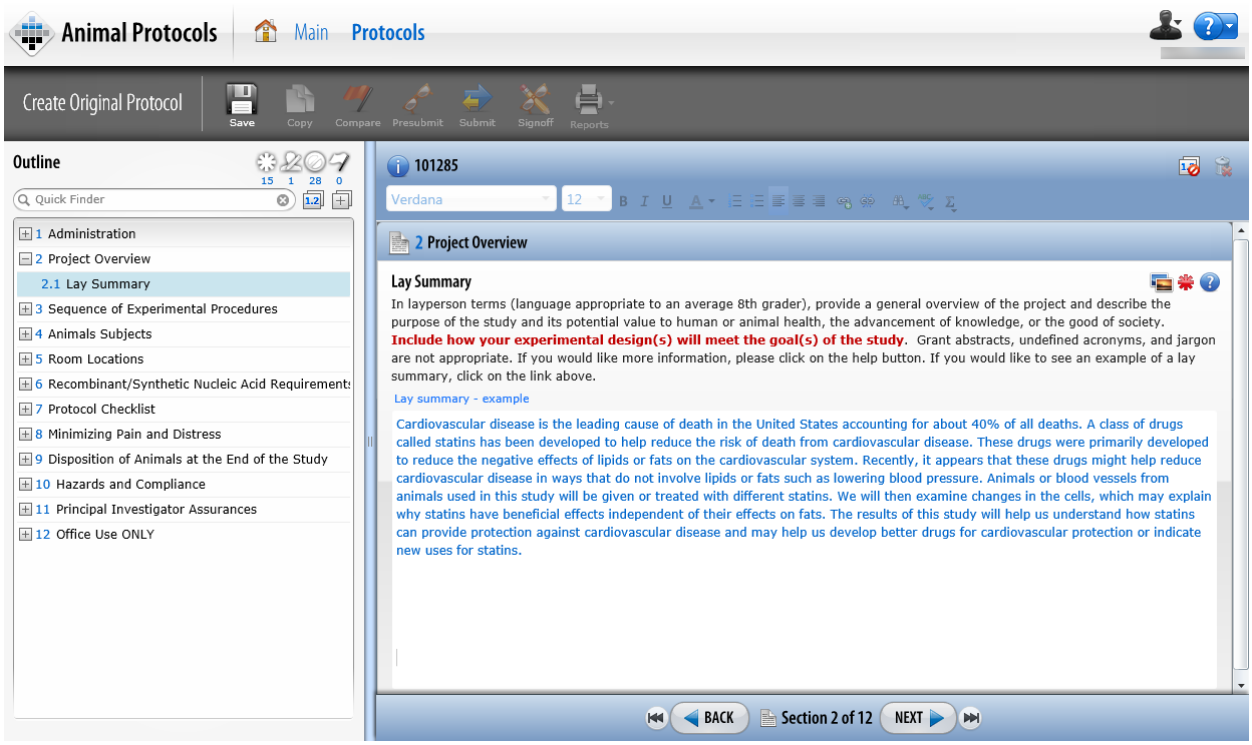
You will need to select what Banner Account(s) is/are associated with this work. You will need to click on icon to add your account(s). When you do this, a list of Banner Accounts will



generate. You will need to select the Banner Account(s) to use by clicking on the checkbox to the left of the account number. If an account is not listed, you will need to contact Center for Comparative Medicine (x2303) to get it added.

2. Project Overview (Required)

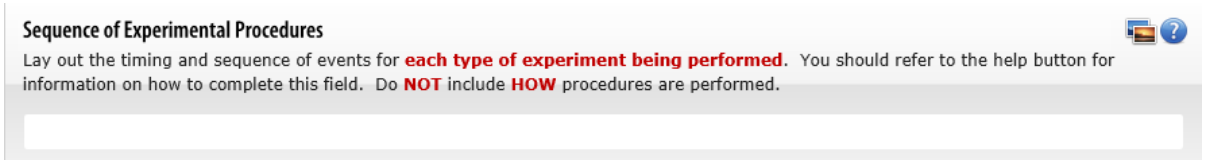
You will need to give a brief overview of your project which describes what you are doing, the purpose of the study, and its potential value to human or animal health, the advancement of knowledge, or the good of society. This has to be done in lay terms; that is, terms an average 8th grader would understand.



If you are unsure of what to write, information can be found in the help icon . Or, to see an example of what is expected, click the Lay Summary – Example hyperlink in the question.

3. Sequence of Experimental Procedures

a. Type in a timeline of experimental procedures, for example:



At day 0, animals will be injected with substance X;
At day 10, animals will be injected with substance Y;

At day 34, animals will have surgery;
At day 36, animals will undergo behavioral tests A and B;
At day 37, animals will have a tail bleed for testing;
At day 38, animals will have x-ray imaging;
At day 43, animals will be euthanized, tissue collected and analyzed.

4. Animal Subjects

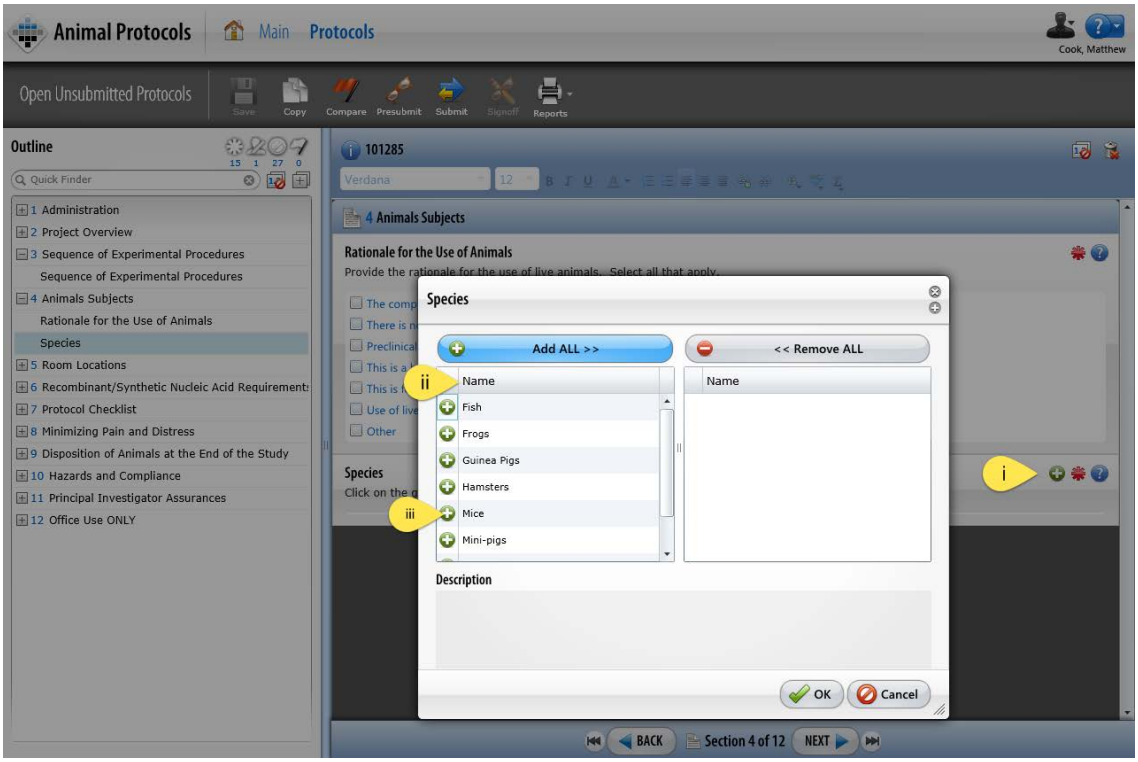
a. **Rationale for the Use of Animals (Required)**

You must provide a rationale of why you are using living animals. Select whatever box(es) are appropriate. If you chose "other", a question box will generate and you will need to explain what the other rationale is. **PLEASE NOTE**: if you have selected multiple species, you will have to answer this question for each species.

b. Species (Required)

You will have to select the species to be used.

i. Click on icon and a list of potential species will generate.
ii. Click the Name row to sort the species.
iii. Click on the green circle with the white + to select your species. Do **NOT** click on the species itself; you **MUST** click on the symbol.



c. **Rationale for the Appropriateness of the Species to be Used (Required)**

You must provide a rationale of why you are using the species you chose. Select whatever box(es) are appropriate. If you chose "other", a question box will generate and you will need to

explain what the other rationale is. **PLEASE NOTE:** if you have selected multiple species, you will have to answer this question for each species.

d. **Strain/Stock/Breed**

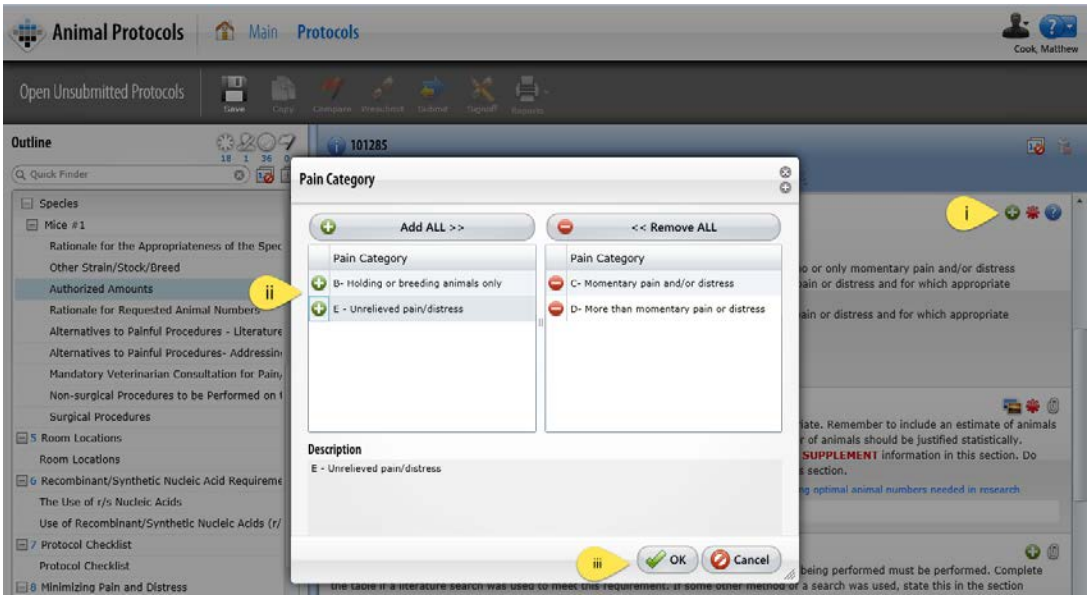
Type in the Strain/Stock/Breed(s) that you plan to use in your study.

e. **Authorized Amounts (Required)**

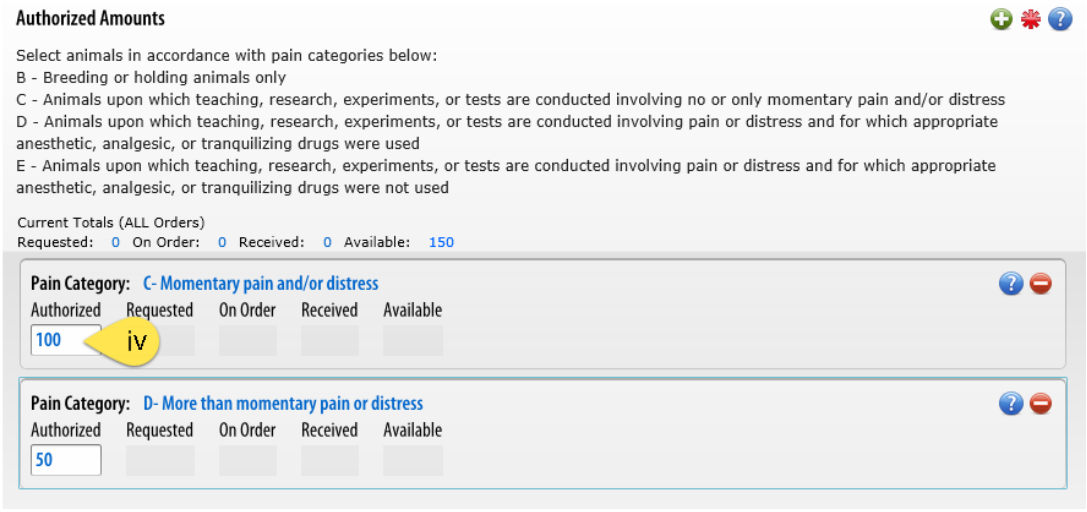
i. Click on ⊕ icon and a list of pain categories appears

ii. Select the ⊕ to the right of the pain categories, to add those involved in your study

iii. Click OK button

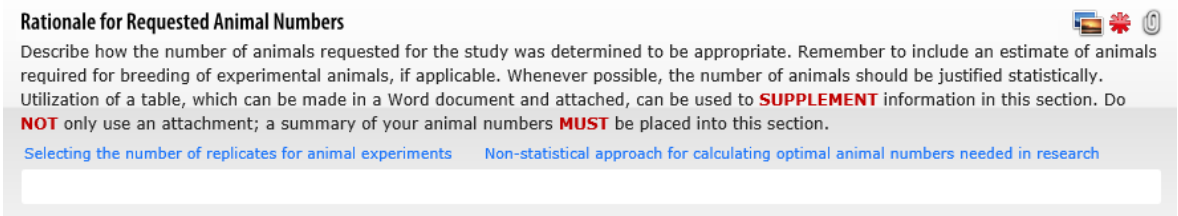


iv. Enter the Number of Animals Required that you are requesting authorization for in each Pain category



f. **Rationale for Requested Animal Numbers (Required)**

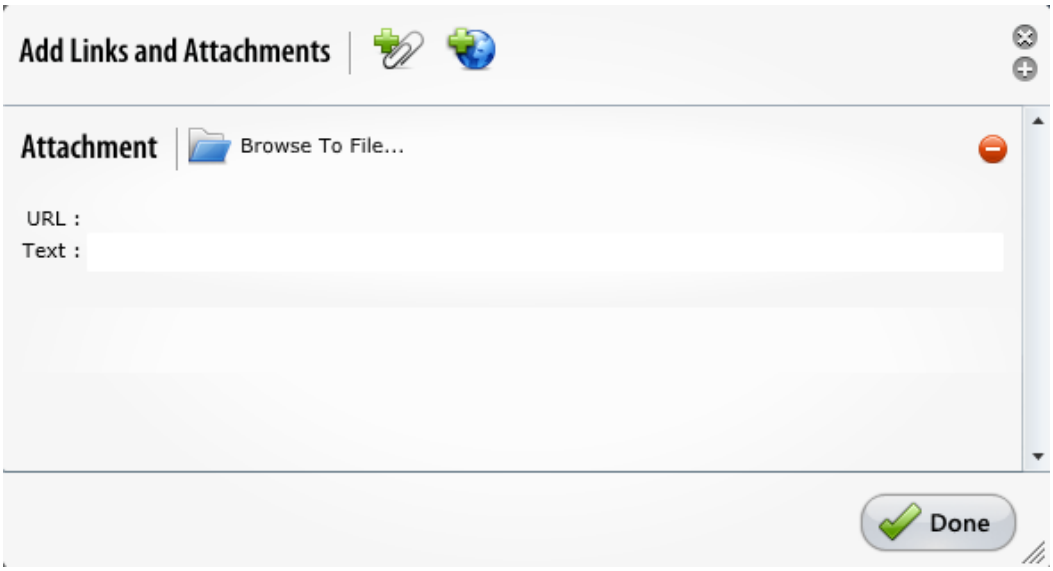
You must provide a justification for animal numbers; this is required in the regulations. This is a free-text field that you can copy and paste into if you wish to.



PLEASE NOTE: the easiest way to copy and paste information in any section is to copy text from your document (Word, etc.) and paste it into NotePad or WordPad to remove the formatting. Then paste from NotePad or WordPad into Topaz Elements.

You can also attach additional information. For instance, say you have a table which lists your experimental parameters and animal numbers requested. Tables will NOT copy into free text fields. You can easily attach your records by clicking on the paperclip icon .

When you do this, a dialogue box will generate. Click on the paperclip to attach documents. In the text box, type the name of the document. Attach it by using the "Browse to File…" icon. Repeat if you want to attach additional files. Click the Done button.



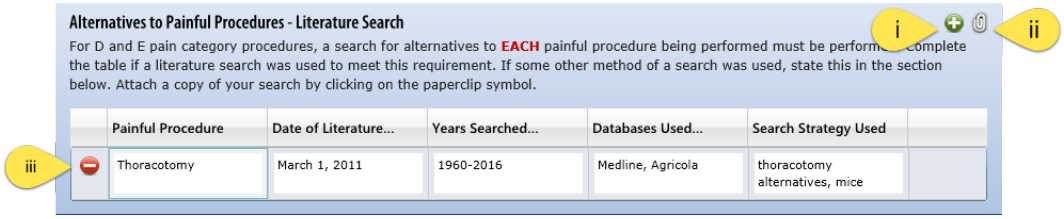
g. Alternatives to Painful Procedures- Literature Search

If you are using pain/distress categories D and/or E, you **MUST** complete the alternatives to painful procedures section. Most people do a literature search to fulfill the search requirement. If you perform a search, then you need to fill out the table in this section.

i. Click on icon to add a row. Each painful procedure **MUST** have its own row. Complete the table with the information requested including Date of Literature, Years searched, databases used, and search strategy used.

ii. Attach a copy of your search by clicking on the Paperclip icon .

iii. If you make a mistake and need to clear a row, Click to remove a row.



h. Alternatives to Painful Procedures

Even if you used a literature search as your alternatives search method, you **MUST** complete the section and type your response below the question text. If you did something other than a literature search, this section must describe what you did (e.g., consultation with an expert in the field, standard practices in a reference book, etc.). **PLEASE NOTE**: if you did something other than a literature search, you must provide all pertinent information so the IACUC can determine if your search method was adequate (e.g., qualifications of an expert and when the discussion happened and what was discussed). You also need to discuss the 3R's of replacement, reduction, and refinement. If you are unsure of what to write in this section, click on the example hyperlink provided and look at the example.

i. Pain/Distress Category D and/or E

If you are using pain/distress category D and/or E, you **MUST** provide the name of the veterinarian you consulted with during the **PLANNING** of the experimental procedure(s). This does not have to be the UConn Health attending veterinarian; however, if it some someone other than the UConn Health attending veterinarian, you must provide contact information.

j. Non-surgical Procedures

You need to select what non-surgical procedures you are going to perform to the species.

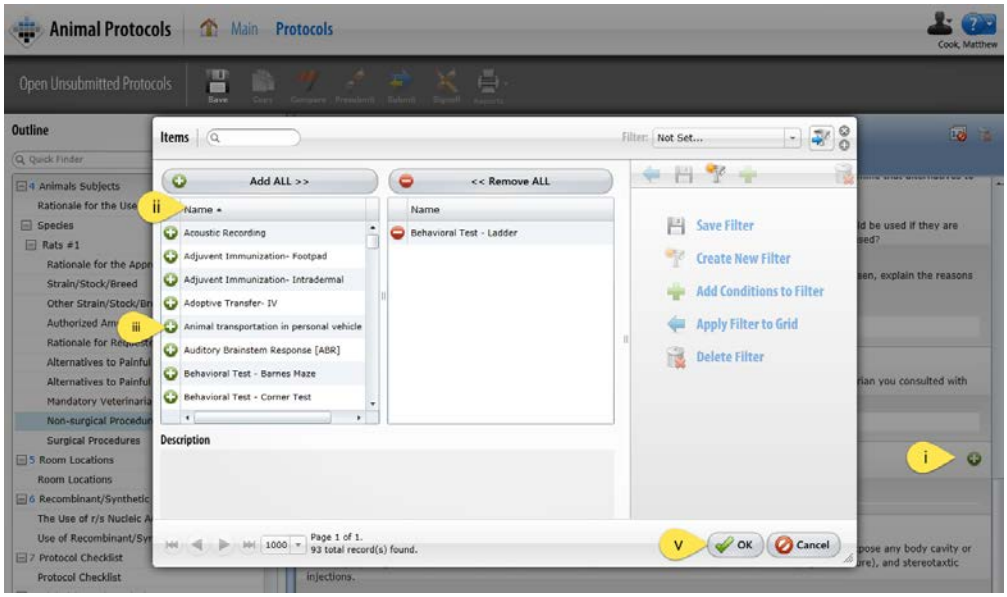
i. Click on icon and a list of potential procedures will generate.

ii. Click the Name column to sort.

iii. Click on the green circle with the white + to select your species. Do **NOT** click on the procedure itself; you **MUST** click on the symbol. If your procedure is not listed, then click the "other" button.

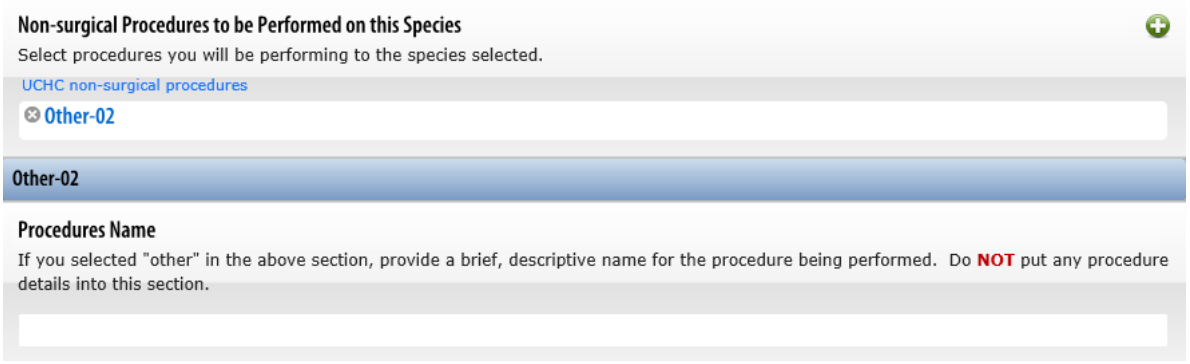
iv. Repeat this process for every non-surgical procedure you will do to the animals.

v. Click OK button



k. Procedures name

If your non-surgical procedure is not listed and you had to select "other", please provide a brief descriptive name in this section.



l. Procedure Description

When you get down to procedure descriptions, you have some options. You can check our non-surgical procedures that are on the web to see if your procedure is there by clicking on the link shown below. We have some procedures written out- you can copy them and paste them into the procedures description section (red arrow) and modify as required. If your procedure is not on this list, then you will have to describe the procedure. **The important point is to be complete**. If you are injecting cells or other things, be sure to include how many, in what

volume, what route, etc. If you expect that the procedure may involve significant morbidity or mortality, state here what is expected.

m. Drug/Chemical Administration and Drug/Chemical and Use of Avertin

If you are using any drugs in your procedure- anesthetics, analgesics, experimental compounds, etc. then you **MUST** check yes in this section. When you check yes, a table will generate. You will need to fill out the table **COMPLETELY**. In addition, if you are requesting to use 2,2,2-tribromoethanol (Avertin), then you must complete the question on the justification for the use of this non-pharmaceutical grade compound.

n. **Animal Monitoring (Required)**

Specify how the animal will be monitored post-non-surgical procedure for this procedure. This is where you inform us what clinical signs for which you are going to assess your animals and how frequently you will be doing this. Check off all boxes that apply. One question will be generated for each item checked: How frequently are you going to check you mice for that parameter. You need to answer each question. At least one check box **MUST** be checked. If you check "not applicable", then you will have to state why it is not applicable to your protocol.

o. Surgical Procedures

i. **Are you performing surgery** - This is a mandatory question which must be answered in order to submit the protocol for review. Simply check the YES box or the NO box. If you check the NO box, no further questions will generate. If you check YES, you will need to continue.

ii. **Type of surgery** - You will need to select the type of surgery for each surgical procedure you are performing- major survival surgery, minor survival surgery, and/or non-survival surgery. If you do not know what type of surgery you are performing, click on the help icon and a help window will generate and show you further information.

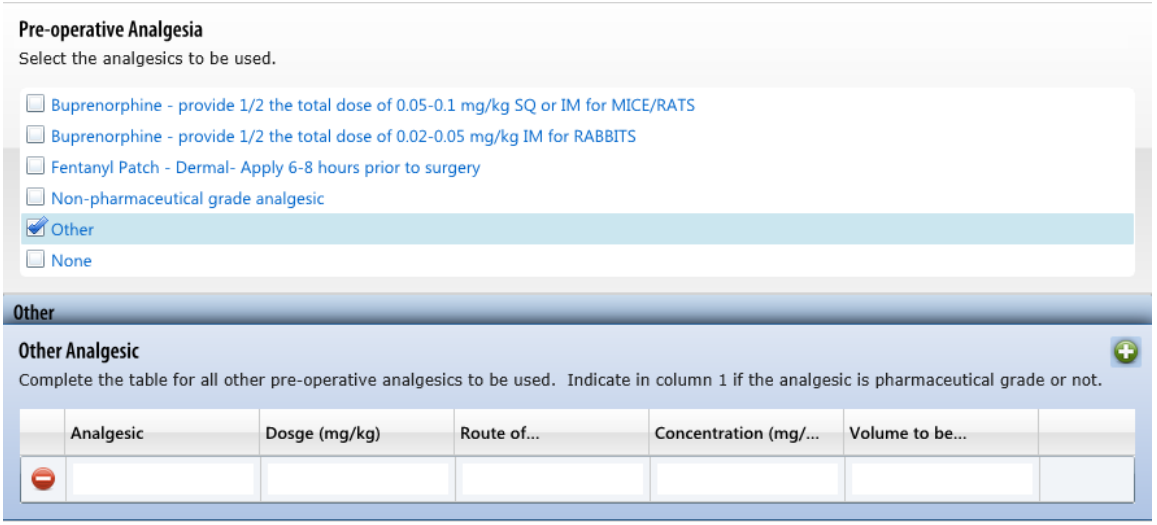
If you select that you are performing major survival surgeries, it will ask you if you are performing multiple major survival surgeries and you will click either yes or no. If you are, you will need to state the justification and time interval between the surgeries.

iii. **Surgical Procedures** - Once you select the type of surgical procedure you are doing, you will have to select the procedure itself. Click on icon to add your procedure. A list of procedures will generate. Click the Name column to alphabetize or use the Quick Find search box. Click on icon the left of the procedure. Repeat for additional procedures. When through, click on the OK button. If your surgery is not there, select "other". You will need to select **EACH** surgical procedure you are performing and answer the questions that will generate for each procedure. If none of your procedures are listed, select "other-1", "other-2", etc. using a separate "other" for each procedure.

iv. **Surgical Procedure Name** - When you select your procedure, it will ask for a name. This should only be answered if you had to select an "other" as a procedure. Provide a brief descriptive name for the procedure.

v. **Pre-operative Preparation** - Next you will to describe the pre-operative preparation and pre-operative analgesics to be used. Describe the pre-operative preparation in detail in the section. If your surgical procedure is on our list of surgical procedure descriptions (blue arrow), you can copy and paste the relevant information from our web document to this protocol form (yellow arrow). **BE COMPLETE** and describe **ONLY** the pre-operative preparation of the area, the surgical instruments, the surgeon, and the animal. Operative details, e.g., how the procedure itself is performed, comes later.

vi. **Pre-operative Analgesics** – Select the pre-operative analgesics. If you choose "other", then you will have to detail the analgesic to be used in an addition question. Click on  icon to add a row to the table. Complete the table for the analgesic to be used. If you choose "none" for pre-operative analgesia, then you will need to justify not using pre-operative analgesics in an additional question that will generate.



vii. **Anesthesia** – Select the choice of anesthetic regimen. Check the boxes which details what you will use. If you select other, you will need to add it as described previously. If you choose Avertin, you will have to justify its use.

viii. **Operative Details** - This is where you put all the details of the surgical details itself. If your surgical procedure is listed in our collection of details on the web, then you can copy the information and paste it in here, modifying the document as required. This section **MUST** be complete. You **MUST** include the methods and materials for ligatures and wound closures. Include how instruments are sterilized between animals.

ix. **Post-operative Care** - In this section, you must include information of how you are going to monitor for normal recovery from anesthesia and the provision for any supportive

care. This should be the immediate post-operative period (e.g., first 24 hours). In addition, include when suture/wound clips will be removed.

x. Post-operative Analgesics - You need to describe the use of post-operative analgesics and this is done exactly as described in (h) above. The only addition is that you will also have to state for how long and how frequently the analgesic will be administered.

5. Room Location

You must select the room location(s) where the non-surgical and surgical procedure described in section 4 of your protocol will be performed.

i. Click on  icon, the list of room locations appear.
ii. Click the Name column to sort the list alphabetically.
iii. Scroll through the list or use type in the Quick Find to search for your locations.
iv. Click on the  icon to the left of the item. Do **NOT** click on the name itself; you **MUST** click on the symbol. If the room location(s) is not in the list, please call the IACUC office (x3429) to get it added.
v. Repeat this process for additional rooms, if needed.
vi. Click OK button.

6. Recombinant/Synthetic Nucleic Acid Requirements (r/s NA)

a. **Use of Recombinant/Synthetic Nucleic Acids (r/s NA) in Animals** – Check all that apply.

b. Transgenic and Gene Targeted (Tg/GT) Animals

This is a mandatory question- it must be answered in order to submit your protocol for review. If you select no, you are finished with this section. If you select YES, then a series of questions will be asked.

PLEASE NOTE: this is a complicated section so you are going to have to **READ ALL INSTRUCTIONS CAREFULLY**.

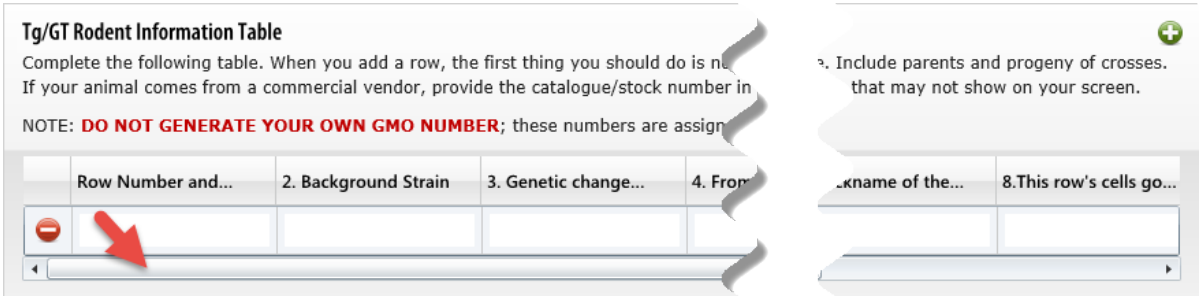
ALSO PLEASE NOTE: if you are using a Tg/GT animal that has not been registered, you will need to register it, but this does not have to happen prior to protocol submission or approval. However, your animal cannot be made until you complete this section, which you can do as a modification to the protocol at a later date. If you have any questions with this section, you should contact the BSO at rwallace@adp.uchc.edu.

c. Tg/GT Information Table

If you are using Tg/GT animals and you answer yes, this table will generate. You will need to complete the table. You will need to click  symbol once for each Tg/GT line you will be using in your protocol- this will generate a row in the table for each Tg/GT line.

PLEASE NOTE: there is an internal scroll bar in the table that are hard to see (red arrow). Not all columns show up when you view this in your computer screen, you will

have to use the internal scroll bar to show all columns. You will need the information that is listed in section 6.1.2.3 in order to complete this table.



i. Column 1- Row Number and Tg/GT Line name
   Put in the row number (e.g., first row in table would be 1, second row in table would be 2, etc.) and the common name for the Tg/GT line
ii. Column 2- Background strain
   Enter the background strain of your Tg/GT line
iii. Column 3- Specific genetic modification
   Indicate what kind of modification (insertion, deletion, point mutation, etc.) of what gene/sequence is in the Tg/GT animal
iv. Column 4- From where was the animal supplied
   State who sent the animal and their affiliated institution. If received from a domestic commercial vendor, state the vendor and the catalogue (stock) number of the Tg/GT line.
v. Column 5- UCHC GMO number (if exists)
   If you have already been assigned a GMO number for this Tg/GT line, enter the GMO number here. If you do not know the GMO number, leave blank.
vi. Column 6- If no GMO number, put regulatory category (X, Y, or Z below)
   Enter X, Y, or Z based on the information given in "Tg/GT Animal Regulatory Issues" below the table.
vii. Column 7- Animal line in column 1 will be crossed with
   If the Tg/GT line in column 1 will be crossed with another Tg/GT line (which also must be listed in the table), simply add the row number of that animal line (e.g., "row 3").
viii. Column 8- Cells from animal line will be implanted into
   If cells from this Tg/GT line will be implanted into another animal, list the strain (if not Tg/GT) or the row number of the Tg/GT line of the recipient.
ix. Column 9- Animal will undergo parabiosis with what line
   If this Tg/GT line will undergo parabiosis with another animal, list the strain (if not Tg/GT) or the row number of the Tg/GT line of the partner.
x. Column 10- Where was the animal made originally
   State where the animal was originally made, if known.
xi. Column 11- Any inserted eukaryotic viral sequences? (Y/N)

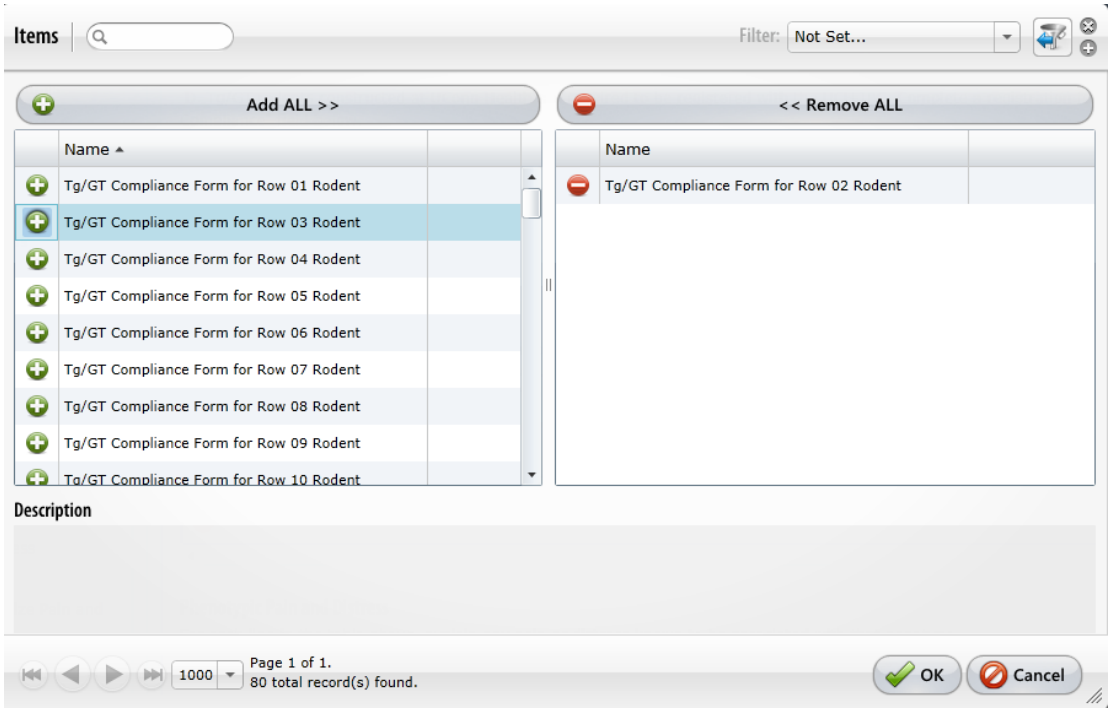
If these animals will be crossed with any other animals that are not of the same background strain or Tg/GT line, the PI must state whether viral sequences are present (Y) or not (N). If animals will not be crossed, leave blank.

d. Phenotypic Pain or Distress

You will need to state if any of the Tg/GT lines listed are known to be associated with any phenotypic pain and/or distress.

e. Tg/GT Rodent Compliance

This is where you start the registration process for any Tg/GT animals that need to be registered here at the UCHC. This generally includes all Tg/GT mice that are produced in the GTTF and any Tg/GT animal that is coming from a foreign institution or agency. Other rodents may require registration- if you are unsure, please contact the BSO at rwallace@adp.uchc.edu. You would start the registration process by clicking on the icon which will generate the row numbers from section (b) above. Click the Name column to alphabetize the list. Select the corresponding row number for the Tg/GT animal line which needs registration by clicking on the to the left the Tg/GT Row Number and then hitting the OK button. There should be a corresponding row number for each line that does not have a GMO number. **IF YOU DO NOT KNOW IF A TG/GT LINE HAS A UCHC GMO NUMBER, CONTACT THE BSO AT rwallace@adp.uchc.edu PRIOR TO STARTING THE REGISTRATION PROCESS.**



You need to answer every question that populates. If you need specific help with any question, please contact the BSO at rwallace@adp.uchc.edu.

i. **IBC Registration number**
Leave blank- once the registration is ready for approval, the number will be enter

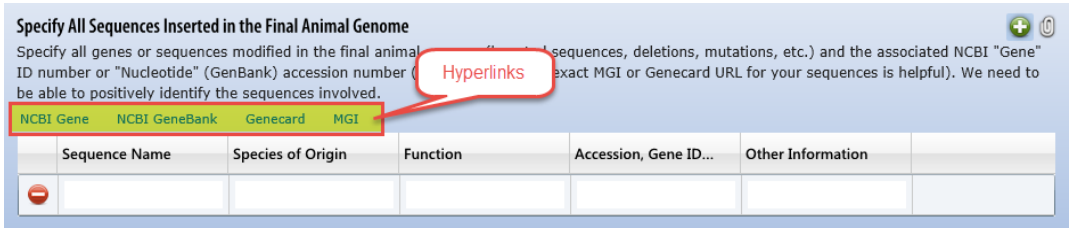
ii. **List all Grants**
List funding source, grant number, and grant title for each grant being used that is not listed in section 1 of the protocol form.

iii. **Describe Sequence of Interest**
The sequence that is being targeted or expressed must be detailed. If it is from a non-domestic source, a research article or reference describing the animal line must be provided.

iv. **rDNA Context**
A short summary about the use of the sequence of interest rDNA in the research must be given. A description of what the sequence does must also be provided.

v. **Type of genetic variation**
Describe how the genome of the animal has been changed (what has been inserted, deleted, etc.).

vi. **Specify all inserted sequences**
Create a row for each functional element of what has been inserted into the animal (e.g., promoter, protein encoding sequence, polyA sequence, loxP sites, etc.). This is done by clicking on the sign. Then you will need to complete all columns in the row with the information requested If you are unsure of the accession, gene ID number or database URL (reference to a commercially published sequence), there are hyperlinks that can help you find this information highlighted below in yellow.



vii. **NIH rDNA Guidelines requirements**
Leave blank. This information will be provided to the PI by the BSO and can be entered after this is done.

viii. **Methods of generation**
Check off the method of generation. If "other" is chosen, a dialogue box will generate. Provide a description of how the Tg/GT line is produced in the text field. If viral vectors are used in any of the methods to produce this line, describe them here.

ix. **Sequences from pathogenic agents**

Select yes or no. If yes is selected, a dialogue box will generate. Provide a description of what organisms, viruses, and/or toxins the sequences originate from.

x. **Sequences that have oncogenic potential**

Select yes, no, or unknown. If yes is selected, a dialogue box will generate. Provide a description of any known connection to cancer or other potential harm from the gene products or their absence.

xi. **Viral vectors**

Select yes or no. If yes is selected, a dialogue box will generate. Provide the identification of the viral vector and the vector production system.

xii. **Foreign/exogenous sequences**

Select yes or no. If yes is selected, a dialogue box will generate. Provide a description of proteins or other gene products that will be produced.

xiii. **Tg/GT associated pain and distress**

Select yes, no, or unknown. If yes, a dialogue box will generate. Provide a description of any pain or distress known to be associated with this genotype.

7. Protocol Checklist **(Required)**

This is where you would state if you may be doing anything that would require approval due to being an exemption to the USDA AWRs or a deviation from the standards in the *Guide for the Care and Use of Laboratory Animals*. Simply check all boxes that may apply. **AT LEAST ONE BOX MUST BE CHECKED**. You would need to answer all questions on any question that generated based upon whatever box(es) you checked.

If death as an endpoint is selected, a dialogue box will generate. You must provide a scientific justification for the use of death as an endpoint.

If animals used in this protocol will develop illness or disease, a dialogue box will generate. You must provide a description of the illness, disease, or physiologic deficits that may develop in the animals.

If animals are going to be deprived of food **OTHER THAN PRE-OPERATIVE SURGICAL PREPARATION**, a dialogue box will generate. You must provide a description of the deprivation and a justification for depriving animals of food for >24 hours.

If animals will have food/fluid restrictions, dialogue box will generate. You must provide a description of the deprivation and a justification for the restriction.

If it selected that a paralytic/neuromuscular blocking agent will be used on an unanesthetized animal, a dialogue box will generate. You must provide scientific and/or veterinary justification.

If animals will undergo prolonged restraint, dialogue boxes will generate. You must describe the method of restraint to be used, the procedure to be used to IACUClimate the animal to the restraint, and the veterinary care associated with the use of the restraint.

If you selected non-standard housing, a dialogue box will generate. Common reasons for non-standard housing are given and you need to choose which you are using. Choose "other" if your non-standard housing is not in the list. A dialogue box will generate in which you must identify the non-standard housing issue and a justification.

If you selected that your animals will not be given species-specific enrichment, a dialogue box will generate. You must provide a justification for not using enrichment.

If you selected that animals will be uniquely identified, a dialogue box generates in which you can select what method(s) of identification will be used. If none are on the list that generates, select "other". Another dialogue box will generate in which you will describe the identification method to be used.

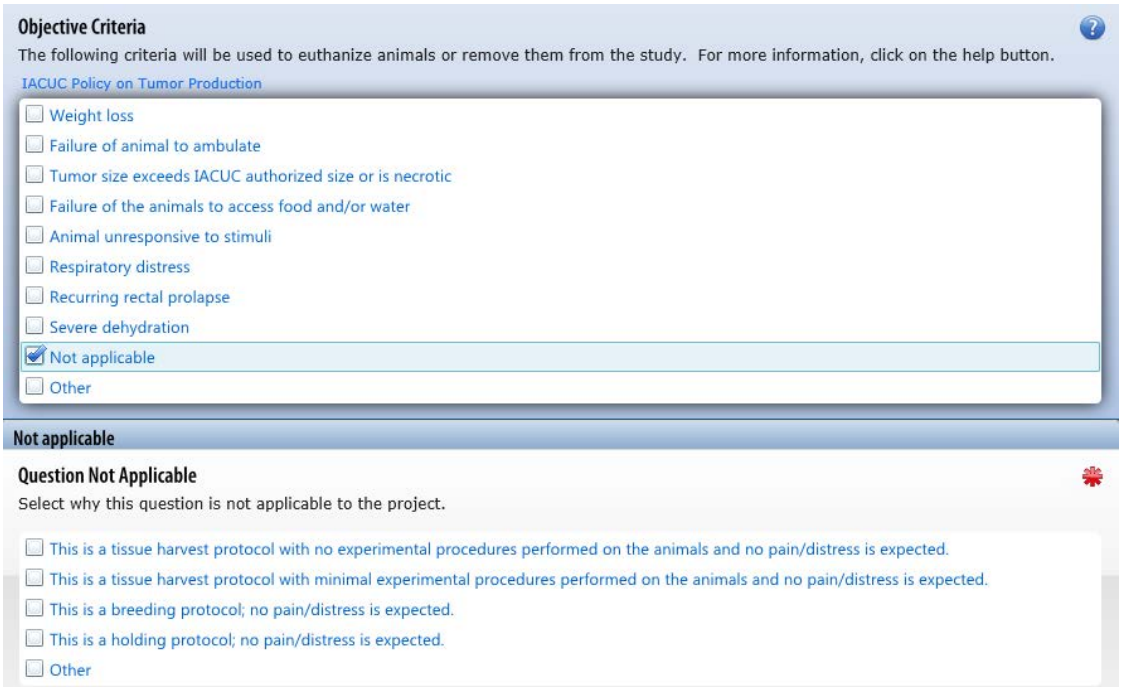
If you are housing animals outside the central animal facility, you will need to describe where you will be housing the animals and provide a justification for housing animals outside the central animal facilities.

If you check that a special diet or water will be used, a dialogue box will generate. You must describe the manipulated or special diet or water to be used with the animals.

If you state that cells lines derived from, or passaged through, rodents will be used, a dialogue box will generate asking you if the cell lines have been tested for pathogens. You must answer yes or no to this question.

8. Minimizing Pain and Distress
    a. **Objective Criteria (Required)**

    Select all that apply. If you select "not applicable", you are going to have to state why it isn't applicable. This tells us when you are going to euthanize animals if their pain/distress is too great. If you select "other", then you will have to describe what criteria you will be using.



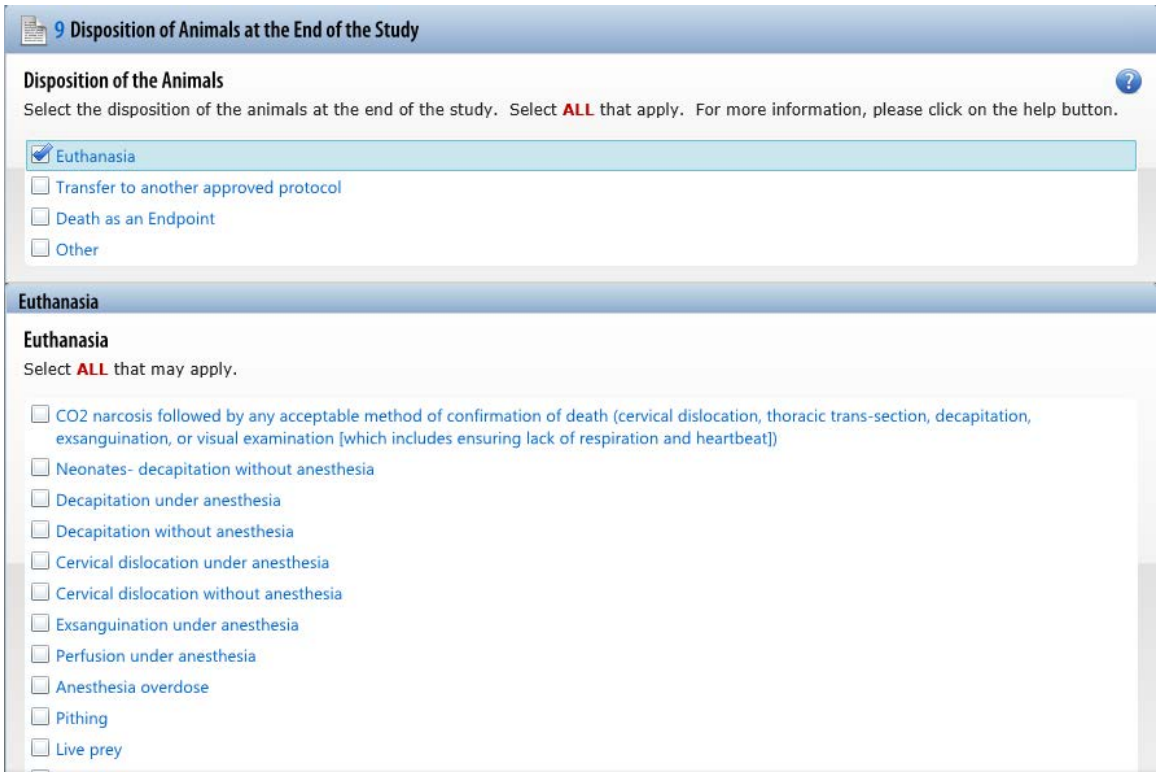
b. **Procedures Used to Minimize Pain and Distress (Required)**

Select all the procedures that apply which are used to ensure that discomfort and injury to the animals will be limited to that which is unavoidable in the conduct of the study. If you select "other", then you will have to describe what procedures will be used. If you select "not applicable", you are going to have to state why it isn't applicable.

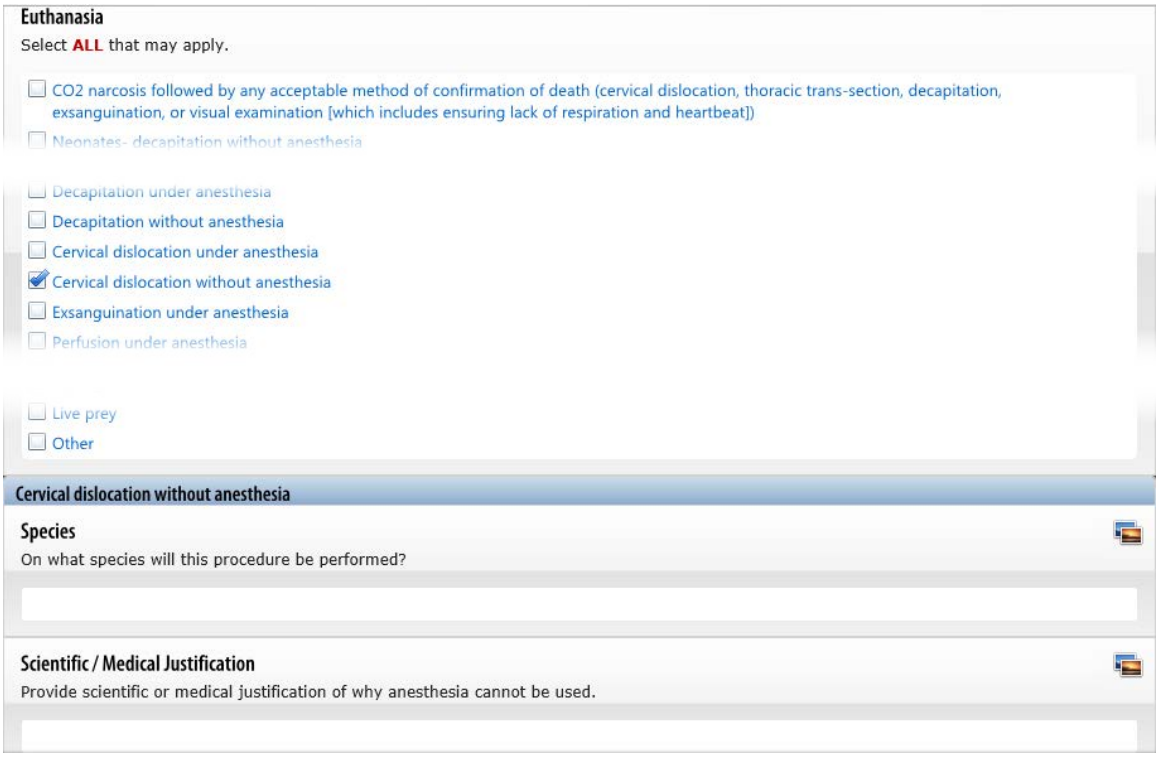
NOTE: "Species specific enrichment will be used" should always be checked unless you are not using it. If you are not using it, you need to specify that you are not using it in section 7 also.

9. Disposition of Animals at the End of the Project

Select all boxes that describe what the disposition of your animals will be at the completion of your study. Additional questions will appear. For example, if you select euthanasia, you will be asked to state what method of euthanasia you will use.



If you choose a method of euthanasia that needs scientific justification, you will be asked to provide it. For instance, if you choose cervical dislocation without anesthesia, you would see the following. You would have to justify using this method of euthanasia (red arrow). All euthanasia methods will ask what species it will be performed on.



10. Hazards and Compliance

a. **Questions about the use of isofurane/other anesthetic gas use, aldehyde, imaging using ionizing radiation, lasers, and physical hazards.**
Answer the Yes/No questions. If yes, additional questions may appear which also must be answered. You may also need to modify prior sections of your protocol as mentioned in the decision tree of questions based on responses to the various hazards. Every protocol is reviewed for potential hazards and if you have answered no, you may still have to account for the use of an agent that reviewers find to be hazardous.

b. **Biological Hazards, Chemical Hazards, and/or Radioactive Materials**
If you answer YES, then questions will generate which you must complete. Every protocol is reviewed for potential hazards and if you have answered no, you may still have to account for the use of an agent that reviewers find to be hazardous.

i. **Hazard List** – If you select yes, the first thing you will need to do is to identify your hazard. Click on icon to generate a list of known hazards. Click the Name column to sort the list alphabetically. To choose a hazard, icon to the left of the hazard to add it to your list. Repeat for additional hazards if needed. Click the OK. Once you choose your hazard, it will appear in a list. If you make a mistake and added a wrong item to the list, click the to the left of the hazard to remove it. If your hazard is not in the list, please contact the IACUC office at (679-3429) to verify it is missing and request that it be added.

ii. **Safety Protocol Hazard Number** – For each hazard, a safety protocol must be created. You do NOT have to complete the safety protocol prior to submission, however it MUST be completed prior to IACUC approval. Enter the safety protocol hazard number associated with this hazard from the form once you create the safety protocol.

Safety Protocols:

- If your hazard list shows ONLY ONE biological agent, you will need to create a new protocol and select "SP - Single Biological Hazard Use" as the protocol form name.
- If your hazard list shows MORE THAN ONE biological agent, you will need to create a new protocol and select "Multiple Biological Agent Safety Protocol" as the protocol form name.
- If your hazard list shows ONLY ONE chemical agent, you will need to create a new protocol and select "SP-Single Chemical Agent Safety Protocol" as the protocol form name.
- If your hazard list shows MORE THAN ONE chemical agent, you will need to create a new protocol and select "Multiple Chemical Agent Safety Protocol" as the protocol form name. If your hazard list shows a COMBINATION OF BIOLOGICAL [B] AND CHEMICAL [C] AGENTS, regardless of the actual number, you will need to create a new protocol and select "Combination hazard Safety Protocol" as the protocol form name.
- If your hazard list shows radioactive materials, you need to consult with the BSO at rwallace@adp.uchc.edu

  Note: To create a Safety Protocol, go to Compliance > Animal Protocols > Create Original Protocol. The choose the form name based on the bulleted list above depending upon your unique situation.

iii. **Other Hazards** – If you chose other, describe your potential hazard in this field.

Refer to the SAFETY PROTOCOL FORM(S) at the end of this document for details on the Safety Protocol forms.

11. **Principal Investigator Assurances** **(Required)**

a. **Assurance Statements**

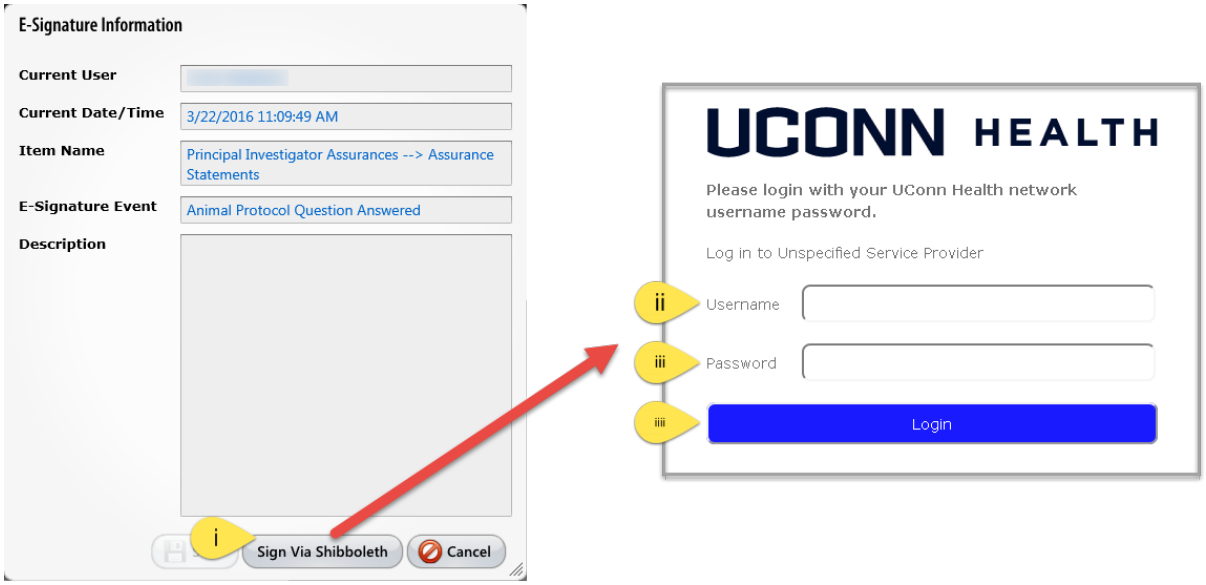
This question is not only mandatory, but will require the e-signature of the PI. If you are authoring the protocol and **ARE NOT THE PI, DO NOT COMPLETE THIS SECTION**. The PI **MUST** complete it prior to submission.

i. Read each statement and check the box.

ii. Click the Save icon.

iii. An e-signature information dialogue box will generate. Enter your username and password. Again, the PI must do this, and no other researcher should sign or it will be returned. Click the cancel button, if you are NOT the PI of the study.

iv. Click the Save button.



12. For IACUC Use only

This area is maintained by the IACUC. Do not write or change anything in this section.

SAFETY PROTOCOL FORM(S) FOR BIOLOGICAL, CHEMICAL OR RADIOLOGICAL AGENTS

SINGLE BIOLOGICAL HAZARD USE SAFETY PROTOCOL

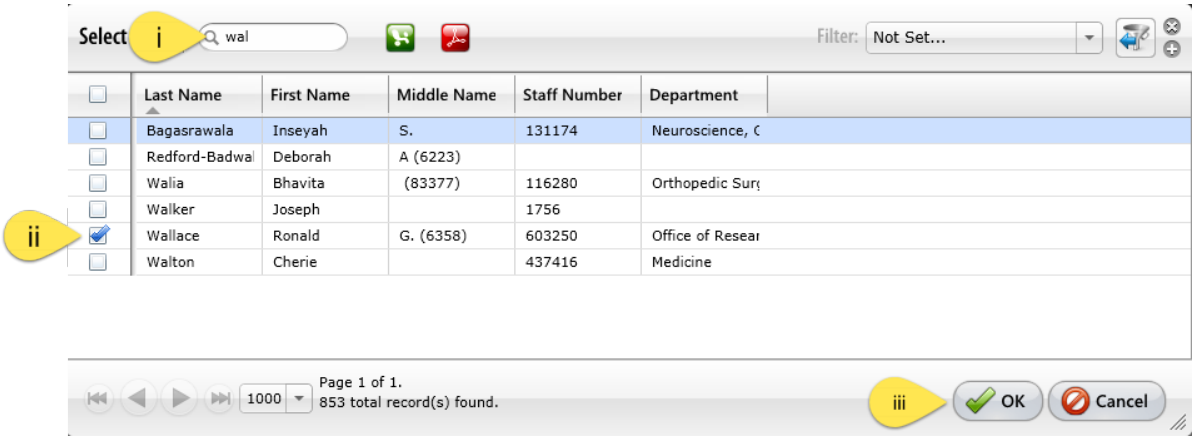
If your hazard list (Section 10 of the IACUC Protocol) shows ONLY ONE biological agent (denoted by a [B] after the hazard's name when, you will need to create a new protocol and select "SP -Single Biological Agent Safety Protocol" as the protocol form name.

For specific questions regarding the safety protocol, please contact the BSO at rwallace@adp.uchc.edu.

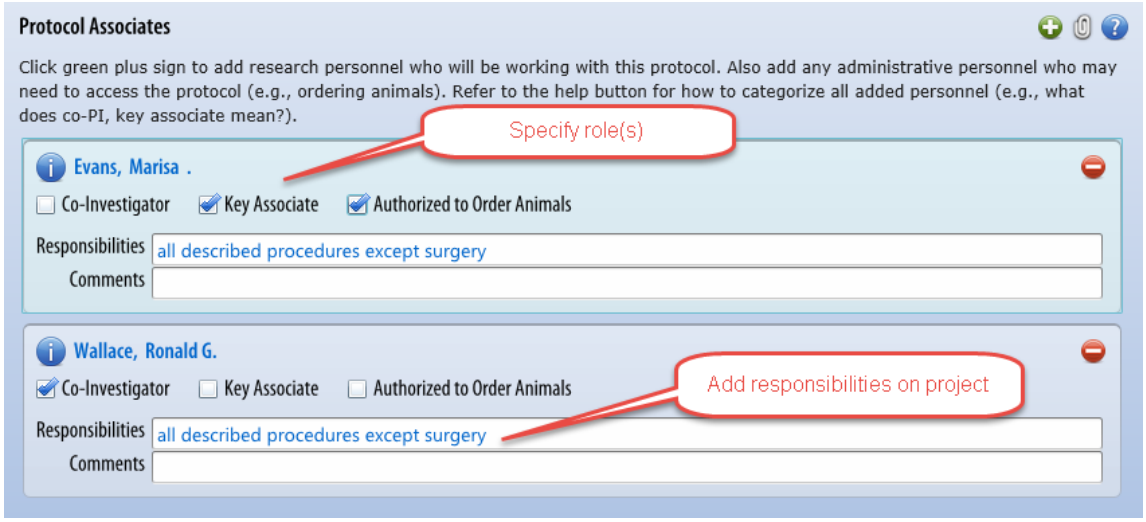
1. Administration
    a. Reference Number
    Assigned automatically. Do not change or add any information.
    b. Hazard Number
    Leave blank, this will be assigned during the review process. Will be generated by the BSO; please leave blank unless instructed to input a number.
    c. Animal Care and Use Protocol Number
    Enter all Animal protocol numbers in which this biological hazard agent will be used. Separate each protocol with a comma.
    d. Principal Investigator (PI, Required)

    Click the  icon to change the PI. Type the persons last name in the Quick Find tool to narrow the list. Click on the PI's name to select them.
    e. Protocol Associates

    To add personnel, click  . A Select Staff grid dialogue box appears.
        i. Entering the person's name (first or last) in the Quick Finder box.
        ii. Select the individual by checking the box to the left of their name. **DO NOT DOUBLE CLICK ON THE PERSON'S NAME**.
        iii. Repeat steps i and ii to add additional persons.
        iv. When you have selected everyone you need, click the OK button  .



The individuals will then be added as Protocol Associates. For each protocol associate, indicate their role and responsibilities. Individuals can be designated in a co-investigators, key personnel, and/or authorized to order animals, if desired. These roles gives them different rights to the specific safety protocol.



Co-investigators- will have the same rights as a PI. They will be able to create and edit protocols, *if they have been authorized by the IACUC Office*. Simply making them co-PIs on your protocol form is not enough. However, if they do have the Research Protocol Writer Access or PI rights to create protocols, they will NOT be able to edit your protocol unless you check the co-investigator box.

Key personnel- will be sent all associated emails generated by the system along with the PI.

If neither Co-investigator nor Key personnel is checked - individual will be able to view approved protocols on which they are listed. Topaz calls this other personnel.

Authorized to Order Animals – individual can order animals on the PI's behalf on this approved protocol. This can include departmental administrators and other research personnel.

Also, put their responsibilities on the project especially the activities they will be performing on live animals and as it relates to the use of the hazard. If their only role is ordering animals, you do not need to put in additional responsibilities if they are not handling or using live animals or hazards.

2. Safety Protocol
    a. Biological Hazard

    Click on  icon to generate a list of known hazards. Click the Name column to sort the list alphabetically. To choose a hazard,  icon to the left of the hazard to add it to your list. Click the OK  button. Choose only Hazards with [B] after their name. Once you choose your hazard, it will appear in a list. If you make a mistake and added a wrong item to the list, click the  to the left of the hazard to remove it.

    b. Describe the Hazardous Biological Agent(s)
    Make sure that you answer all the questions asked in this field.

    c. Animals/Materials Flow
    In order to properly assess whether an agent is hazardous in the circumstances it will be used, the safety reviewers must completely understand how the biohazardous agent(s) will be used. Click on the blue help button for instructions on what needs to be entered into this text field. The timing between when various agents are used on the animals and when they have to leave the biocontainment facility or are euthanized determines when people may be exposed to the biohazardous agent(s) used.

    Example:

    1) before inoculation, animals housed in CCM tower;

    2) animals brought to ABSL-2 procedure room (or where?) for inoculation (or other procedure);

    3) animals brought to an ABSL-2 animal room for housing after inoculation;

    4) after 3,7, 14 and 30 days animals are euthanized in the ABSL-2 procedure room, and tissue is harvested in the Class II BSC (state where euthanized and where tissue harvest is); 5) carcasses are double bagged and labeled (HAZ# on biohazard label) and delivered to the biohazard carcass freezer in CCM necropsy (LB003) or the cold box in the ABSL-2 procedure room.

6) If animals are euthanized in the lab, cages are to be bagged and labeled (HAZ# on biohazard label) and brought into ABSL-2, where they are unbagged and placed on the dirty cage rack inside ABSL-2. If animals are euthanized in ABSL-2, cages are put on the dirty cage rack inside ABSL-2. CCM personnel will process dirty cages from the cage rack.
7) harvested tissues are used in the lab, maintaining BSL-2 until there is a "kill step" in the procedure. If there is no "kill step", BSL-2 will always be maintained with samples where the pathogen had not cleared before euthanasia.

d. Risk Assessment
The risk assessment will be completed by the BSO. Leave blank until you are instructed to input information. There will be a risk assessment for each agent.

e. Storage

Click the  to add a row to the table. Complete the table for all rooms that where the biological agent will be stored. For each storage room location, enter the room number and temperature the materials will be stored at.

f. Storage Room Location

Identify all rooms that the hazards will be stored in. Click the  to add a location. Click on Name to sort the list alphabetically. Click the  to the left of the room number(s) to add it. Click the OK  button. If you make a mistake and added a wrong item to the list, click the  to the left of the room to remove it.

g. Traits of the Biological Agent
Select all statements that apply.

1. Infects humans and/or animals
NOTE: This is to identify all procedures that will be done with infectious agents to understand where exposures to personnel might occur.

i. Room Location

Click the  to add a location. Click on Name to sort the list alphabetically. Click the  to the left of the room number(s) to add it. Click the OK button. If you make a mistake and added a wrong item to the list, click the  to the left of the room to remove it.

ii. Preparation of the Agent for Inoculation - Part I
Check all that apply. Refer to the instructions on the form. Select all aerosol-producing processes that may be used to prepare the agent for inoculation. Answer any questions that may be generated when each process is selected.

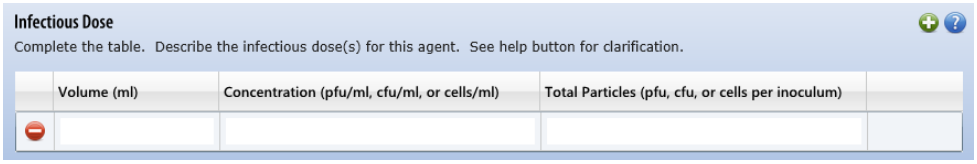
iii. Preparation of the Agent for Inoculation - Part II
Refer to the instructions on the form. Note how people are known to acquire infection from the agent being used. Note which steps in your procedures could produce conditions for personnel to acquire infections. Note maximum culture volumes of potential spills.

iv. Signs and Symptoms of Human Infection
Describe the signs and symptoms of human infection with the agent being used.

v. Biological Safety Cabinets (BSC)
Also known as BSCs or tissue culture hoods. You need to list all the BSCs you are working in with this agent. Complete the table by clicking on to add a row. Type the Room Location, Serial Number and Certification Expiration Date for each BSC. Repeat to add additional rows as needed.

vi. Location of Inoculation
Check all that apply. Select where the inoculation will occur. If "outside CCM biocontainment" or "Multiple locations" are selected, dialogue boxes will generate where you must list the room numbers. Use the to add locations.

vii. Infectious Dose
Click the to add a row to the table. Enter the volume in ml, concentration, and total particles. Refer to help icon for additional details.



viii. Number of animals
List a range of the number of animals that will be inoculated per session.

ix. Performance of Inoculation
Check all who will perform the inoculation. If PI staff or CCM Veterinary Staff is selected, dialogue boxes will generate and you must state who will perform the inoculation.

x. Personnel protective equipment
Select from a list of person protective equipment all that will be used by person.

xi. Restraint
Select the answer to the question. If “Restrained with a devise” is selected, a dialogue box will generate. Describe the device to be used.

xii. Route of Inoculation
Select all routes to be used.

- If “Intranasal Inoculation” is selected, the technique must be described.
- If “topical application” is selected, the technique must be described.
- If “injection” is selected, questions will generate regarding the use of needles will be generated; you must answer all questions.
- If “aerosol” is selected, a dialogue box will generate and you must describe the technique and safety equipment to be used.
- If “in food” is selected, a dialogue box will generate and description of how food is prepared and presented to the animals is required.
- If “gavage” is selected, a dialogue box will generate and you must describe the technique be used.
- If “other” is chosen, a dialogue box will generate and the route needs to be described.

xiii. Clearing of Infection from Animals
Select yes or no. “Clearing” means the animal cures itself of the microorganism so that it can no longer be shed by the animal. If “yes” is selected a dialogue box will appear that asks how long it takes for the clearing to occur. Enter the time from inoculation to the animal being no longer infected.

xiv. Infection from Agent after Inoculation into Animals
This question is about animals shedding, by what route, and under what circumstances personnel may become infected.

xv. Risk group 1
Provide the source of the risk group classification you are using.

xvi. Risk group 2

xvii. Risk group 3

xviii. Attenuated strain

xix. Drug Resistant strain

h. Regulated as a CDC/USDA Select Agent
You need to discuss with the BSO the use of any select agents.

i. Information about CCM ABSL-2
Read the first 6 statements and check off ALL of them, indicating that you have read, understood, and will comply with each statement. As all the statements reflect standard ABSL-2 practices, if you cannot comply with all statements, leave those you can not comply

with unchecked and check the "other" box and explain why in the text box. Also answer the questions about taking portions of the experiment outside CCM ABSL-2.

j. Disposal of Infected Carcasses
Check all the disposal method(s) of the infected carcasses. If “other” is selected, a dialogue box will generate and the method of disposal if infected carcasses must be provided.

k. Disposal of Post-Infection Cage Bedding
Select disposal method of the contaminated bedding. If “other” is selected, a dialogue box will generate and the method of disposal if contaminated bedding must be provided.

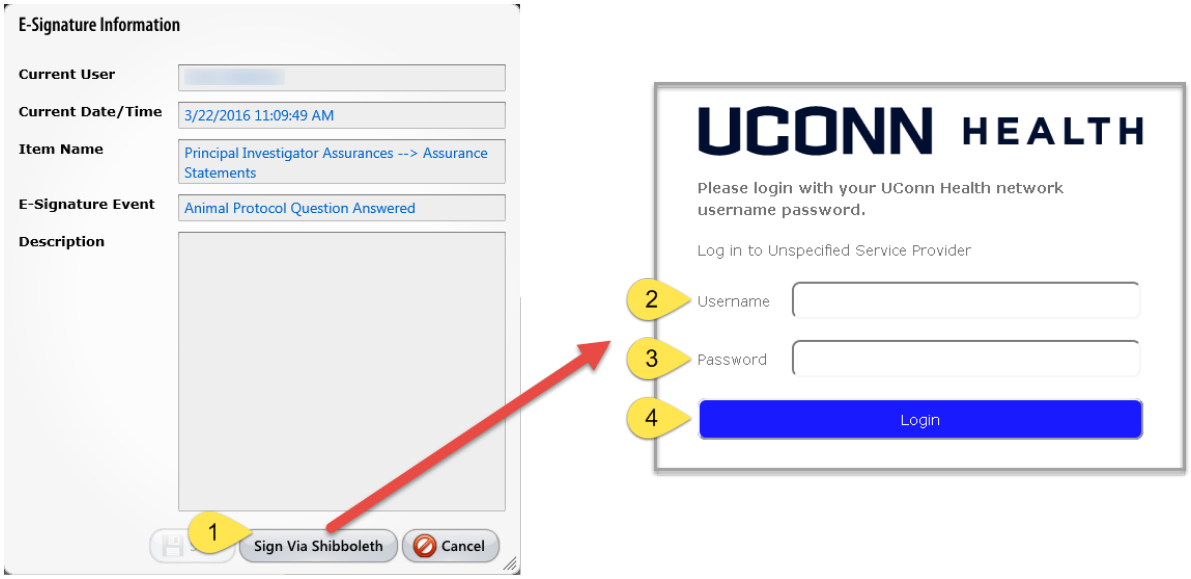
l. Other Potential Infectious Explores to Personnel
Select yes or no. If “yes” is selected, a dialogue box generates and a description of procedure(s) that could cause exposure must be provided.

m. Special Instructions Based on Risk Assessment
PI must consider the potential health status of individuals using the biohazardous agent and note any health statuses that require special restrictions (e.g., pregnancy, personnel with asthma, etc.).

n. Other Pertinent Information
Do not complete this field unless directed to do so by a review.

o. PI Assurances
Read and select all boxes. An e-Signature dialog appears, please

i. Click Sign Via Shibboleth button.
ii. Enter your UConn Health domain name **username.**
iii. Enter your UConn Health domain name **password**.
iv. Click Login button
v. After successful login, you will be returned to the protocol.



3. ACC Office Use Only
   This section is served for IACUC and BSO Office Use Only. Please do not complete or change anything in this section.
   a. Author
      Please do not change any information.
   b. Other Information
   c. Hazardous Materials

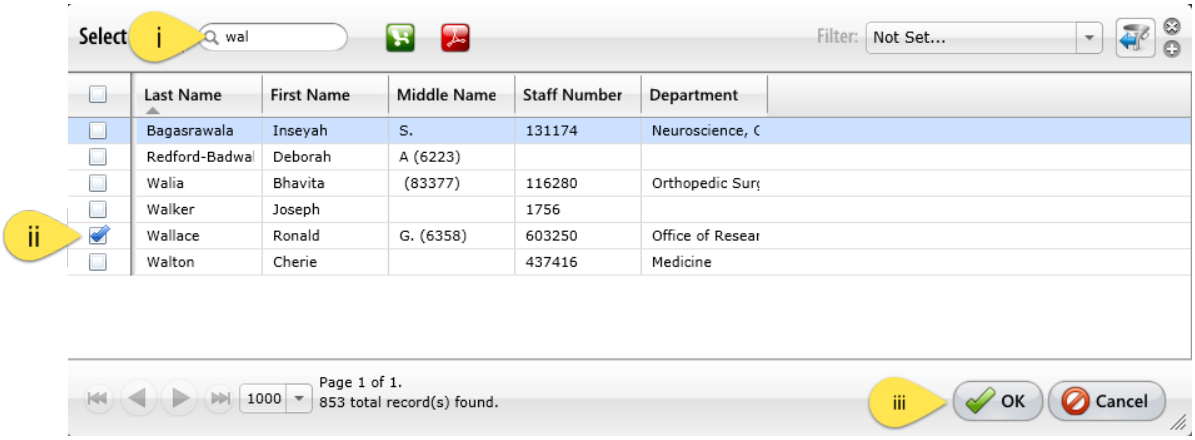
SINGLE CHEMICAL HAZARD USE SAFETY PROTOCOL

For specific questions regarding the safety protocol, please contact the BSO at rwallace@adp.uchc.edu.

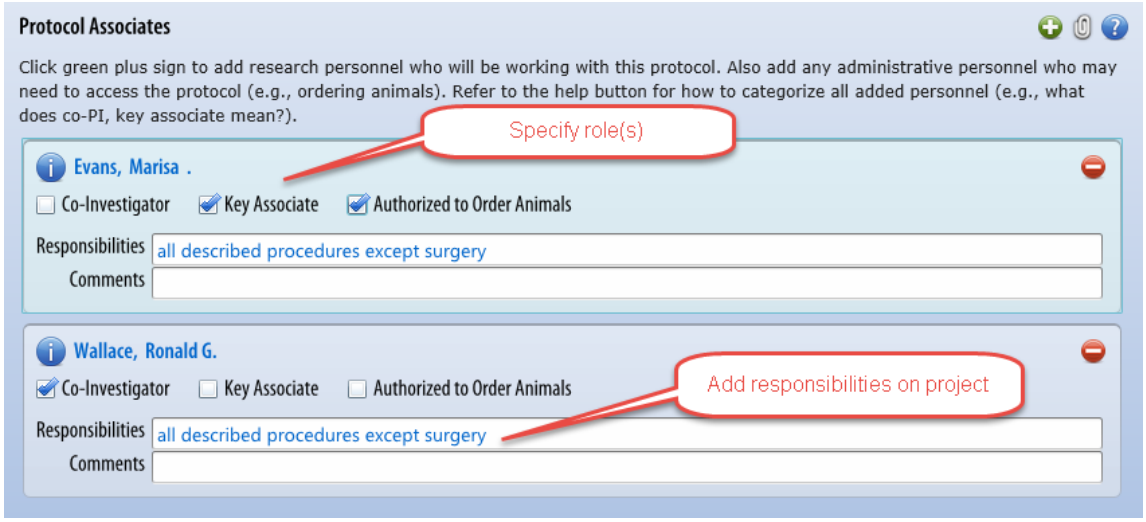
1. Administration
   a. Reference Number
      Assigned automatically. Do not change or add any information.
   b. Hazard Number
      Leave blank, this will be assigned during the review process. Will be generated by the chemical safety specialist; please leave blank unless instructed to input a number.
   c. Animal Care and Use Protocol Number
      Enter all Animal protocol numbers in which this biological hazard agent will be used. Separate each protocol with a comma.
   d. Principal Investigator (PI, Required)

      Click the  icon to change the PI. Type the person's last name in the  Quick Find tool to narrow the list. Click on the PI's name to select them.
   e. Protocol Associates

      To add personnel, click  . A Select Staff grid dialogue box appears.
      i. Entering the person's name (first or last) in the Quick Finder box.
      ii. Select the individual by checking the box to the left of their name. **DO NOT DOUBLE CLICK ON THE PERSON'S NAME**.
      iii. Repeat steps i and ii to add additional persons.
      iv. When you have selected everyone you need, click the OK button  .



The individuals will then be added as Protocol Associates. For each protocol associate, indicate their role and responsibilities. Individuals can be designated in a co-investigators, key personnel, and/or authorized to order animals, if desired. These roles gives them different rights to the specific safety protocol.



Co-investigators- will have the same rights as a PI. They will be able to create and edit protocols, *if they have been authorized by the IACUC Office*. Simply making them co-PIs on your protocol form is not enough. However, if they do have the Research Protocol Writer Access or PI rights to create protocols, they will NOT be able to edit your protocol unless you check the co-investigator box.

Key personnel- will be sent all associated emails generated by the system along with the PI.

If neither Co-investigator nor Key personnel is checked - individual will be able to view approved protocols on which they are listed. Topaz calls this other personnel.

Authorized to Order Animals – individual can order animals on the PI's behalf on this approved protocol. This can include departmental administrators and other research personnel.

Also, put their responsibilities on the project especially the activities they will be performing on live animals and as it relates to the use of the hazard. If their only role is ordering animals, you do not need to put in additional responsibilities if they are not handling or using live animals or hazards.

2. Safety Protocol
    a. Chemical Hazard

    Click on  icon to generate a list of known hazards. Click the Name column to sort the list alphabetically. To choose a hazard,  icon to the left of the hazard to add it to your list. Click the OK  button. Choose only Hazards with [C] after their name. Once you choose your hazard, it will appear in a list. If you make a mistake and added a wrong item to the list, click the  to the left of the hazard to remove it.

    b. Describe the Hazardous Biological Agent(s)
    Make sure that you answer all the questions asked in this field.

    c. Animals/Materials Flow
    In order to properly assess whether an agent is hazardous in the circumstances it will be used, the safety reviewers must completely understand how the chemical will be used. Click on the blue help button for instructions on what needs to be entered into this text field. The timing between when various agents are used on the animals and when they have to leave the isolation facilities or are euthanized determines when people may be exposed to the chemicals used.

    d. Chemical
    Based on your response, additional questions appear

        i. Amount Received
        Enter the amount in grams or ml depending on the chemical form.

    e. Potential Chemical Spill
    Describe how you would manage a potential chemical spill

    f. Chemical Preparation
    If yes is selected, additional questions will generate asking for specific information on stock preparation, preparation procedures, and a spill protocol for the stock solution.

    g. Preparation Procedures
    Check all that apply.

        i. Work & Storage Areas

a) Location of Storage

Click the to see a list of room locations. Click Name to alphabetize the list. Enter a room in the Quick Finder to filter through the list. Click the to the left of the room to add it. Select additional rooms if needed. Click the OK button.

b) Location of Preparation

Click the to see a list of room locations. Click Name to alphabetize the list. Enter a room in the Quick Finder to filter through the list. Click the to the left of the room to add it. Select additional rooms if needed. Click the OK button.

c) Work and Storage Area Labeling

Please respond affirmatively.

h. Potential Chemical Spill

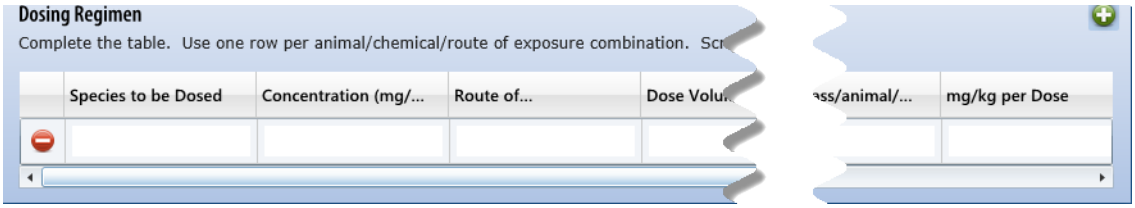
i. Personal Protective Equipment – Preparation

Select from a list of person protective equipment all that will be used by personnel preparing the chemical.

j. Personnel will wear gloves

k. Dosing Regimen

This field is designed to show how a single chemical is used in multiple ways (e.g., gavage, IP, etc.) or with multiple species. You cannot explain how multiple chemicals are used in this table. Select a row for every species or every route of administration the chemical will be given to by clicking on the to add a row. Complete the table. Be careful to observe the internal scroll bar so you do not miss columns to the right.



NOTE: Frequency of dosing is the number of doses per time increment (e.g., twice per day); Number of doses to be given is total number of doses (e.g., if you are giving twice per day for 7 days the total doses is 14); Total mass/animal/dose is would be the concentration x volume given.

l. Risk Assessment

Risk assessment will be completed by the IACUC chemical safety officer. Do not enter anything unless directed to do so.

m. Dosing Personnel
Select who will be dosing the animals. If PI staff and/or CCM staff is selected, dialogue boxes will generate and you must list all personnel who will be dosing the animals.

n. Dosing Procedures
Select all statements that apply.
- If conventional needles/syringes is selected, additional questions will generate regarding the use of safety needles and contaminated sharps disposal.
- If non-conventional needles/syringes is selected, additional questions will generate regarding the description of the needles/syringes to be used and contaminated sharps disposal.
- If dosing will take place neither inside a chemical fume hood nor inside a BSC, a additional questions will generate requesting a justification of why a fume hood or BSC is not used.
- If left over doses will require disposal is checked, additional questions will generate asking for a description of disposal.

o. Potential Chemical Spill
This section describes a chemical spill of the working solution. Answer all bullet points listed in the section.

p. Animal Carcass Disposal
Select how animal carcasses will be disposed. If "other" is selected, a dialogue box will generate and you will have to explain the disposal of the carcasses.

q. Bedding Disposal
Select how bedding will be disposed. If "other" is selected, a dialogue box will generate and you will have to explain the disposal of the bedding.

r. Other Potential Chemical Exposure to Personnel
Select yes or no. If yes is selected, a dialogue box will generate and you will have to describe the procedures that could cause exposure of personnel to the chemical.

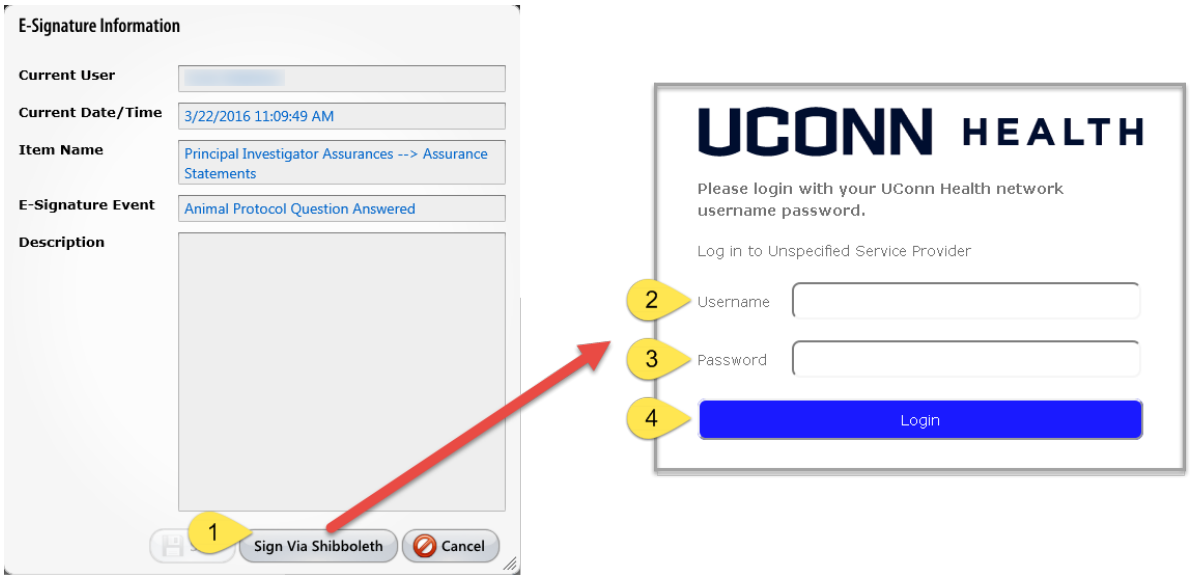
s. Special Instructions Based on Risk Assessment
PI must consider the potential health status of individuals using the chemical and note any health statuses that require special restrictions (e.g., pregnancy, personnel with asthma, etc.).

t. Other Pertinent Information
Do not complete this section unless directed to do so by a review.

p. Pi Assurances
Read and select all boxes. An e-Signature dialog appears, please
    i. Click Sign Via Shibboleth button.
    ii. Enter your UConn Health domain account **username.**
    iii. Enter your UConn Health domain account **password**.

iv. Click Login button

v. After successful login, you will be returned to the protocol.



3. ACC Office Use Only

   This section is served for IACUC and BSO Office Use Only. Please do not complete or change anything in this section.

   a. Author

      Please do not change any information.

   b. Other Information

   c. Hazardous Materials