Topaz Electronic Protocol Development
Information on Filling out the UCHC Protocol Form

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

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THE ACC ANIMAL CARE AND USE PROTOCOL FORM

1. Administration Section
    a. Title

    Enter the title of your protocol. Do not use the enter button when you are finished- simply click on the save button.

    b. Protocol renewal information

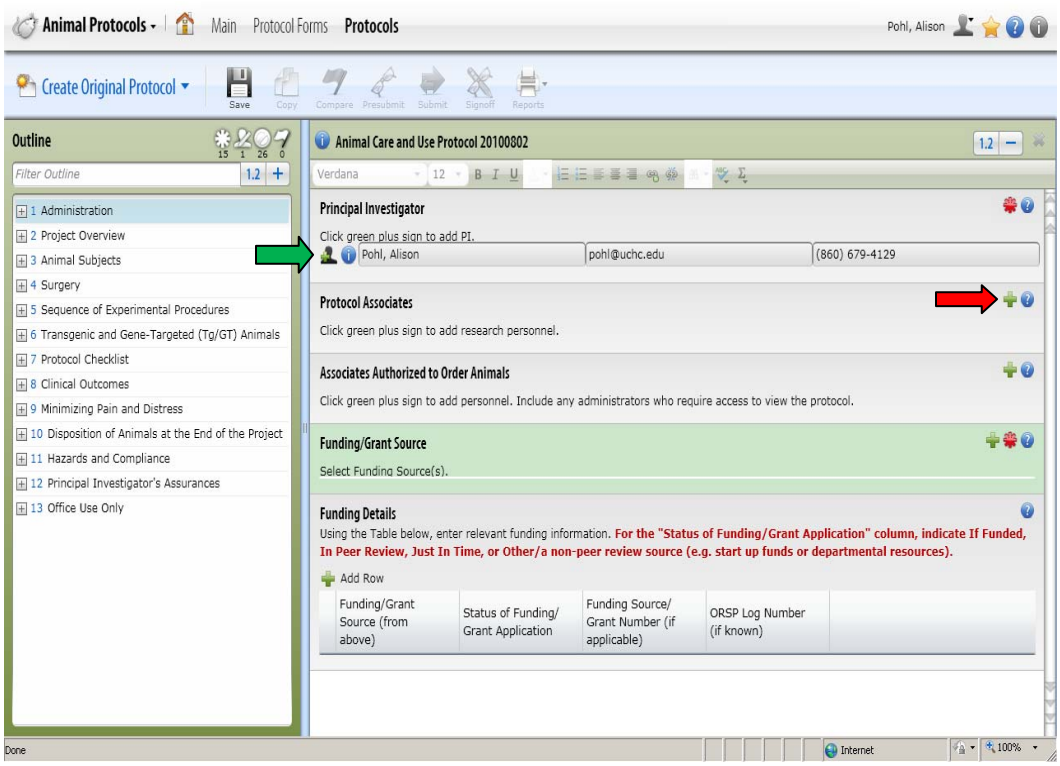
    Select if this project is a new protocol or a 3 year renewal. If it is a 3 year renewal, place the old ACC number in the spot provided.

    c. Principal Investigator

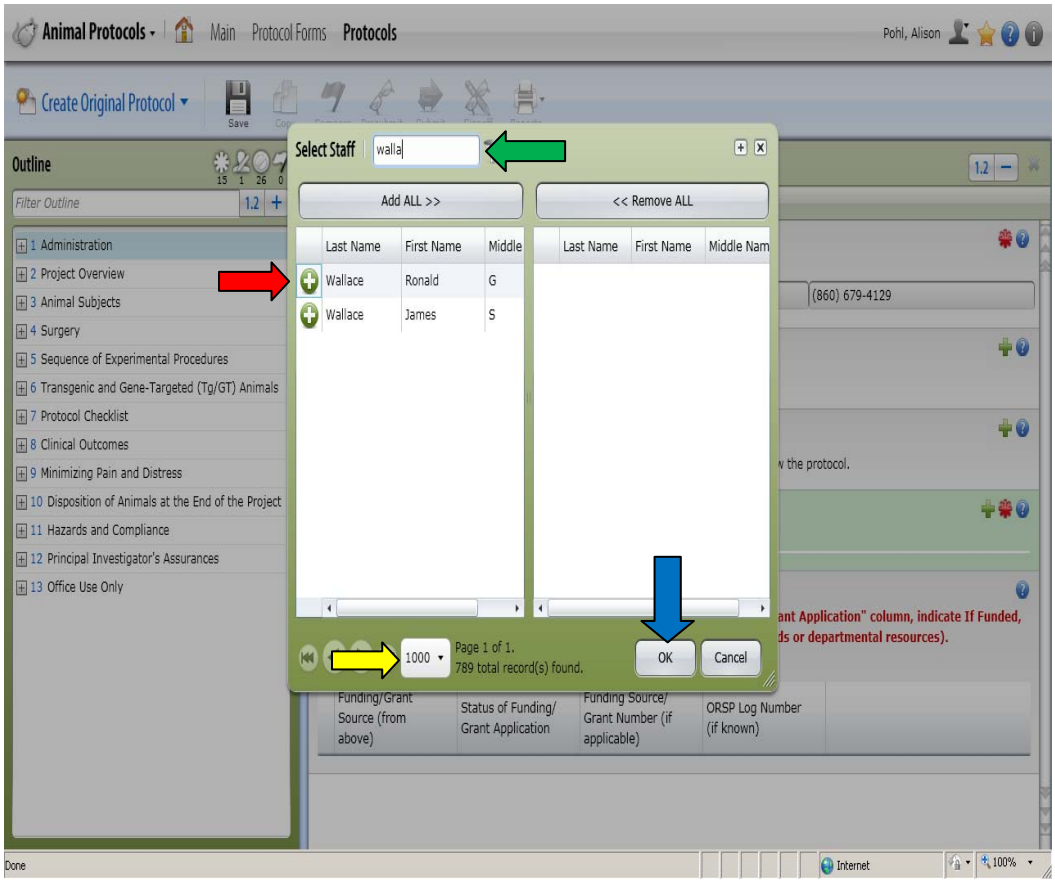
    If you are **NOT** the PI, select the PI now. Click on the person symbol with the green + on it (green arrow) and select the PI as described in (d) below.

    d. Protocol Associates

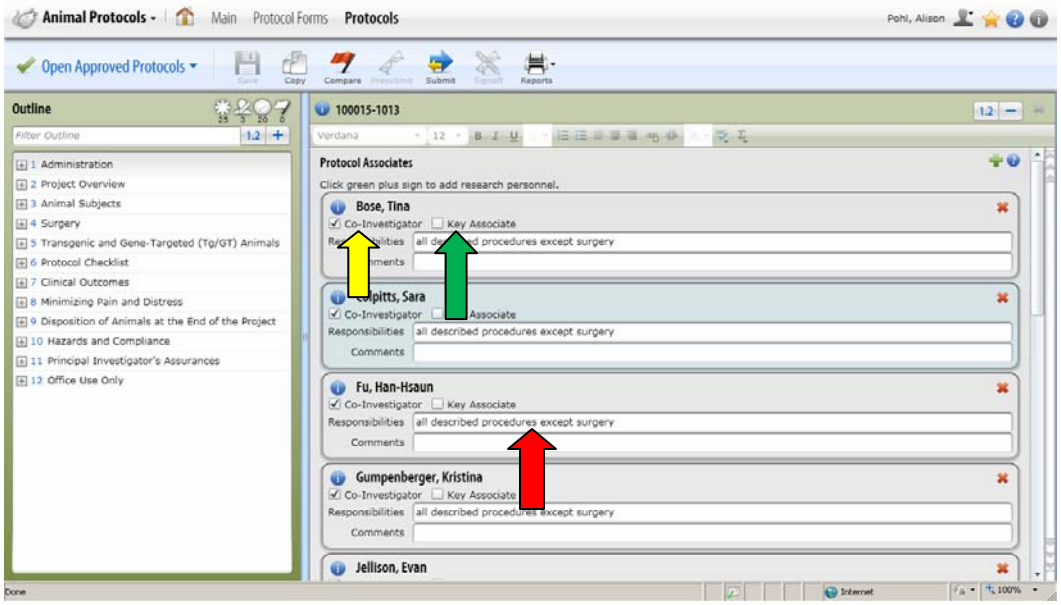
    One of the first items you will come to is entering personnel. To add personnel, you will need to click on the + symbol (red arrow).



When you do this, a list will come up. Make the number default 1,000 (it automatically is set at 100 [yellow arrow]). Then start entering the person's name (first or last) in the filter box (green arrow). Select the individual by clicking on the green circle with the white **+** sign (red arrow). **DO NOT DOUBLE CLICK ON THE PERSON'S NAME**. Repeat this process (entering names in the filter) with every individual you need to add to the protocol. When you have selected everyone you need, click the OK button (blue arrow).



The individuals will then be generated in the protocol. The first thing you will need to do is to put their responsibilities for what activities they will be performing on live animals in the document (red arrow). After that, you will be able to make them either co-investigators (yellow arrow) or key personnel (green arrow) if you chose to do so. This gives them different rights to the protocol.

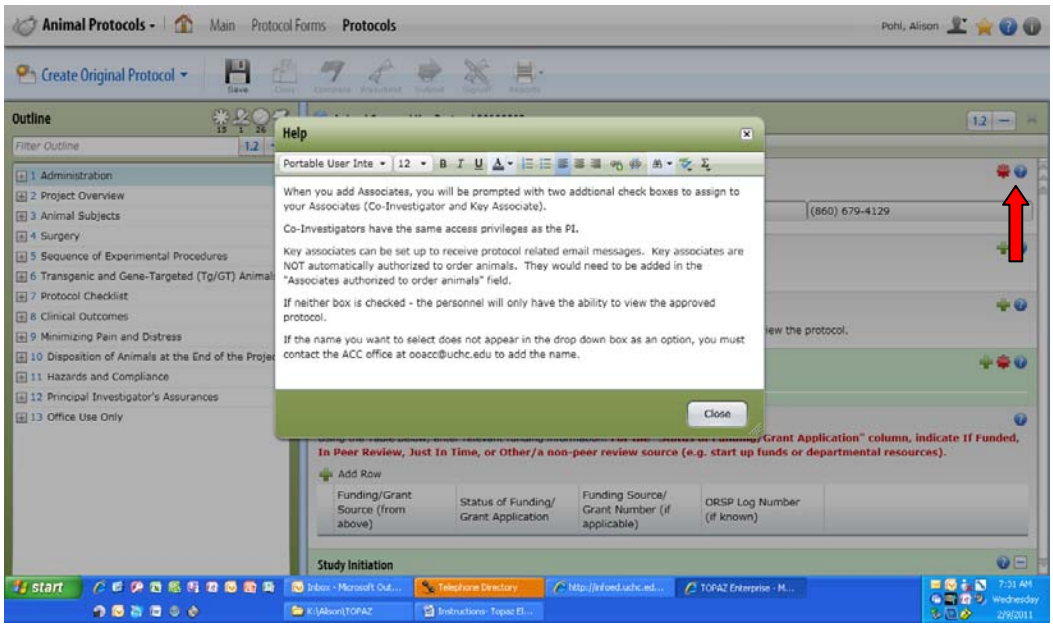


Co-investigators- will have the same rights as a PI. They will be able to create and edit protocols **IF THEY HAVE BEEN GIVEN THAT PRIVILEGE BY THE ACC OFFICE IN THE TOPAZ SYSTEM**. Simply making them co-PIs on your form is not enough. However, if they do have the access rights to create protocols, they 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.

Neither box checked- individual will be able to view approved protocols on which they are listed.

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

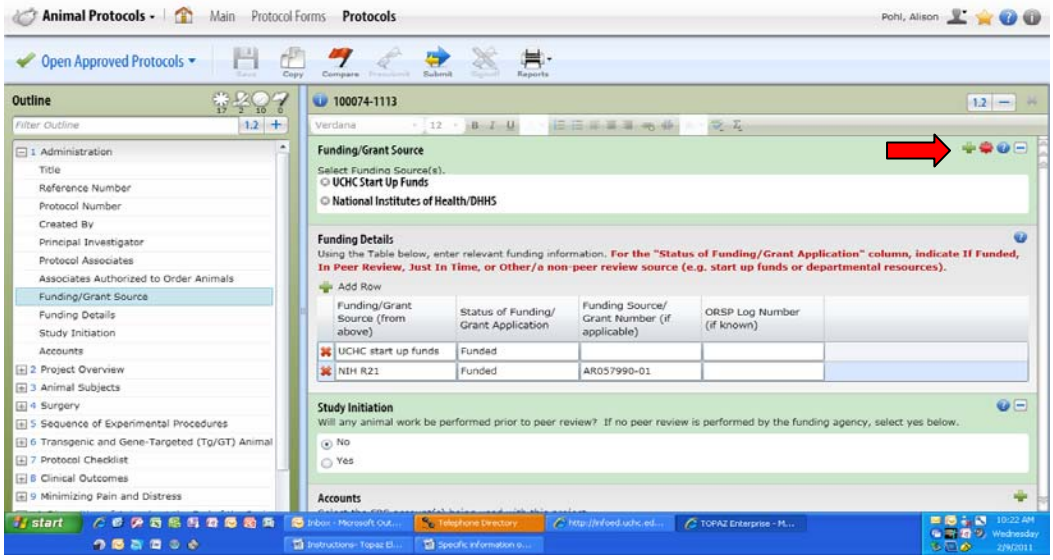


e. Associates authorized to order animals

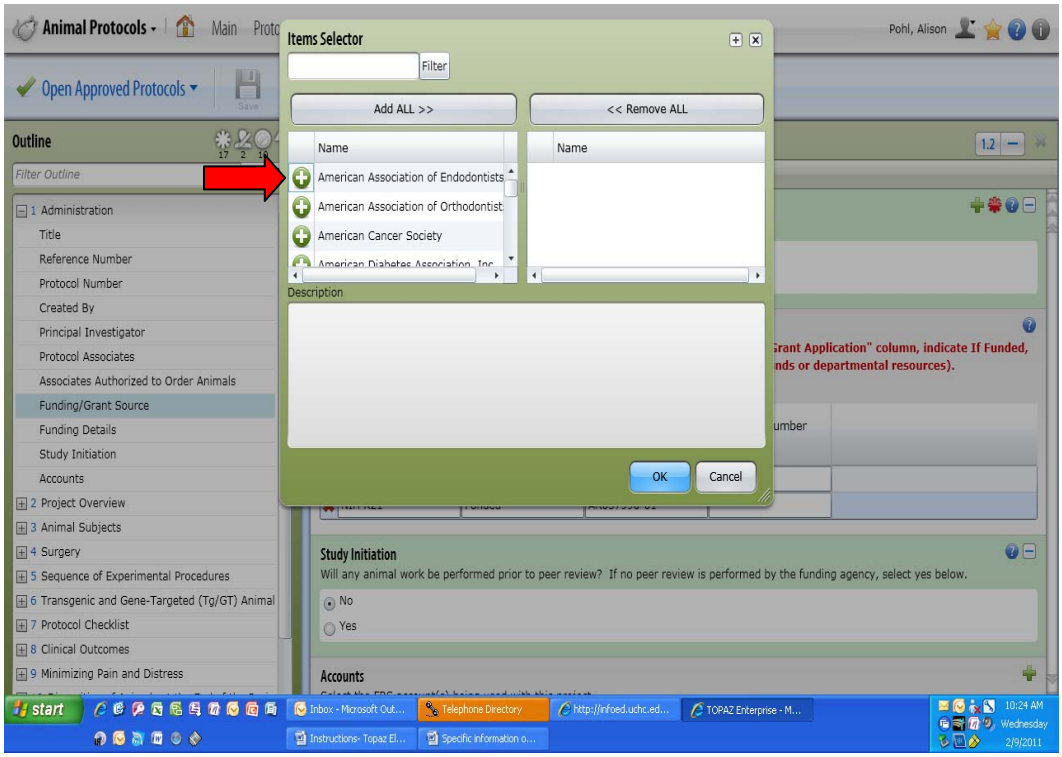
Select any person that you want to be able to order animals on this protocol. This can include departmental administrators and research personnel. Do this step just like (d) above. You do **NOT** have to put in the responsibilities in this section. If someone is listed in the protocol associates box, you will still need to list them in this section if they are to order animals.

f. Funding/Grant Source

You will need to select the funding source. Click on the **+** button (red arrow).

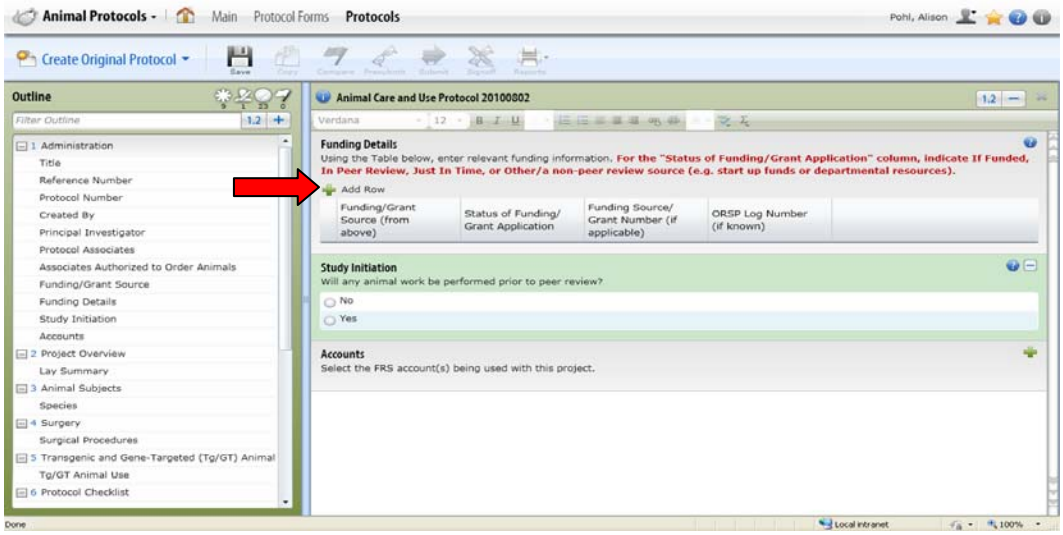


This will generate a list from which to choose. Select your funding sources by clicking on the green circle with the plus sign (red arrow). If you don't see your selection, you can do one of two things: you can call the ACC office (x3429) and ask to have the source added to the list or you can select "other".



g. Funding Details

You will first need to click on the + sign (red arrow) to add a row.



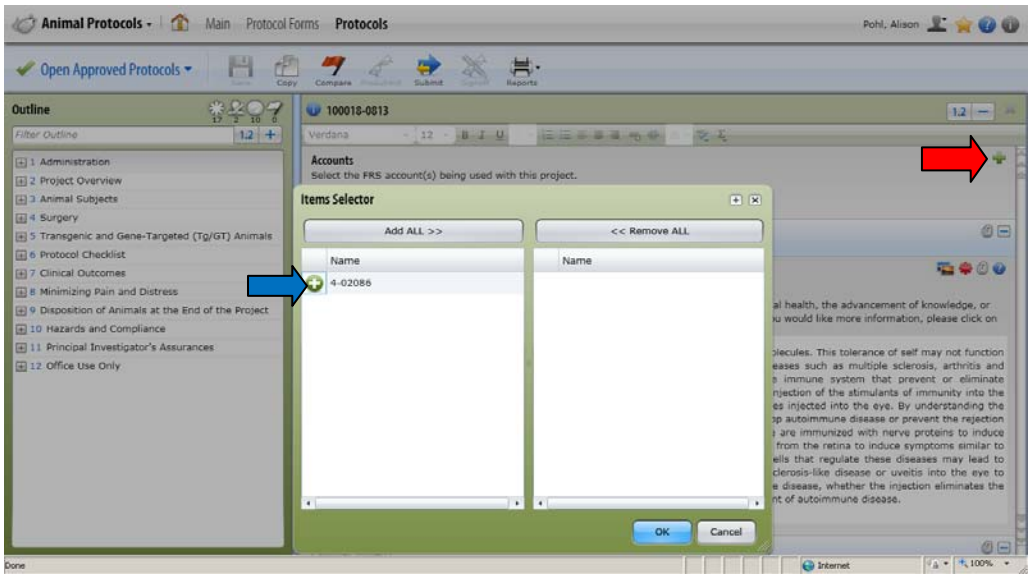
In each row, put the name of the funding source that you entered in section (f) above. Then complete the table. You **MUST** enter either the Grant Number or the ORSP Log number in the table.

h. 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 reviewer not associated with the protocol.

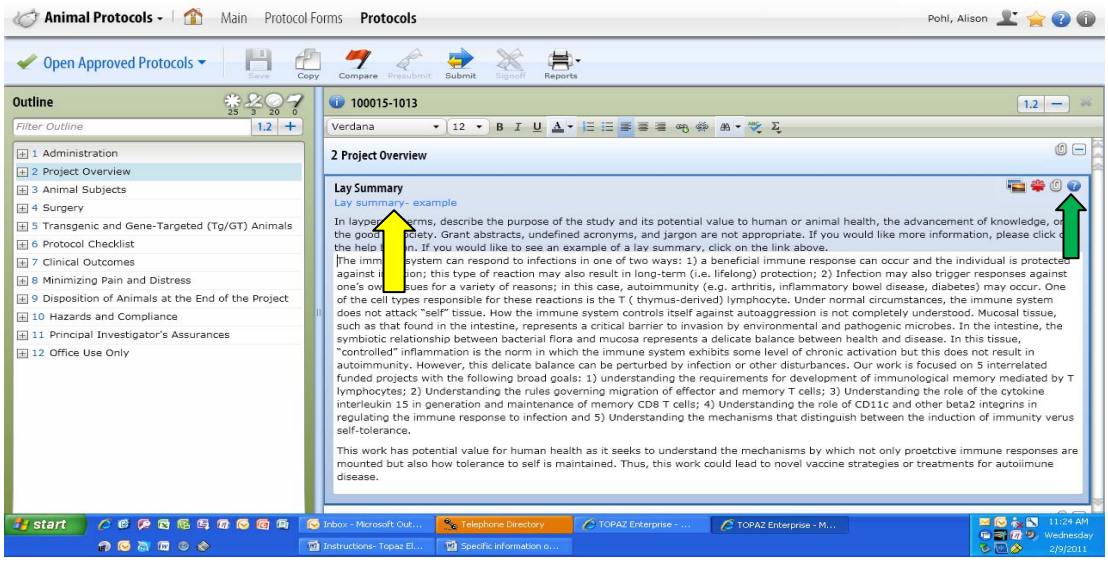
i. Accounts

You will need to select what FRS account is associated with this work. You will need to click on the + button to select your account (red arrow). When you do this, a list of FRS accounts will generate. You will need to select the FRS account(s) to use by clicking on the green circle with the white + (blue arrow). If an account is not listed, you will need to contact Comparative Medicine (x2731) to get it added.



2. Project Overview

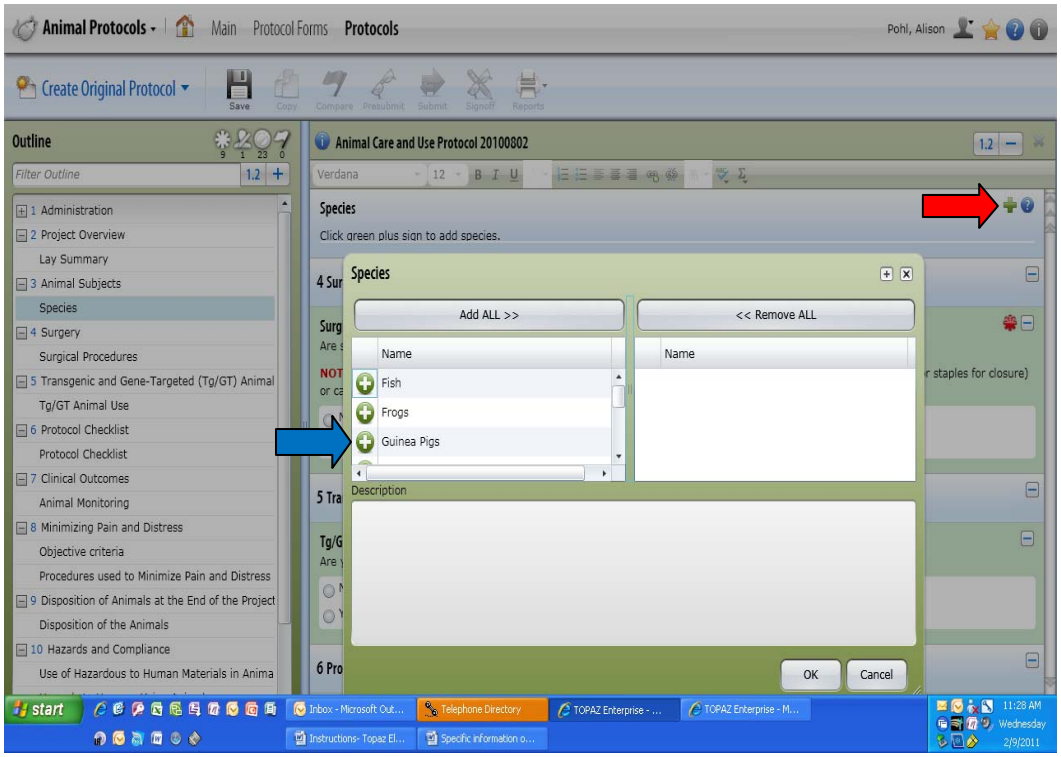
You will need to give a brief overview of your project which describes what you are doing, the purpose of the study, and its potential value to human or animal health, the advancement of knowledge, or the good of society. This has to be done in lay terms; that is, terms an average 8th grader would understand.



If you are unsure of what to write, information can be found in the information button (green arrow). Or, to see an example of what is expected, click the link provided (yellow arrow).

3. Animal Subjects
    a. Species

    You will have to select the species to be used. Simply click on the + sign (red arrow) and a list of potential species will generate. Click on the green circle with the white + to select your species (blue arrow). Do **NOT** click on the species itself; you **MUST** click on the symbol.



    b. Rationale for the Use of Animals

    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.

    c. Rationale for the Appropriateness of the Species to be Used

    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.

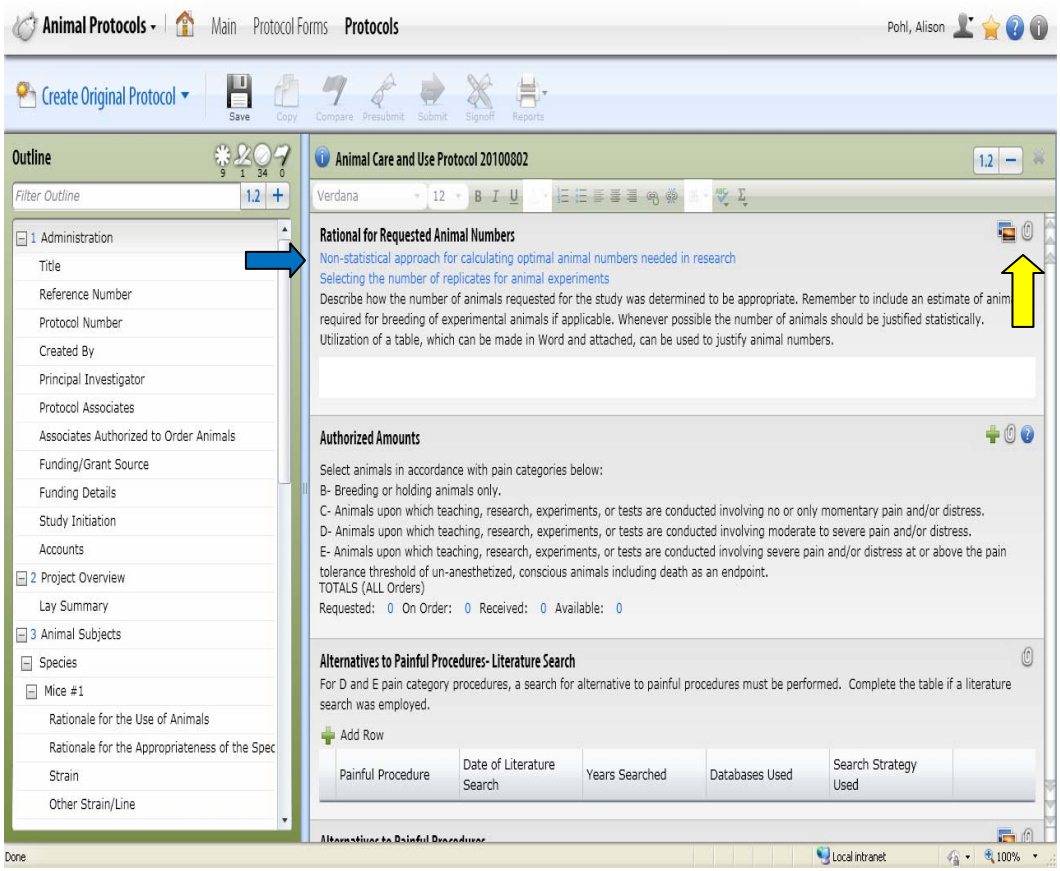
    d. Strain

    You have the opportunity to select the strain(s) you are planning to use. This is optional. You would select your strain exactly as described in section (a) above.

e. Rationale for Requested Animal Numbers

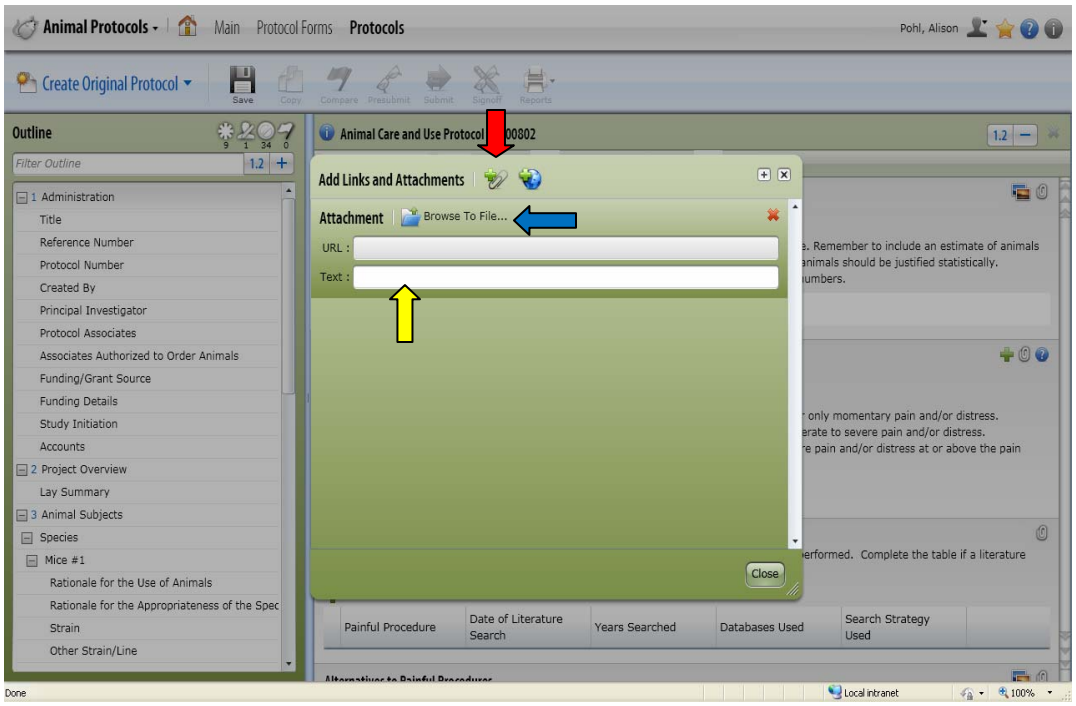
You must provide a justification for animal numbers; this is required in the regulations. This is a free-text field that you can copy and paste into if you wish to.

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.



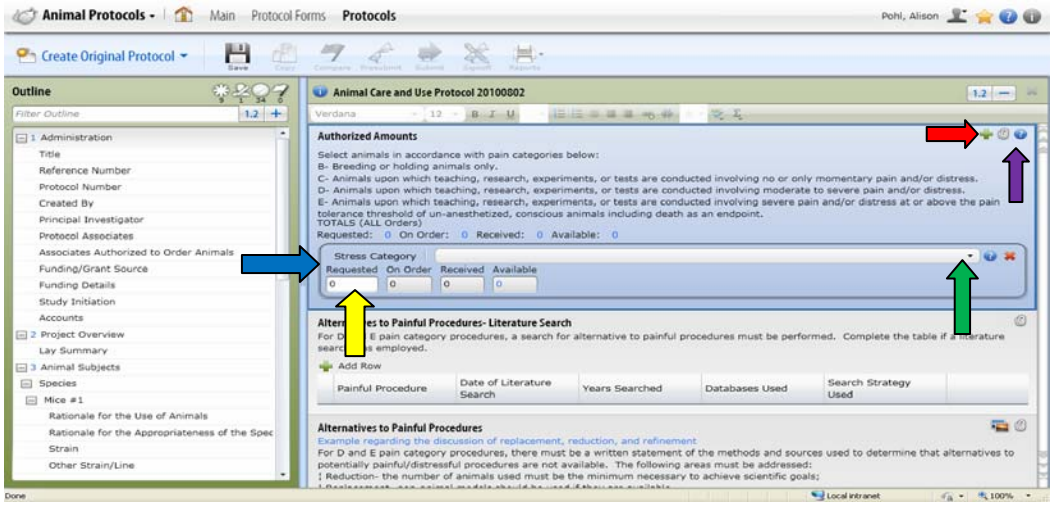
If you are unsure how to get animal numbers, you can check out the help we have provided by clicking on the links (blue arrow). You can also attach additional information. For instance, say you have a table which lists your experimental parameters and animal numbers requested. Tables will NOT copy into free text fields. You can easily attach your records by clicking on the paperclip icon (yellow arrow).

When you do this, a dialogue box will generate. Click on the paperclip to attach documents (red arrow). In the text box (yellow arrow), give the name of the document. Attach it by using the "Browse to File…" icon (blue arrow).



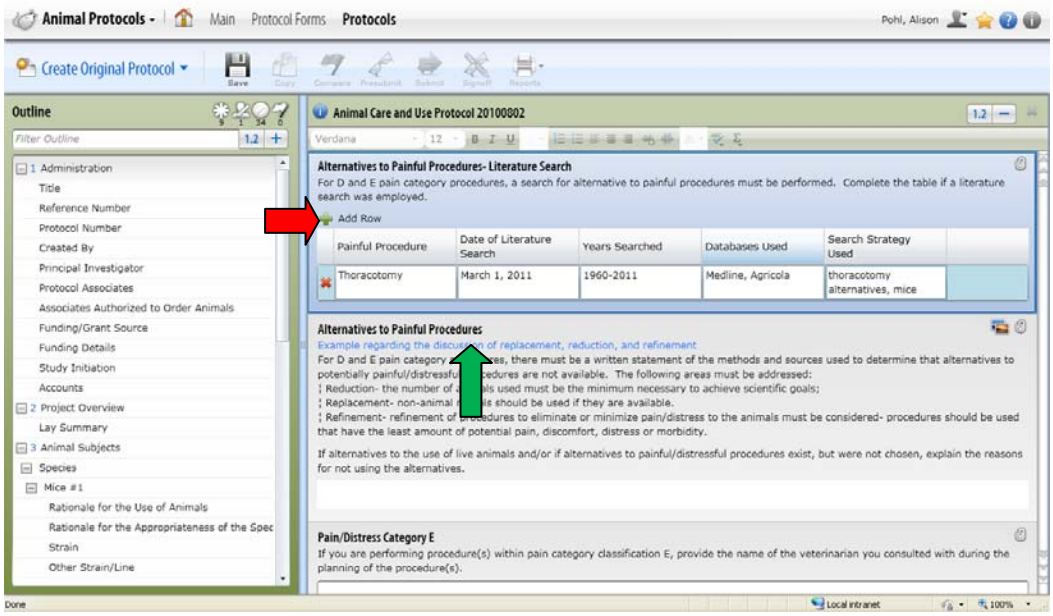
f. Authorized Amounts

You **MUST** enter the amounts you need in each pain category. When you click on the + symbol (red arrow), a line will generate (blue arrow). You must select the stress category from the pull down menu (green arrow) and put the number of animals requested in the requested column (yellow arrow). You need to have one line per stress category for each species. If you are unsure of a pain/distress category, this information is given to you if you click on the information button (purple arrow).



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. Click on the + button (red arrow) to add a row. Each painful procedure **MUST** have its own row. Complete the table with the information requested.



h. Alternatives to Painful Procedures

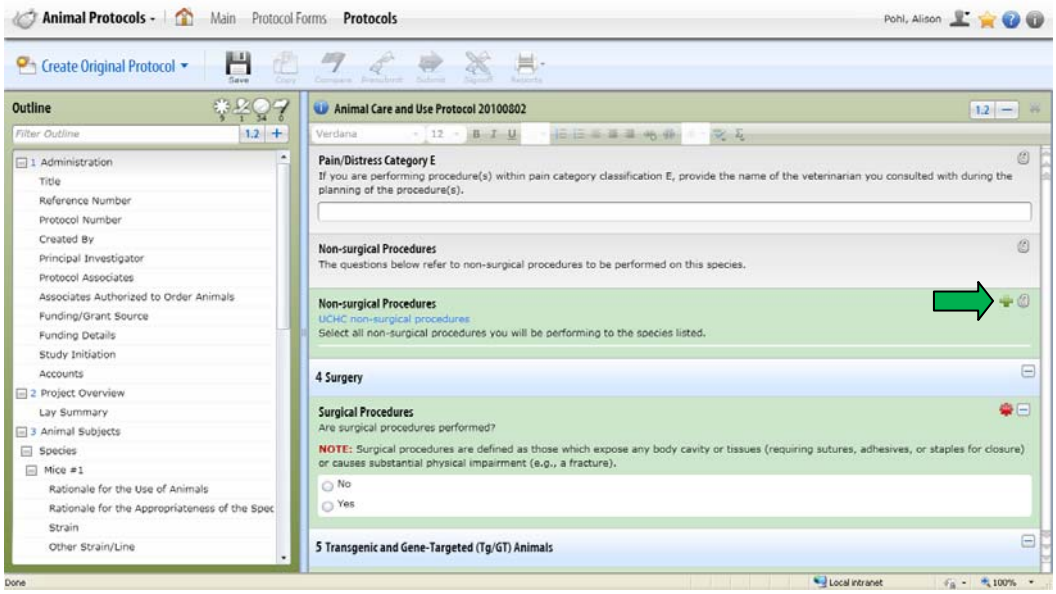
Even if you used a literature search as your alternatives search method, you **MUST** complete the section. If you did something other than a literature search, this section must contain what you did (e.g., consultation with an expert in the field, standard practices in a reference book, etc.). **PLEASE 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 link provided (green arrow above) and look at the example.

i. Pain/Distress Category E

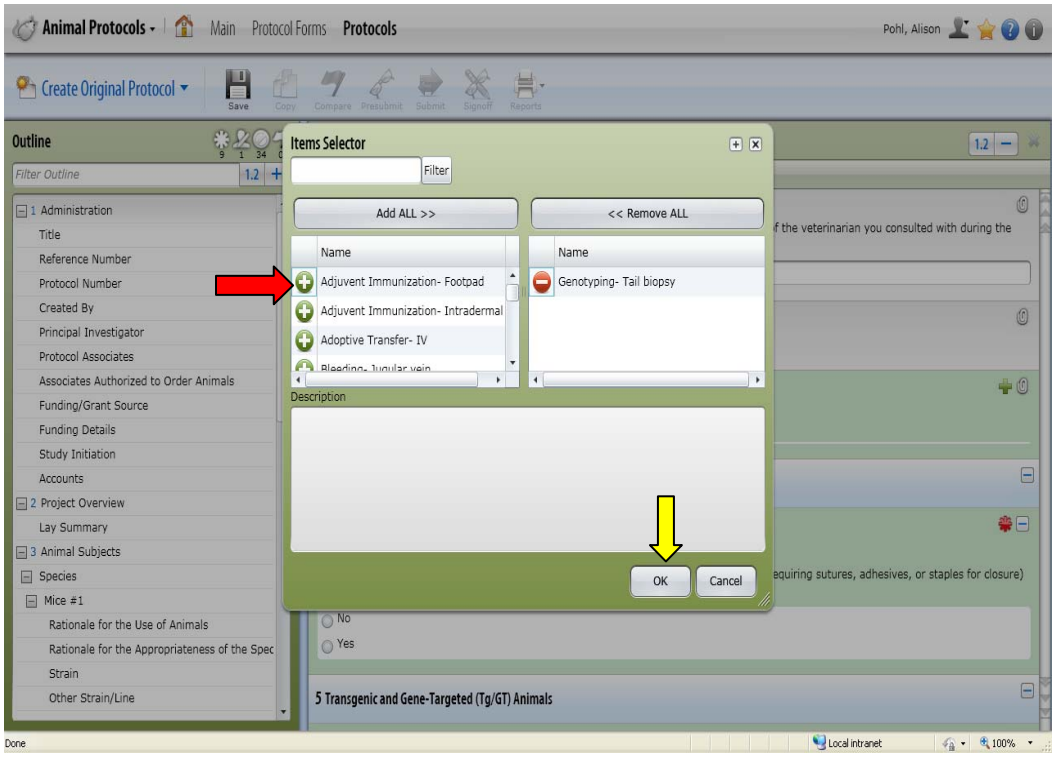
If you are using pain/distress category E, you **MUST** provide the name of the veterinarian you consulted with during the **PLANNING** of the experimental procedure(s). This does not have to be the UCHC attending veterinarian; however, if it some someone other than the UCHC attending veterinarian, you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

j. Non-surgical Procedures

You need to select what non-surgical procedures you are going to perform to the species. Click on the + button (green arrow) to add your non-surgical procedure.



Once you do this, a list of procedures will generate in a dialogue box. Select your procedure(s) by clicking on the green circle with the white + symbol (red arrow); do **NOT** click on the procedure name. If your procedure is not listed, then click the "other" button. Then select the OK button (yellow arrow). Repeat this process for every non-surgical procedure you will do to the animals.

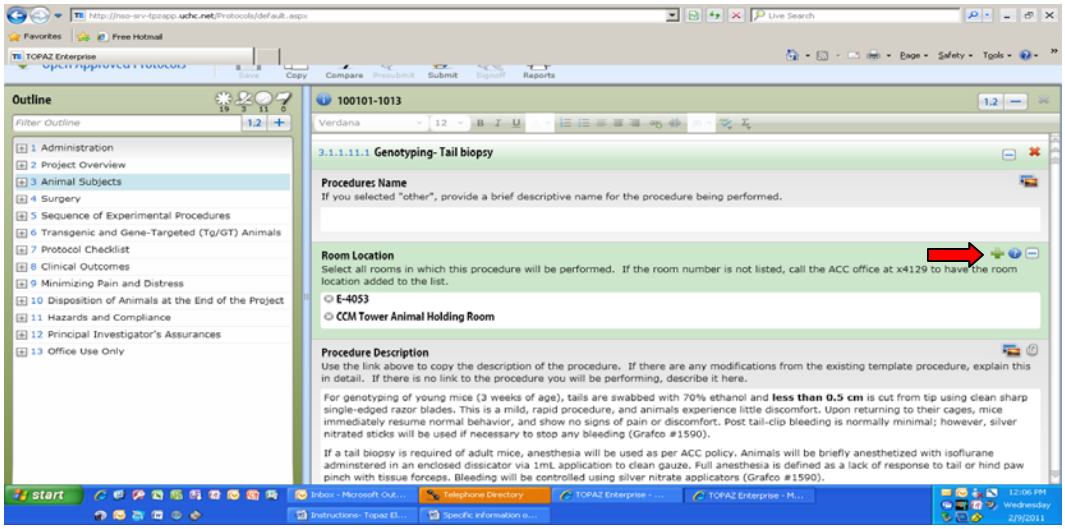


k. Procedures name

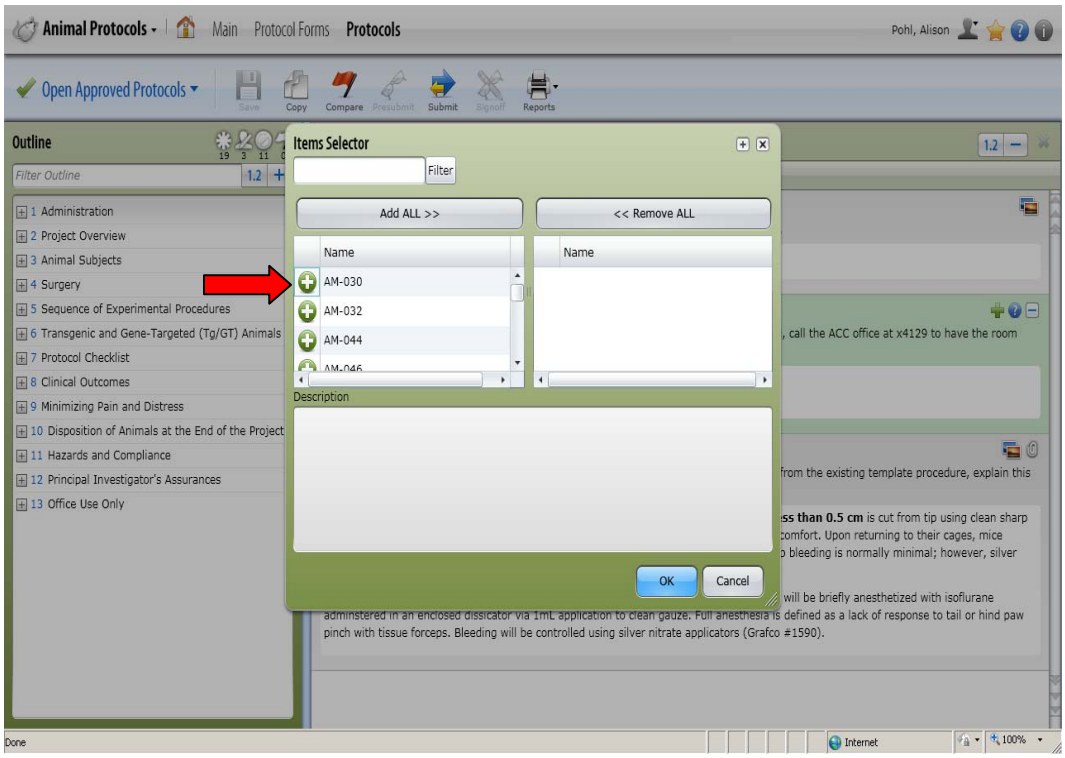
If your procedure is not listed and you had to select “other”, please provide a brief descriptive name in this section.

l. Room Location

You must select the room location(s) where this procedure will be performed. Click on the + button to generate a list of room numbers (red arrow).

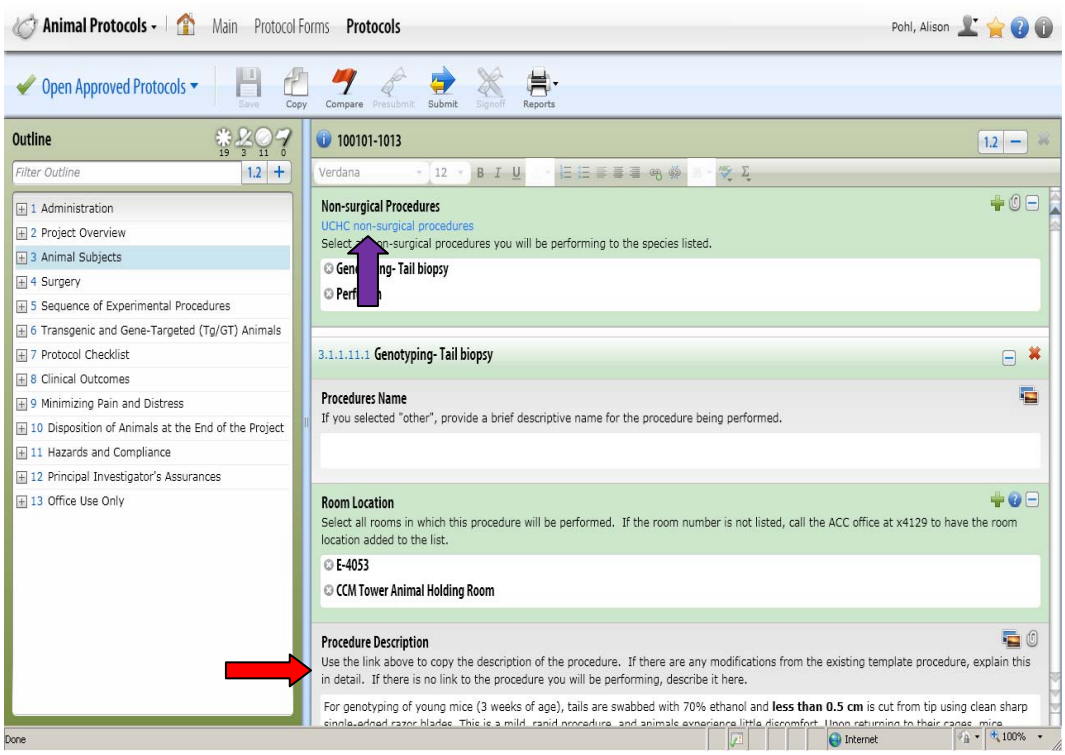


A list will populate. Select all room location(s) in which this procedure will be performed by clicking on the + symbol (red arrow) by the room location. If the room location(s) is not in the list, please call the ACC office (x3429) to get it added.



m. Procedure Description

When you get down to procedure descriptions (red arrow), 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 (purple arrow). 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.



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

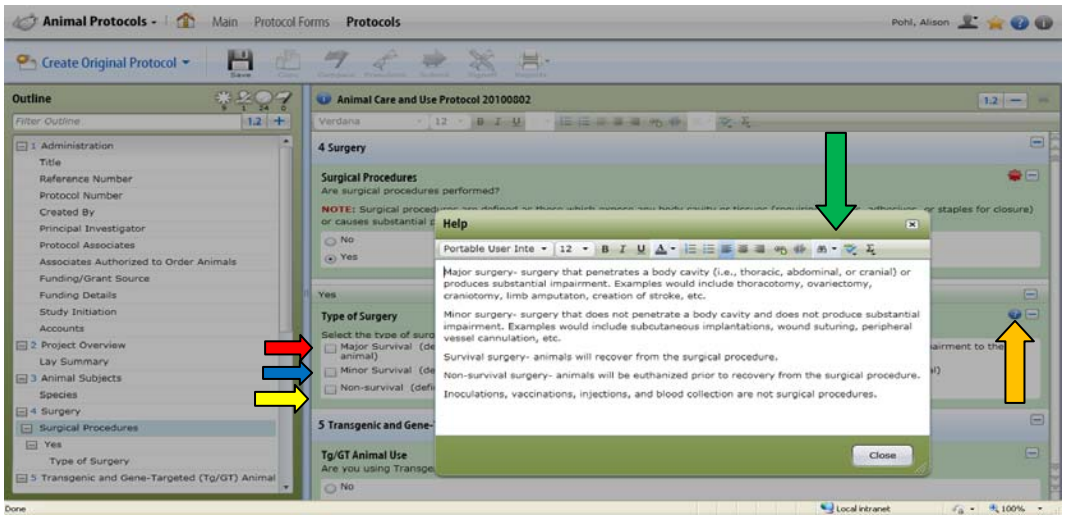
If you are using any drugs in your procedure- anesthetics, analgesics, experimental compounds, etc. then you **MUST** check yes in this section. When you check yes, a table will generate. You will need to fill out the table **COMPLETELY**. In addition, if you are requesting to use 2,2,2-tribromoethanol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

4. Surgery
    a. Are you performing surgery

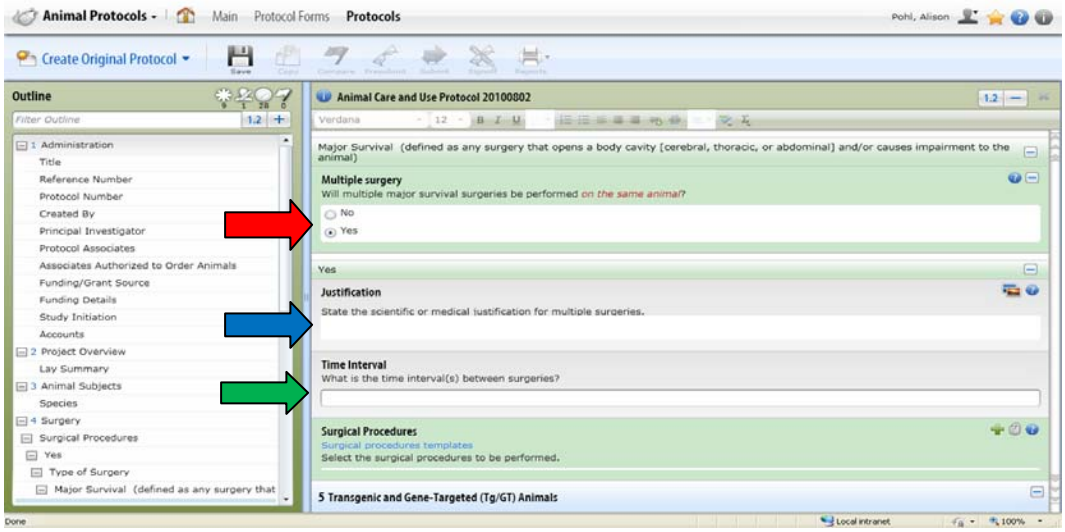
    This is a mandatory question which must be answered in order to submit the protocol for review. Simply check the YES box or the NO box. If you check the NO box, no further questions will generate. If you check YES, you will need to continue.

    b. Type of surgery

    You will need to select the type of surgery for each surgical procedure you are performing- major survival surgery (red arrow), minor survival surgery (blue arrow), and/or non-survival surgery (yellow arrow). If you do not know what type of surgery you are performing, click on the information button (orange arrow) and a help box will generate and give you that information (green arrow).

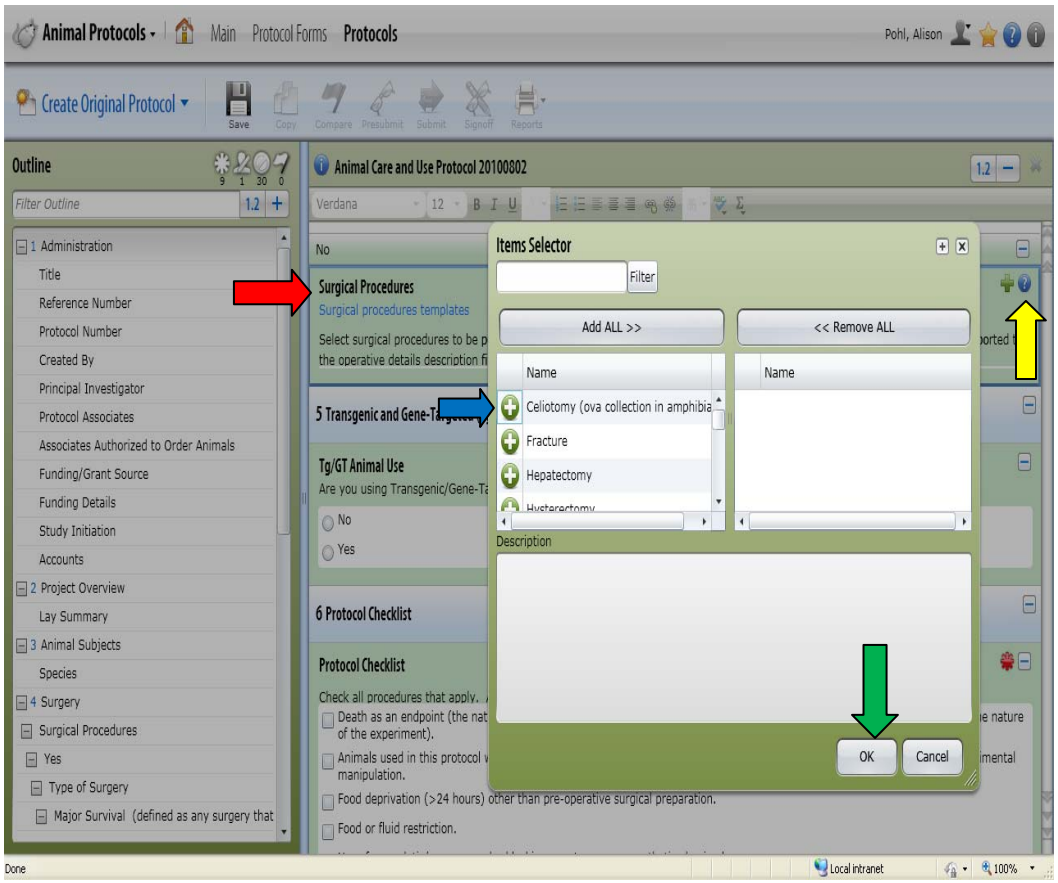


If you select that you are performing major survival surgeries, it will ask you if you are performing multiple major survival surgeries (red arrow) and you will click either yes or no. If you are, you will need to state the justification (blue arrow) and time interval between the surgeries (green arrow).



c. Surgical Procedures

Once you select the type of surgical procedure you are doing, you will have to select the procedure itself. In the surgical procedures section (red arrow), you click on the + to add your procedure (yellow arrow). A list of procedures will generate. You click on the white + in the green circle (blue arrow) to select your surgery then hit OK (green 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.

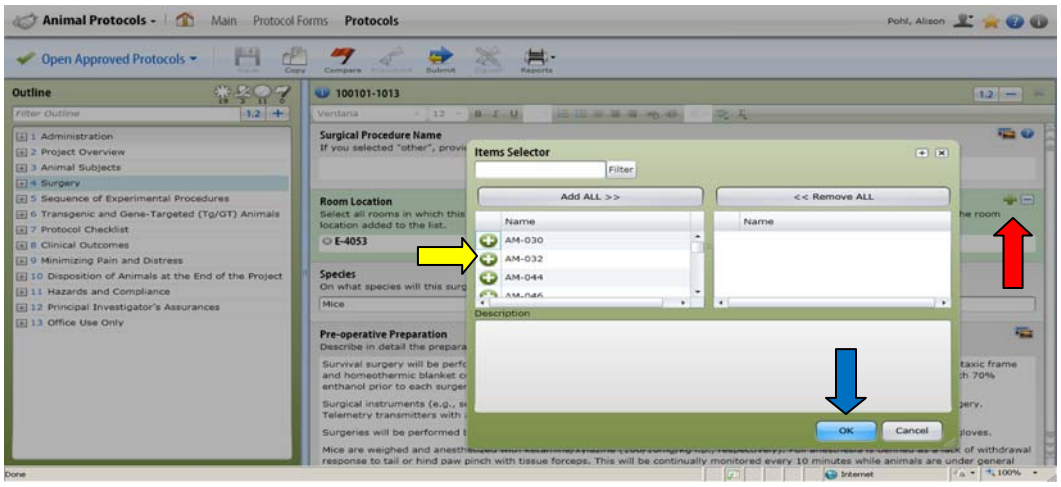


d. Surgical Procedure Name

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.

e. Room Location

Then you will have to select the room location(s) this surgical procedure will be performed in. Select the + button (red arrow) to generate a list and then click on the white + in the green circle (yellow arrow) to select each room. Then hit OK (blue button).

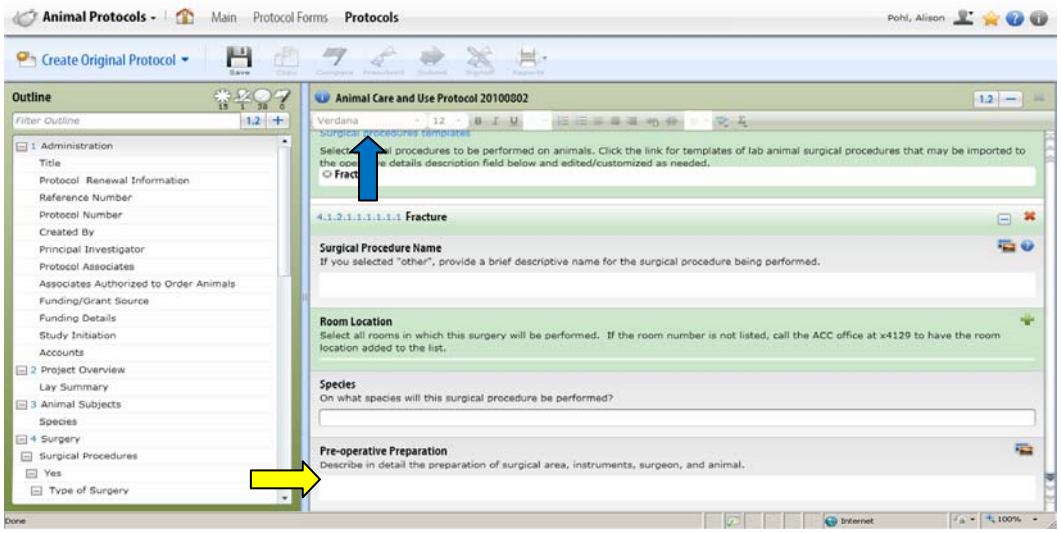


f. Species

Next you will have to detail what species this surgical procedure will be performed on. If it will be performed on multiple species, mention all species.

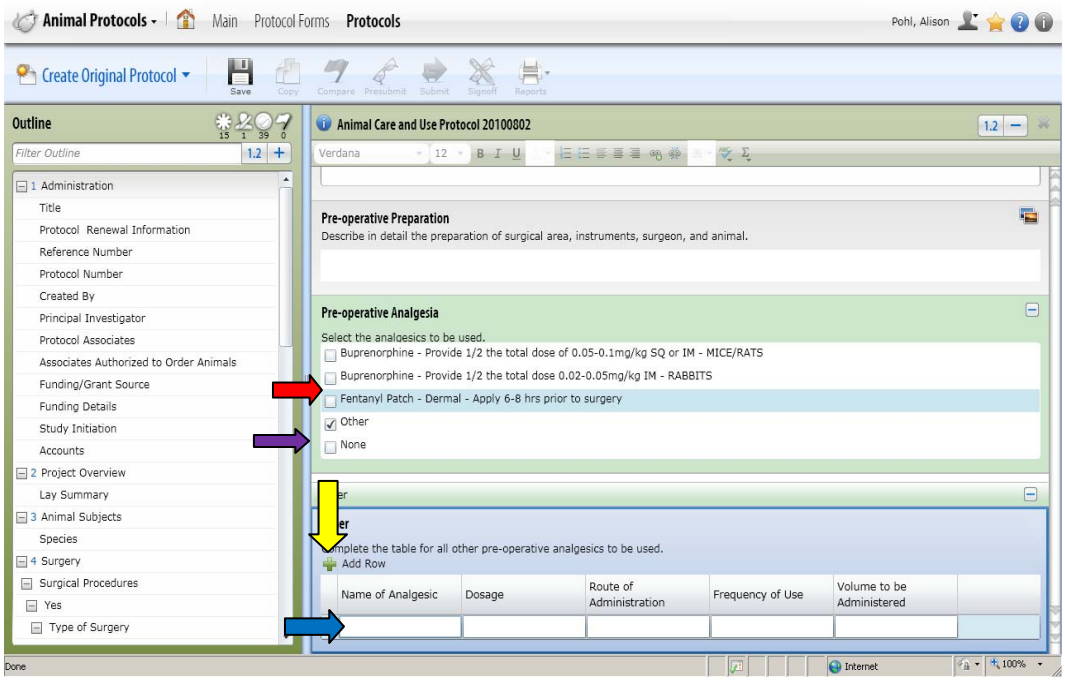
g. Pre-operative Preparation

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.



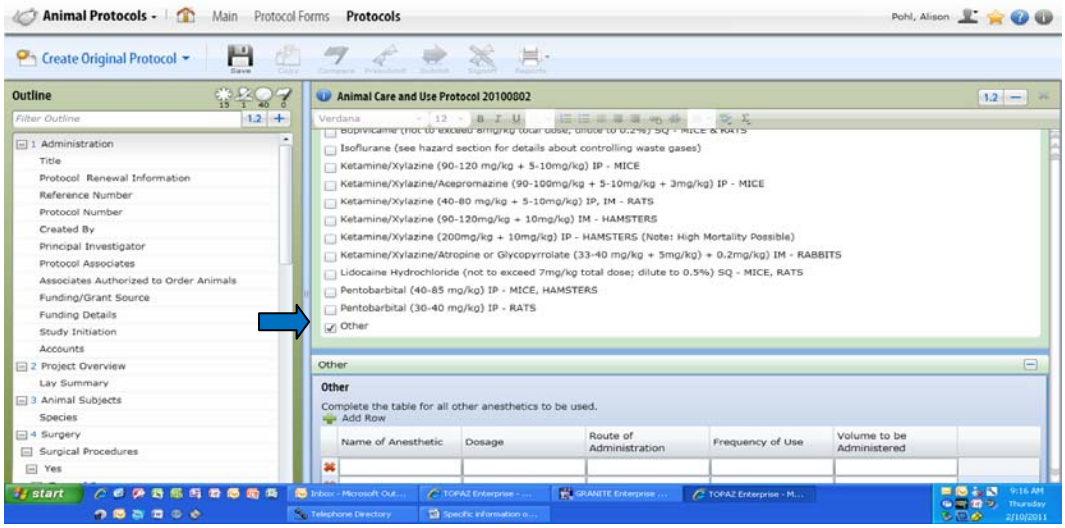
h. Pre-operative Analgesics

You will need to state if you are using pre-operative analgesics. You simply check on the appropriate box (red arrow). If you choose "other", then you will have to detail the analgesic to be used. You would need to click on the + (yellow arrow) to add a row to the table that will generate and complete the table for the analgesic to be used (blue arrow). If you choose "none" (purple arrow), then you will need to justify not using pre-operative analgesics in a question that will generate (not shown).



i. Anesthesia

Next you need to detail the anesthesia you will use. Simply select on the box which details what you will use (blue arrow). If you select other, you will need to add it as described in (h) above. If you choose Avertin, you will have to justify its use.



j. 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 (see g above), 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.

k. Post-operative Care

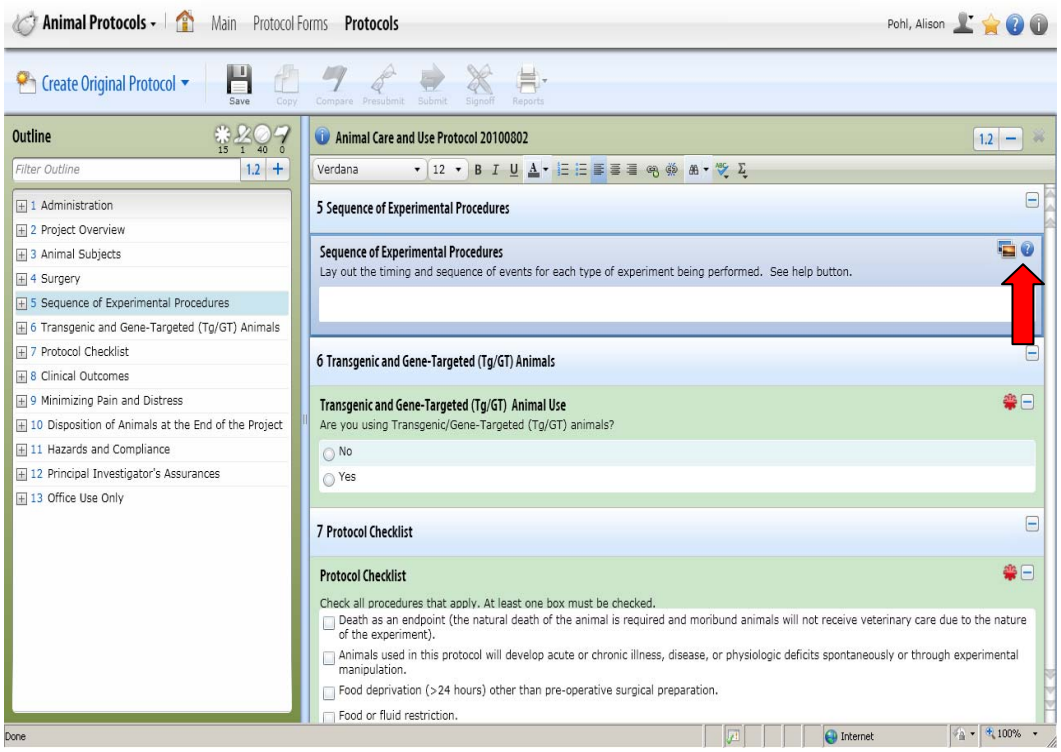
In this section, you must include information of how you are going to monitor for normal recovery from anesthesia and the provision for any supportive care. This should be the immediate post-operative period (e.g., first 24 hours). In addition, include when suture/wound clips will be removed.

l. 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. Sequence of Experimental Procedures

This is the section where you explain how all your different procedures fit together so that the committee understands what you are doing. The timing between various procedures and surgeries is important to understand, so take care when filling out this section. If you are unsure as to what is required, click on the help button (red arrow) and a help screen will generate to give you an idea of what is required.



6. Transgenic and Gene Targeted (Tg/GT) Animals
    a. 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.

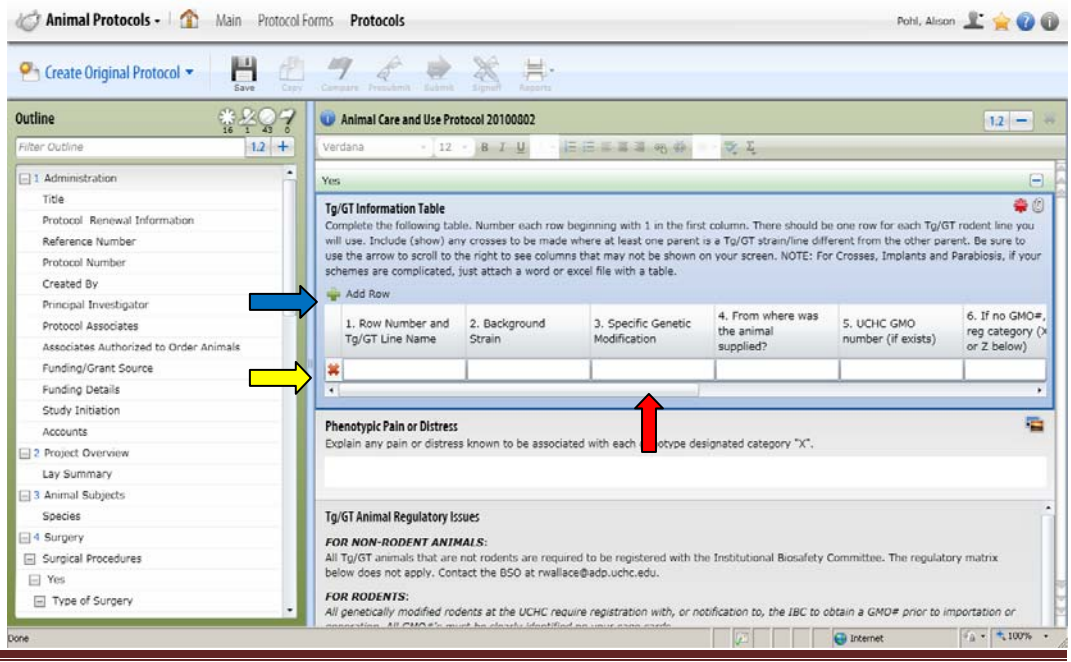
       PLEASE NOTE: this is a complicated section so you are going to have to **READ ALL INSTRUCTIONS CAREFULLY**.

       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.

    b. 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 on the + symbol (blue arrow) once for each Tg/GT line you will be using in your protocol- this will generate a row in the table (yellow arrow) 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.

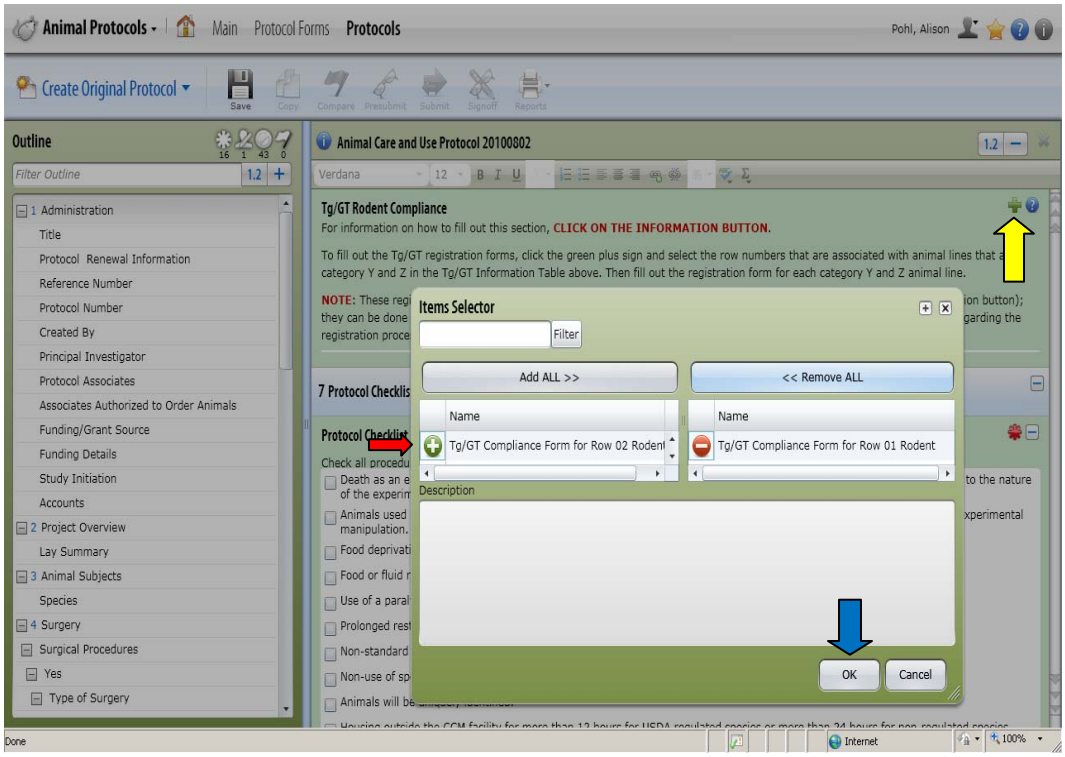


i. Column 1- Row Number and Tg/GT Line name
   Put in the row number (e.g., first row in table would be 1, second row in table would be 2, etc.) and the common name for the Tg/GT line
ii. Column 2- Background strain
   Enter the background strain of your Tg/GT line
iii. Column 3- Specific genetic modification
   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.

c. 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.

d. 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 + button (yellow arrow) which will generate the row numbers from section (b) above. Select the corresponding row number for the Tg/GT animal line which needs registration by clicking on the green symbol (red arrow) and then hitting the OK button (blue arrow). 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 CONTINUING WITH 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

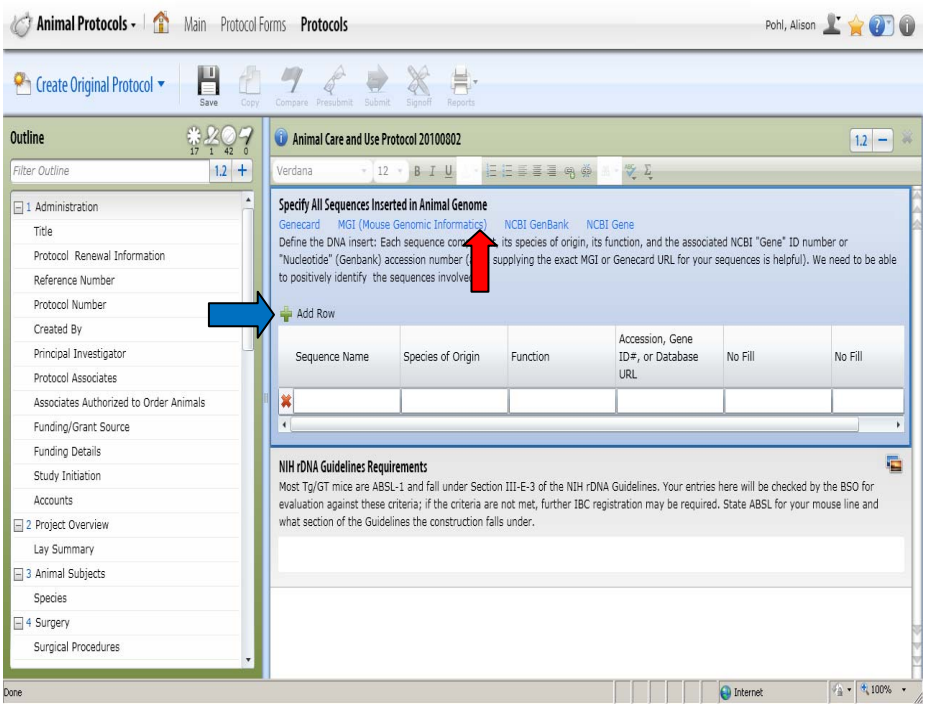
A short summary about the use of the sequence of interest rDNA in the research must be given. A description of what the sequence does must also be provided.

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 (blue arrow). 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 links that can help you find this information (red arrow).



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

This is a mandatory question, which means it must be answered in order to submit your protocol for approval. 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 acclimate 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.

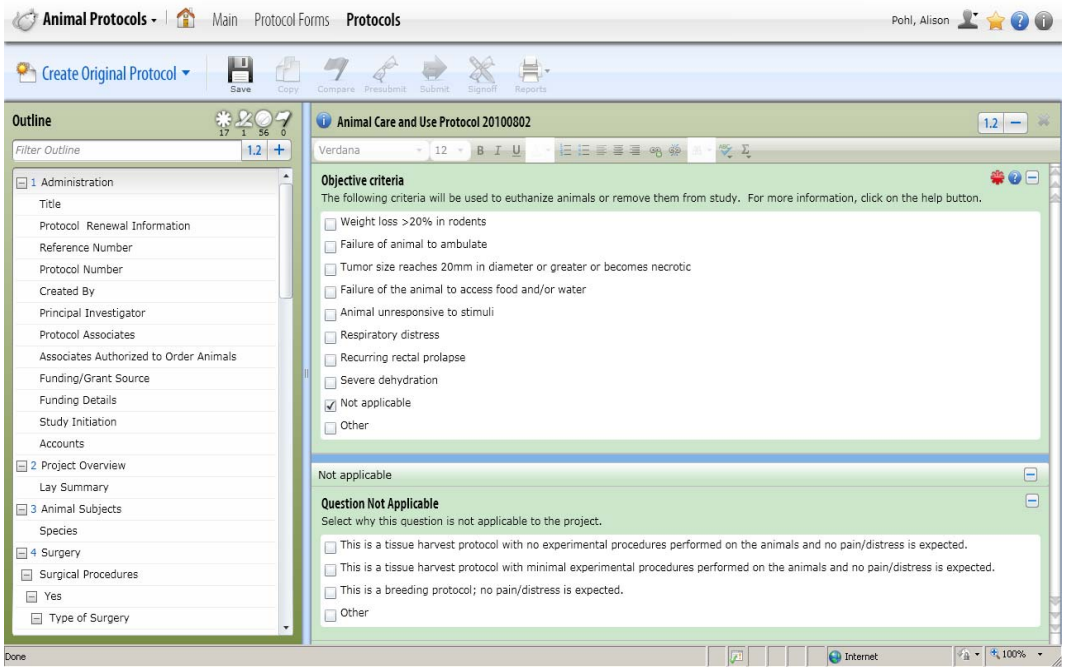
If you state that cells lines derived from, or passaged through, rodents will be used, a dialogue box will generate asking you if the cell lines have been tested for pathogens. You must answer yes or no to this question.

8. Animal Monitoring

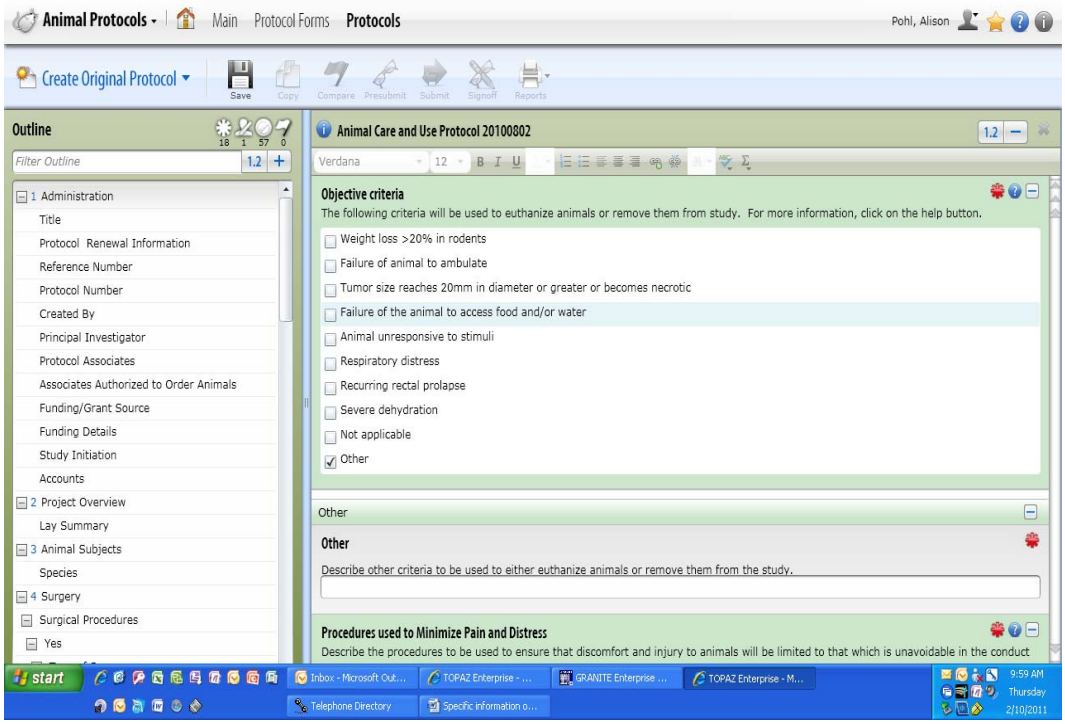
This is where you inform us what clinical signs for which you are going to assess your animals and how frequently you will be doing this. Check off all boxes that apply. One question will be generated for each item checked: How frequently are you going to check you mice for that parameter. You need to 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.

9. Minimizing Pain and Distress

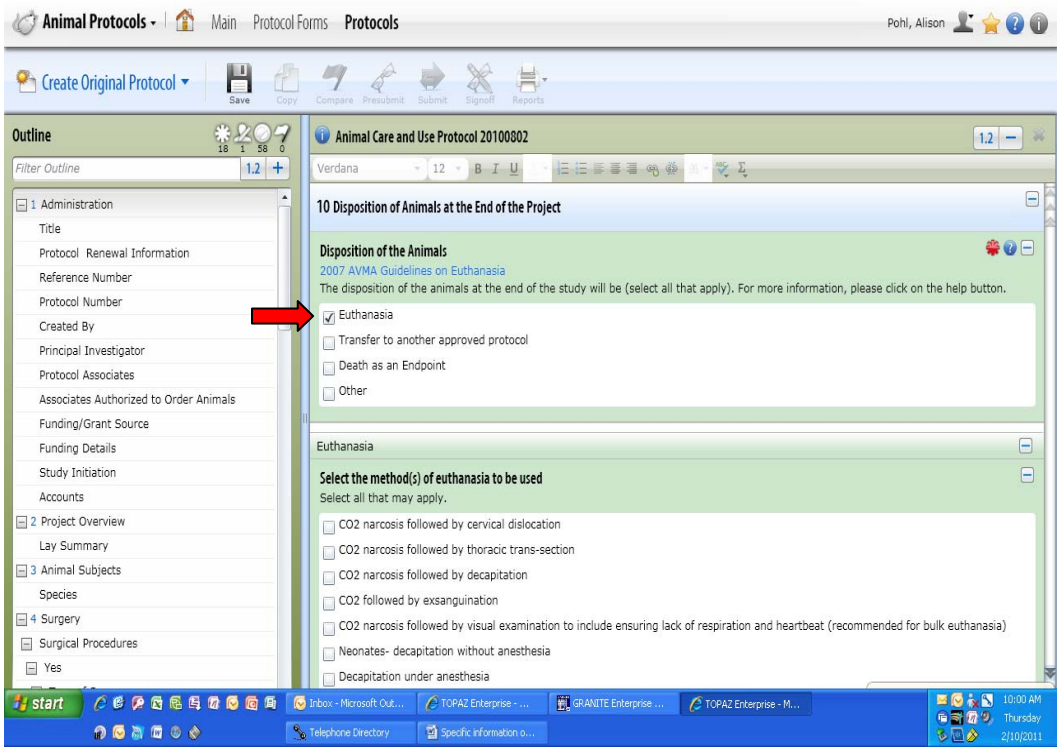
This is a mandatory question, which means at least one box must be checked in order to submit your protocol for submission. If you select "not applicable", you are going to have to state why it isn't applicable. This tells us when you are going to euthanize animals if their pain/distress is too great.



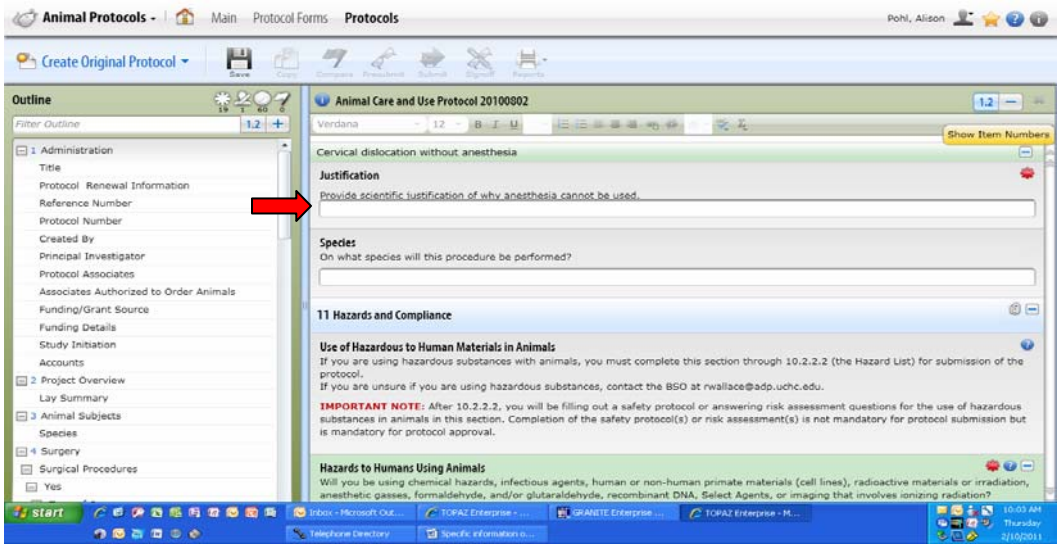
If you select "other", then you will have to describe what criteria you will be using.



10. Disposition of Animals at the End of the Project
    a. This is a mandatory question that must be answered in order for your protocol to be submitted for review. You simply select which box describes what the disposition of your animals will be at the completion of your study. If you select euthanasia (red arrow), you will be asked to state what method of euthanasia you will use.



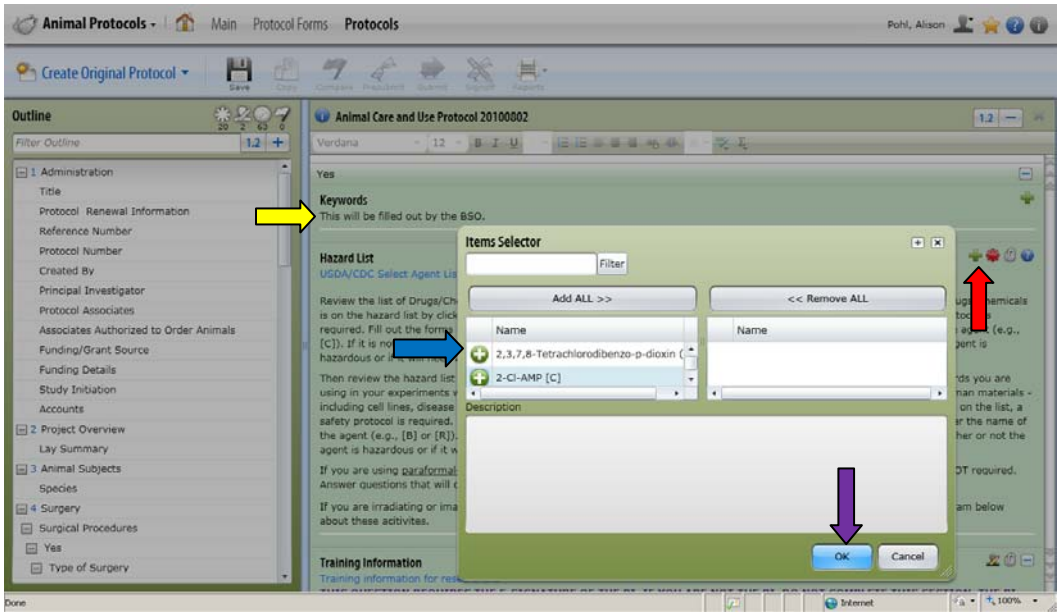
    b. If you choose a method of euthanasia that needs scientific justification, you will be asked to provide it. For instance, if you choose cervical dislocation without anesthesia, you would see the following. You would have to justify using this method of euthanasia (red arrow). All euthanasia methods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



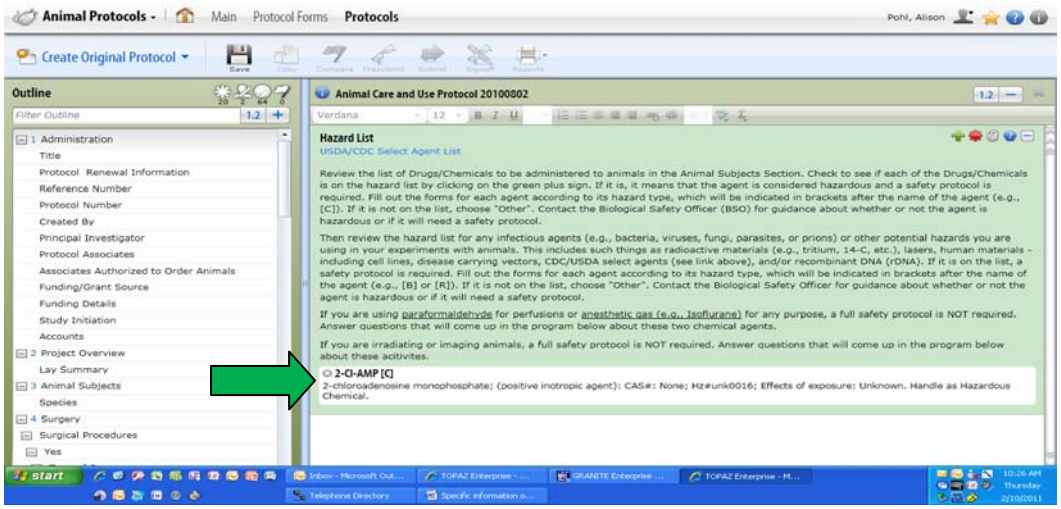
11. Hazards and Compliance
    a. Hazardous Agent Use

    This is a mandatory question, meaning it must be answered in order to submit your protocol for review. If you answer NO, then you are finished. 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.

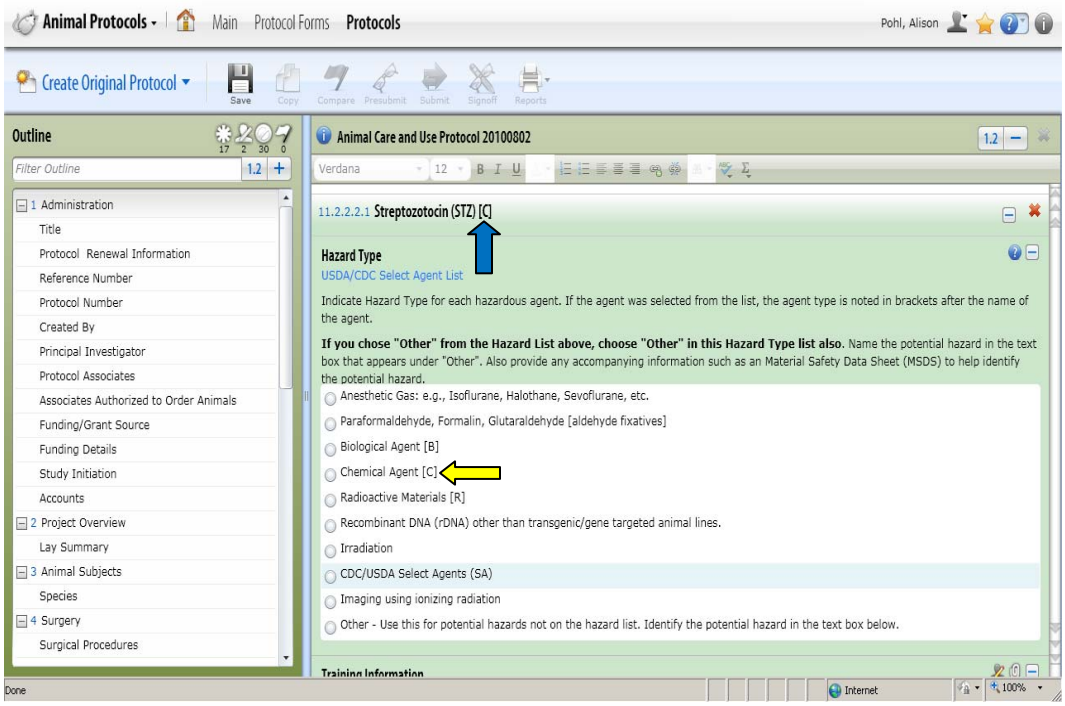
    b. If you select yes, the first thing you will need to do is to identify your hazard. Click the + button (red arrow) to generate a list of known hazards. To choose a hazard, click on the symbol (blue arrow) and then hit the OK button (purple button). If you don't you're your hazard, proceed to step **e** below. Ignore the Keywords question (yellow arrow), that information will be provided by the BSO or Chemical Hygiene Officer at a later date.



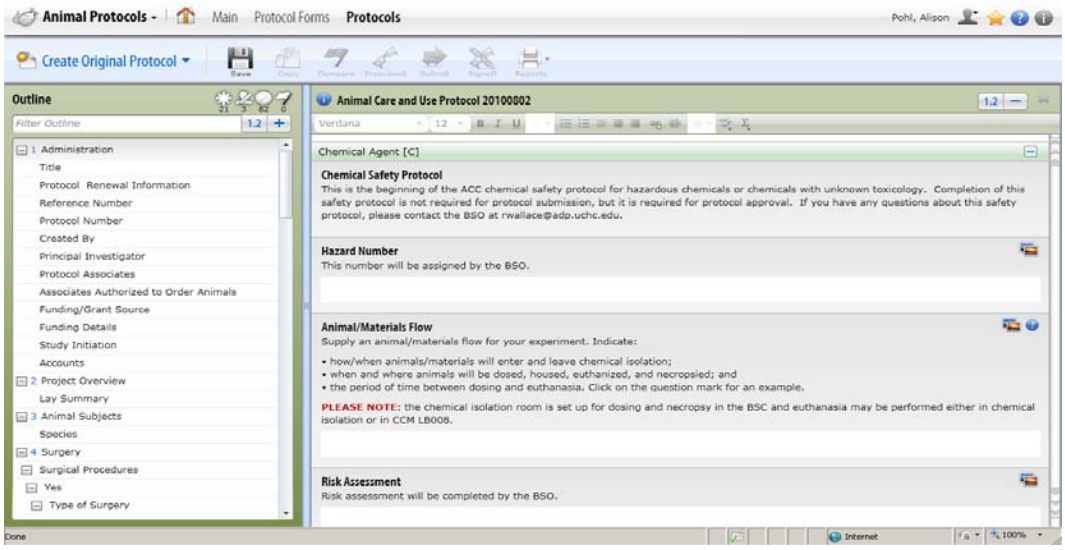
Once you choose your hazard, it will be shown on the screen (green arrow).



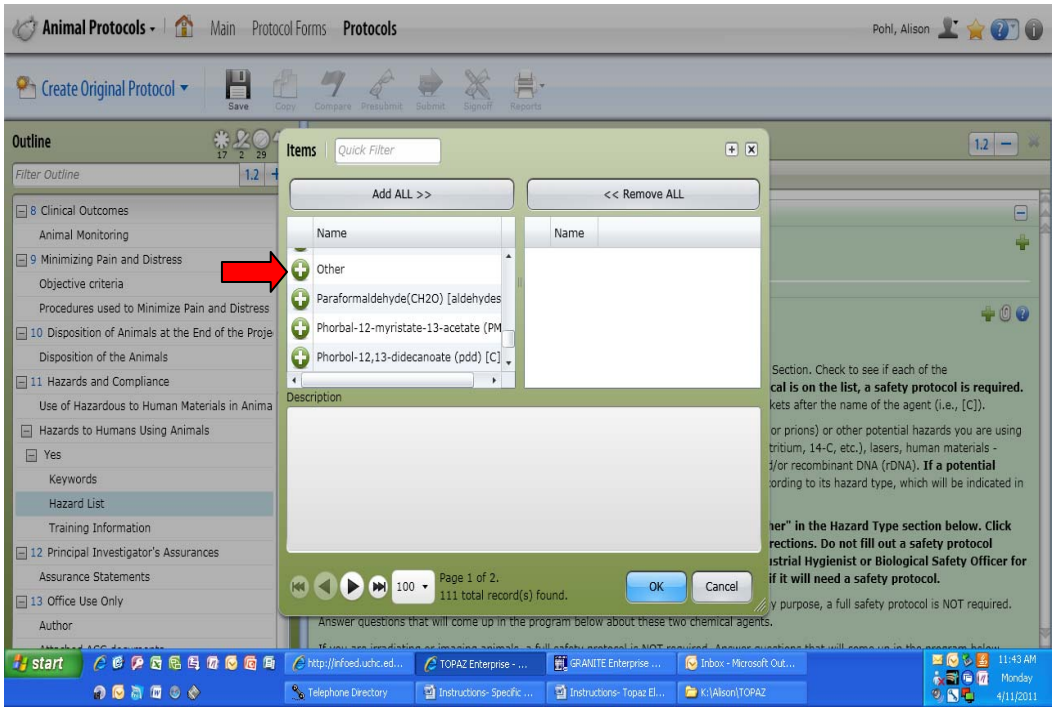
c. Then you will have to select a hazard type. The hazard types are shown in the hazard itself that you selected (blue arrow). Anything in brackets [] will be the hazard type. All you need to do is select the hazard type given. In this example, the selected hazard, Streptozotocin is a chemical hazard and has a [C] after it (blue arrow)- check the hazard type that has the [C] (yellow arrow).



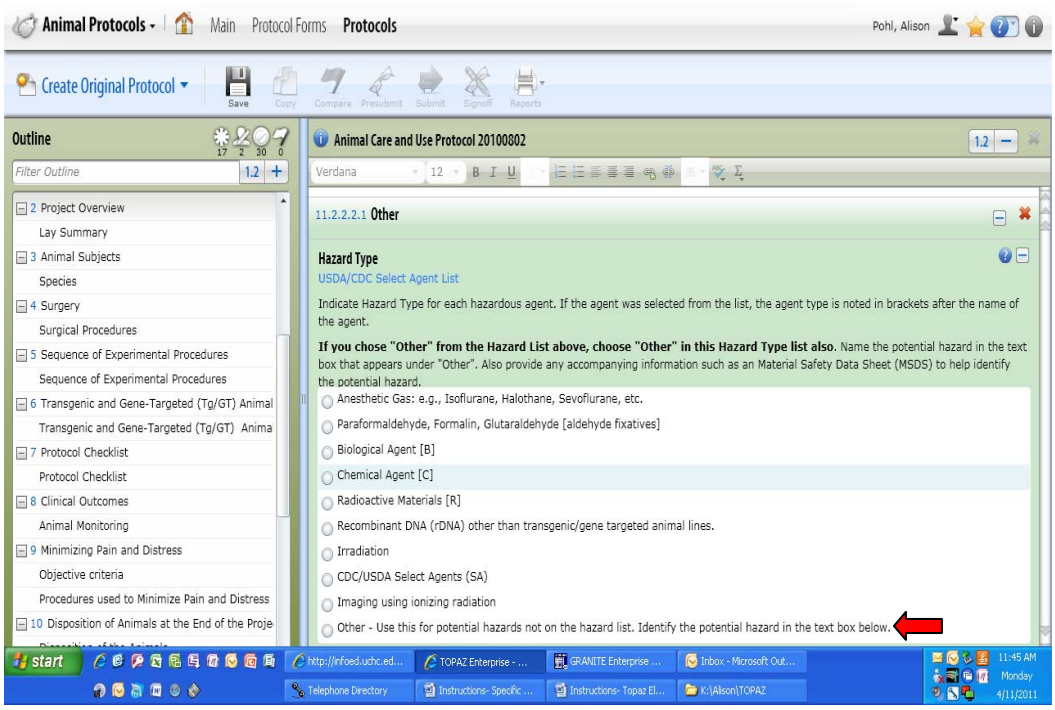
d. When you do this for each hazardous agent, a safety protocol form for each agent according to its type of hazard will be generated. You do **NOT** have to fill out the safety protocol prior to submission, but it **MUST** be completed prior to approval.



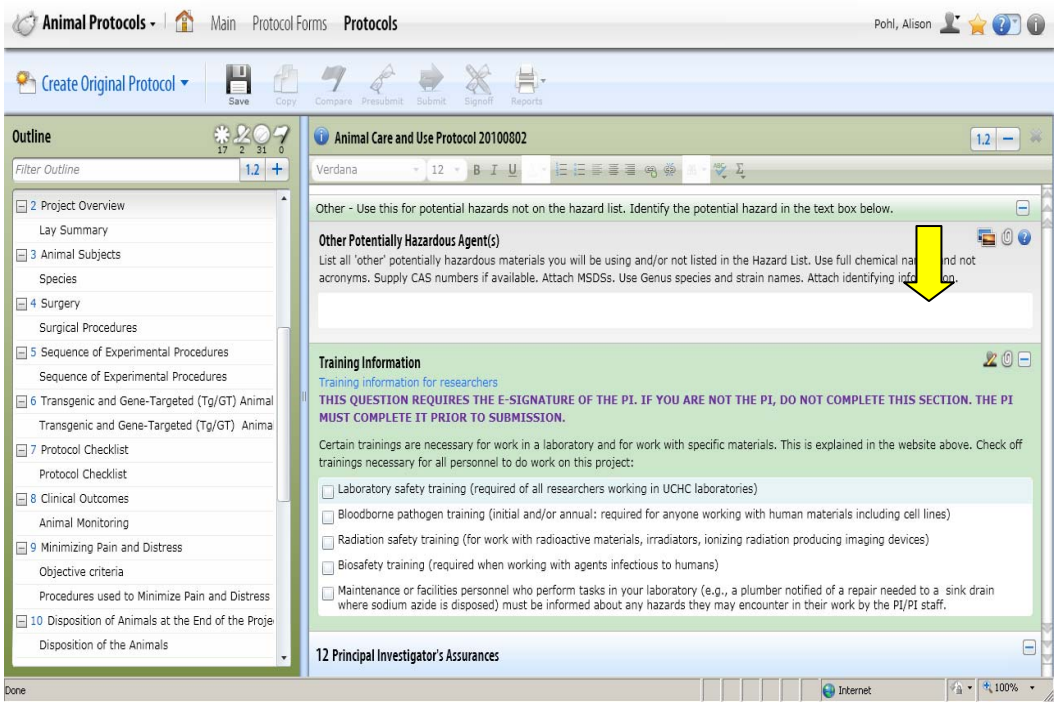
e. If you do not find what you believe to be a hazardous agent in the list, select “other” in the hazard list by clicking on the symbol (red arrow). Then click on the OK button.



Once you select “other”, the hazard type field will generate. Select “other” (red arrow).



This will generate a text field (yellow arrow). List all potentially hazardous materials in this field with any available identifying information (e.g., CAS numbers, MSDSs, etc.). If any are determined to be hazardous agents by the reviewers, they will be then be added to the hazard list and you will be required to choose it and complete the safety protocol during the resubmission process prior to protocol approval. **DO NOT FILL OUT ANY SAFETY PROTOCOL BEFORE YOU HAVE BEEN INFORMED THAT YOU AGENT IS CONSIDERED HAZARDOUS**.



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

f. Chemical Safety Protocols

i. Hazard number

Leave blank, this will be assigned during the review process.

ii. Animal/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.

iii. Risk assessment

Leave blank with initial submission. The BSO or chemical hygienist will inform you during the review what needs to be added here.

iv. Chemical

Select in what form the chemical will be received. Regardless of what is selected, dialogue boxes will generate in which you will have to describe how much is received and how the chemical is accessed.

v. Volatility

Select yes or no.

vi. Potential chemical spill

This section describes a spill or breakage of the source container. Spillage of diluted stocks or doses will be taken up in later sections. Be sure to answer all questions detailed in the section.

vii. Chemical preparation

Select yes or no. If yes is selected, dialogue boxes will generate asking for specific information on stock preparation, preparation procedures, and a spill protocol for the stock solution.

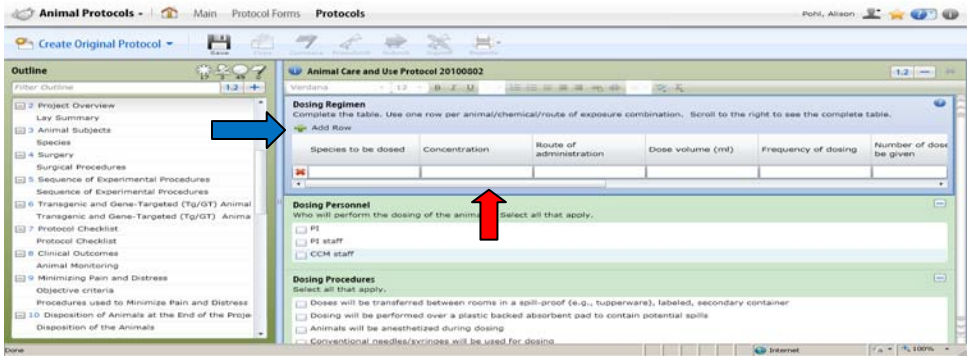
viii. Personal protective equipment- preparation

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

ix. 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 + sign (blue arrow). Complete the table. Be careful to observe the internal scroll bar (red arrow) so you do not miss columns.

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.



x. 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.

xi. Dosing procedures

Select all statements that apply.

1. If conventional needles/syringes is selected, dialogue boxes will generate regarding the use of safety needles and contaminated sharps disposal.
2. If non-conventional needles/syringes is selected, dialogue boxes will generate regarding the description of the needles/syringes to be used and contaminated sharps disposal.
3. If dosing will take place neither inside a chemical fume hood nor inside a BSC, a dialogue box will generate requesting a justification of why a fume hood or BSC is not used.
4. If left over doses will require disposal is checked, a dialogue box will generate asking for a description of disposal.

xii. Potential chemical spill

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

xiii. Personal protective equipment- dosing

Select from a list of person protective equipment all that will be used by personnel during dosing of the chemical to the animal.

xiv. 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.

xv. 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.

xvi. 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.

xvii. 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.).

xviii. PI assurances

Read and select all boxes.

g. Biological Safety Protocols

i. Hazard number

Leave blank, this will be assigned during the review process.

ii. Describe the hazardous biological agent

Make sure that you answer all the questions asked in this field.

iii. Storage

Identify all rooms and at what temperature the biological agents will be stored.

iv. Traits of infectious agents

Select all statements that apply.

a. Contains recombinant DNA

If this box is selected, you need to state if your recombinant agent has been registered with the UCHC IBC. Select either yes or no or unknown.

b. 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.

1. Preparation of the agent for inoculation 1

   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.

2. Preparation of the agent for inoculation 2

   - 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.

3. Signs and symptoms of human infection

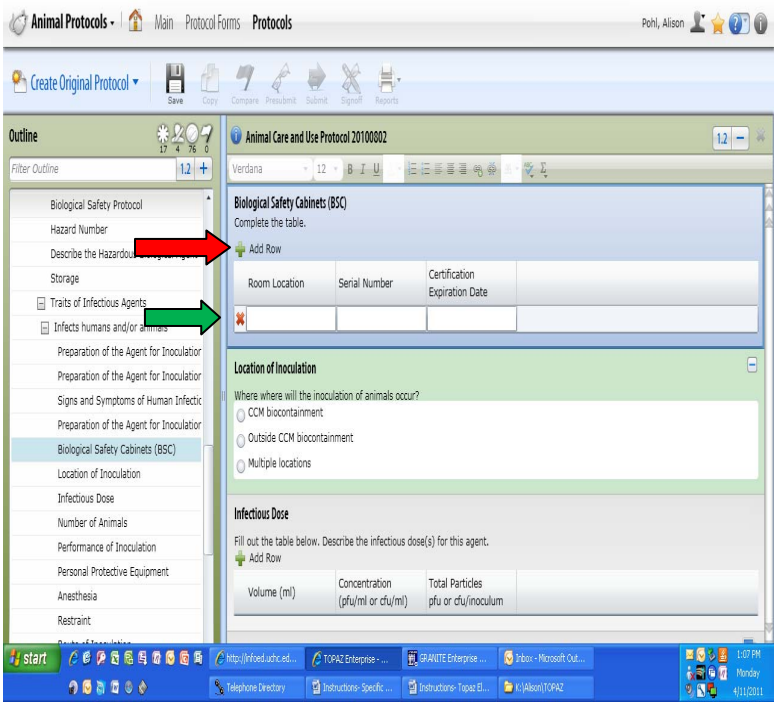
   Describe the signs and symptoms of human infection with the agent being used.

4. Preparation of the agent for inoculation 3

   Select all personnel protective equipment to be used for inoculation into the animals. Answer any questions that may be generated when each item is checked.

5. Biological safety cabinets

   Also known as BSCs or tissue culture hoods. You need to list all the BSCs you are working in with this agent. Click on the + symbol (red arrow) to generate a row (blue arrow)in the table. Complete the table.

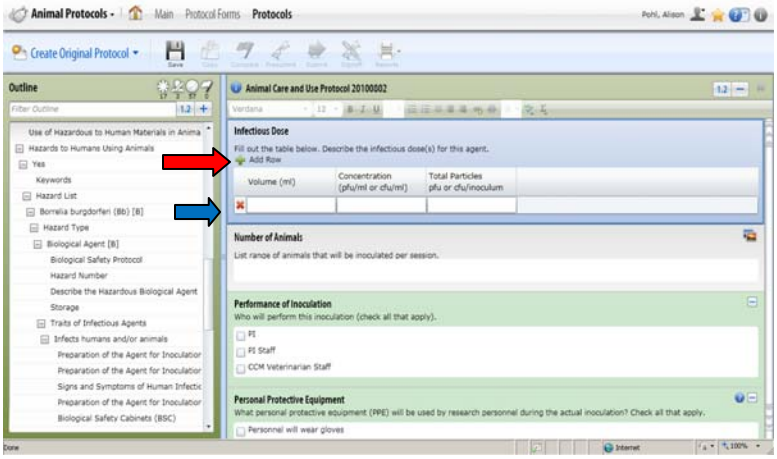


6. Location of inoculation

   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.

7. Infectious dose

   For each infectious dose, click the + sign (red arrow) to add a row to the table (blue arrow). Enter the information requested.



8. Number of animals
   List a range of the number of animals that will be inoculated per session.
9. Performance of inoculation
   Select 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.
10. Personnel protective equipment
    Select from a list of person protective equipment all that will be used by personnel preparing the chemical.
11. Anesthesia
    Select yes or no.
12. 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.
13. Route of inoculation
    Select all routes to be used.
    a. If "Intranasal Inoculation" is selected, the technique must be described.
    b. If "topical application" is selected, the technique must be described.
    c. If "injection" is selected, questions will generate regarding the use of needles will be generated; you must answer all questions.
    d. If "aerosol" is selected, a dialogue box will generate and you must describe the technique and safety equipment to be used.
    e. If "in food" is selected, a dialogue box will generate and description of how food is prepared and presented to the animals is required.
    f. If "gavage" is selected, a dialogue box will generate and you must describe the technique be used.
    g. If "other" is chosen, a dialogue box will generate and the route needs to be described.
14. Clearing 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.

15. Infection from agent after inoculation into animals
    This question is about animals shedding, by what route, and under what circumstances personnel may become infected.

c. Risk group 1
   Provide the source of the risk group classification you are using.
d. Risk group 2
   Provide the source of the risk group classification you are using.
e. Risk group 3
   Provide the source of the risk group classification you are using.
f. Attenuated strain
   If your strain is considered attenuated, you must describe its attenuation.
g. Drug resistant strain
   Describe the strain and to which drug(s) it is resistant. State what other drug could be used to treat laboratory acquired infections.
h. Regulated as a CDC/USDA select agent
   You need to discuss with the BSO the use of any select agents.
i. Laboratory is registered by the CT DPH
   Labs that use infectious agents need to be registered with the CT Department of Public Health. List the expiration date of the registration of your laboratory; if you need registration, contact the BSO.

v. Information about CCM biocontainment
   Read and select all statements. The e-signature that you will generate when answering this questions implies that you understand and agree to each statement.

vi. Animal/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.

vii. Animals leaving biocontainment
   Check off if animals are leaving biocontainment or not. If “yes” is selected;
   a. Information about Leaving Biocontainment. You must read and check off each statement.
   b. Not Returning. Select yes or no. If “yes” is selected, an explanation and justification for why infected animals will leave biocontainment and not return must be provided. Be sure to address all bullet points.

c. Leave and Return. Select yes or no. If “yes” is selected, an explanation and justification for why infected animals will leave biocontainment and return must be provided. Be sure to address all bullet points.

viii. Disposal of infected carcasses
Select the disposal method of the infected carcasses. If “other” is selected, a dialogue box will generate and the method of disposal if infected carcasses must be provided.

ix. Post-infection cage bedding disposal
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.

x. Other potential infectious exposures 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.

xi. 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.).

xii. PI assurances
Read and select all boxes.

h. Anesthetic gasses
1. If anesthetic gasses are checked as a hazard, the PI will have to list for what purposes the anesthetic gas will be used.
2. Then the PI will need to select all the methods of use from the selections generated.

i. Paraformaldehyde
1. If aldehydes are checked as a hazard, the PI will have to list for what purposes the aldehydes will be used.
2. Then the PI will need to detail what protections or controls will be used to protect researchers.

j. Radioactive Materials
The use of radioactive materials requires training, a radiation safety protocol, and an animal safety protocol. The PI must contact the BSO.

k. Recombinant DNA
The use of recombinant DNA requires registration with the IBC. The PI must contact the BSO.

l. Irradiation
The use of irradiation requires training and fingerprinting. The PI must contact the radiation safety office

m. CDC/USDA select agents

The use of select agents (other than exempt quantities of toxins) is prohibited at the UCHC.

n. Imaging using ionizing radiation

Use of imaging that involves ionizing radiation requires training. The PI must contact the radiation safety office.

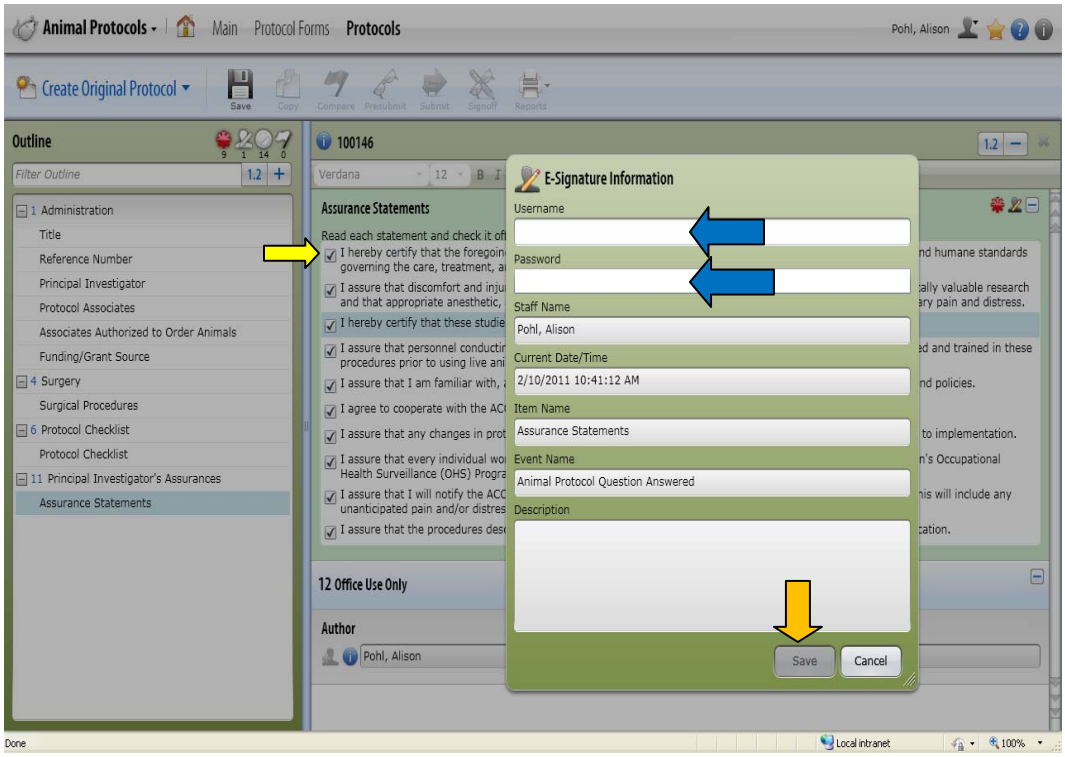
o. Other

1. If “other” is checked, the PI must contact the Research Safety Industrial Hygienist or the BSO.
2. The PI must list all the “other” potentially hazardous materials which will be used. DO NOT FILL OUT ANY SAFETY PROTOCOL.

p. Training Information

The PI must select each applicable box.

12. Investigator Assurances
    a. 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.
    b. Simply check off **EACH BOX** after you read the corresponding statement (yellow arrow). When you hit the save button (red arrow) a dialogue box will generate which will ask you for your username and password (blue arrows). Enter that information and then hit the save button (orange arrow) which will not be grayed out.



13. For ACC Use only

    Do not write or change anything in this field. The ACC office will generate an individual as an ACC Only Author; you will not be able to change this name.