

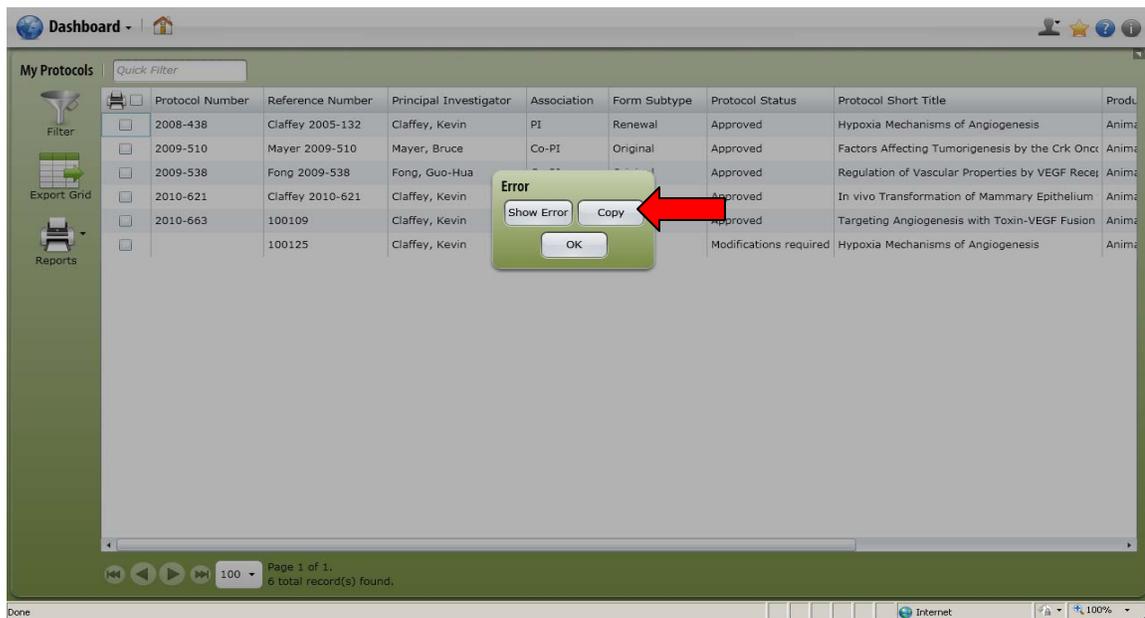
Topaz Electronic Protocol Development

Instructions for Researchers

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HANDY HINTS:

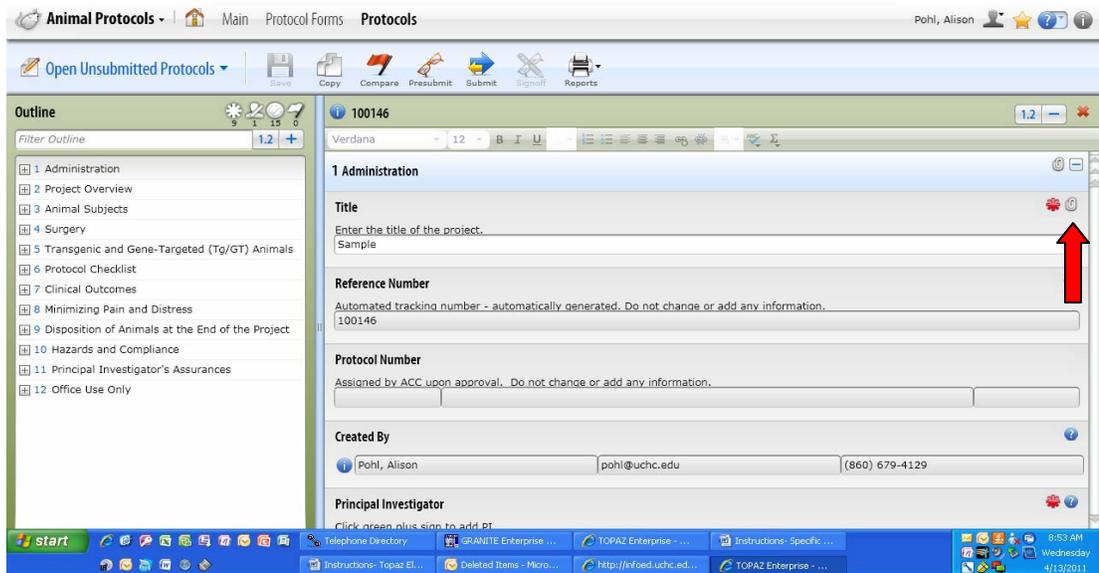
- **Use the information buttons.** If you are unsure how to answer a question, clicking on this button will help you and/or give you an example.
- **Save often.** This program is web-based and if you lose your connection to the web, you will regret not saving. But do not click the save button twice in a row. Most times, the system won't register it because the save button will be grayed out. But double clicking the save button can sometimes cause the system to crash- so be careful. If you are going to walk away from your work for any length of time (say >5 minutes), save your work and close your document! Leaving the work open on the screen can sometimes cause errors in the system.
- **Use your outline view effectively.** Your outline view can show you which questions must be answered in order to submit your protocol. Your outline view can show you which questions you must change when you submit your revisions. You can use your outline as a navigation tool to bring you to any question in the document itself.
- **Be careful scrolling.** Some screens have internal scroll bars which you have to use, but can be difficult to see. Take some time to getting used to scrolling through the document.
- **Error messages.** You might get error messages. If you do, you will need to notify the ACC office of them. Simply click on the copy button when an error message generates (you won't see the whole error message when you click on the copy button [red arrow]) and paste it into an email and send it to the ACC office at ooacc@uchc.edu. Please give a brief description of what you were trying to do when the error occurred.



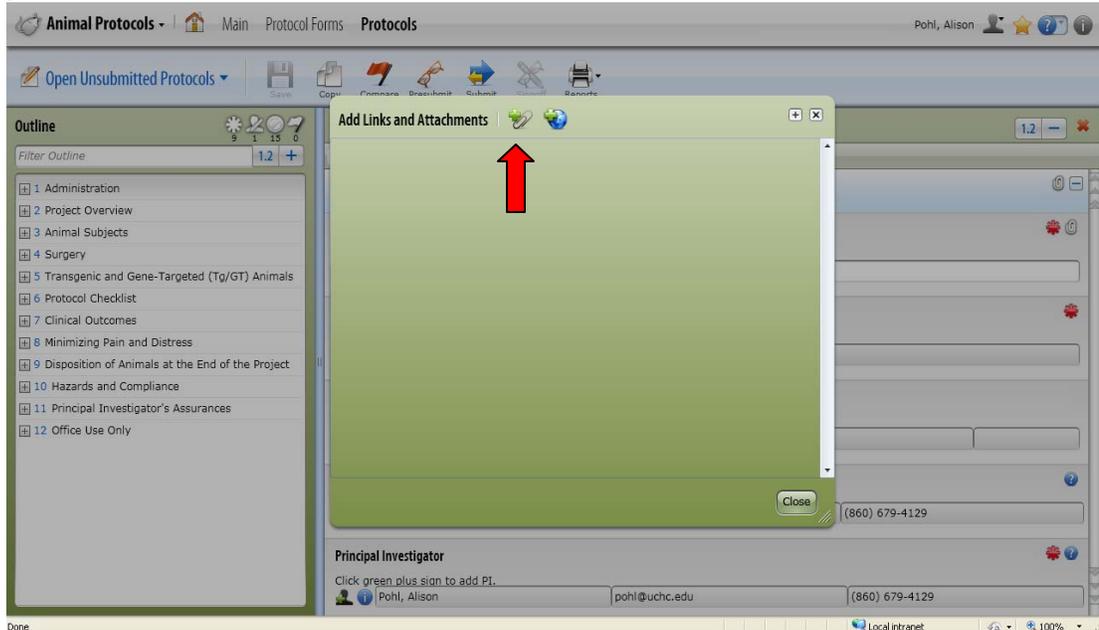
- **Attaching documents to your protocol.**

Attaching documents to the protocol is simple, but the FIRST TIME you attach, you will need to map your computer within the Topaz System.

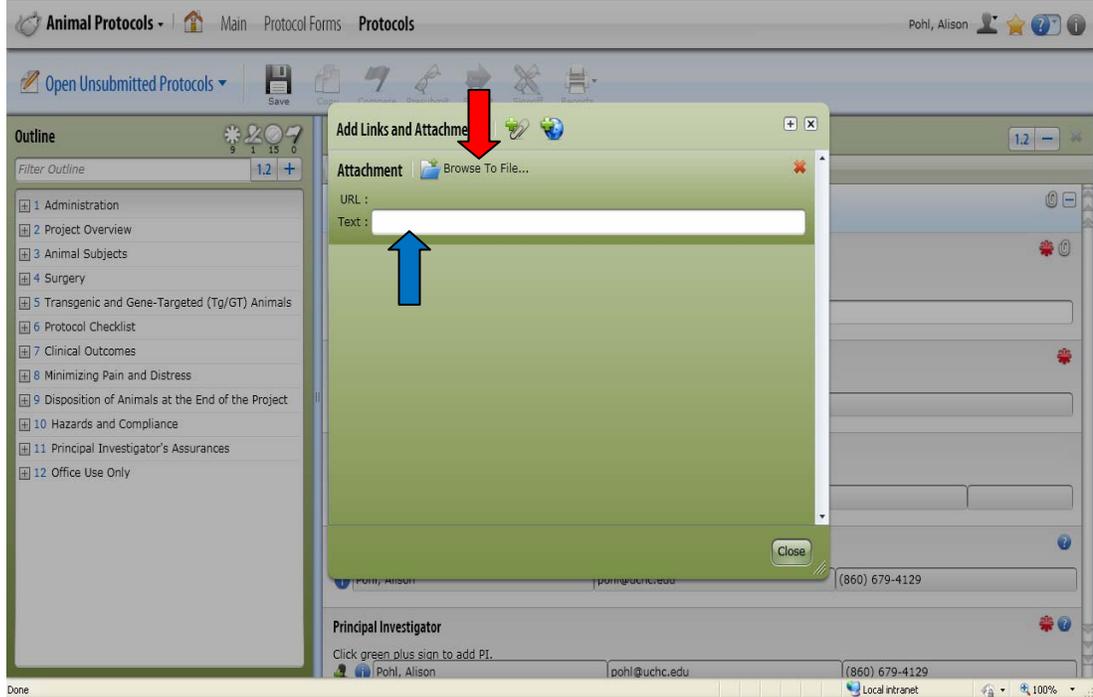
1. When you are in a section that accepts attachments, there will be a paperclip icon. Click on this icon (red arrow).



2. Then a dialogue box will generate. Click on the paperclip (red arrow) to add a document, picture, etc.

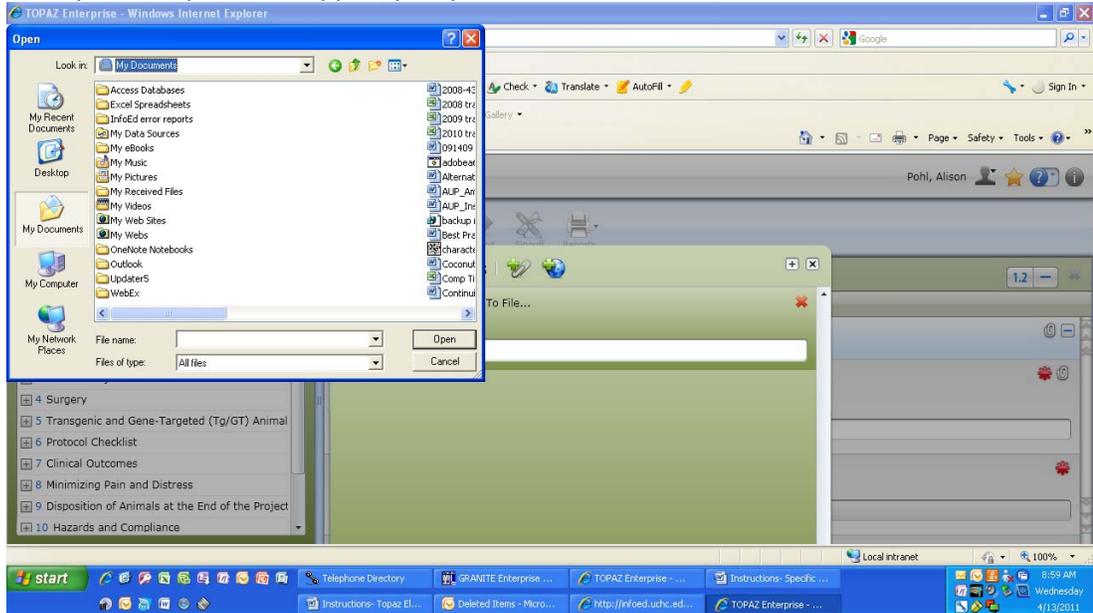


- Then another dialogue box will generate. In the text field (blue arrow), label your document. Then click on the “Browse to File” (red arrow) to attach the document.



- You'll need to map your computer. You will see “C\$ client on...”. Click on that. Then find “documents and settings” and click on that. Then find your name, and click on that. Then find “desktop” and click on that. Your computer will now be mapped and you will NOT have to repeat this.

- Once your computer is mapped, pick your file to attach.



Creating New Animal Care and Use Protocols

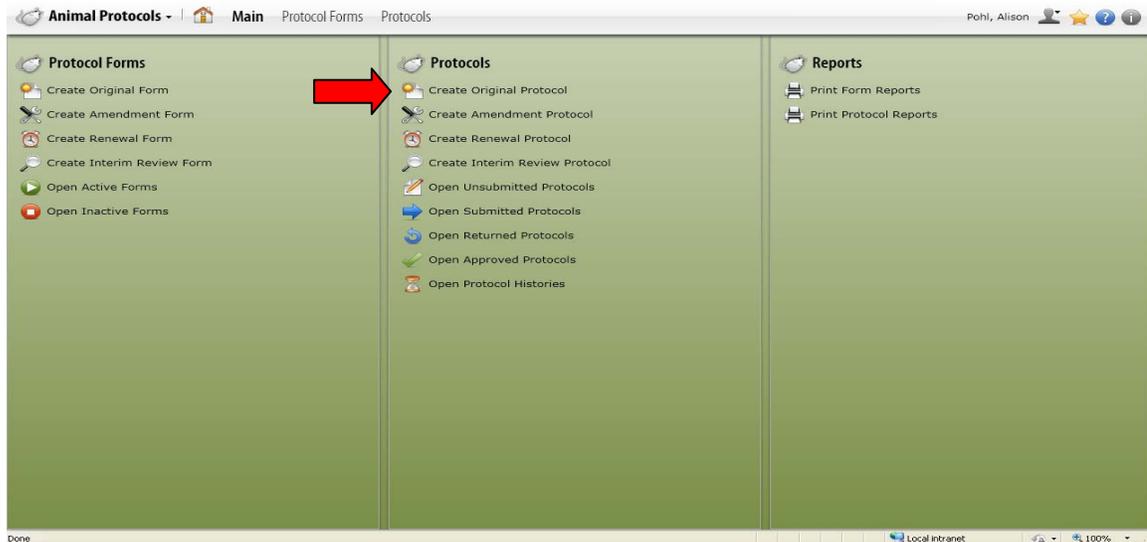
1. When you open up the Topaz system through Citrix, you will see the following screen.



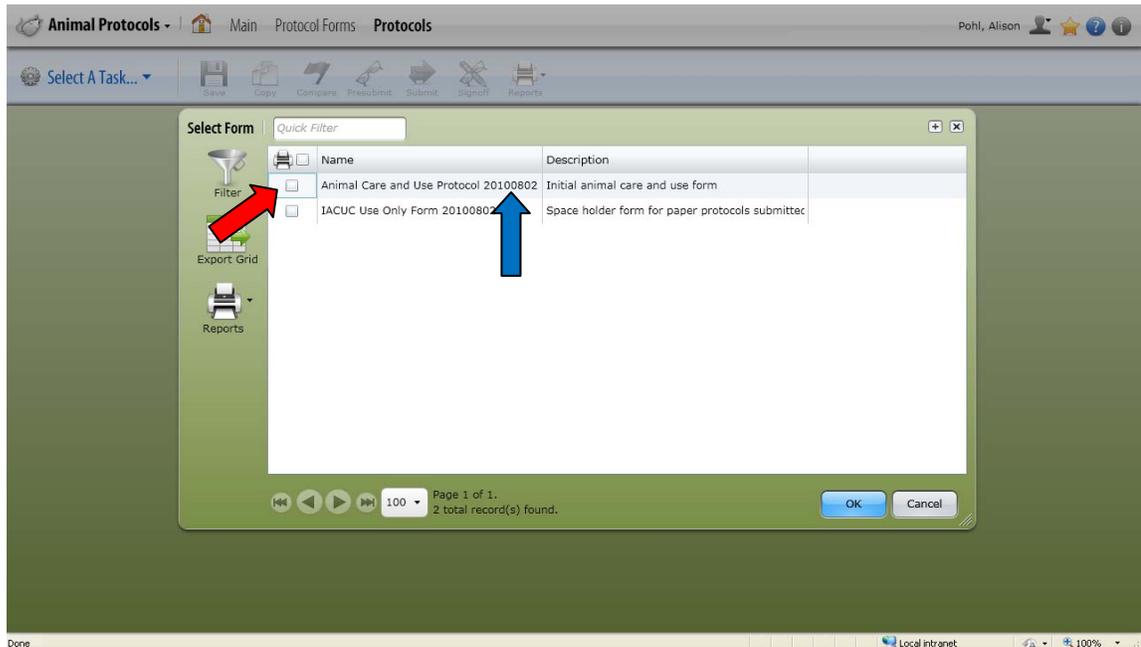
2. You will need to enter your username and password. Typically, the username will be the same as your username in Granite and your password will be your last name. If you are unsure, please call the ACC office (x3429) to get your password re-set. Once you enter your username and password for the first time (or after a re-set), you will have to change your password. Then the Topaz Home Page will generate. You will need to click on Protocols under the Animals heading (red arrow) to start a new protocol.



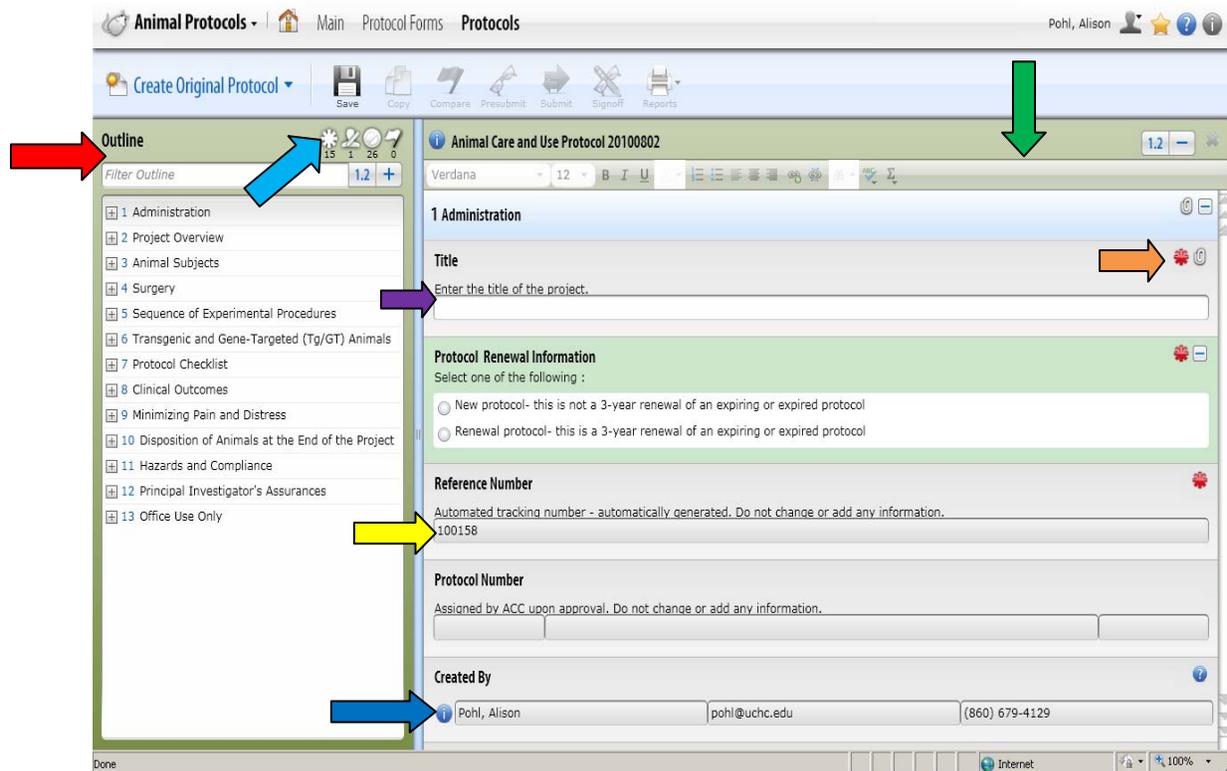
3. Then you will need to click on Create Original Protocol under the Protocols heading (red arrow). **IF YOU DO NOT HAVE THIS OPTION**, it means you are not set up to create protocols. Do **NOT** go any further- contact the ACC coordinator (x4129) to arrange to have the user privileges to create protocols. If you are not a PI, your PI will need to send an email to the ACC (oacc@uchc.edu) to ask that you have these privileges.



4. When you select this option, you will be asked to select which form to use as a template to build your protocol from. There typically will be only 1 form at any given time to use- it will always be labeled the Initial Animal Care and Use Protocol. **USE ONLY THIS FORM**. Select this form by clicking on it (blue arrow), not on the box next to it (red arrow).



5. The protocol form will then generate. It is important to understand some of the functions you will have with this program to write your protocol in an efficient manner.
 - a. You can get to questions either by the outline (red arrow) or the protocol form itself (green arrow).
 - b. You can see that a reference number (yellow arrow) will automatically generate. You cannot change the reference number and it will always be associated with this protocol. In fact, once the protocol is approved, the reference number with an added suffix will be the protocol number.
 - c. The name of whomever starts the creation process of a protocol will automatically be generated in the created by section (dark blue arrow).
 - d. You will notice some questions have red stars (orange arrow)- this means that these questions **MUST** be answered in order for you to ultimately submit your protocol. You can also see what questions these are in the outline section by clicking on the same symbol (light blue arrow).



IMPORTANT INFORMATION TO REALIZE:

In order to save your protocol, 3 fields **MUST** be completed: the reference number (yellow arrow), a title (purple arrow), and the PI name (which is not shown on this screen). You will not be able to save your document unless these fields are completed. As stated, the reference number is automatically generated, so you will only have to worry about the other two fields.

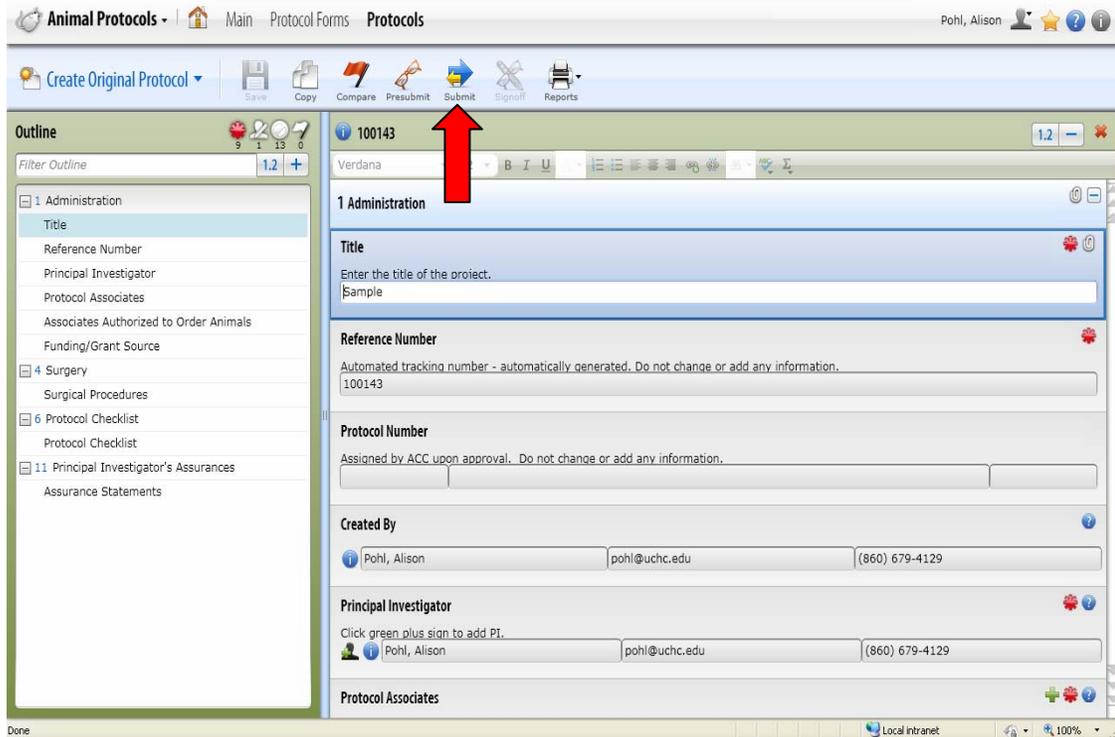
6. Start filling out the protocol form. Refer to the supporting document if you have questions on each protocol section.

IMPORTANT NOTE: Even though the protocol will allow you to submit it for review if you have answered only the mandatory questions, please realize that all questions must eventually be answered. The more complete you are in filling out the application, the quicker it will be to get your protocol reviewed and approved.

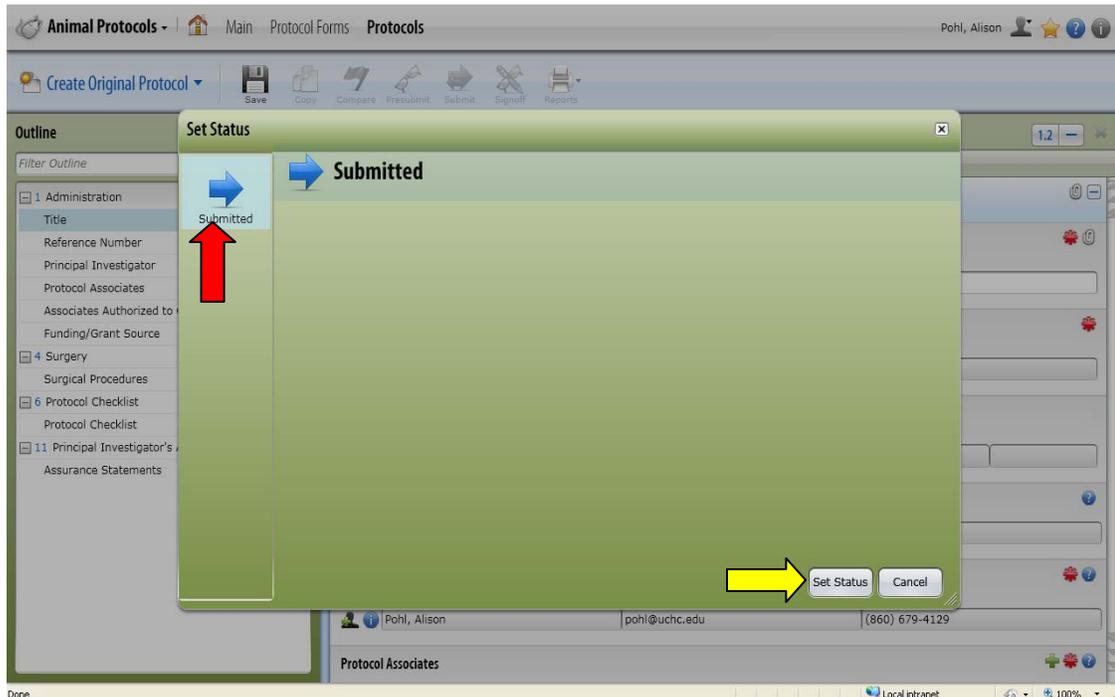
7. There are sections that will require an e-signature by the PI. These sections **MUST** be completed by the PI prior to submission. In addition, the submission **MUST** be performed by the PI. If either e-signatures or submission are performed by anyone other than the PI, **IT WILL BE RETURNED**. These sections are clearly labeled in the document. When you answer these questions, a dialogue box will generate. You must put in your username and password (blue arrows) and then hit the save button (which will not be grayed out [red arrow]).

The screenshot displays the 'Animal Protocols' software interface. On the left, an 'Outline' pane shows a tree view of protocol sections, with '11 Principal Investigator's Assurances' and its sub-section 'Assurance Statements' selected. A blue arrow points from this section to the 'E-Signature Information' dialog box. The dialog box is titled 'Animal Care and Use Protocol 20100802' and contains the following fields: 'Username' (empty), 'Password' (empty), 'Staff Name' (filled with 'Pohl, Alison'), 'Current Date/Time' (filled with '2/9/2011 8:06:10 AM'), 'Item Name' (empty), 'Assurance Statements' (empty), 'Event Name' (filled with 'Animal Protocol Question Answered'), and 'Description' (empty). At the bottom of the dialog box, there are 'Save' and 'Cancel' buttons. A red arrow points to the 'Save' button, and a blue arrow points to the 'Password' field. The background shows the main application window with a toolbar and a sidebar.

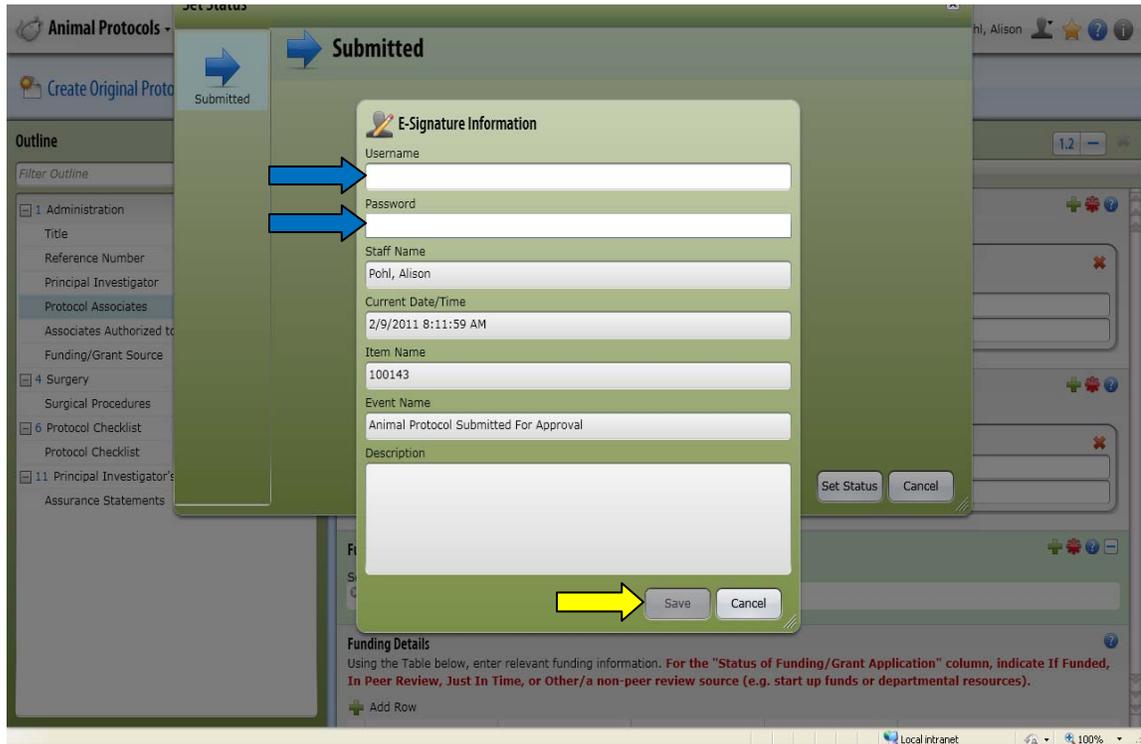
8. Once you are sure the protocol is ready to be submitted, you can start the submission process. You will need to click on the submit button (red arrow).



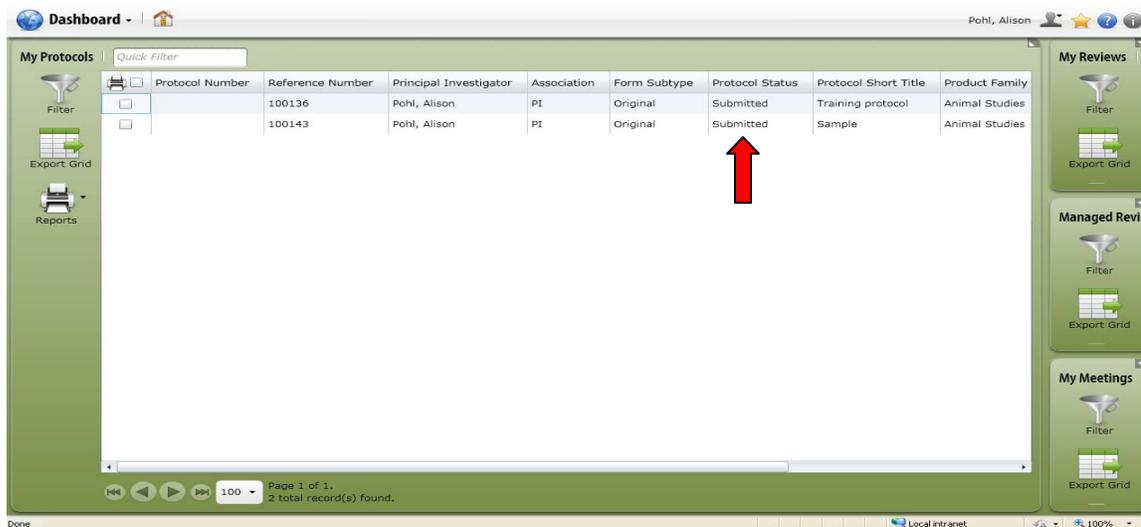
9. Then a dialogue box will generate. Select submitted (red arrow) and then click on the set status button (yellow arrow)



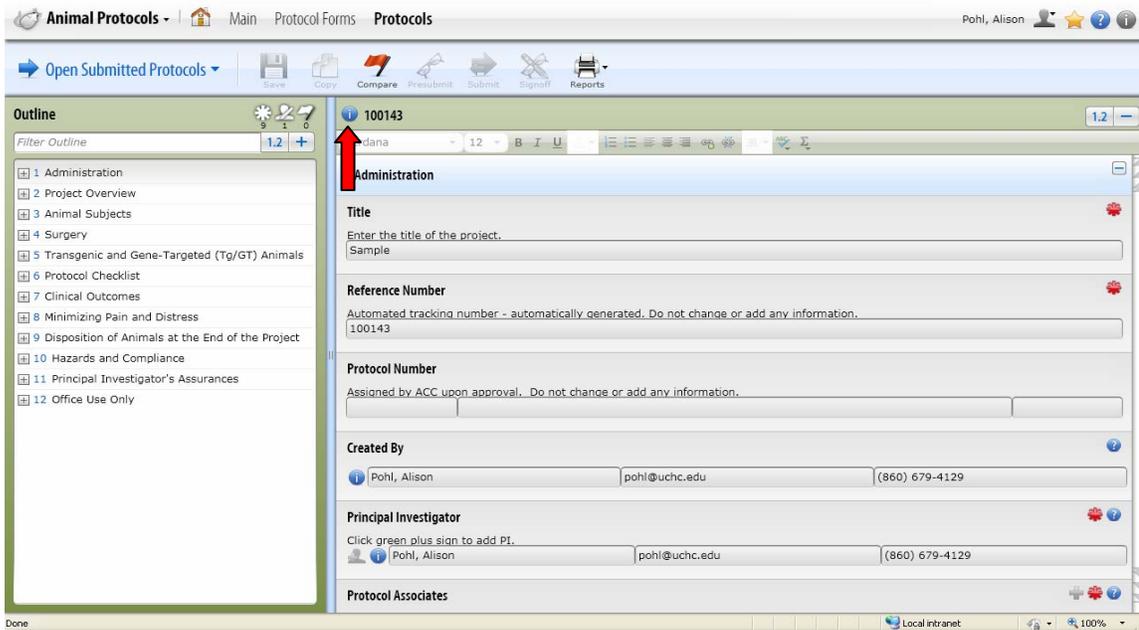
10. Then a dialogue box will generate. Put in your user name and password (blue arrows) and hit the save button (which will not be grayed out [yellow arrow]).



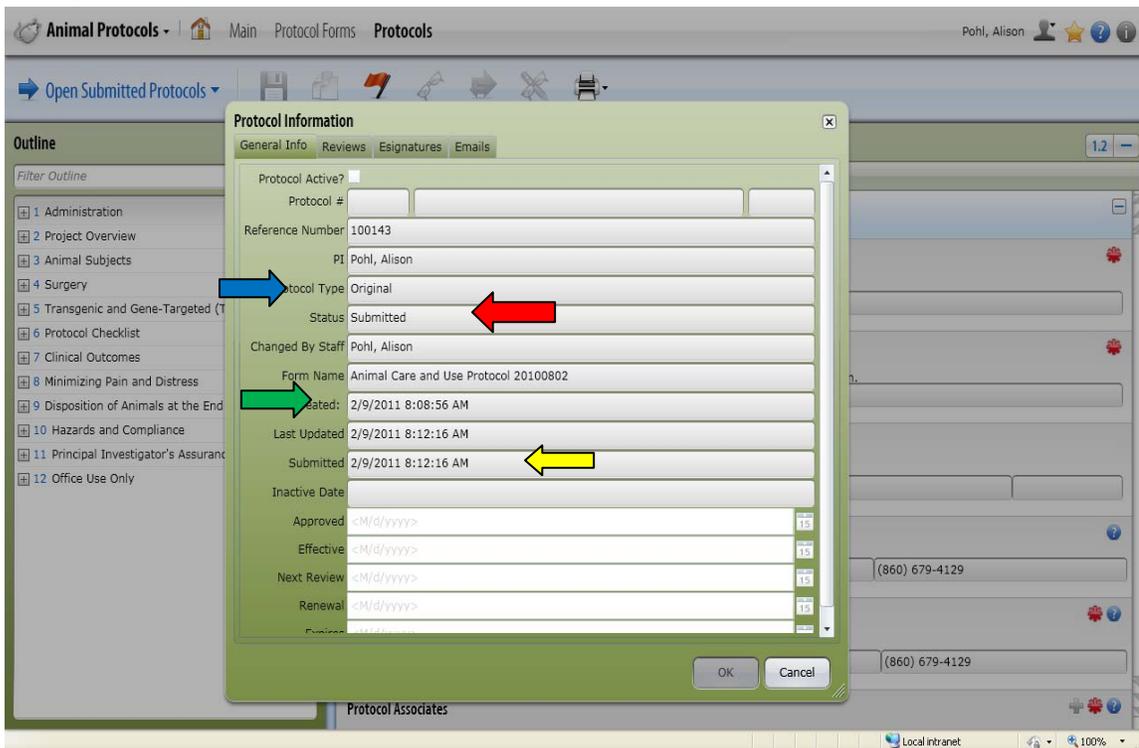
11. Your protocol has been submitted. Please do **NOT** send an email to the ACC office; the Topaz system automatically generates an email to the office to inform of the submission. The way you can tell that your protocol was submitted is to go to "my protocols" on your dashboard. Look for the protocol you just submitted- the Protocol Status should say "submitted" (red arrow). If it doesn't, then something went wrong. Simply go back into the protocol and re-submit.



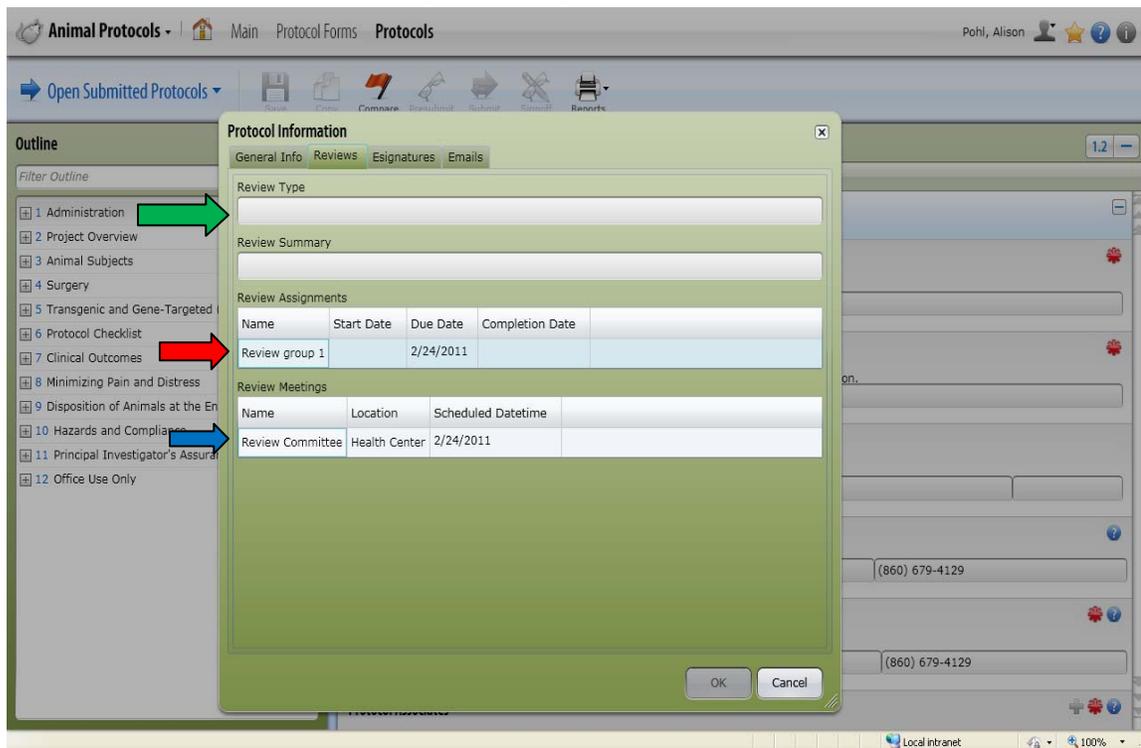
12. You do have the ability to see what review step your protocol is at any time you want. Simply open up your protocol and click on the blue **i** button that is by the reference number (red arrow).



13. The General Information tab will tell you the protocol's status (red arrow), the protocol type (blue arrow), when it was created (green arrow), and when it was submitted for review (yellow arrow).



14. The review tab will show you the due date for reviewers to finish the review (red arrow) and, if the review is going to the full committee, the review meeting date the protocol has been scheduled to will be shown as well (blue arrow).



NOTE: Even though the Review Type is missing in this screen shot (green arrow), you will see either “Full Committee Review” or “Designated Member Review”. You should look in the “Review Meetings” section and you can see when your protocol is scheduled for the full committee review. If a designated member review is the requested review, there may not be a meeting date associated with it.

At this point, the protocol has been successfully submitted to the ACC for review.

Revising Protocols after ACC Review

1. If your protocol was not approved outright, you will get an email generated to your Outlook inbox stating that your protocol has been reviewed and requires changes prior to approval. It will instruct you to go to your dashboard, open your protocol, and all changes to be addressed will be seen.
2. Open your dashboard and go into your “My Protocols” screen. You will see your protocol listed as “Returned for Modification” (red arrow). Open up your protocol by clicking on it.

The screenshot shows a web application interface for 'My Protocols'. It features a table with columns: Protocol Number, Reference Number, Principal Investigator, Association, Form Subtype, Protocol Status, and Protocol Short Title. The table contains six rows of data. A red arrow points to the 'Returned For Modification' status in the 'Protocol Status' column for the protocol with number 100148. The interface also includes a 'Quick Filter' box, a 'Filter' button, and an 'Export Grid' button. The bottom of the table shows 'Page 1 of 1. 6 total record(s) found.'

Protocol Number	Reference Number	Principal Investigator	Association	Form Subtype	Protocol Status	Protocol Short Title
100136	100136	Pohl, Alison	PI	Original	Submitted	Training protocol
100146	100146	Pohl, Alison	PI	Original	Not Submitted	Sample
100038	100143	Pohl, Alison	PI	Renewal	Approved	Sample
100038	100143	Pohl, Alison	PI	Renewal	Returned For Modification	Sample
100147	100143	Pohl, Alison	PI	Original	Not Submitted	Training protocol
100148	100148	Pohl, Alison	PI	Original	Returned For Modification	Sample Protocol to do a Topaz I

3. To see which questions have comments, you need to click on the “Questions with Summary Comments” button in the outline (red arrow). This will show you all the questions that require some type of explanation or change (green arrows); usually these are lines that don't have boxes with minus signs in them.

The screenshot shows the 'Animal Protocols' dashboard for protocol 100148. The 'Outline' section on the left lists various sections of the protocol form, including Administration, Project Overview, Animal Subjects, Surgery, and Post-operative Care. A red arrow points to the 'Questions with Summary Comments' button in the outline. Green arrows point to various sections in the outline, indicating which sections have comments. The main content area shows the 'Administration' section with fields for Title, Reference Number, Protocol Number, Created By, and Principal Investigator.

Outline:

- 1 Administration
- 2 Project Overview
- 3 Animal Subjects
 - Species
 - Mice #1
 - General Experimental Design
 - Alternatives to Painful Procedures
- 4 Surgery
 - Surgical Procedures
 - Yes
 - Type of Surgery
 - Major Survival (defined as any surgery that op
 - Multiple surgery
 - No
 - Surgical Procedures
 - Ovariectomy
 - Operative Details
 - Post-operative Care

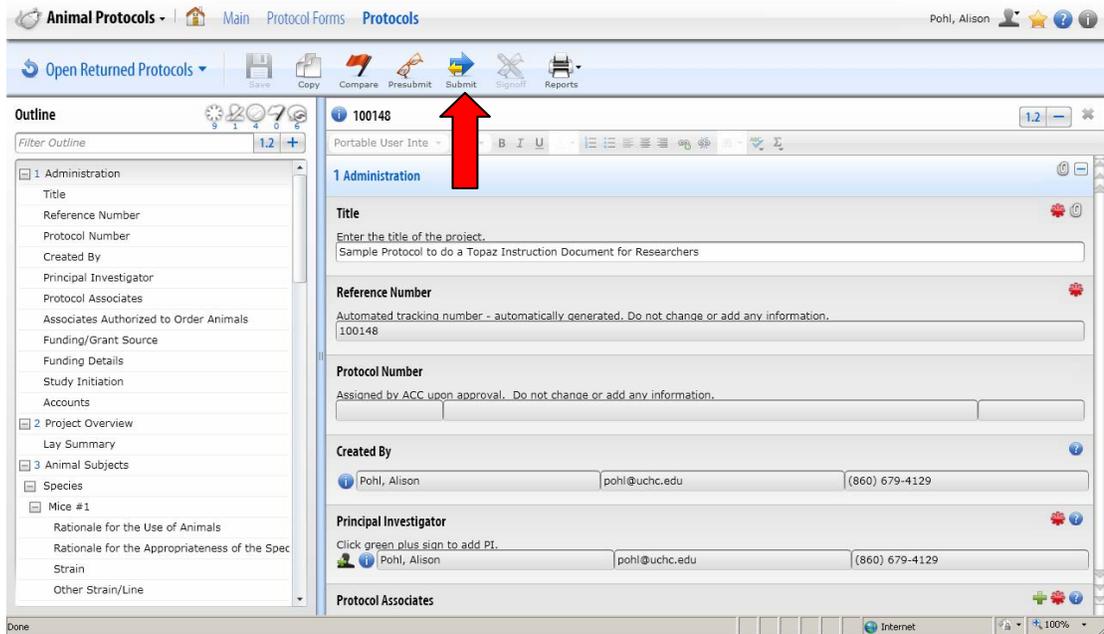
4. You can use your outline to navigate to that question to review the comments (red arrow). Double click on the outline and that section will populate on the protocol form.

The screenshot shows the 'Animal Protocols' software interface. The 'Outline' pane on the left lists various sections, with 'General Experimental Design' selected. A red arrow points from this section in the outline to the 'General Experimental Design' section in the main editor. The main editor displays the text for 'General Experimental Design' and a yellow comment box with the text 'This needs more detail.' and a timestamp of '2/23/2011 9:11:46 AM'. Below the comment box is the 'Rational for Requested Animal Numbers' section, which includes a non-statistical approach for calculating animal numbers and a table of requirements.

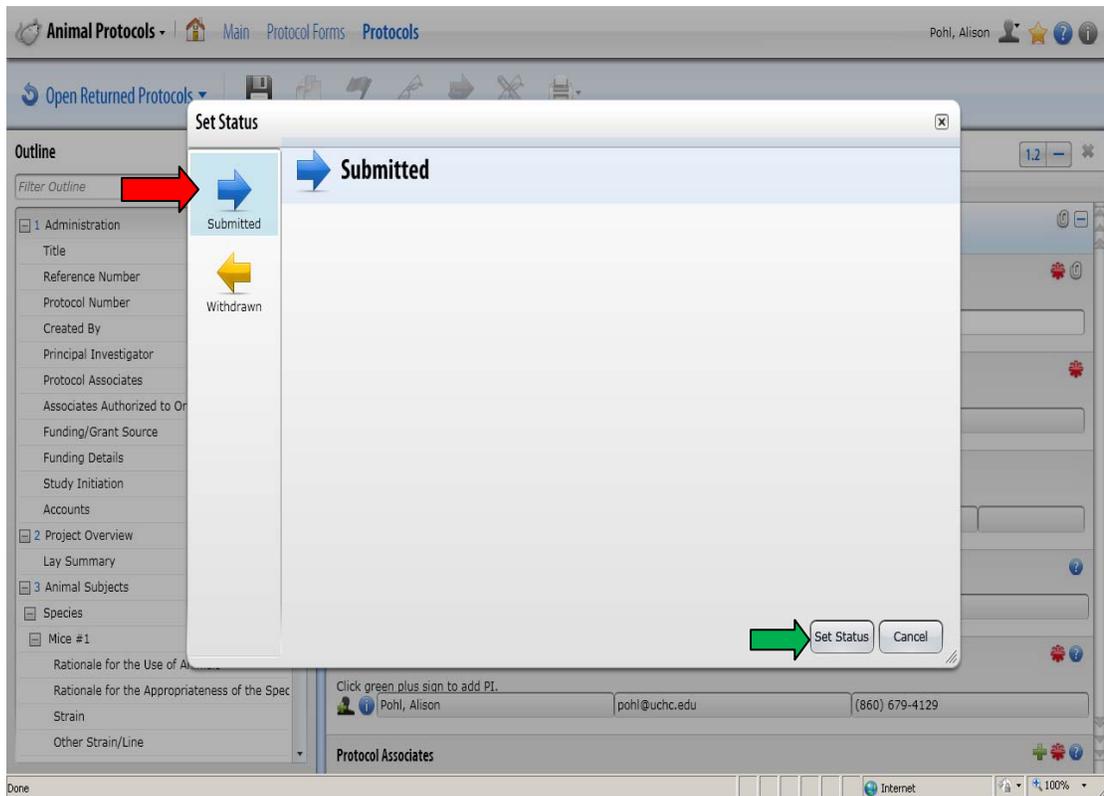
5. Then simply put the cursor in the box and type whatever changes are required (blue arrow). Hit the save button (red arrow). Do this for every question where changes are required. You do **NOT** need to use a different font, color, or anything else for the changes.

The screenshot shows the 'Animal Protocols' software interface. The 'Outline' pane on the left lists various sections, with 'General Experimental Design' selected. A red arrow points to the 'Save' button in the top toolbar. The main editor displays the text for 'General Experimental Design' and a yellow comment box with the text 'This needs more detail.' and a timestamp of '2/23/2011 9:11:46 AM'. Below the comment box is the 'Rational for Requested Animal Numbers' section, which includes a non-statistical approach for calculating animal numbers and a table of requirements. A blue arrow points to the text 'Then we will determine what benefits the chemical had to the animals.' in the 'General Experimental Design' section.

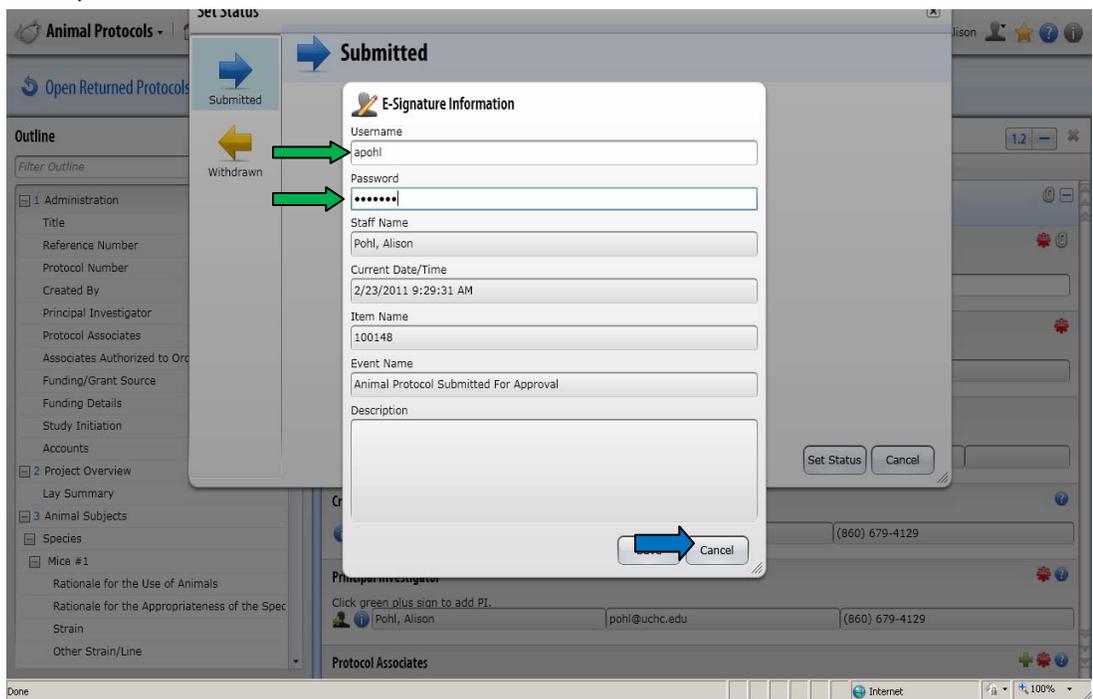
6. Once you are satisfied that all the changes are made, then you will need to re-submit the protocol. You will need to click on the “submit” icon (red arrow) to submit the protocol.



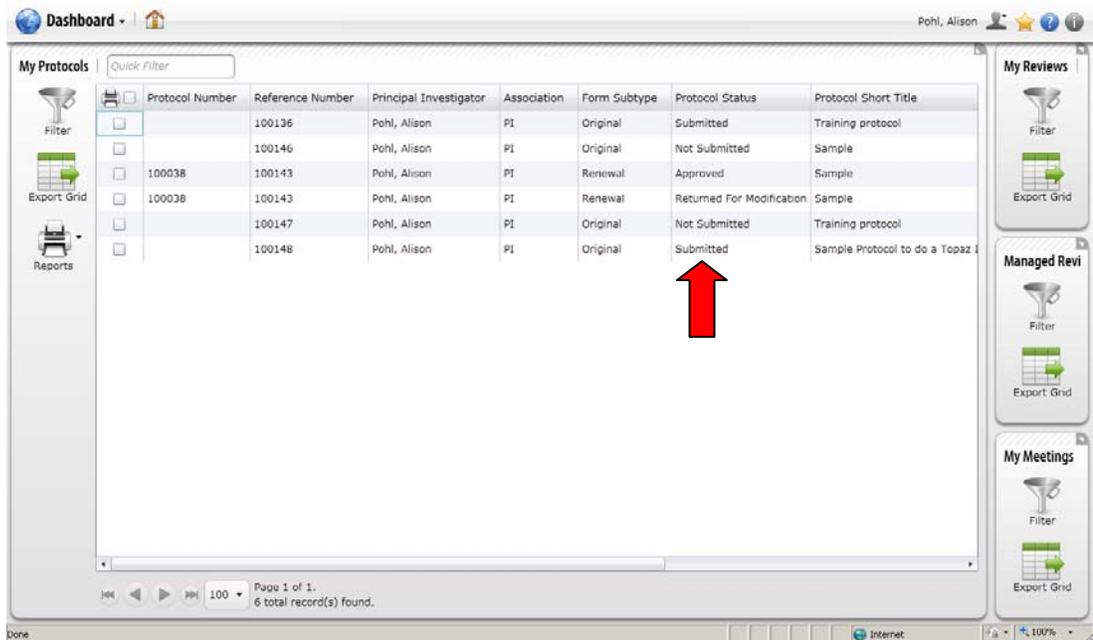
7. Once you do this, you will need to select the status of your protocol. You can either submit it for review, or withdraw the protocol. Click on the submit icon (red arrow) and then click on the set status button (green arrow).



- Once you hit the set status button, a dialogue box will populate asking for your user name and password (green arrows). Enter this information and then click on the save button (blue arrow).



- To see the protocol's status – to ensure that the submission occurred – go to your “My protocols” dashboard and you will see that its status is back to submitted (red arrow).



Now you have successfully submitted your revisions for an ACC re-review.

Protocol Approvals

1. You will receive an email in your Outlook inbox when a protocol is approved. It will state the following:

Hi, Dr. [PI]-

Your ACC protocol [Protocol Number], [Protocol Title], has been approved by the ACC on [Protocol Approval Date]. This protocol will expire on [Expiration Date].

Please remember that any changes you may wish to make to your protocol, including the addition of qualified personnel, require that a modification be submitted to, and approved by, the ACC prior to the implementation of those changes. If you have animals with cage cards with an old protocol number, it is your responsibility to make sure those cage cards have been updated with the new protocol.

It is a condition of approval to use animals that the PI will report any adverse incidences (including unexpected morbidity and mortality) involving animals to the ACC. This action is required by ACC policy (<http://clacc.uchc.edu/ACC/Policies/MorbidityMortality.htm>) in order to comply with federal regulations and laws.

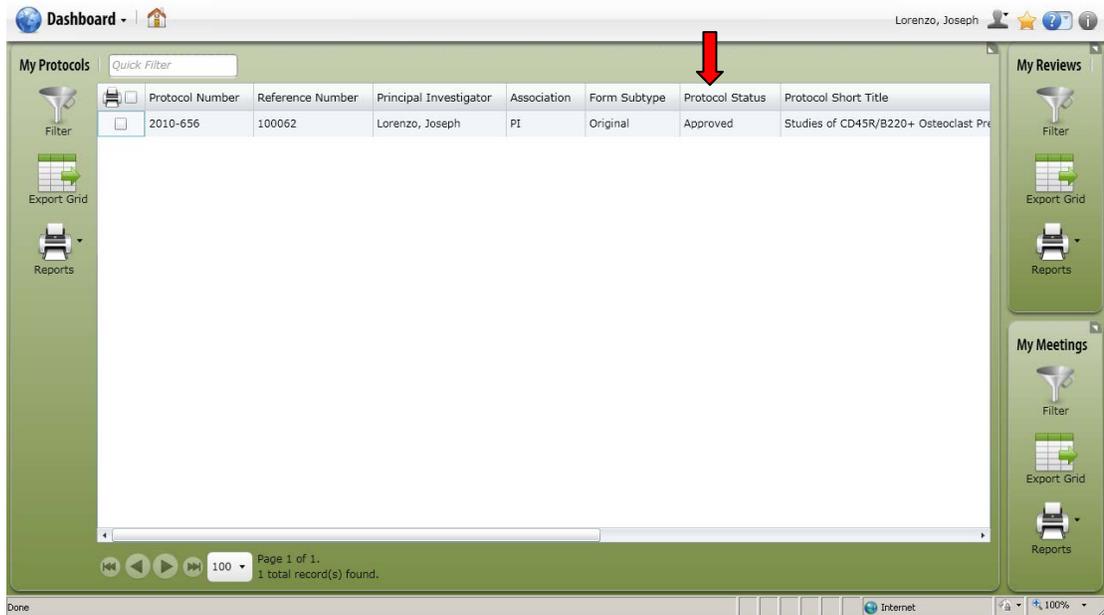
Please review section 12 of your protocol to ensure that you are familiar with all the assurances you have agreed to.

If you need a formal, signed approval letter, please contact the ACC at ooacc@uchc.edu.

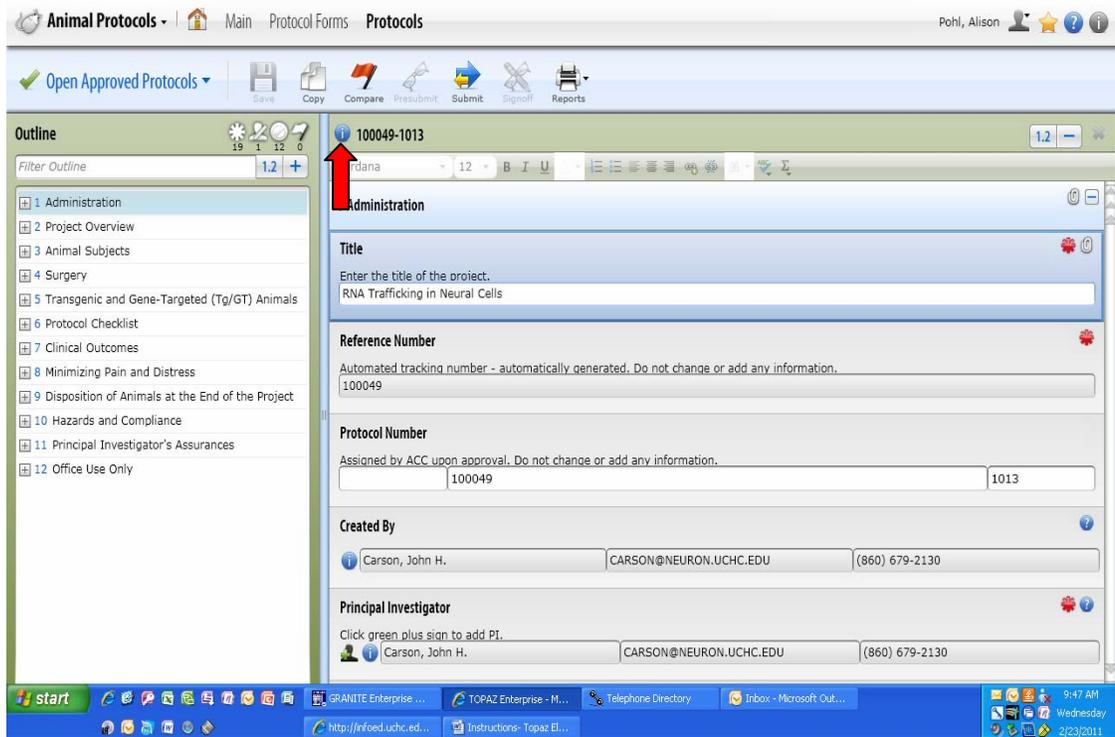
Thank you.

ACC Office

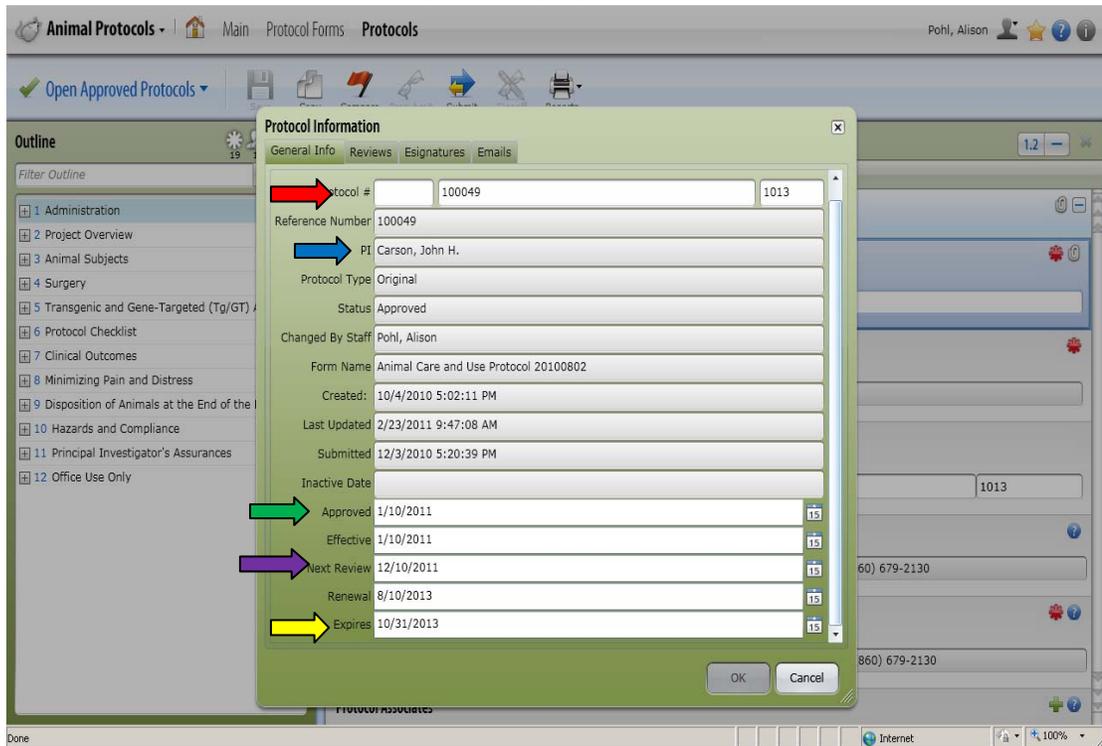
- If you go to your “My Protocols” dashboard, all protocols that are approved will state “approved” in the status section (red arrow). Simply click on your protocol you want to review.



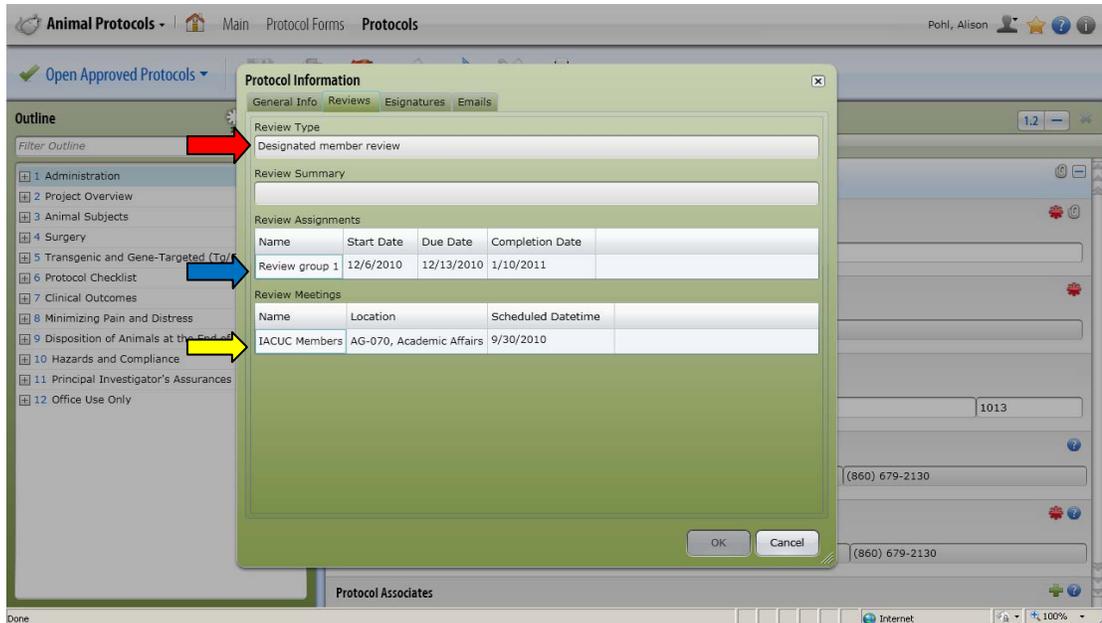
- You can get a lot of information by clicking on the protocol information button (red arrow).



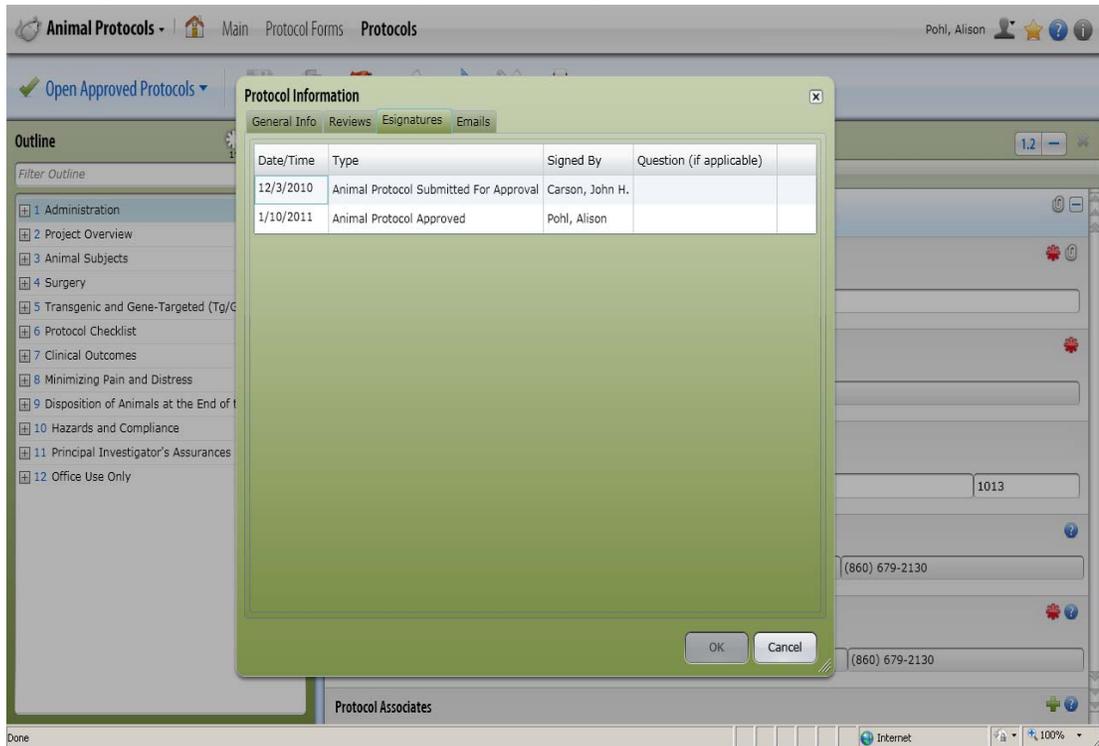
- The **General Information Screen** will show you the protocol number (red arrow), the PI (blue arrow), the approval date (green arrow), the expiration date (yellow arrow), and the date the next review is due for the protocol (purple arrow).



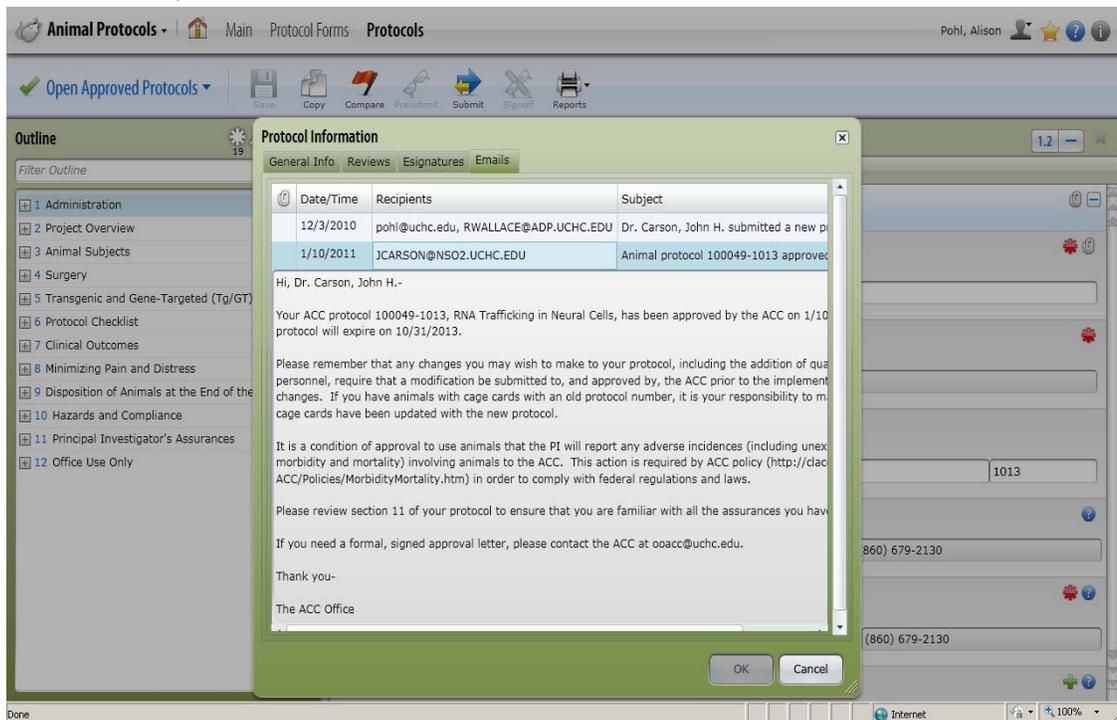
- The **Reviews Screen** will show you the type of review the protocol had (red arrow), the review groups that reviewed the protocol (blue arrow) and the ACC meeting to which the protocol was assigned (yellow arrow).



6. The **E-signatures Screen** will show you all the e-signatures associated with the protocol.

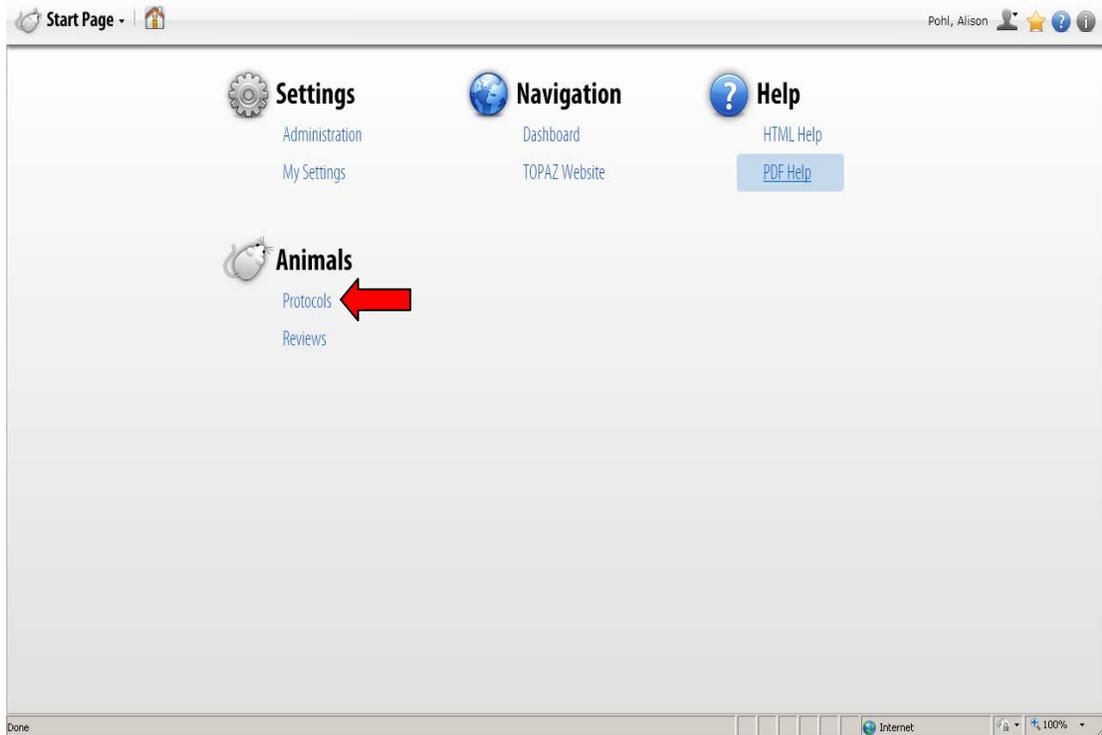


7. The **E-mails Screen** will show you all the emails associated with the protocol. Clicking on the line will show you the email itself.

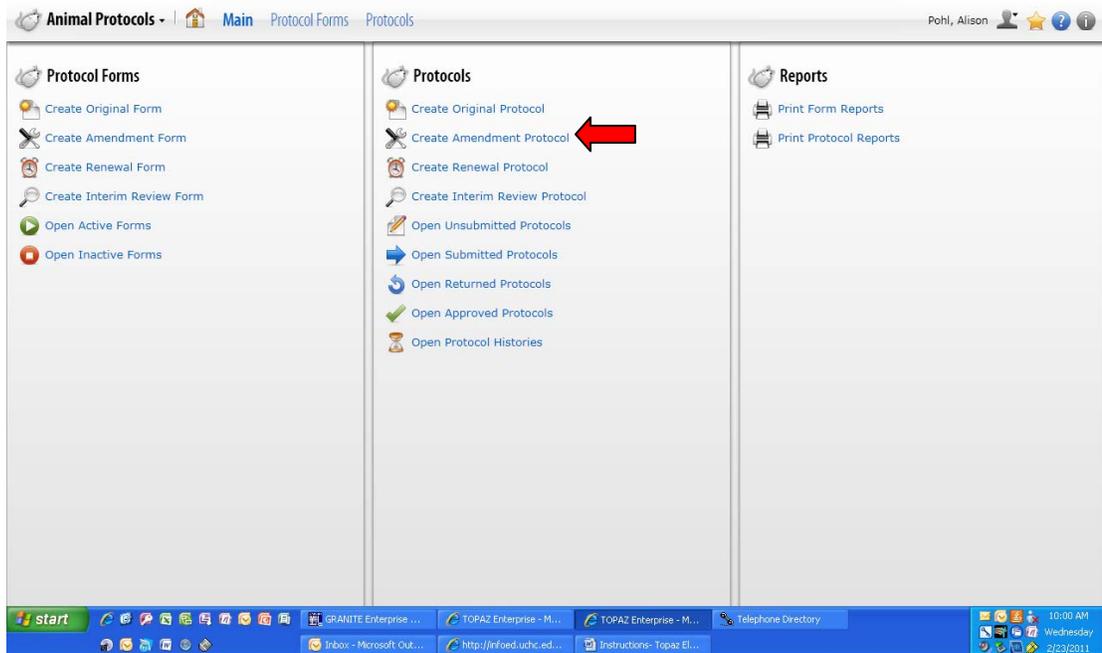


Creating Modifications to Protocols

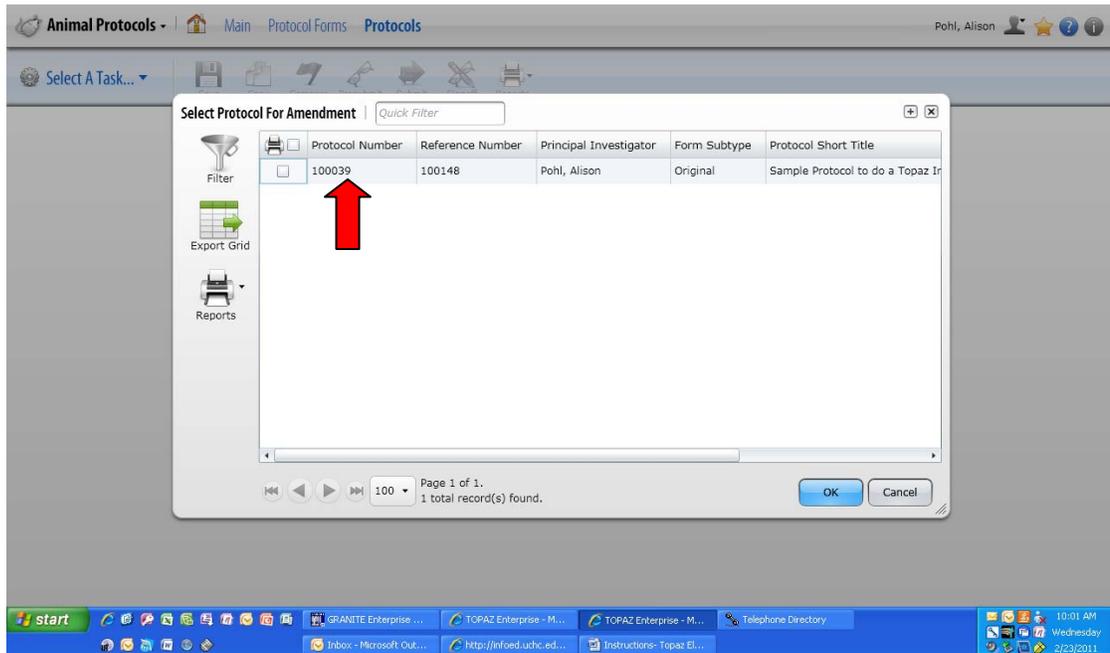
1. Go to the Topaz Home Page and click on protocols (red arrow) under the Animals heading.



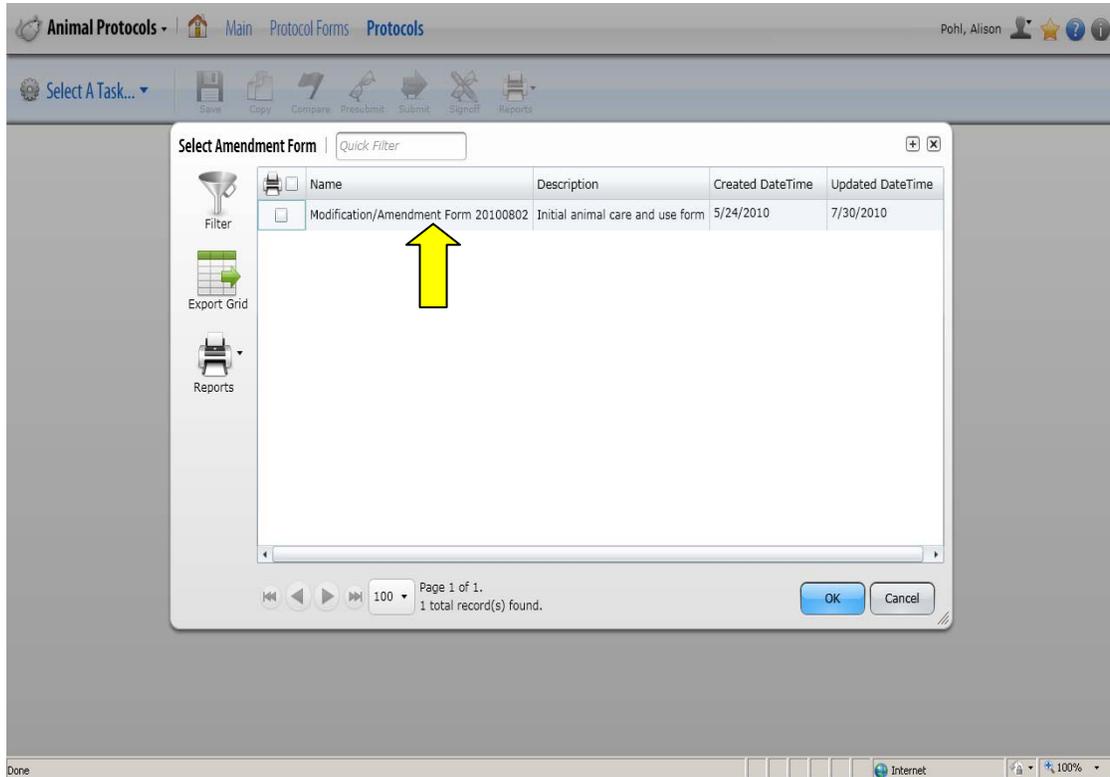
2. Then click on "Create Amendment Protocol" under the Protocols heading (red arrow).



3. A dialogue box will generate which will list all your approved protocols. Select the protocol you wish to modify by clicking on it (red arrow).



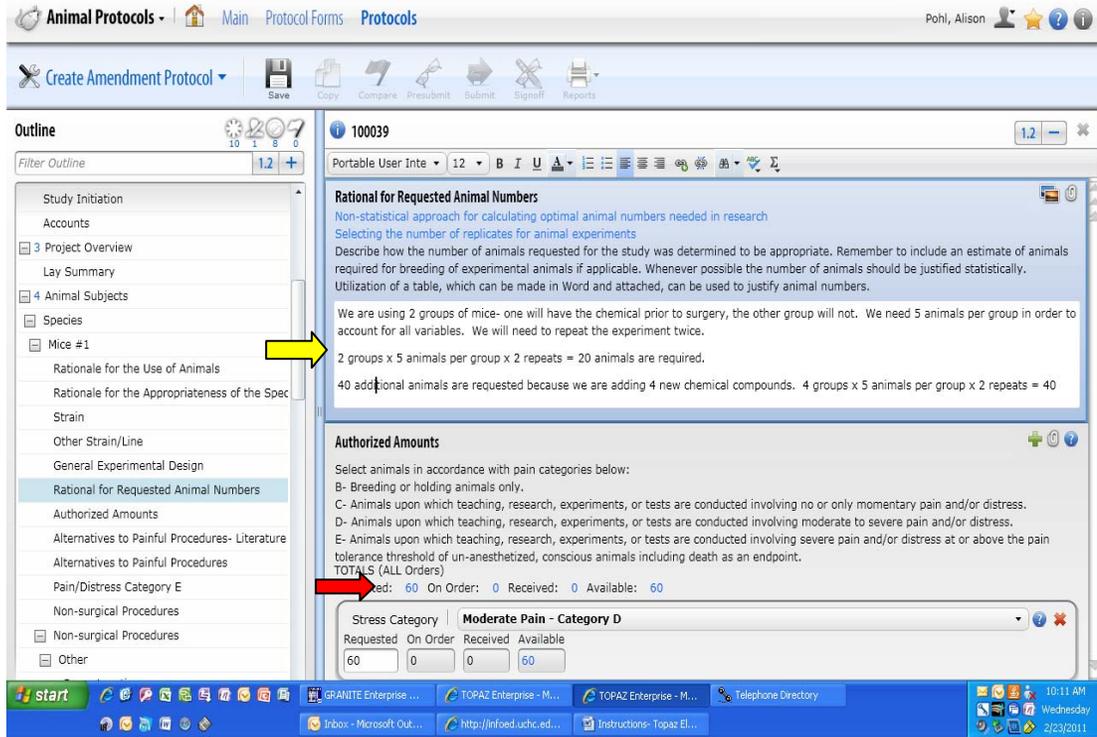
4. At this point, another dialogue box will generate asking you which form to use. There should be only one form to select, simply click on the form (yellow arrow).



5. Your approved protocol will generate with a modification header. You need to click on the box(es) that state(s) what the modification(s) are associated with (blue arrows).

The screenshot displays the 'Animal Protocols' software interface. The top navigation bar includes 'Animal Protocols', 'Main', 'Protocol Forms', and 'Protocols'. The user is identified as 'Pohl, Alison'. The main window title is '100039'. The left-hand 'Outline' pane shows a tree view with sections: 1 Modification/Amendment, 2 Administration, 3 Project Overview, and 4 Animal Subjects. Under '1 Modification/Amendment', the 'Modification/Amendment Type' section is expanded, showing a list of options: 'Addition of animals', 'Additional Animals', 'Title', 'Reference Number', 'Protocol Number', 'Created By', 'Principal Investigator', 'Protocol Associates', 'Associates Authorized to Order Animals', 'Funding/Grant Source', 'Funding Details', 'Study Initiation', 'Accounts', 'Lay Summary', and 'Species'. Three blue arrows point to the 'Addition of animals', 'Addition/deletion of personnel', and 'Addition/change in method of euthanasia' options. The main content area shows the 'Modification/Amendment Type' section with a checklist of options: 'Addition of animals' (checked), 'Addition/change of experimental procedures', 'Addition of hazardous substances', 'Addition/deletion of personnel' (checked), 'Addition/change of drugs and/or dosing regimen', 'Change in laboratory location', 'Addition/change in method of euthanasia' (checked), 'Addition/change in surgical procedures', and 'Other'. Two yellow notes are present: 'NOTE: you must update appropriate sections within the protocol below.' The bottom taskbar shows the Windows Start button, several open applications (GRANITE Enterprise, TOPAZ Enterprise, Microsoft Outlook, Internet Explorer), and the system tray with the date 'Wednesday 2/23/2011' and time '10:08 AM'.

- Then you must go to the section of your protocol that deals with each change and modify your document. For example, if you need to add animals, you must go to the animal section and change your animal numbers in the “authorized amounts” section (red arrow) and also put in a justification for the additional animals you are requesting in the “rational for requested animal numbers” section (yellow arrow).



IMPORTANT NOTE: You need to make the changes in the document for each modification requested. Modification requests will be returned to you if this is not done.

- Then you would submit your protocol as directed on pages 9 and 10 of this document.
- If changes are required in order to get your modifications approved, you would follow the instructions given for revising protocols after ACC review detailed on pages 11-14 of this document.

ANOTHER IMPORTANT NOTE: Once you make a modification to your protocol, that change gets incorporated into the document. This is an advantage over the old system of layering modifications on top of approved protocols- especially if you are eventually going to submit a 3-year renewal of the protocol.

Annual Reviews

1. Approximately 2 weeks prior to the due date, you will receive an email generation from Topaz in your Outlook inbox that you need to complete an annual review. It should look something like this:

Hi, Dr. [PI]-

The PHS and USDA require annual reviews of all animal related activities. Your animal protocol [Protocol Number] "[Protocol Title]" requires an annual review form to be submitted to the ACC by [Due Date]. You will need to use the "Create renewal protocol" form to submit this annual review.

If you have any questions regarding this process, please contact Dr. Jim Watras at x2896 for assistance.

Thank you-

The Animal Care Committee Office

2. You will need to go into your dashboard. The protocol requiring an annual review will be in your dashboard as a "Returned for Modification" protocol in the protocol status column (blue arrow) which states "Renewal" in the form subtype column (red arrow).

The screenshot shows the TOPAZ dashboard interface. The main content area is a table titled "My Protocols" with the following columns: Protocol Number, Reference Number, Principal Investigator, Association, Form Subtype, Protocol Status, and Protocol Short Title. The table contains several rows of data. A red arrow points to the "Renewal" entry in the "Form Subtype" column, and a blue arrow points to the "Returned For Modification" entry in the "Protocol Status" column.

Protocol Number	Reference Number	Principal Investigator	Association	Form Subtype	Protocol Status	Protocol Short Title
	100136	Pohl, Alison	PI	Original	Submitted	Training protocol
	100146	Pohl, Alison	PI	Original	Not Submitted	Sample
100038	100143	Pohl, Alison	PI	Original	Approved	Sample
100038	100143	Pohl, Alison	PI	Renewal	Returned For Modification	Sample
	100147	Pohl, Alison	PI	Original	Not Submitted	Training protocol
	100157	Pohl, Alison	PI	Original	Not Submitted	Sample Protocol to do a Topaz 1
100148-1113	100148	Pohl, Alison	PI	Renewal	Approved	Sample Protocol to do a Topaz 1

- Open up the document by clicking on it. You will need to fill out section 1 of the form. You need to select whichever answer is appropriate in each header.

The screenshot displays a web browser window with the URL 'Animal Protocols'. The page title is 'Animal Protocols - Main Protocol Forms Protocols'. The user is identified as 'Pohl, Alison'. The main content area is titled '100038' and shows the '1 Annual Review' form. The form is divided into three sections: 'Protocol Status', 'Adverse Events', and 'Alternatives to Animal Use'. Each section contains a question and radio button options. The 'Protocol Status' section asks to select the appropriate protocol status, with options: 'Protocol active, work initiated', 'Protocol active, work not yet initiated', 'Request protocol termination, work never initiated', and 'Request protocol termination, work completed'. The 'Adverse Events' section asks 'Have there been any adverse events which have not been previously reported to the ACC?' with options 'No' and 'Yes'. The 'Alternatives to Animal Use' section asks 'Have any alternatives to the use of live animals become available since the protocol was originally approved?' with options 'No' and 'Yes'. The left sidebar shows an 'Outline' with 13 items, including '1 Annual Review', '2 Administration', '3 Project Overview', '4 Animal Subjects', '5 Surgery', '6 Transgenic and Gene-Targeted (Tg/GT) Animals', '7 Rationale for Number of Animals', '8 Protocol Checklist', '9 Clinical Outcomes', '10 Minimizing Pain and Distress', '11 Disposition of Animals at the End of the Project', '12 Hazards and Compliance', and '13 Principal Investigator's Assurances'. The bottom of the screen shows a Windows taskbar with the start button, several open applications (TOPAZ Enterprise, Telephone Directory, GRANITE Enterprise, Microsoft Outlook), and the system clock showing 6:39 AM on Wednesday, 4/13/2011.

- Then you submit the annual review as described on pages 9 and 10 of this document.

PLEASE NOTE: An annual review cannot be submitted if a modification to the protocol is pending; alternately, a modification to the protocol cannot be submitted if an annual review is pending. It is important to submit your annual review in a timely manner once you have been informed that it is due.

3 Year Renewals

1. You will receive an email approximately four months prior to your protocol expiring that you will need to submit a renewal protocol if you wish to continue the work described in the expiring protocol. The email should look similar to the following:

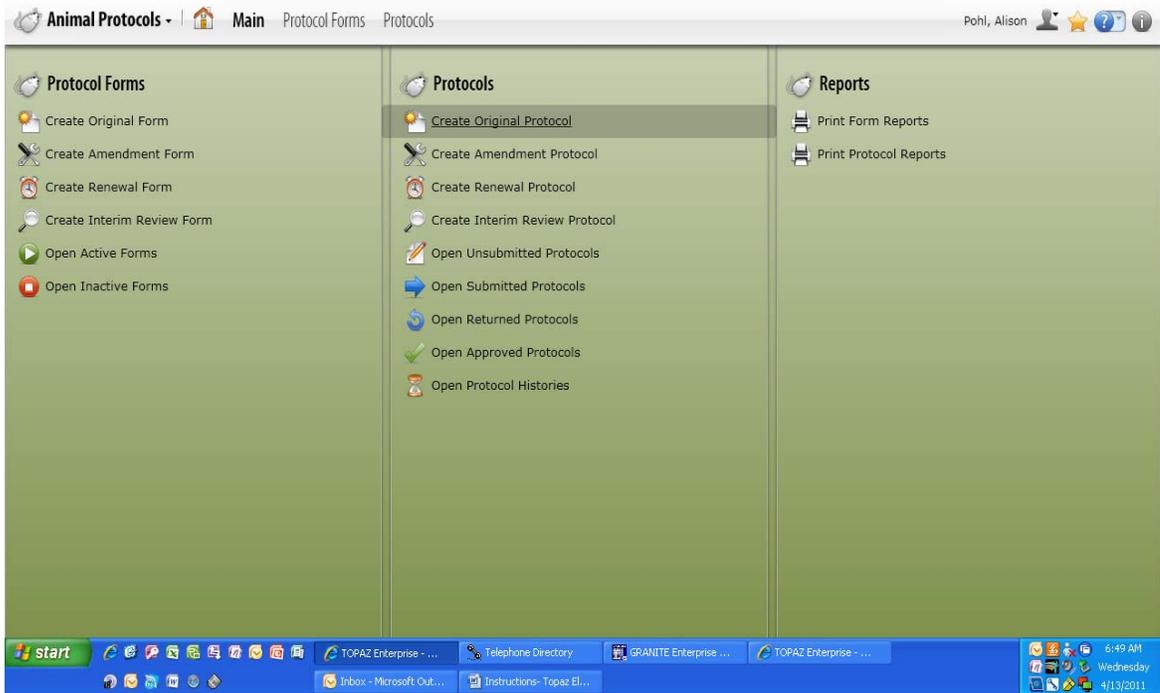
Hi, Dr. [PI]-

This is to let you know what your current protocol [Protocol Number] "[Protocol Title]" will expire on [Expiration Date]. The renewal due date is [Protocol Renewal Date]. You will need to create a new protocol in Topaz to do this. To be compliant with federal regulations, there can be no extensions of expired protocols.

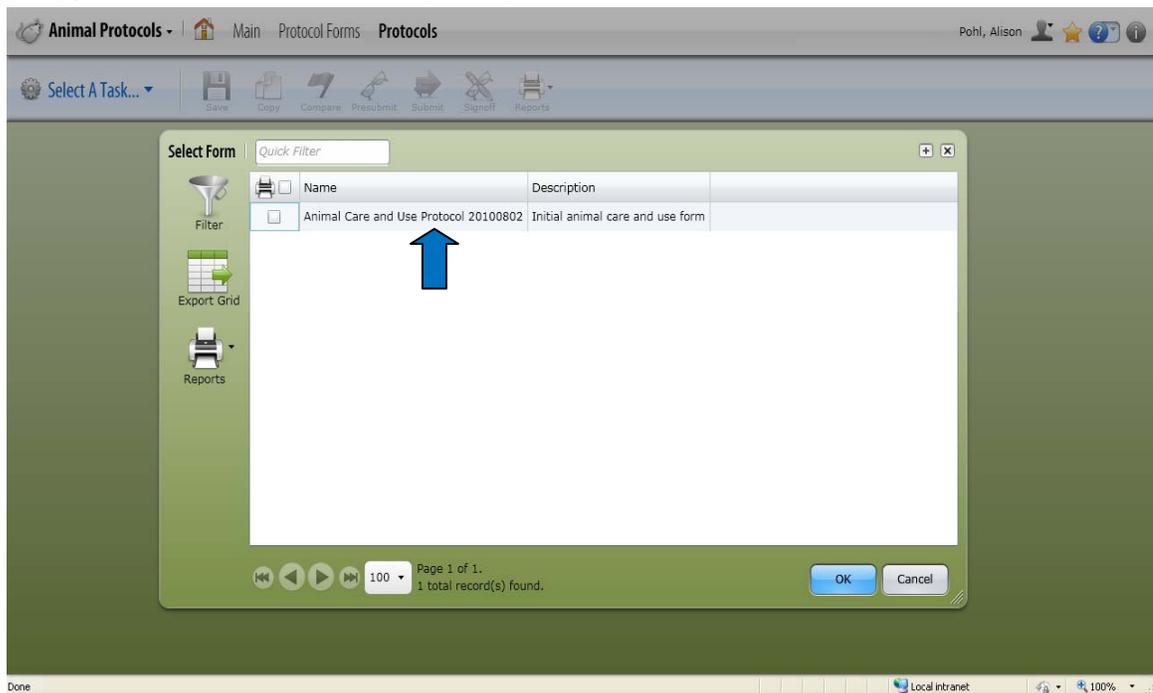
Thank you for your attention to this matter.

The ACC Office

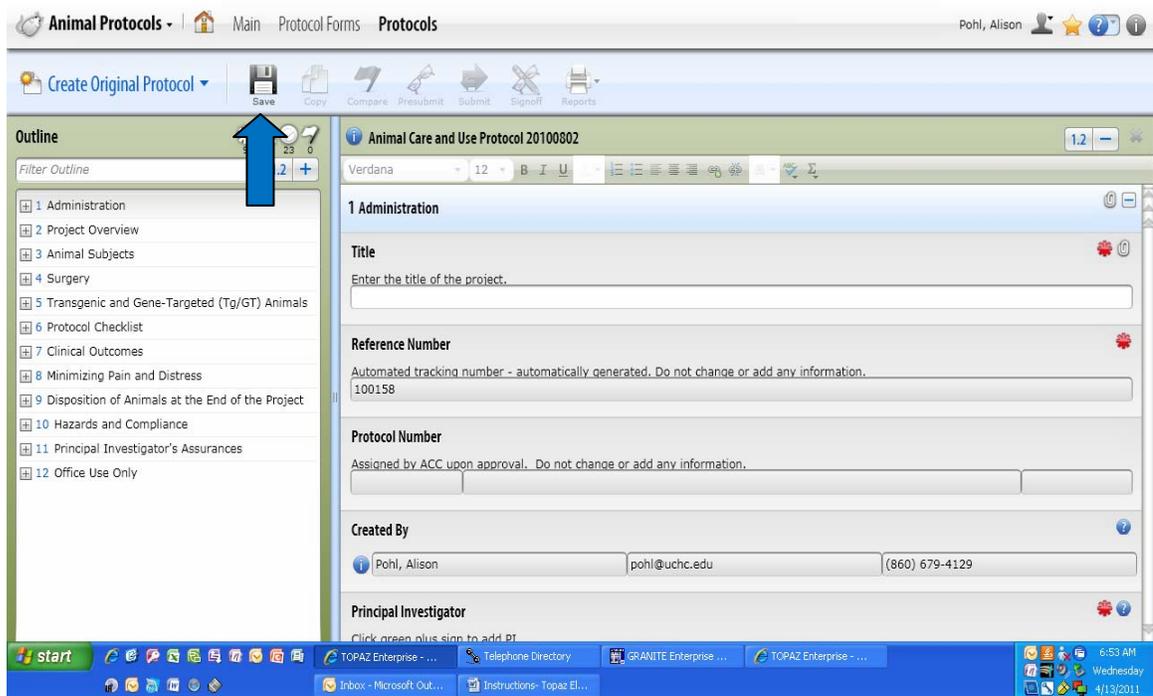
2. You will need to select "Create Original Protocol". Please do not get confused regarding the form to use. Even though you are submitting a protocol to replace a current one, every time you have a 3-year renewal protocol, it is considered to be a new protocol.



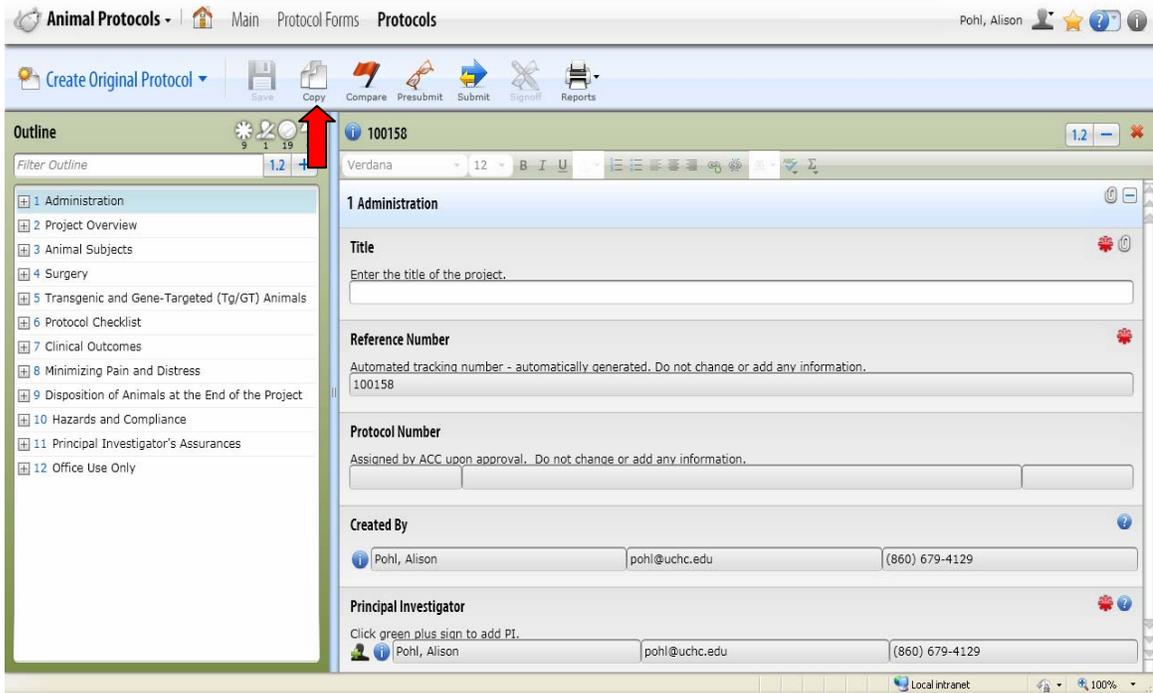
- Once you select the “create original protocol”, a dialogue box will generate. Select the correct protocol form (blue arrow). There should be only one form to choose from; if this is not the case, please contact the ACC office (x3429) for clarification.



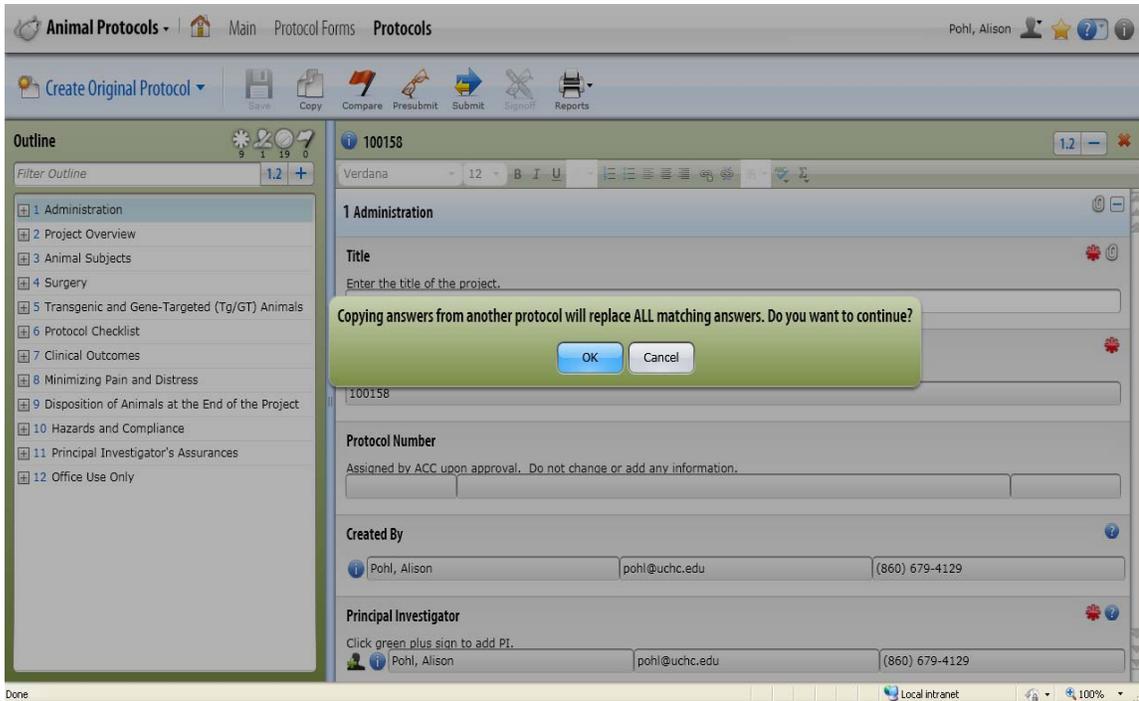
- The protocol form will then generate. Hit the save button (blue arrow).



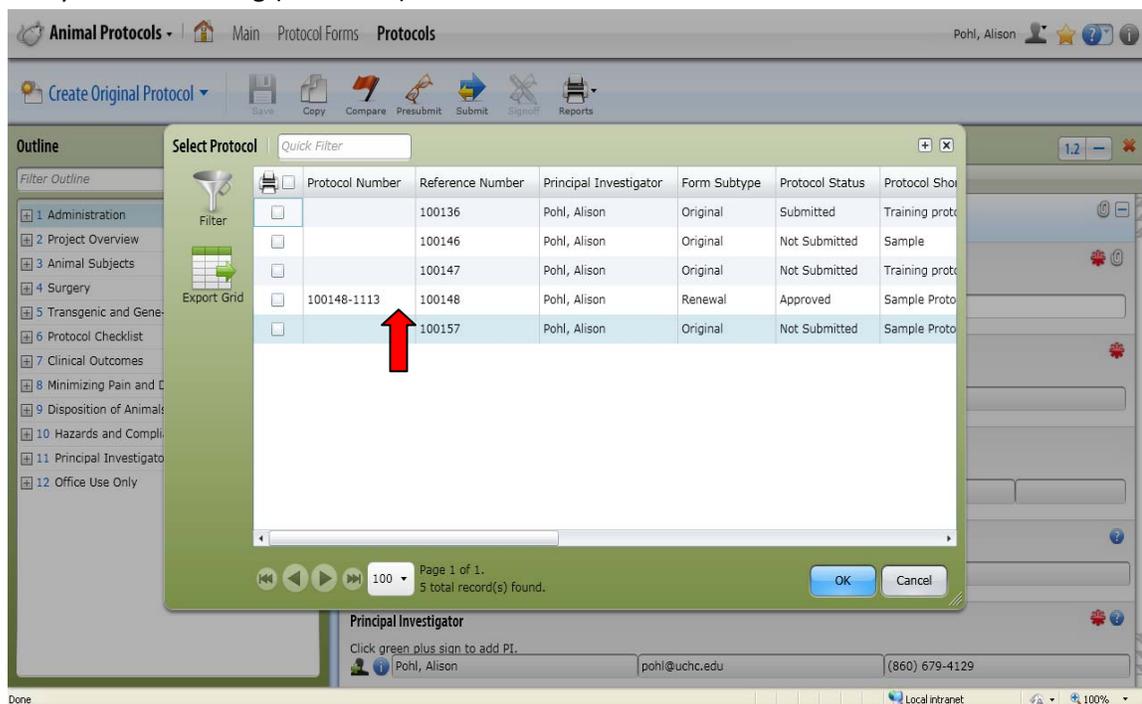
5. Then click on the copy button (red arrow).



6. A dialogue box will then generate. Select "OK".



- Another dialogue box will generate showing all the approved protocols you have. Click on the one you are renewing (red arrow).



- The new form will generate with all the old information. You need to review the form, as this process has some limitations. For instance, there are some sections on the protocol that are set to not be allowed to copy (e.g., search for alternatives). Make any changes that are necessary.
- Once you review the document, you can submit it as described on pages 9 and 10 of this document.