TOPAZ | Elements

Animal Protocol Development

Instructions for Researchers

UCONN
H E A L T H

**OFFICE OF THE
VICE PRESIDENT FOR
RESEARCH**

Topaz Elements Animal Protocol Development Instructions for Researchers

TIPS:
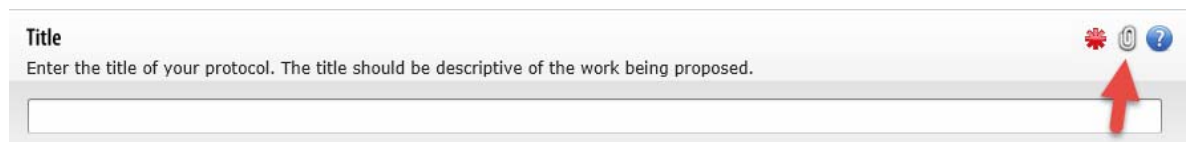
- **Use the help** ⓘ **icons.** If you are unsure how to answer a question, clicking on the help icon will help you with specific instructions and/or provide an example.

- **Save** 💾 **often.** Topaz Elements is a web-based system. If you lose your connection to the Internet, you will regret not saving. If you are going to stop working on your protocol for any length of time, save your work and close your form!

- **Use your outline view effectively**. Your outline view can show you which required questions ✳ must be answered in order to submit your protocol. Your outline view can show you which questions are required and are missing before you can you submit your revisions (e.g. required ✳ and incomplete 🚫). You can also 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 protocol form.

- **Error messages**. You might get error messages. If you do, you will need to notify the eRA Help Desk of them. Click **Show Error** button to view the error. Then 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. Paste the error message into an email and send it to the Office of the Vice President for Research eRA Help Desk at era-help@uconn.edu. Please also include a brief description of what you were trying to do when the error occurred. Include any relevant protocol numbers.

- **Attaching documents to your protocol**.
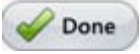
   1. For question that allow attachments, there will be a paperclip 📎 icon. Click on the paperclip icon to add an attachment.

    2. The Add Links and Attachments dialogue box appears. Click on the plus paperclip 📎 icon to add a document, picture, etc.

3. Click the blue folder ![folder icon] Browse To File icon. You can then browse to the location of the file on your computer and open it to add it as an attachment.

4. If desired, in the text: field, revise the name for the file by typing in this area.
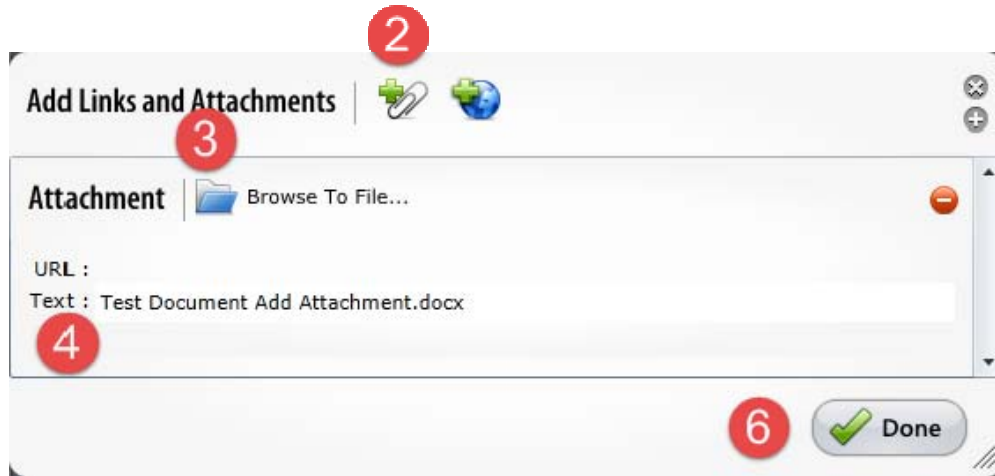
5. Repeat steps 2-4, if you want to add additional files. Use the ⛔ icon to delete any attachments made in error.

6. Click Done ![Done button] button when finished adding attachments. The attachment document names should appear underneath the question text as clickable hyperlinks.

Logging into TOPAZ Elements

You must be granted access to login and use TOPAZ Elements. Submit a User Access Request at https://uar.uchc.edu/.

1. In your preferred, up-to-date web-browser (except Google Chrome), click or type this web address, https://uconnprod.topazti.net/ucelements, into the address bar, being mindful to include https://.

    Note: Google Chrome is not compatible with Topaz Elements and should not be used.

2. Enter your UConn Health domain username and password, then click Login.
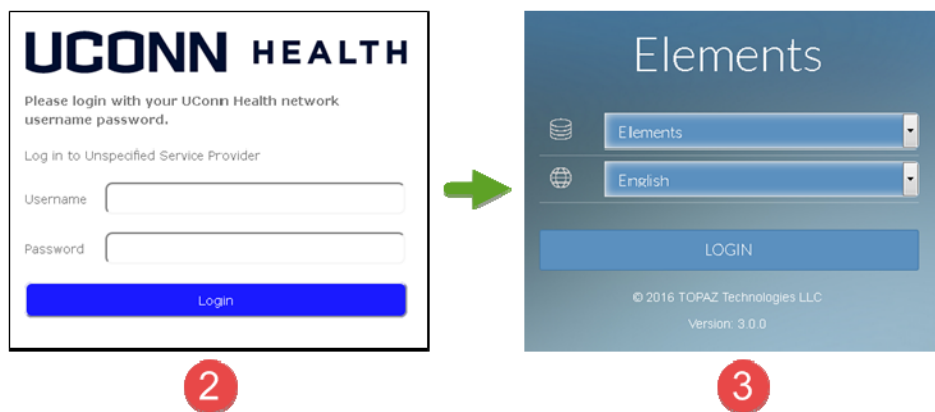
3. On the Elements sign in page, click Login. The Topaz Elements home navigation screen appears.

4. The Topaz | Elements home screen appears.

Creating Initial Animal Care and Use Protocols

1. Under the Compliance ![icon] Menu, click **Animal Protocols**.

2. From the Protocols menu items, click ![icon] **Create Original Protocol.**
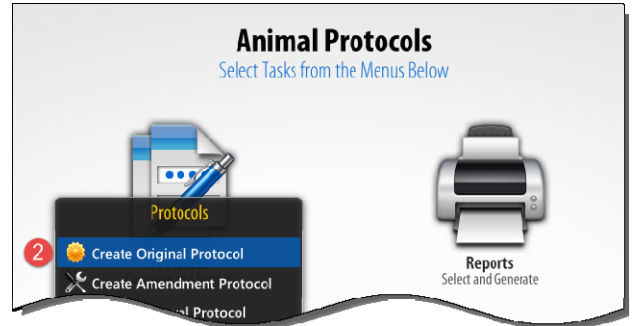
    Note: **IF YOU DO NOT HAVE THIS OPTION**, it means you are not set up to create protocols. Do **NOT** go any further. Request these Topaz Elements Application privileges through the UConn Health User Access Request system at https://uar.uchc.edu. If you are not a PI, your PI will need to complete the User Access Request for your user account to ask that you have these privileges.

3. On the Select Form Grid, click on the **Initial Animal Care and Use Form**. The protocol form will be created.

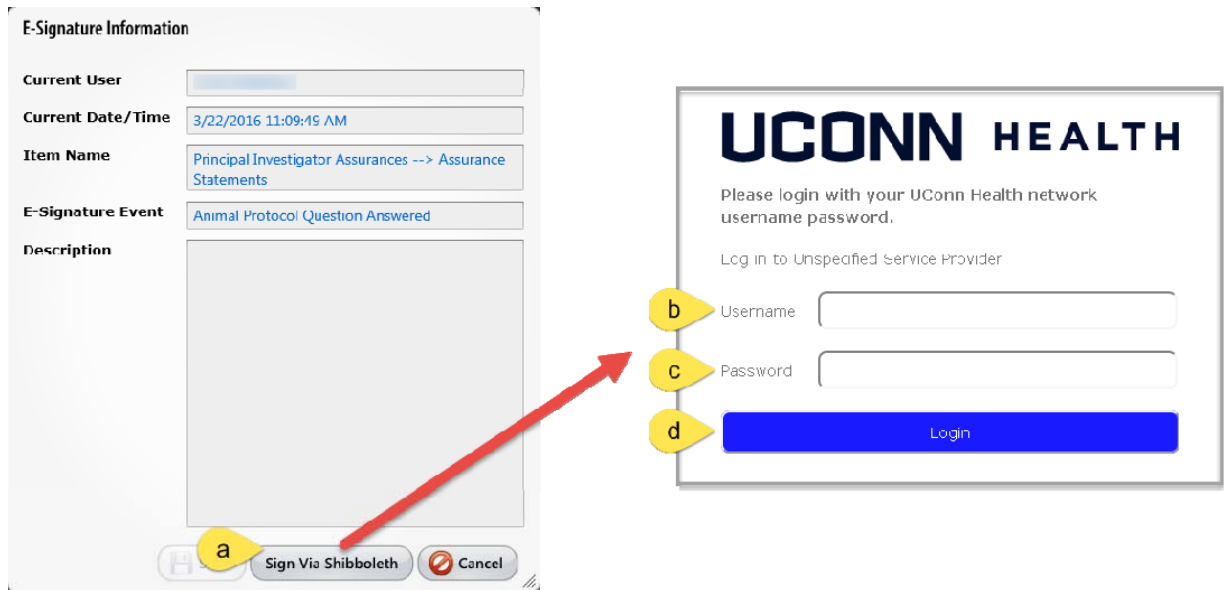| Name	Description	Type
Animal protocol new form v.2013	Initial animal care and use form	Original
MCh- Multiple Chemical Safety Pr		Original
SP- Single Biological Hazard Use	Form for Safety protocol for a single biological...	Original
SP- Single Chemical Hazard Use	Hazard protocol for a single chemical hazard	Original

4. Complete the protocol form. 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 or the protocol form itself.
    b. You can see that a reference number 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. You will notice some questions have red asterisk stars 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.

TIP: In order to save your protocol, three fields **MUST** be completed: 1) the reference number (b), 2) a title (d), and 3) the PI name (not shown). You will not be able to save your document unless these three fields are completed.
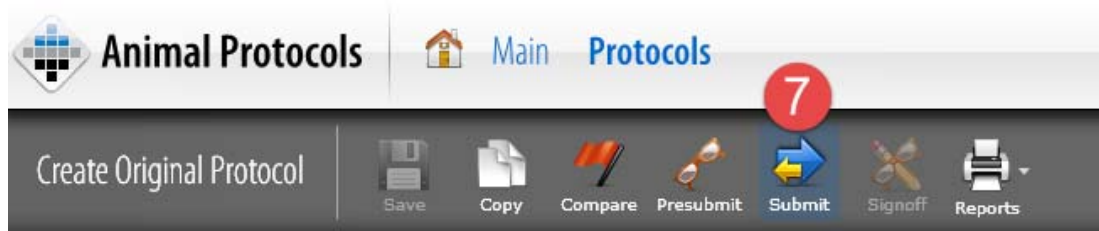

5. Start filling out the protocol form. Refer to the supporting document if you have questions on each protocol section.

   TIP: 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.
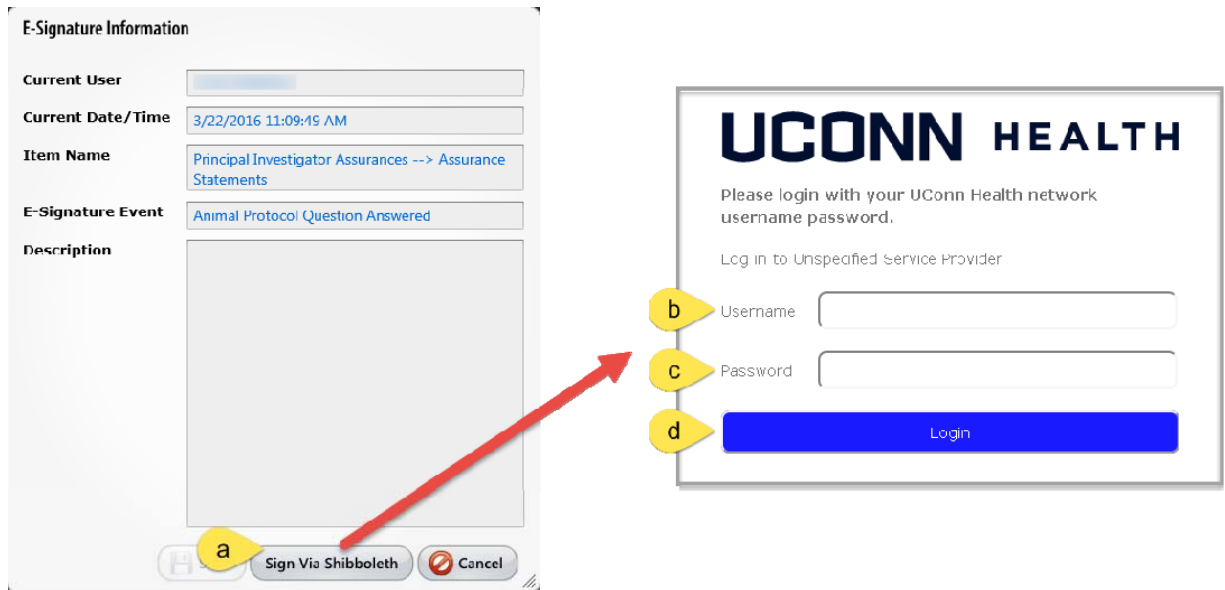
6. There are sections that will require an e-signature by the PI. These sections **MUST** be completed by the PI prior to submission. In addition, the submission **MUST** be performed by the PI. If either e-signatures or submission are performed by anyone other than the PI, **IT WILL BE RETURNED**. These sections are clearly labeled in the document. When you answer these questions, a dialogue box will generate.
   a. Click Sign Via Shibboleth button.
   b. Enter your UConn Health domain name **username.**
   c. Enter your UConn Health domain name **password**.
   d. Click Login button
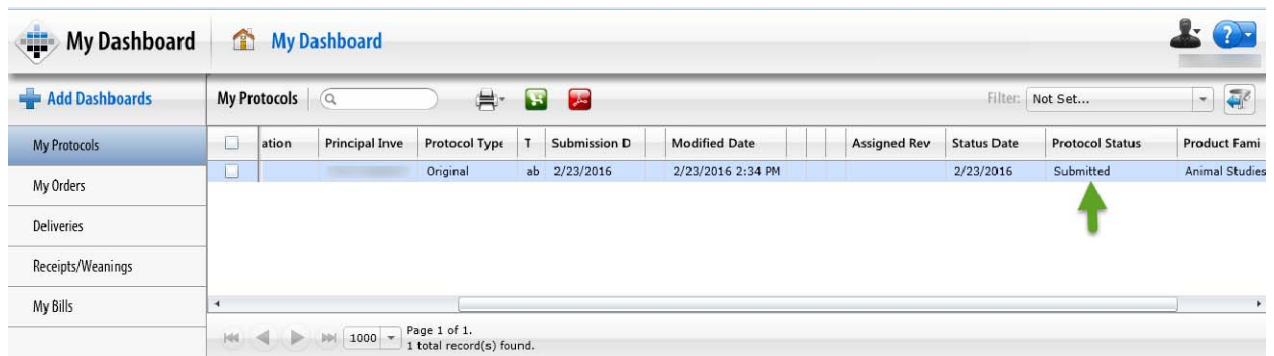   e. After successful login, you will be returned to the protocol.

7. Once you are sure the protocol is ready to be submitted, click the **Submit** button. The Set Status dialog box appears

8. On the Set Status dialog box, click **Submitted** and then **Set Status** button .

9. An e-Signature dialog appears, please
   a. Click Sign Via Shibboleth button.
   b. Enter your UConn Health domain name **username**.
   c. Enter your UConn Health domain name **password**.
   d. Click Login button.
   e. After successful login, you will be returned to the protocol.

10. Your protocol has been submitted. To confirm that your protocol was submitted using the Product Selector go to **My Dashboard > My Protocols**. Look for the protocol you just submitted. The Protocol Status should report "Submitted". If it doesn't, then something went wrong. Simply go back into the protocol by clicking on it and re-submit by repeating steps 7-9 above.

# Viewing Animal Protocol Review Steps & Statuses

You do have the ability to see what review step your protocol is on at any time.

1. Open your protocol (e.g. My Dashboard > My Protocols and click on the protocol you wish to view).
2. Click the i icon near the Protocol Reference Number. The General Protocol Information tab appears.
3. On the General Info tab, review the following:
    a. Protocol type
    b. Protocol's status
    c. Date Created
    d. Date Submitted for review
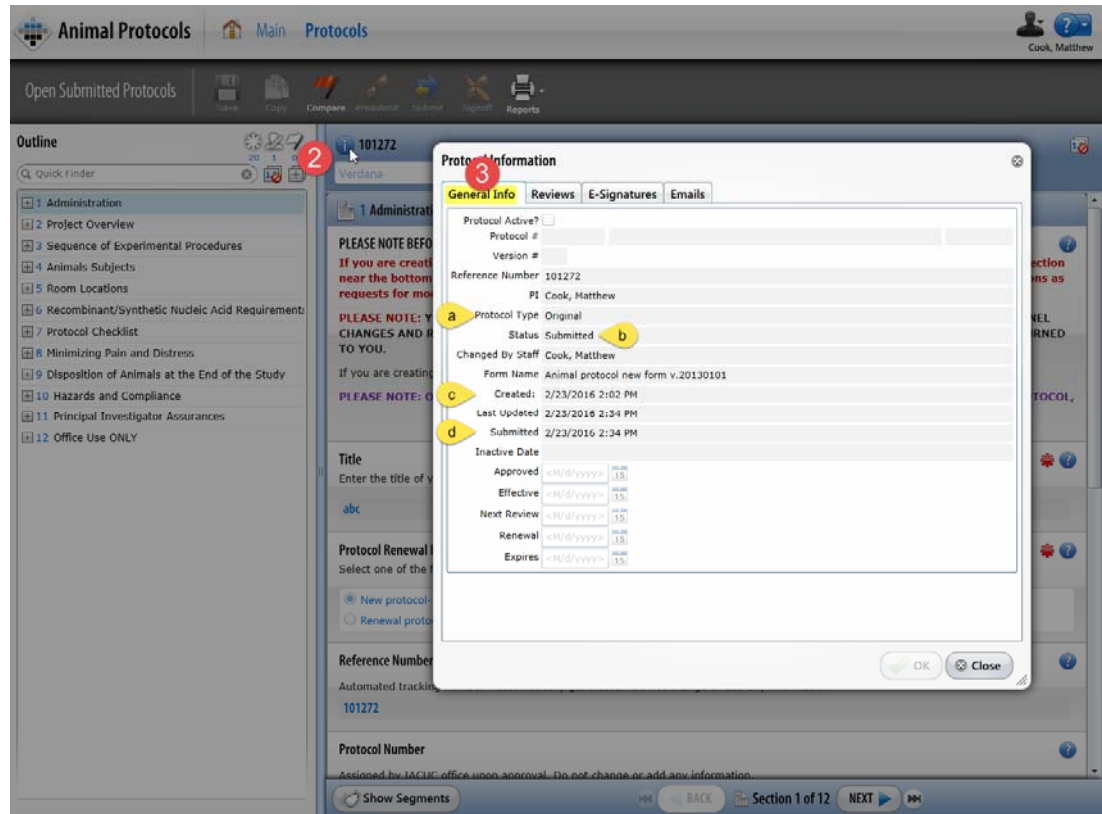
4. Click the **Reviews** tab. On the Reviews tab, you can view:
   a. Type of review (e.g. Full Committee, Designated Member Review)
   b. Due Date for reviewers to finish the review
   c. If going to the full committee, the meeting date
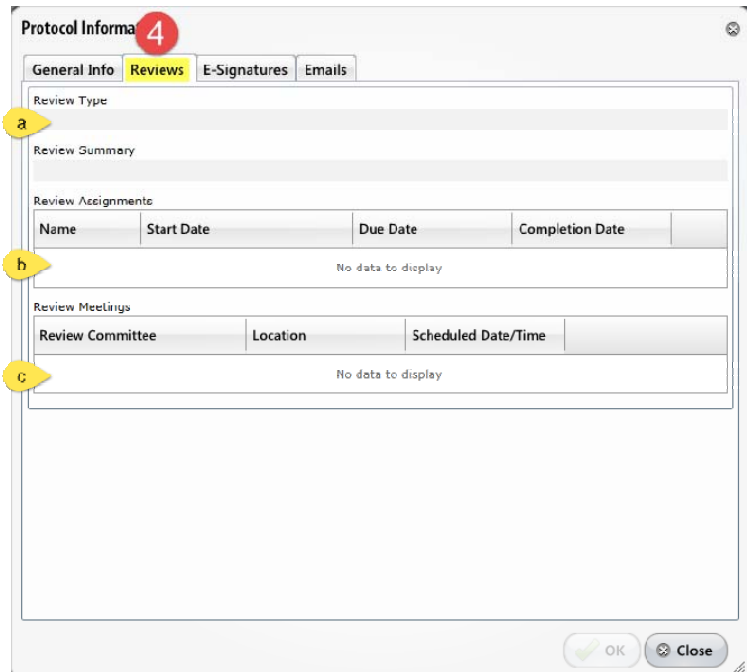
Revising Protocols Returned for Modifications after IACUC Review

If your protocol was not approved from the start, you will receive an email message stating that your protocol has been reviewed and requires changes prior to approval. It will instruct you to go to your My protocols dashboard in Topaz Elements (My Dashboard > My Protocols), open your protocol (double click on it), and all changes that need to be addressed will be shown.

1. Login to Topaz Elements at https://uconnprod.topazti.net/ucelements (if not already).

2. Click on My Dashboard under Places on the Main Home Screen or if using the Product Selector on the top left side of the screen, select My Dashboard.

3. Select My Protocols dashboard panel. You will see a list of your protocols.

4. Click on the appropriate protocol with "Returned for Modification" status to open it.

5. In the Outline Panel, click the Questions with Summary Comments 🐛 icon. This will show you all the questions that require some type of explanation. Comments appear in a yellow field below the question.
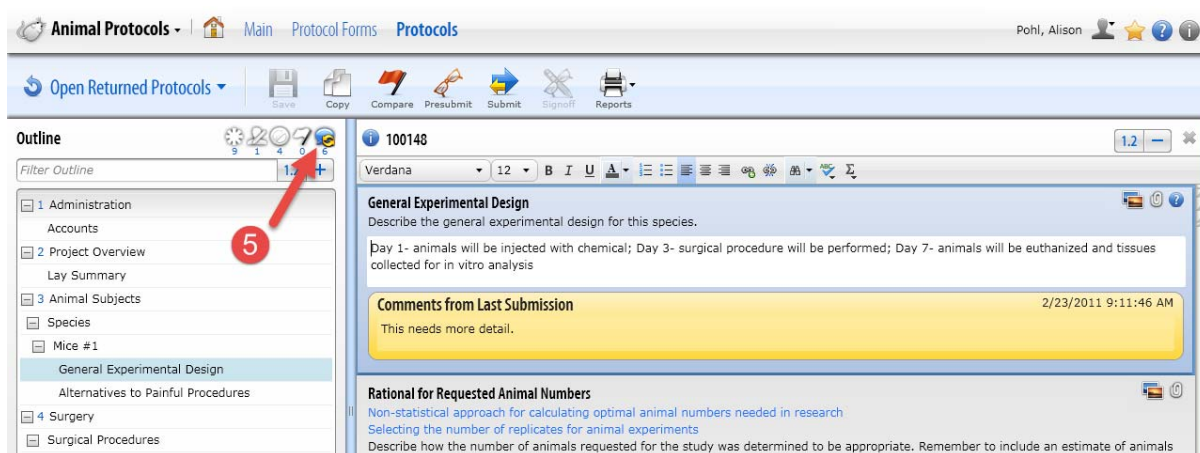

6. View the comment summaries, make the recommended modifications to the question above by comment, and click Save 💾 . Note: You do **NOT** need to use a different font, color, or anything else for the changes.

7. Resubmit the protocol by clicking Submit 🔁 .

8. On the Set Status dialog box, click **Submitted.**

9. Click Set Status ⚒.

10. An e-Signature dialog appears, please
    a. Click Sign Via Shibboleth button.
    b. Enter your UConn Health domain name **username.**
    c. Enter your UConn Health domain name **password**.
    d. Click Login button
    e. After successful login, you will be returned to the protocol.
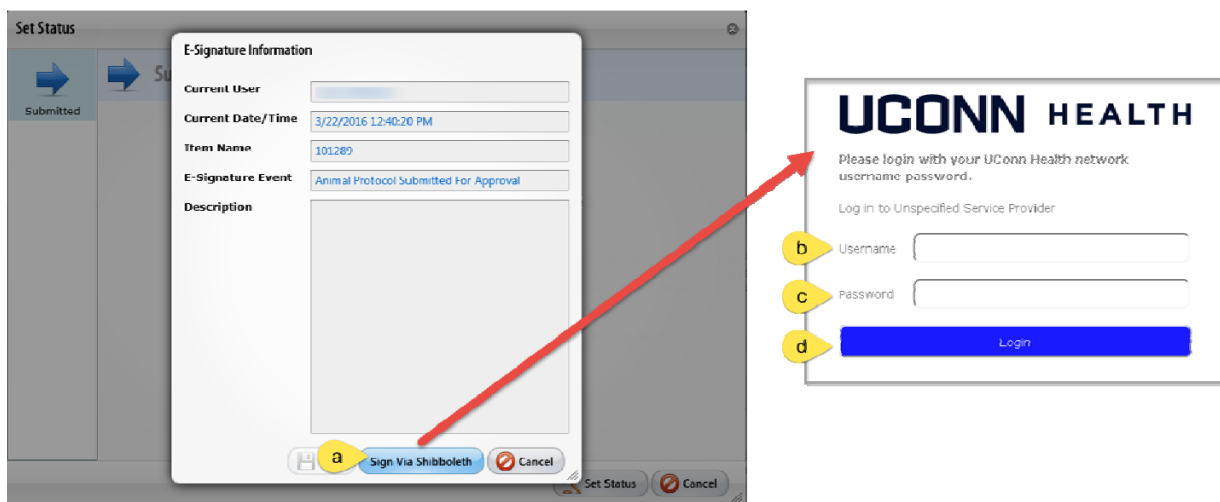
11. To double check that the submission occurred, go to your My Protocols dashboard (Product Selector > My Dashboard > My Protocols) and you will see that its status is back to submitted.
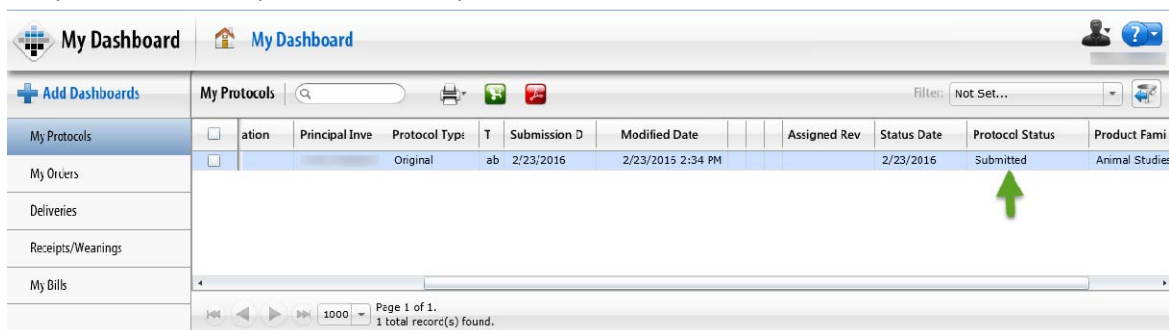
Now you have successfully submitted your revisions for an IACUC re-review.

View Protocol Approvals

1. You will receive an email when a protocol is approved. It will be similar to the following:

> Hi, Dr. [PI]-
>
> Your IACUC protocol [Protocol Number], [Protocol Title], has been approved by the IACUC 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 IACUC 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 IACUC policy (http://research.uchc.edu/animal/iacuc/policies/reporting-unexpected-or-unusual-morbidity-and-mortality/) 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.
>
> IACUC Office

2. Within the My Protocols dashboard (My Dashboard > My Protocols), all protocols that are approved will show "Approved" in the Protocol status column.

3. Click on your protocol that you want to review its details.

4. Click the i icon near the Protocol Reference Number. The General Protocol Information tab appears.

5. On the General Info tab, you can review:
   a. Protocol number
   b. Principal Investigator
   c. Approval Date

d. Date of Next Review

e. Expiration Date
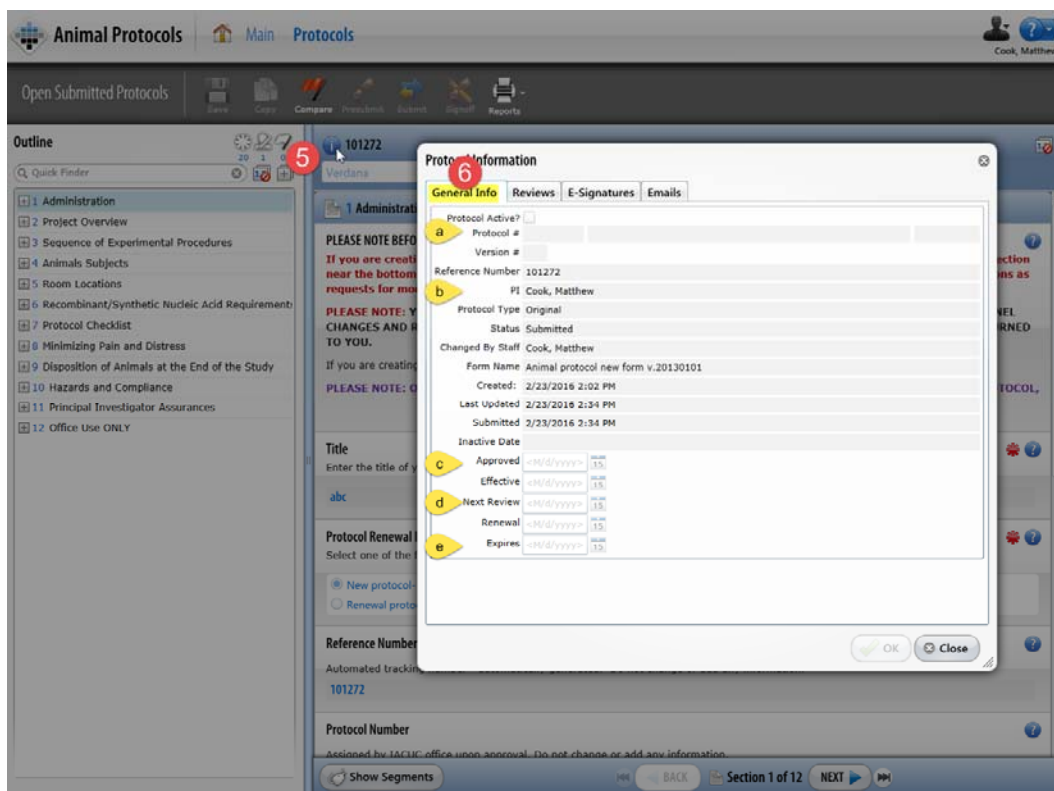

6. Click the **Reviews** tab. On the Reviews tab, you can view:

f. Type of review (e.g. Full Committee, Designated Member Review)

g. Review Group

h. IACUC Meeting Date Protocol was Reviewed

7. Click the **E-signatures** tab to view all the e-signatures associated with the protocol submissions.

8. The **Emails** tab shows all the emails associated with the protocol. Clicking on the an email row will show you the email itself.
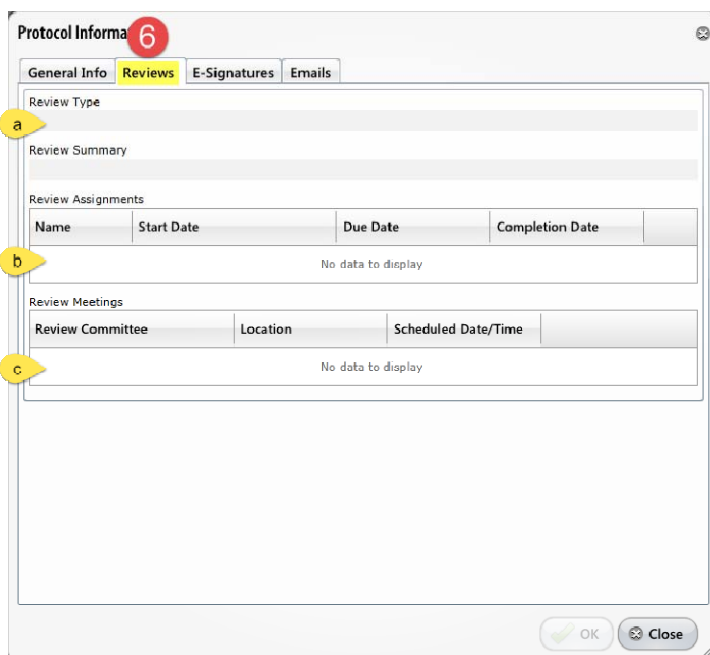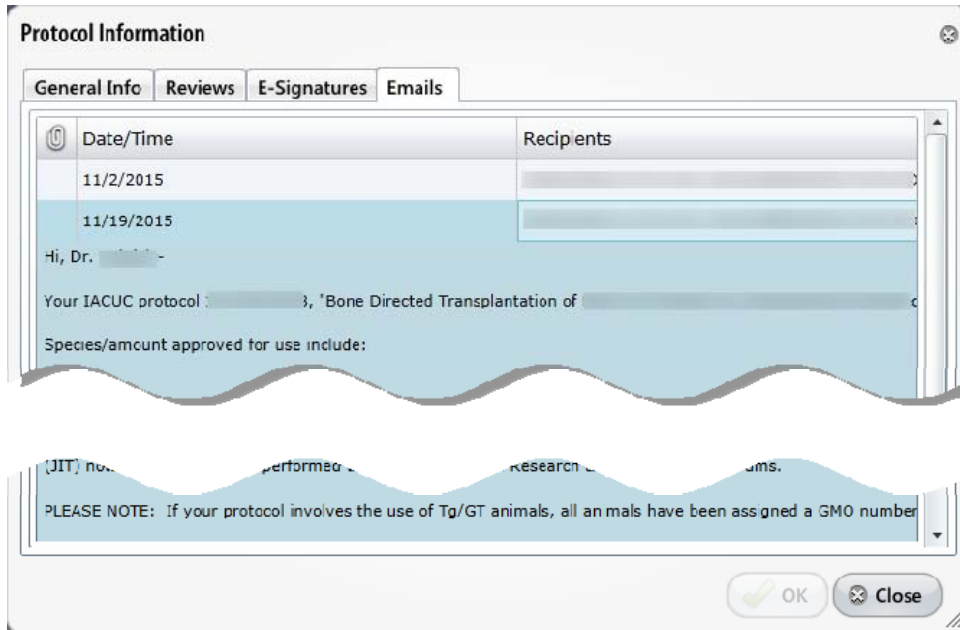
9. Click the Close button, when finished.

Creating Modifications/Amendments to Animal Protocols

1. From the Main Home Screen under the Compliance Menu, click **Animal Protocols**.

2. On the Protocols Menu, select **Create Amendment Protocol.**

3. A dialogue box will generate which will list all your approved protocols. **Select the desired protocol** from the grid to amend and modify by clicking on it.

---
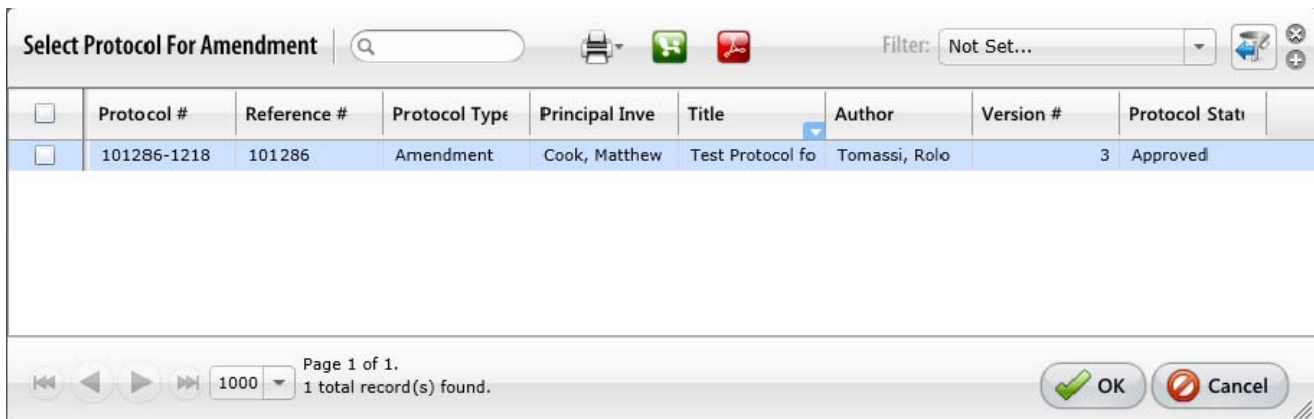
4. Click on the **Modification/Amendment form** from the Select Protocol for Amendment grid.

5. Your approved protocol will generate with a modification header in Section 12 Modification/Amendment of the outline. **Click on the box(es) that state(s) what the modification(s)** are associated with your protocol.
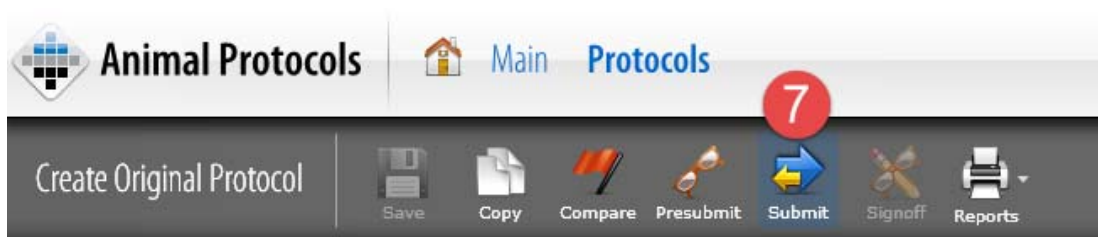
6. **Amend the protocol** by going to the section of your protocol that is associated with each change and modify your protocol. For example, if you need to add animals, you must go to the animal section and change your animal numbers in the "authorized amounts" section (a) and also put in a
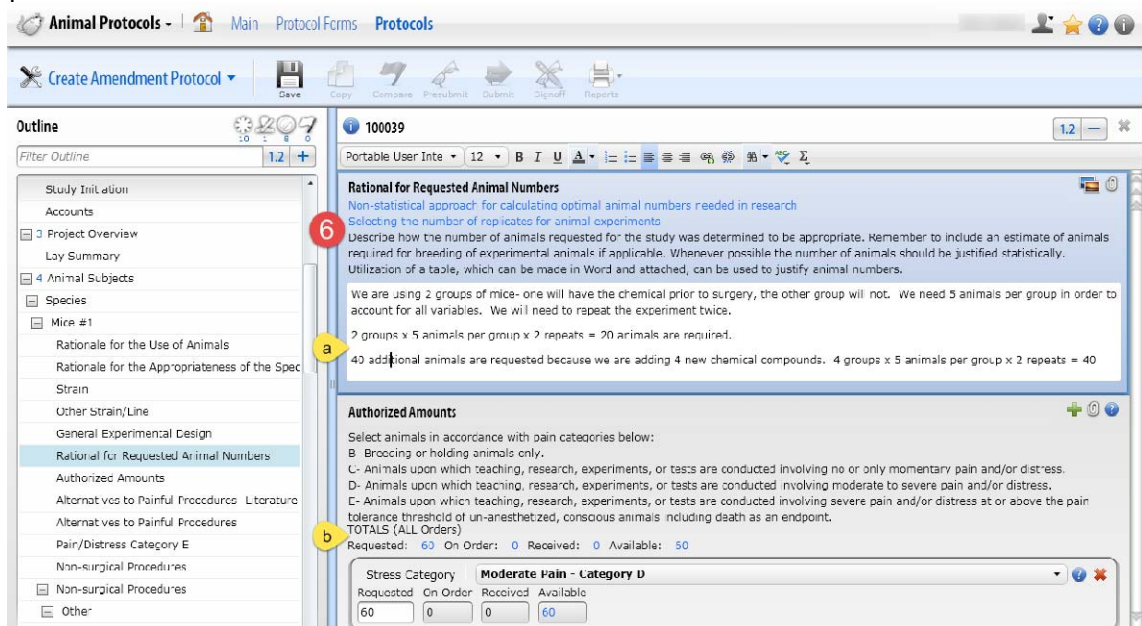
r the additional animals you are requesting in the "rational for requested animal numbers" section (b).
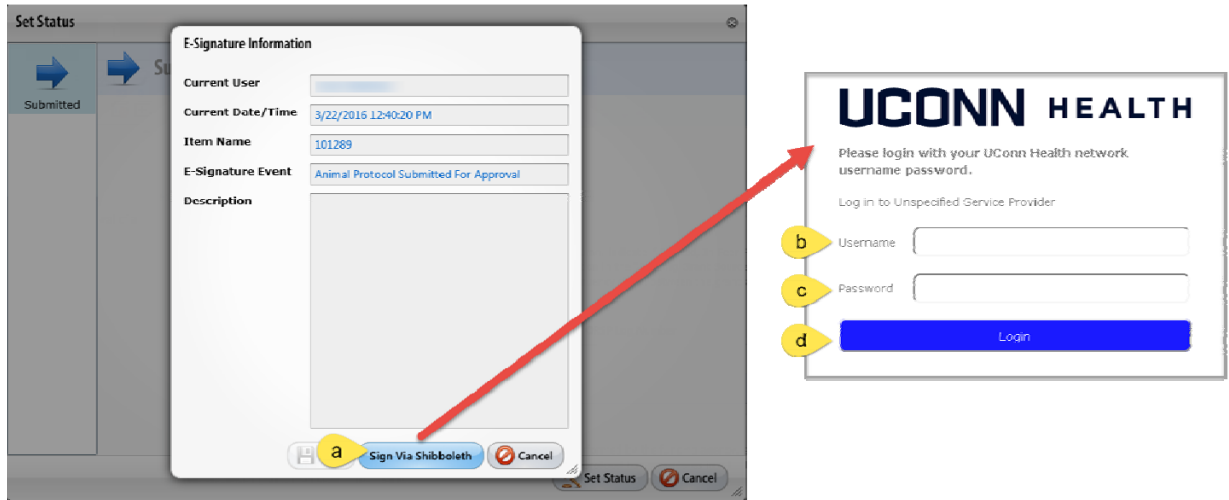
   NOTE: *You need to make the changes in the document for each modification requested. Modification requests will be returned to you if this is not done.*

7. Once you are sure the protocol is ready to be submitted, click the **Submit** button. The Set Status dialog box appears.

8. On the Set Status dialog box, click **Submitted** and then **Set Status** button .

9. An e-Signature dialog appears, please
   a. Click Sign Via Shibboleth button.
   b. Enter your UConn Health domain name **username.**
   c. Enter your UConn Health domain name **password**.
   d. Click Login button
   e. After successful login, you will be returned to the protocol.

10. Your protocol has been submitted. To confirm that your protocol was submitted using the Product Selector go to **My Dashboard > My Protocols**. Look for the protocol you just submitted. The Protocol Status should report "Submitted". If it doesn't, then something went wrong. Simply go back into the protocol by clicking on it and re-submit by repeating steps 7-9 above.

Creating Annual (Interim) Reviews

1. Approximately 2 weeks prior to the due date, you will receive an email generation from Topaz Elements reminding you that you need to complete an annual review. It should look something like this:
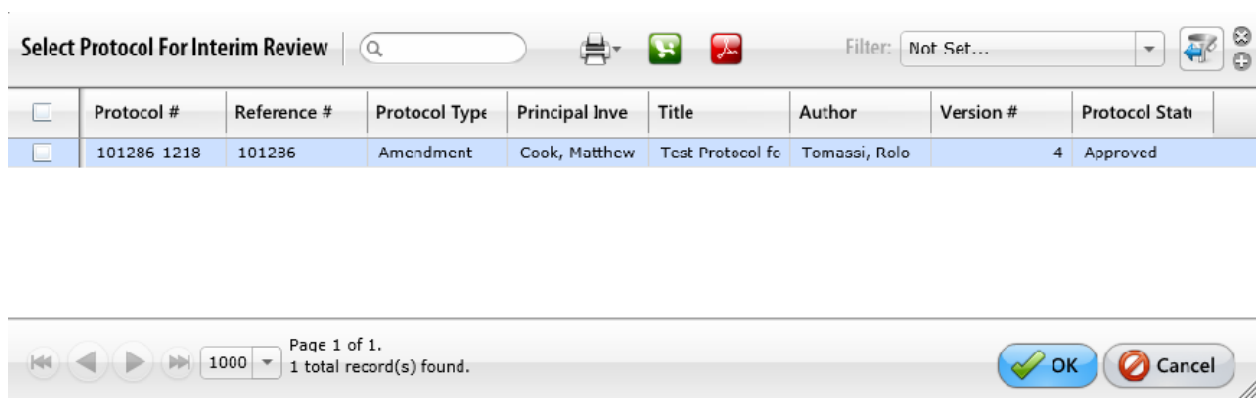
   > Hi, Dr. [PI]-
   >
   > The PHS and USDA require annual reviews of all animal related activities. Your animal protocol [Protocol Number] "[Protocol Title]" requires an annual review form to be submitted to the ACC by [Due Date]. You will need to use the "Create renewal protocol" form to submit this annual review.
   >
   > If you have any questions regarding this process, please contact Dr. Jim Watras at x2896 for assistance.
   >
   > Thank you-
   >
   > IACUC Office

2. Login to Topaz Elements at https://uconnprod.topazti.net/ucelements with your UConn Health domain username and password.

3. Under the Compliance Menu, click **Animal Protocols**.

4. Click **Create Interim Review Protocol** from the Protocols menu items.

5. Click on the appropriate protocol for Interim (annual) review on the Select Protocol grid. This should be the protocol that you need to submit an annual review for.
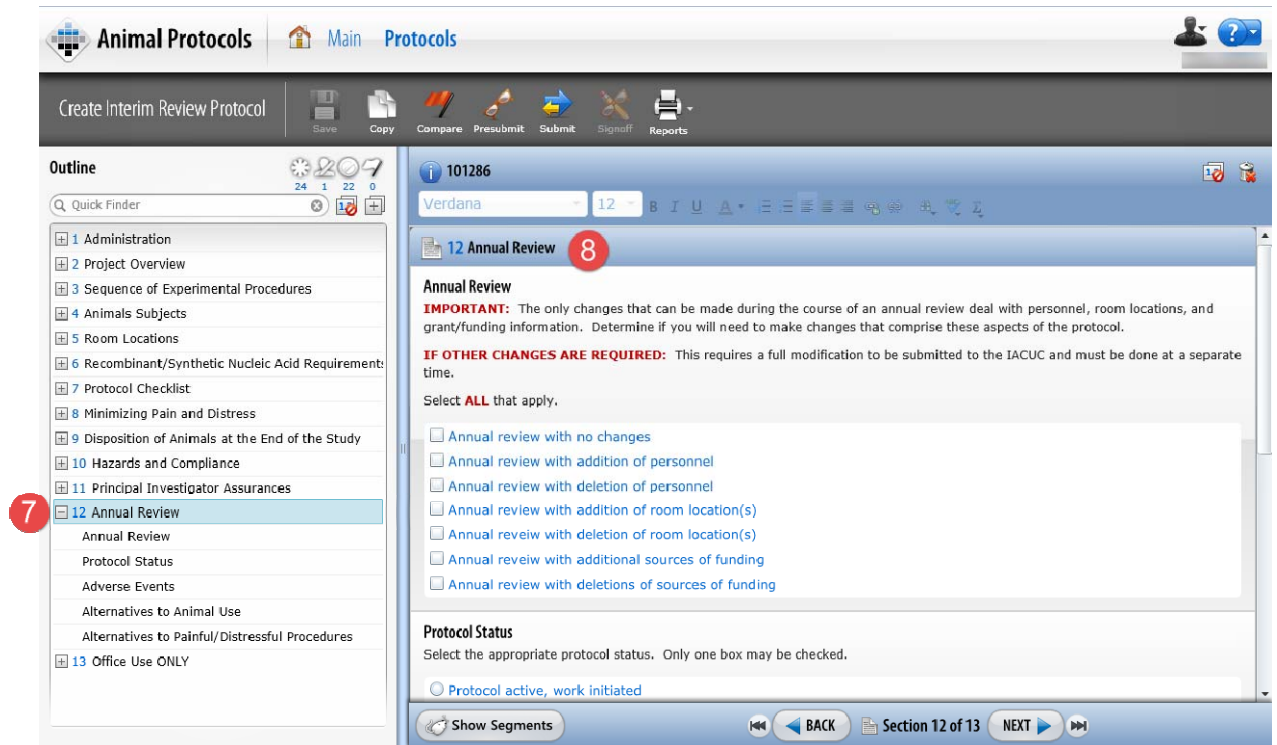

6. Click on the appropriate protocol renewal form (i.e. Review Form for first and second annual reviews).
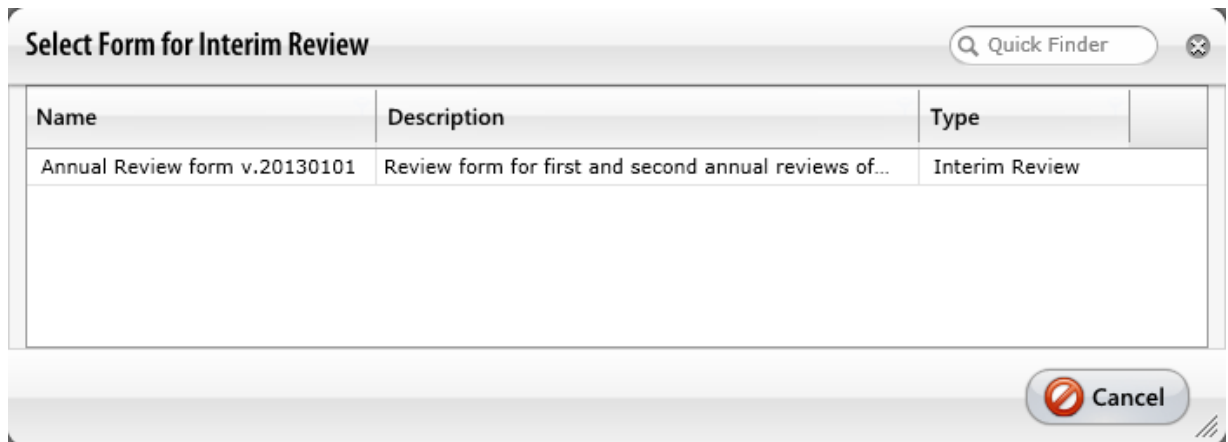
7. The Protocol form opens. Using the Outline, go to, expand (click + to the left) and complete Section 12 Annual Review of the protocol form.

8. In Section 12, complete your responses to each question.

9. Click Save 💾 .

10. Once you are sure the protocol is ready to be submitted, click the **Submit** button. The Set Status dialog box appears

11. On the Set Status dialog box, click **Submitted** and then **Set Status** ⚒ button .

12. An e-Signature dialog appears, please
    a. Click Sign Via Shibboleth button.
    b. Enter your UConn Health domain name **username**.
    c. Enter your UConn Health domain name **password**.
    d. Click Login button.
    e. After successful login, you will be returned to the protocol.
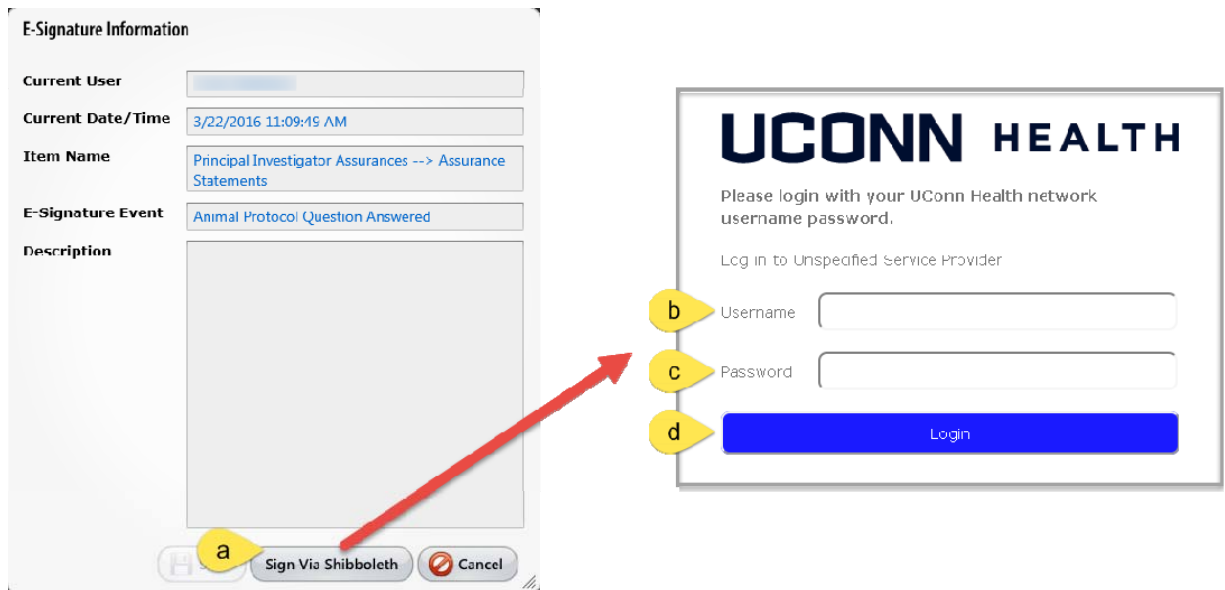
13. Your protocol has been submitted. To confirm that your protocol was submitted using the Product Selector go to **My Dashboard > My Protocols**. Look for the protocol you just submitted. The Protocol Status should report "Submitted". If it doesn't, then something went wrong. Simply go back into the protocol by clicking on it and re-submit by repeating steps 10-12 above.

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 Elements 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 IACUC Office

2. Under the Compliance ![icon] Menu, click **Animal Protocols**.

3. From the Protocols menu items, click ![icon] **Create Original Protocol.** Although 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.

4. On the Select Form Grid, click on the **Initial Animal Care and Use Form**.   The protocol form will be created.
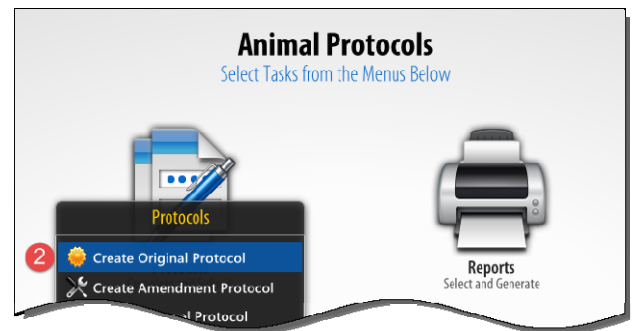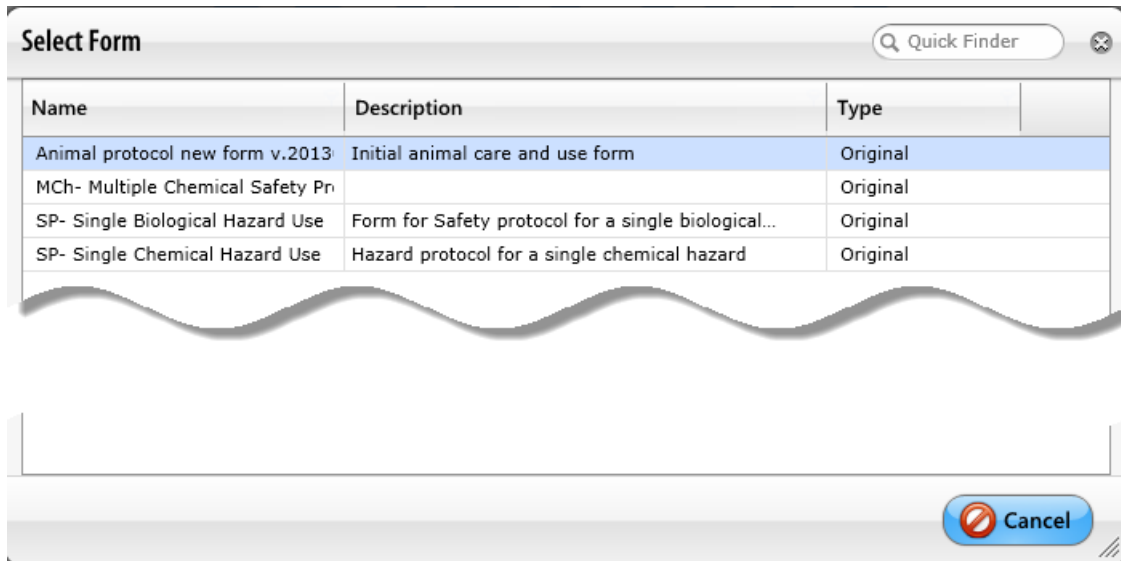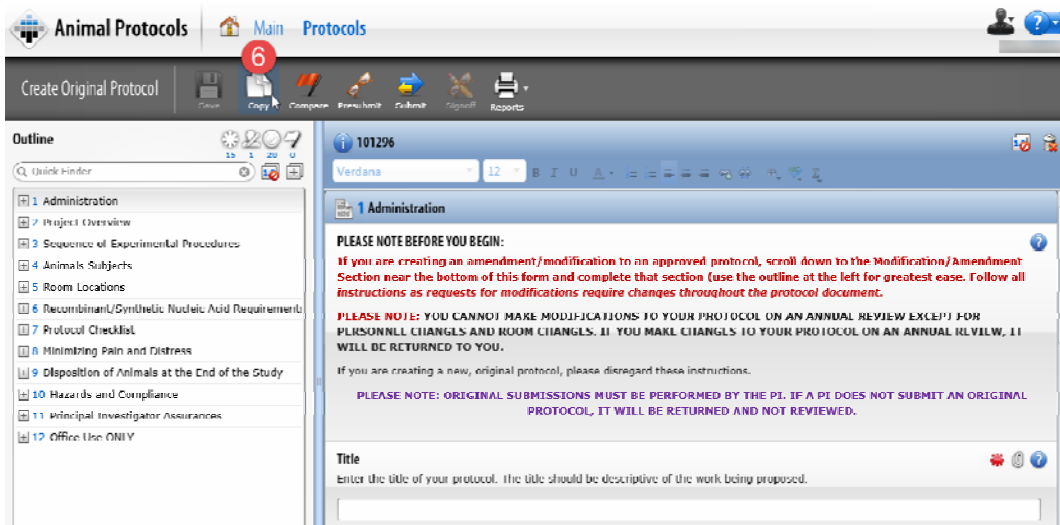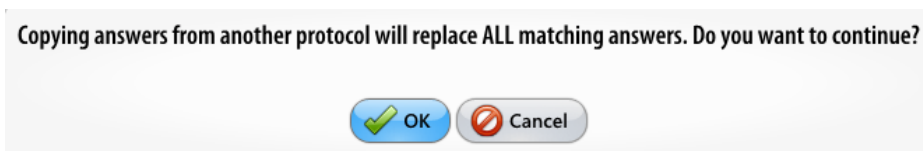
5. The protocol form will then generate. Click the Save 💾 icon.
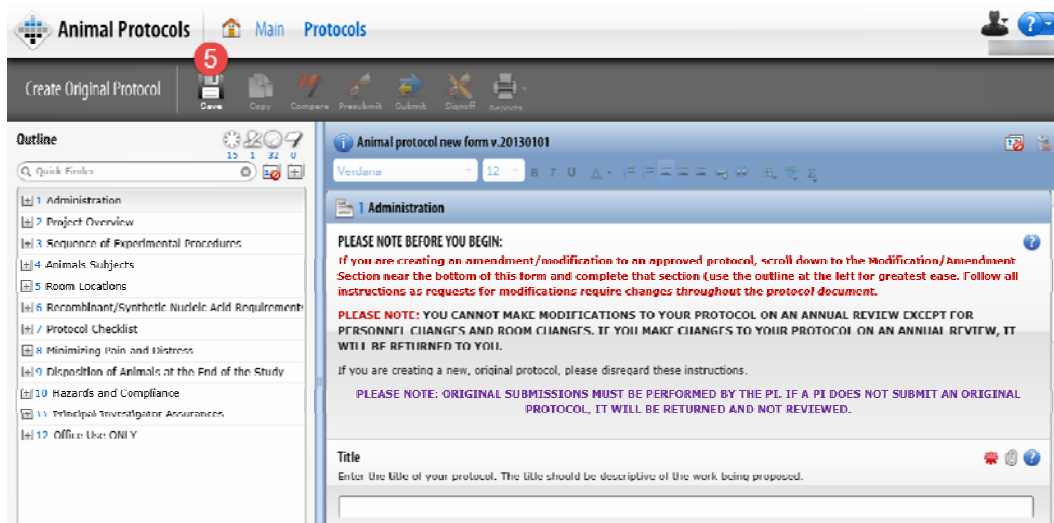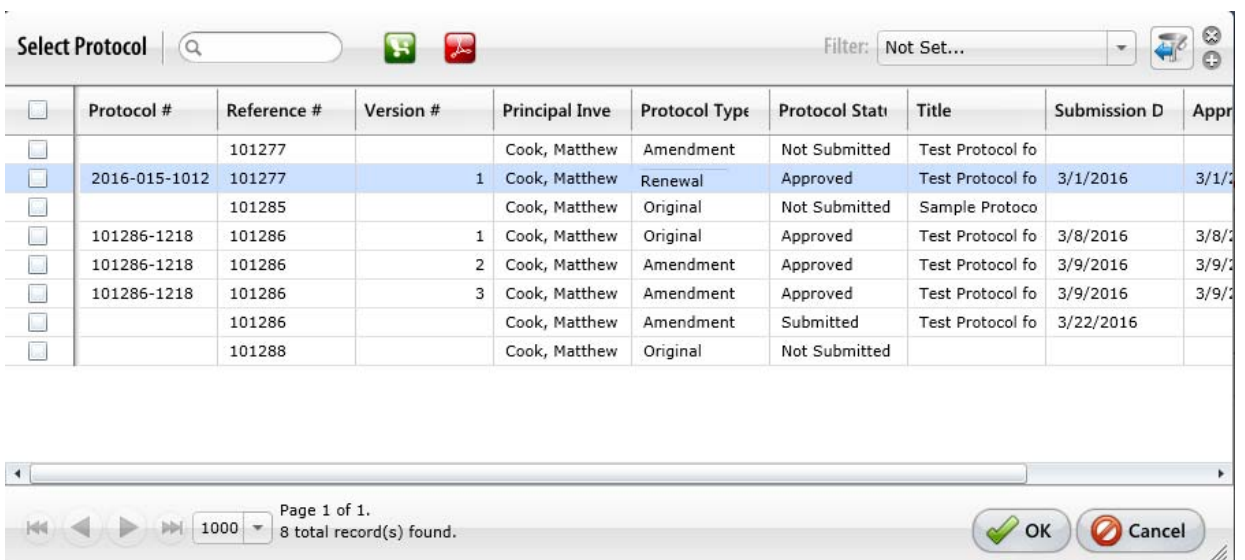
6. Click on the Copy ⧉ icon.

7. A dialogue box with a warning will then generate. Click on the "OK" button.

8. The Select Protocol grid will appear, showing all the approved protocols you have. The protocol would have a Protocol Type of Renewal and be in Approved Status.

9. 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.

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

    TIP: 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.

11. 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.
    a. Click Sign Via Shibboleth button.
    b. Enter your UConn Health domain name **username.**
    c. Enter your UConn Health domain name **password**.
    d. Click Login button
   e. After successful login, you will be returned to the protocol.
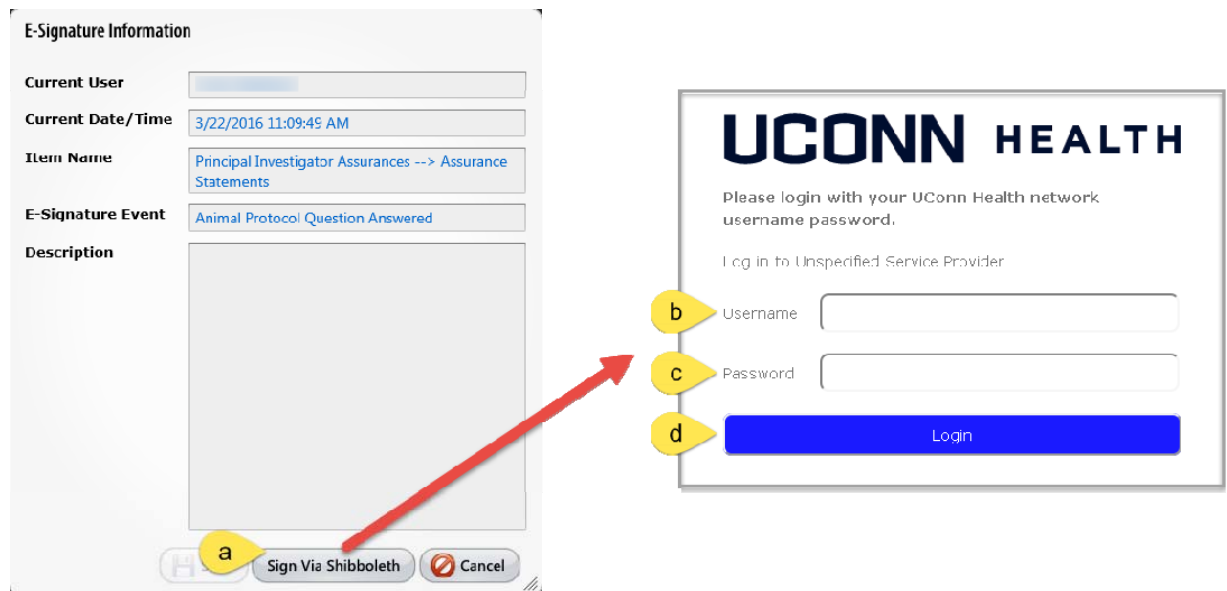
12. Once you are sure the protocol is ready to be submitted, click the **Submit** ⬅️ button. The Set Status dialog box appears
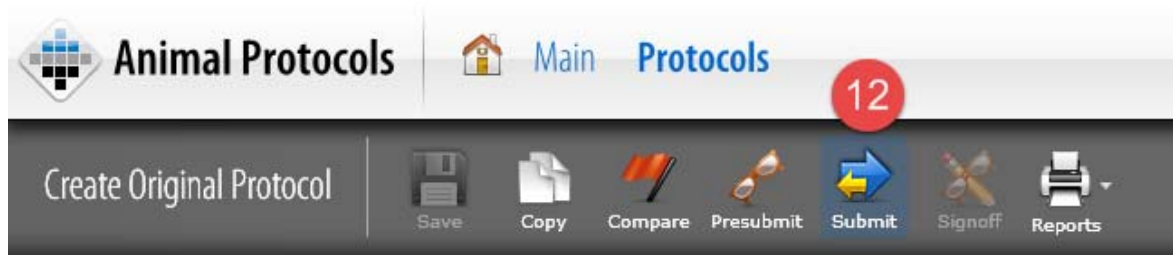
13. On the Set Status dialog box, click **Submitted** and then **Set Status** 🔨button .

14. An e-Signature dialog appears, please
    a. Click **Sign Via** Shibboleth.
    b. **Enter** your username.
    c. Enter your **password**.
    d. Click **Login** button to submit your protocol.
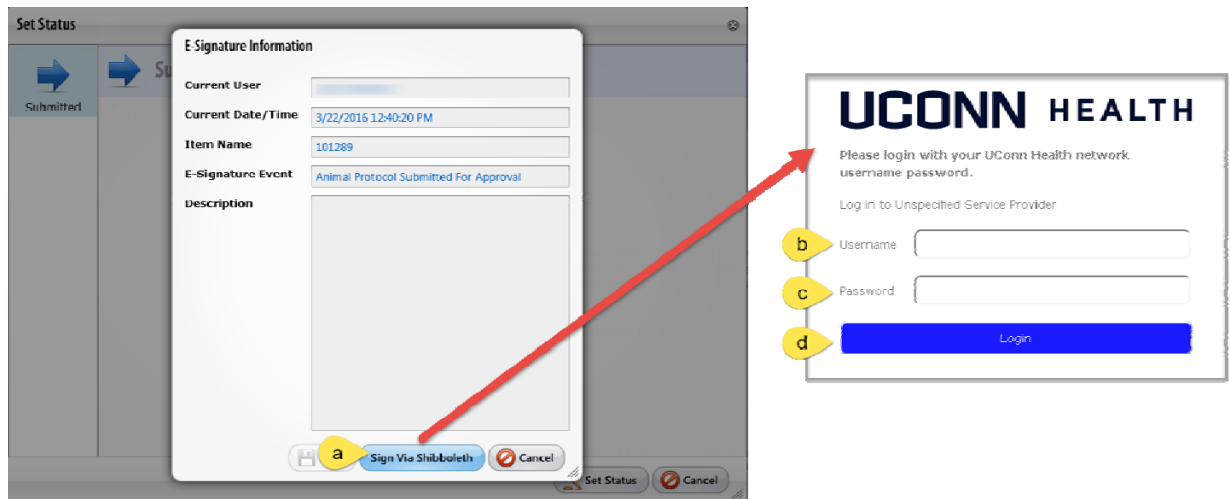
15. Your protocol has been submitted. To confirm that your protocol was submitted using the Product Selector and go to **My Dashboard > My Protocols**. Look for the protocol number you just submitted. The Protocol Status should report "Submitted". If it doesn't, then something went wrong. Simply go back into the protocol by clicking on it and re-submit by repeating steps 10-14 above.