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 <u>ooacc@uchc.edu</u>. Please give a brief description of what you
 were trying to do when the error occurred.



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• 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).

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| 1 Administration | 1 Administration | | | | | 0 - | |
| 1 2 Project Overview | | | | | | | |
| 1 3 Animal Subjects | Title | | | | | ÷ 🛈 | |
| + 4 Surgery | Enter the title of the project. | | | | | | |
| 1 5 Transgenic and Gene-Targeted (Tg/GT) Animals | Sample | | | | | 11 | |
| 1 6 Protocol Checklist | | | | | | _ | |
| 1 7 Clinical Outcomes | Reference Number | | | | | | |
| 8 Minimizing Pain and Distress | Automated tracking number - automatic | Automated tracking number - automatically generated. Do not change or add any information. | | | | | |
| + 9 Disposition of Animals at the End of the Project | 100146 | | | | | | |
| 10 Hazards and Compliance | B | | | | | | |
| 11 Principal Investigator's Assurances | Protocol Number | | | | | | |
| 12 Office Use Only | Assigned by ACC upon approval. Do not | t change or add any informatior | ۱, | | η | | |
| | Created By | | | | | • | |
| | Pohl, Alison | pohl@uchc.edu |) | (860) 679-4129 | | | |
| | Principal Investigator | | | | | *0 | |
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| n 🖸 🗑 🖉 | 👹 Instructions- Topaz El 😡 Deleted Items - Micr | o 🌈 http://infoed.uchc.ed | C TOPAZ Enterprise | | | Wednesday 4/13/2011 | |

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



TOPAZ- Protocol Development Instructions for Researchers

3. 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.

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| Open Unsubmitted Protocols • | | |
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| + 1 Administration | URL : | 0 |
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| + 3 Animal Subjects | | 🙂 🖗 |
| + 4 Surgery | | |
| 1 5 Transgenic and Gene-Targeted (Tg/GT) Animals | | |
| 1 6 Protocol Checklist | | |
| 1 7 Clinical Outcomes | | <u>ت</u> |
| 1 8 Minimizing Pain and Distress | | |
| 1 9 Disposition of Animals at the End of the Project | | |
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| 12 Office Use Only | | |
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| | Principal Investigator | \$ 0 |
| | A Pohl, Alison pohl@uchc.edu | (860) 679-4129 |
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- 4. 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.
- 5. Once your computer is mapped, pick your file to attach.

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TOPAZ- Protocol Development Instructions for Researchers

Creating New Animal Care and Use Protocols

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

| TOPAZ Enterprise | | | |
|---|----------------|-----------------|-----------------|
| | | | |
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| | | | |
| | Login | | |
| | Password | | |
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| | Login | | |
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| Copyright 2010 © TOPAZ Technologies. All rights reserved. | | Second Intranet | www.topazti.com |

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.

| Start Page - 🗌 🏠 | | | | Pohl, Alison 上 🚖 🕐 🕕 |
|------------------|----------------|---------------|--------------|----------------------|
| | Settings | 🛞 Navigation | 🕜 Help | |
| | Administration | Dashboard | HTML Help | |
| | My Settings | TOPAZ Website | PDF Help | |
| | Animals | | | |
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| | Reviews | | | |
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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 (ooacc@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).



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- 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).

| Outline | 25 0 Animal Care and Use Protocol 20100802 |
|--|--|
| Filter Outline 1. | 2 + Verdana • 12 • B I U = E E E E E E E E E E E E E E E E E E |
| + 1 Administration | 1 Administration |
| 1 2 Project Overview | |
| 🕂 3 Animal Subjects | Title |
| + 4 Surgery | Enter the title of the project. |
| + 5 Sequence of Experimental Procedures | |
| 1 6 Transgenic and Gene-Targeted (Tg/GT) Ani | imals |
| 1 7 Protocol Checklist | Protocol Renewal Information |
| 1 8 Clinical Outcomes | Selectione or the following : |
| | New protocol- this is not a 3-year renewal of an expiring or expired protocol |
| \pm 10 Disposition of Animals at the End of the Pi | roject |
| ⊞ 11 Hazards and Compliance | |
| 12 Principal Investigator's Assurances | Reference Number |
| 13 Office Use Only | Automated tracking number - automatically generated. Do not change or add any information. |
| | 100136 |
| | Protocol Number |
| | Assigned by ACC upon approval. Do not change or add any information |
| | |
| | |
| | Constant Dr. |

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]).



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).

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| Reference Number | Title | 🏶 🛈 |
| Principal Investigator | Enter the title of the project. | |
| Protocol Associates | [\$ample | |
| Associates Authorized to Order Animals | | |
| Funding/Grant Source | Reference Number | # |
| - 4 Surgery | Automated tracking number - automatically generated. Do not change or add any information. | |
| Surgical Procedures | 100143 | |
| 6 Protocol Checklist | | |
| Protocol Checklist | Protocol Number | |
| 🖃 11 Principal Investigator's Assurances | Assigned by ACC upon approval. Do not change or add any information. | |
| Assurance Statements | | |
| | Created By | 0 |
| | Pohl, Alison pohl@uchc.edu (860) 679 | -4129 |
| | Principal Investigator | * 0 |
| | Click green plus sign to add PI. | |
| | 🔹 🕕 Pohl, Alison pohl@uchc.edu (860) 67 | 9-4129 |
| | Protocol Associates | + * 0 |
| Done | Second in the second | ıtranet 🦙 🔹 100% 🔹 |

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

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| Outline | Set Status | | | | × | 1.2 - * |
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| Principal Investigator | | | | | | |
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| - 4 Surgery | | | | | | |
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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]).

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| - 1 Administration | | Password | +*0 |
| Title | | | |
| Reference Number | | Staff Name | * |
| Principal Investigator | | Pohl, Alison | |
| Protocol Associates | | Current Date/Time | |
| Associates Authorized to | | 2/9/2011 8:11:59 AM | |
| Funding/Grant Source | | Item Name | |
| - 4 Surgery | | 100143 | 440 |
| Surgical Procedures | | Event Name | |
| 🗐 6 Protocol Checklist | | Animal Protocol Submitted For Approval | |
| Protocol Checklist | | Description | * |
| - 11 Principal Investigator's | | | |
| Assurance Statements | | Set Status Ca | ncel |
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| | | Funding Details | 0 |
| | | Using the Table below, enter relevant funding information. For the "Status of Funding/Grant Applicat | ion" column, indicate If Funded, |
| | | In Peer Review, Just In Time, or Other/a non-peer review source (e.g. start up funds or depart | mental resources). |
| | | Add Row | |
| | | Sector Se | al intranet 🥢 🔹 🔍 100% 🔹 . |

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.

| 🛞 Dashboa | ard - | | | | | | | | Pohl, Alison | 1 🔶 🕐 1 |
|--------------|-------|--------------------|--|------------------------|-------------|--------------|-----------------|----------------------|----------------|-----------------------|
| My Protocols | Quick | Filter | | | | | | | | My Reviews |
| 50 | | Protocol Number | Reference Number | Principal Investigator | Association | Form Subtype | Protocol Status | Protocol Short Title | Product Family | 50 |
| Filter | | | 100136 | Pohl, Alison | PI | Original | Submitted | Training protocol | Animal Studies | Filter |
| Export Grid | | | 100143 | Pohl, Alison | PI | Original | Submitted | Sample | Animal Studies | Export Grid |
| | | | | | | | | | | My Meetings |
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| Done | | | | | | | | Second Second | intranet 4 | 🚡 🔹 🔍 100% 🔹 🚲 |

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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).

| | Copy Compare Presubmit Submit Signoff Reports | |
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| 4 Surgery | Enter the title of the project. | |
| 5 Transgenic and Gene-Targeted (Tg/GT) Animals | Sample | |
| 6 Protocol Checklist | | |
| 7 Clinical Outcomes | Reference Number | • |
| 8 Minimizing Pain and Distress | Automated tracking number - automatically generated. Do not change or add any | information. |
| 9 Disposition of Animals at the End of the Project | 100143 | |
| 10 Hazards and Compliance | Deskeed Musekee | |
| 11 Principal Investigator's Assurances | Protocol Number | |
| 12 Office Use Only | Assigned by ACC upon approval. Do not change or add any information. | |
| | Created By | 0 |
| | pohl, Alison pohl@uchc.edu | (860) 679-4129 |
| | Principal Investigator | ÷ 0 |
| | Click green plus sign to add PI. | |
| | Bobl Alizon Dobl@ushs.adu | (960) 670-4120 |

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).

| Open Submitted Protocols - Protocol Information Outline General Lino Reviews: Bigmatures, Emails Fater Outline Protocol Information Image: Sigmatures, Emails I Administration Protocol Active? Protocol 1 I Administration Protocol Cactive? Protocol 1 I Administration Protocol Active? Protocol 1 I Administration Protocol Cactive? Protocol 1 I Stranselsubjects Ipolity Original I Stranselsubjects Form Name Administration I Concol Othecklist Changed By Staff Polit, Alison Image: Polity Staff Polit, Alison I Disposition of Animals at the End I Disposition of Anim | 🎸 Animal Protocols - 🗌 🏠 | Main Protocol Form | is Protocols | | Pohl, | Alison 上 🚖 🕗 🕕 |
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| Image: Animal Subjects Image: Animal | + 2 Project Overview | Reference Number | 100143 | | | |
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| I 10 Hazards and Compliance Last Updated 2/9/2011 8:12:16 AM Submitted 2/9/2011 8:12:16 AM Inactive Date Approved M/d/yyyy> Effective Approved M/d/yyyy> Renewal M/d/yyyy> Renewal M/d/yyyy> Kerion M/d/yyyy> Kerion M/d/yyy> Kerion M/d/yyy> Kerion M/d/yyy> Kerion M/d/yyy> Kerion Keri | 9 Disposition of Animals at the End | eated: | 2/9/2011 8:08:56 AM | | | |
| Il 11 Principal Investigator's Assurant I 12 Office Use Only Effective Submitted 2/9/2011 8:12:16 AM Inactive Date Approved Inactive Date (Isoo) 679-4129 Inactive Date Isoo Isoo | 10 Hazards and Compliance | Last Updated | 2/9/2011 8:12:16 AM | | | |
| El 12 Office Use Only Inactive Date Approved Approved Approved Approved Effective M(d/yyy>> Renewal CM/d/yyy>> Renewal CM/d/yyy>> Concel (860) 679-4129 (860) 679- | 11 Principal Investigator's Assurance | Submitted | 2/9/2011 8:12:16 AM | | | |
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| Effective Next Review Next Review Renewal | | Approved | <m d="" yyyy=""></m> | 15 | | |
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TOPAZ- Protocol Development Instructions for Researchers

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).

| 🎸 Animal Protocols - 🗌 🏠 | Main Protocol Forms Protocols | | Pohl, Alison 上 🚖 🕖 🕕 |
|------------------------------------|--|----|----------------------|
| ➡ Open Submitted Protocols ▼ | Sure Const Constant State | | |
| Outline | Protocol Information | × | |
| ouume | General Info Reviews Esignatures Emails | | 1.2 - |
| Filter Outline | Review Type | | |
| + 1 Administration | | | |
| + 2 Project Overview | Review Summary | | |
| 🖽 3 Animal Subjects | | | ÷ |
| + 4 Surgery | Review Assignments | | |
| 1 5 Transgenic and Gene-Targeted | Name Start Date Due Date Completion Date | | J |
| 6 Protocol Checklist | Paview group 1 2/24/2011 | -1 | |
| 7 Clinical Outcomes | | | 00 |
| H 8 Minimizing Pain and Distress | Review Meetings | | |
| 10 Hazards and Compliance | Name Location Scheduled Datetime | | |
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NOTE: Even though the Review Type is missing is 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

- 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.



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.



TOPAZ- Protocol Development Instructions for Researchers

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.



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.

| C Animal Protocols - Animal Protocol | Forms Protocols | Pohl, Alison 上 🚖 🕡 |
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| Sopen Returned Protocols ▼ | y Compare Presubmit Submit Supmit Reports | |
| Outline 🔅 🏭 🏹 🥪 | 100148 | 1.2 - * |
| Filter Outline + | Portable User Inte ▼ 12 ▼ Β Ι U Δ ▼ Ε Ε Ξ Ξ ጫ ∰ Β ▼ 💱 Σ | |
| 1 Administration Accounts | General Experimental Design Describe the general experimental design for this species. | 🖬 () 🕑 |
| 2 Project Overview | Day 1- animals will be injected with chemical; Day 3- surgical procedure will be performed collected for in vitro analysis. Then we will determine what benefits the chemical had to the | l; Day 7- animals will be euthanized and tissues ne animals |
| □ 3 Animal Subjects | Comments from Last Submission | 2/23/2011 9:11:46 AM |
| Species Mice #1 | This needs more detail. | |
| General Experimental Design | | |
| Alternatives to Painful Procedures | Rational for Requested Animal Numbers | 🔁 🛈 📄 |
| 4 Surgery | Non-statistical approach for calculating optimal animal numbers needed in research | |
| Surgical Procedures | Describe how the number of animals requested for the study was determined to be approp | riate. Remember to include an estimate of animals |
| E Yes | required for breeding of experimental animals if applicable. Whenever possible the number | of animals should be justified statistically. |
| Type of Surgery | Utilization of a table, which can be made in Word and attached, can be used to justify anim | nal numbers. |
| Major Survival (defined as any surgery that op | We are using 2 groups of mice- one will have the chemical prior to surgery, the other grou | p will not. We need 5 animals per group in order to |
| Multiple surgery | account for all variables. We will need to repeat the experiment twice. | |
| No | 2 groups x 5 animals per group x 2 repeats = 20 animals are required | |
| Surgical Procedures | | |
| Ovariectomy | Authorized Amounts | 🚽 🛈 🕜 |
| Operative Details | Select animals in accordance with pain categories below: | |
| Post-operative Care | B- Breeding or holding animals only. C- Animals upon which teaching, research, experiments, or tests are conducted involving n | o or only momentary pain and/or distress. |
| 🯄 start 🔰 🤌 🕫 🖗 🛱 🖗 🖗 🖗 | 🖉 TOPAZ Enterprise - M 🛛 🎆 GRANITE Enterprise 💋 TOPAZ Enterprise - M 🌯 Telephone Directo | ory 🧧 🛃 🙀 9:22 AM |
| n 🖸 🕅 🖉 🗞 🚺 | 😼 Inbox - Microsoft Out 🛛 🌈 http://infoed.uchc.ed 🛛 🗃 Instructions- Topaz El | ● ● ■ ● 2/23/2011 |

TOPAZ- Protocol Development Instructions for Researchers

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.

| C Animal Protocols - 1 👔 Main Protocol | Pohl, A | Pohl, Alison 上 🚖 🕡 🚺 | | | | | | |
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| Outline Ozeogo | 100148 | | | | | | [| 1.2 - * |
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| 1 Administration | 1 Administration | | | | | | | 0 - |
| Title | | - | | | | | | |
| Reference Number | Title | | | | | | | ۵ 🏶 |
| Protocol Number | Enter the title of the proj | ect. | | | | | | |
| Created By | Sample Protocol to do a | Topaz Instruction Docume | nt for Researchers | | | | | |
| Principal Investigator | | | | | | | | |
| Protocol Associates | Reference Number | | | | | | | * |
| Associates Authorized to Order Animals | Automated tracking num | ber - automatically genera | ited. Do not change or ad | d any info | mation. | | | |
| Funding/Grant Source | 100148 | | | | | | | |
| Funding Details | 11 | | | | | | | |
| Study Initiation | Protocol Number | | | | | | | |
| Accounts | Assigned by ACC upon ap | oproval. Do not change or | add any information. | | | | | |
| 2 Project Overview | | | | | | | - L | |
| Lay Summary | Constant Day | | | | | | | 0 |
| 3 Animal Subjects | Created by | | | | | | | • |
| Species | Pohl, Alison | | pohl@uchc.edu | | | (860) 679-4129 | | |
| - Mice #1 | | | | | | | | |
| Rationale for the Use of Animals | Principal Investigator | | | | | | | * 0 |
| Rationale for the Appropriateness of the Spec | Click green plus sign to a | dd PI. | ~ | | | | | |
| Strain | nohl, Alison | | pohl@uchc.edu | | | (860) 679-4129 | | |
| Other Strain/Line | Protocol Associates | | | | | | | +*0 |
| lone | 11 | | | | | A Internet | 4 <u>6</u> - | * 100% * |

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).

| 🖒 Animal Protocols - | 🟦 Main Protoco | Forms Protocols | | Pohl, Alis | son 上 🚖 🕡 🕕 |
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| Open Returned Protocol | s• 🖪 A | n n & . * * | | | |
| | Set Status | | | × | |
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| Filter Outline | | Submitted | | | |
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| 1 Administration | Submitted | | | | |
| Title | | | | | aita (0) |
| Reference Number | | | | | ₩ 🛛 |
| Protocol Number | Withdrawn | | | | |
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| Principal Investigator | | | | | ala |
| Protocol Associates | | | | | |
| Associates Authorized to Or | | | | | |
| Funding/Grant Source | | | | | / |
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| Study Initiation | | | | | |
| Accounts | | | | | |
| 2 Project Overview | | | | | |
| Lay Summary | | | | | 0 |
| 🖃 3 Animal Subjects | | | | | |
| 🖃 Species | | | | | |
| Mice #1 | | | | Set Status Cancel | * 0 |
| Rationale for the Use of A | | | | | * 🛛 |
| Rationale for the Appropri | iateness of the Spec | Click green plus sign to add PI. | | γ | |
| Strain | | Poni, Alison | pohl@uchc.edu | (860) 679-4129 | |
| Other Strain/Line | | Protocol Associates | | | +*0 |
| Done | | | | Internet | 🖓 • 🔍 100% • |

TOPAZ- Protocol Development Instructions for Researchers

8. 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).

| Animal Protocols - | Set Status | | | × | lison 🔰 👍 🙆 🚳 |
|------------------------------|---------------------|-------------------------------------|---------------|-------------------|---------------|
| | | Submitted | | | |
| A Open Returned Protocol | | - | | | |
| • open netamed i totocol. | Submitted | 🗶 E-Signature Information | | | |
| Outline | 4 | Username | | | 1.2 - * |
| Filter Outline | | apohi |] | | |
| | Withdrawn | Password | | | |
| 1 Administration | | | | | |
| Title | | Staff Name | | | |
| Reference Number | | Pohl, Alison | | | * 0 |
| Protocol Number | | Current Date/Time | | | |
| Created By | | 2/23/2011 9:29:31 AM | | | |
| Principal Investigator | | Item Name | | | |
| Protocol Associates | | 100148 | | | * |
| Associates Authorized to Ord | c | Event Name | | | i |
| Funding/Grant Source | | Animal Protocol Submitted For Appro | oval | | |
| Funding Details | | Description | | | |
| Study Initiation | | |] | | |
| Accounts | | | | | |
| 🖃 2 Project Overview | | | | Set Status Cancel | |
| Lay Summary | | G | | | 0 |
| 3 Animal Subjects | | | | | |
| Species | | • | | (860) 679-4129 | |
| Mice #1 | | | Cancel | | |
| Rationale for the Use of A | nimals | Principar investigator | | | * 🙂 |
| Rationale for the Appropri- | ateness of the Spec | Click green plus sign to add PI. | | | |
| Strain | | Poni, Alison | poni@uchc.edu | (860) 679-4129 | |
| Other Strain/Line | | Protocol Associates | | | +*0 |
| Done | | | | linternet | |

9. 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).

| | Quick | Filter | | | | | | | My Re |
|------|-------|-----------------|------------------|------------------------|-------------|--------------|---------------------------|---------------------------------|-------|
| 8 | - | Protocol Number | Reference Number | Principal Investigator | Association | Form Subtype | Protocol Status | Protocol Short Title | |
| er | | | 100136 | Pohl, Alison | PI | Original | Submitted | Training protocol | F |
| | | | 100146 | Pohl, Alison | PI | Original | Not Submitted | Sample | |
| | | 100038 | 100143 | Pohl, Alison | PI | Renewal | Approved | Sample | |
| Grid | | 100038 | 100143 | Pohl, Alison | PI | Renewal | Returned For Modification | Sample | Exp |
| | | | 100147 | Pohl, Alison | PI | Original | Not Submitted | Training protocol | _ |
| 4 | | | 100148 | Pohl, Alison | PI | Original | Submitted | Sample Protocol to do a Topaz I | (111) |
| | | | | | | | | | Exp |
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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

2. 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.

| 🛞 Dashboa | ard - 🗌 🏠 | | | | | | Lorenzo, Joseph | Ľ 🚖 🕐 🛈 |
|--------------|-----------------|------------------------|------------------------|-------------|--------------|-----------------|---------------------------------------|--------------|
| My Protocols | Quick Filter | | | | | Ļ | | My Reviews |
| 50 | Protocol Number | Reference Number | Principal Investigator | Association | Form Subtype | Protocol Status | Protocol Short Title | 10 |
| Filter | 2010-656 | 100062 | Lorenzo, Joseph | PI | Original | Approved | Studies of CD45R/B220+ Osteoclast Pre | Filter |
| Export Grid | | | | | | | | Export Grid |
| Reports | | | | | | | | Reports |
| | | | | | | | | My Meetings |
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| | | Page 1 of 1. | | | | | | Reports |
| | | 1 total record(s) four | nd. | | | | | |
| Done | | | | | | | Internet | ▲ • • 100% • |

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

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|--|--|----------------------|
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| Outline # 207 | 100049-1013 | 1.2 - 🕷 |
| Filter Outline 1.2 + | rdana → 12 → B I U · 日日目言言言 % ※ * ♥ Σ | |
| + 1 Administration | Administration | 0 - |
| + 2 Project Overview | Title | 2 |
| + 3 Animal Subjects | litie | • • |
| | Enter the title of the protect. RNA Trafficking in Neural Cells | |
| S Transgenic and Gene-Targeted (1g/GT) Animals | | |
| | Reference Number | * |
| H 7 Clinical Outcomes | Automated tracking number - automatically generated. Do not change or add any information | |
| H 8 Minimizing Pain and Distress | 100049 | |
| 9 Disposition of Animals at the End of the Project | | |
| 10 Hazards and Compliance | Protocol Number | |
| 11 Principal Investigator's Assurances | Assigned by ACC upon approval. Do not change or add any information. | |
| ± 12 Office Use Only | 100049 | 1013 |
| | Created By | Ø |
| | Carson, John H. CARSON@NEURON.UCHC.EDU (860) 679- | 2130 |
| | Principal Investigator Click green plus sign to add PI. Carson, John H. CARSON@NEURON.UCHC.EDU (860) 679 | * 0 9-2130 |
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| n 🖸 🗟 🖬 🖉 🖉 | 🏈 http://nfoed.uchc.ed 🛛 📓 Instructions- Topaz El | 2/23/2011 |

4. 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).

| 🧭 Animal Protocols - 🕴 🏠 Main | Protocol Forms Protocols | Pohl, Alison 上 🚖 👔 🗊 |
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| ✓ Open Approved Protocols ▼ | 1 🖆 🥂 🖉 🚖 🔌 🖶 | |
| Outline 🛞 | Protocol Information General Info Reviews Esignatures Emails | × 1.2 - * |
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| + 1 Administration | tocol # 100049 1013 | 0 - |
| 1 2 Project Overview | Reference Number 100049 | |
| 1 3 Animal Subjects | PI Carson, John H. | • 0 |
| H 4 Surgery | Protocol Type Original | |
| 1 Transgenic and Gene-Targeted (Tg/GT) | Status Approved | |
| 1 6 Protocol Checklist | Changed By Staff Pohl, Alison | |
| 1 7 Clinical Outcomes | Form Name Animal Care and Use Protocol 20100802 | |
| 1 8 Minimizing Pain and Distress | Crosted: 10/4/2010 5:02:11 DM | |
| 1 9 Disposition of Animals at the End of the | | |
| 10 Hazards and Compliance | Last Updated 2/23/2011 9:47:08 AM | |
| 11 Principal Investigator's Assurances | Submitted 12/3/2010 5:20:39 PM | |
| 12 Office Use Only | Inactive Date | 1013 |
| | Approved 1/10/2011 15 | |
| | Effective 1/10/2011 15 | Ø |
| | Next Review 12/10/2011 | 60) 679-2130 |
| | Renewal 8/10/2013 | |
| | Evoires 10/31/2013 | ÷ 0 |
| | | |
| | | 860) 679-2130 |
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| Done | | 😜 Internet 🦷 🔹 🔍 100% 💌 |

5. 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).

| Open Approved Protocols | Protocol Informa | ation | | | | 0 | |
|---|------------------|-----------------|----------------|--------------------|----------|----------------|-------|
| | General Info | eviews Esign | atures Email | S | | | |
| Dutline | Review Type | | | | | 1 | 1.2 - |
| Filter Outline | Designated me | mber review | | | | | |
| + 1 Administration | Review Summa | ry | | | | | Q |
| 1 2 Project Overview | | | | | | | |
| + 3 Animal Subjects | Review Assignm | nents | | | | | * |
| + 4 Surgery | Name | Start Date | Due Date | Completion Date | | | |
| 5 Transgenic and Gene-Targeted (| Ta/ | 12/6/2010 | 12/13/2010 | 1/10/2011 | | | |
| 🗄 6 Protocol Checklist | | 1 12/0/2010 | 12/13/2010 | 1/10/2011 | | | |
| 1 7 Clinical Outcomes | Review Meeting | s | | | | | |
| 8 Minimizing Pain and Distress | Name | Location | | Scheduled Datetime | | | |
| 🗄 9 Disposition of Animals at th <mark>e End</mark> | IACUC Member | s AG-070, Ac | ademic Affairs | 9/30/2010 | | | |
| 10 Hazards and Compliance | ~/ ' | | | | | | |
| 11 Principal Investigator's Assuran | ces | | | | | | |
| 12 Office Use Only | | | | | | | 1013 |
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| | | | | | | | * |
| | | | | | K Cancel | (860) 679-2130 | |
| | | Protocol Associ | ator | | | - | - |

TOPAZ- Protocol Development Instructions for Researchers

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

| 🐼 Animal Protocols - 🗌 🏠 Mai | in Protocol Fo | rms Protocols | | | | Pohl, A | lison 上 Y | 200 |
|--|-----------------|--|-----------------|--------------------------|-------|----------------|-----------|------------|
| ✓ Open Approved Protocols ▼ | Protocol Inform | nation Reviews Esignatures Emails | | | × | | | |
| Outline | Date/Time | Type | Signed By | Question (if applicable) | | | 1 | .2 — 💥 |
| Filter Outline | 12/2/2010 | Asimal Parkeral Cubrithed For Asimal | Company John II | Question (in applicable) | | | | |
| 1 Administration | 1/10/2011 | Animal Protocol Submitted For Approval | Carson, John H. | | | - | | 0 E |
| 1 2 Project Overview | 1/10/2011 | Animal Protocol Approved | Porit, Alison | | | | | |
| 🖽 3 Animal Subjects | | | | | | | | *0 |
| H 4 Surgery | | | | | | | | |
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| | | Protocol Associates | | | | | | +0 |
| Done | | | | | | Internet | · 6 | 💐 100% 🔹 |

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.

| Outline Protocol Information Image: Comparison of the protocol information of the protocol informating the protocol information of the protocol information of the pr | | Save | Copy Comp | pare Presubmit Submit Signoff Reports | | |
|---|--|---|--|--|---|-----------------------------------|
| Filter Outline General Info Reviews Esignatures Emails I Administration Date/Time Recipients Subject Imails I Administration 12/3/2010 pohl@uchc.edu, RWALLACE@ADP.UCHC.EDU Dr. Carson, John H. submitted a new p Imails I Stransgenic and Gene-Targeted (Tg/GT) Fitters Outline Imails | Outline | Proto | col Informatio | on | (| × 1.2 - |
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Creating Modifications to Protocols

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

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



TOPAZ- Protocol Development Instructions for Researchers

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).

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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).

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TOPAZ- Protocol Development Instructions for Researchers

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).



6. 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.

- 7. Then you would submit your protocol as directed on pages 9 and 10 of this document.
- 8. 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

 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).

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TOPAZ- Protocol Development Instructions for Researchers

3. 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.

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| 3 Project Overview 4 Animal Subjects | Protocol Status Select the appropriate protocol status. | = |
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| 8 Protocol Checklist | O Request protocol termination, work completed | |
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| | Alternatives to Animal Use Have any alternatives to the use of live animals become available since the protocol was originally approved? | |
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4. 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.

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TOPAZ- Protocol Development Instructions for Researchers

3. 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.



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

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| | Dehl, Alison | pohl@uchc.edu | (860) 679-4129 |
| | Principal Investigator | | * 0 |
| | Click green plus sign to add PI. | pobl@uchc.odu | (950) 670 4120 |
| | - V Poni, Anson | Ibouleacuciena | [(000) 0/9-1129 |

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

| C Animal Protocols - Main Protocol | Forms Protocols | | Pohl, Alison 上 🚖 🕧 🛈 |
|---|----------------------------------|---|-------------------------------|
| Create Original Protocol - | Compare Presubmit Submit | Reports | |
| Outline ** * * ? ? | 100158 | | 1.2 - 🗰 |
| Filter Outline | Verdana 12 B | IU - EEEEE | Ę |
| ± 1 Administration | 1 Administration | | 0 🗆 |
| 1 2 Project Overview | | | |
| 🕀 3 Animal Subjects | Title | | 😤 🛈 🕌 |
| # 4 Surgery | Enter the title of the project. | | |
| \pm 5 Transgenic and Gene-Targeted (Tg/GT) Animals | Conving answers from another pro | tocol will replace ALL matching answers. Do y | ou want to continue? |
| 1 6 Protocol Checklist | copying answers normanother pro | totor win replace ALL matching answers. Do y | ou want to continue: |
| 1 7 Clinical Outcomes | | OK Cancel | * |
| 1 8 Minimizing Pain and Distress | 1100150 | | |
| \boxplus 9 Disposition of Animals at the End of the Project | 100138 | | |
| 10 Hazards and Compliance | Protocol Number | | |
| 11 Principal Investigator's Assurances | | | |
| + 12 Office Use Only | Assigned by ACC upon approval. L | to not change or add any information. | |
| | Created By | | 0 |
| | Dohl, Alison | pohl@uchc.edu | (860) 679-4129 |
| | Principal Investigator | | *0 |
| | Pohl, Alison | pohl@uchc.edu | (860) 679-4129 |
| Done | | | 📢 Local intranet 🦛 + 🔍 100% 🔸 |

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

| 🧭 Animal Protocols | 🐼 Animal Protocols - 👔 Main Protocol Forms Protocols pohl, Alison 上 🚖 🕢 🗊 | | | | | | | | |
|----------------------------|---|----|-----------------|------------------------|------------------------|--------------|-----------------|----------------|--------------|
| Create Original Protocol - | | | | | | | | | |
| Outline | Select Protoco | Qu | ick Filter | | | | | + 🗙 | 1.2 - 🗮 |
| Filter Outline | 50 | | Protocol Number | Reference Number | Principal Investigator | Form Subtype | Protocol Status | Protocol Sho | |
| 1 Administration | Filter | |] | 100136 | Pohl, Alison | Original | Submitted | Training proto | 0 - |
| + 2 Project Overview | | | | 100146 | Pohl, Alison | Original | Not Submitted | Sample | 2 |
| 🕀 3 Animal Subjects | | | | 100147 | Pohl, Alison | Original | Not Submitted | Training prote | *0 |
| H 4 Surgery | Export Grid | | 100148-1113 | 100148 | Pohl, Alison | Renewal | Approved | Sample Proto | |
| | | | 4 | 100157 | Pohl. Alison | Original | Not Submitted | Sample Proto | |
| 6 Protocol Checklist | | | | 100137 | rony anson | original | Not Submitted | Dumple i loto | |
| Clinical Outcomes | | | | | | | | | |
| O Disposition of Animals | | | | | | | | | |
| 10 Hazards and Compli | | | | | | | | | |
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| 12 Office Use Only | | | | | | | | - | |
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| | | | | Page 1 of 1 | | | | - | |
| | | | | 5 total record(s) four | nd. | | ОК | Cancel | |
| | | _ | Principal In | vestigator | | | 19 | | ÷0 |
| | | | Click green | plus sign to add PI. | | | | | 3 |
| | | | 2 0 Po | hl, Alison | pohl | @uchc.edu | | (860) 679-4129 | |
| Done | | | | | | | | Sucal intranet | 🐴 • 🔍 100% • |

- 8. 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.
- 9. Once you review the document, you can submit it as described on pages 9 and 10 of this document.