



**TOPAZ Elements
PI & Associates
User's Guide**

Updated February 2023

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Introduction

Montana State University (MSU) utilizes TOPAZ Elements to manage protocols associated with the Institutional Biosafety Committee (IBC), Radiation Safety Committee (RSC), Institutional Review Board (IRB), or the Institutional Animal Care and Use Committee (IACUC). This guide will serve as an overview of the process of submitting protocols in TOPAZ. TOPAZ can be accessed using the button at the top of this page: <http://www.montana.edu/orc/topaz/topaz.html>.

Please note, some images will vary based on permissions granted depending on your role (e.g., PI, Administrator).

Navigating TOPAZ


TOPAZ has different modules depending on the required protocol type. These modules are listed below. Each type of protocol can only be accessed through the specific module.

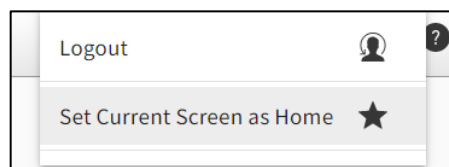
- Animal Protocols
 - IACUC Required Protocols
- Human Protocols
 - IRB Required Protocols
- Biosafety Protocols
 - IBC Required Protocols
 - Radiation/X-ray/Laser Required Protocols

Setting Your Home Page

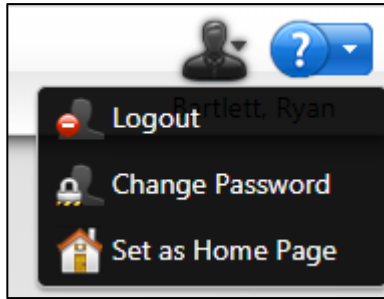
Depending on which module(s) you access, you can set your Home Page for convenient access. If you have protocols in multiple modules, it may be beneficial to set your Home Page for the TOPAZ landing page that is visible when you first log in to the software.

TOPAZ | Elements

			
Places	Compliance	Operations	Management
Administration My Dashboard TOPAZ Website	Animal Protocols Human Protocols Biosafety Protocols Staff Training	Animal Orders Animal Census Animal Billing Cost Accounting	Veterinary Management TOPAZ Reporter

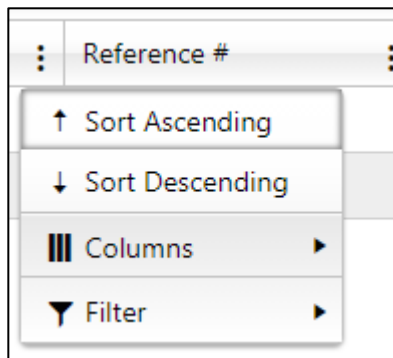


If you only utilize one module, you can set your Home Page to that specific module. After you log in to TOPAZ, click on the desired module. After you open the module, click on the profile silhouette in the top right of the page. Then select “Set as Home Page.”



After choosing a module, you can select My Dashboard. This will open a page that displays all protocols that you are associated with in that module.

Protocol #	Reference #	Version #	Association	Principal Investigat...	Protocol Type	Title	Submission Date	Expiration Date
	242		Author, Creator	PI, IBC	Original			



After finding the protocol that you wish to view, click anywhere on the protocol’s row and the protocol will open.

Sorting and Filtering Columns

As discussed above, columns in TOPAZ may be sorted and filtered based on preference. When viewing a page or window with columns, you can click and drag the columns to reorder. You can also drag a column into the top of the table to create a sorting tree based on that column header.

The example below shows protocols sorted by Protocol Type. Each subheading can be minimized by clicking the black triangle next to the Protocol Type.

↑ Protocol Type ×			
<input type="checkbox"/>	Protocol #	Reference #	Version #
Protocol Type: Amendment			
<input type="checkbox"/>	2020-139	139	6
<input checked="" type="checkbox"/>	2020-315	315	2
<input type="checkbox"/>	2018-50-19	50	3
Protocol Type: Interim Review			
<input type="checkbox"/>	2019-25-47	25	2
<input type="checkbox"/>	2019-26-49	26	3
<input type="checkbox"/>	2018-85-45	85	2
<input type="checkbox"/>	2019-97-85	97	2
Protocol Type: Original			
<input type="checkbox"/>	2020-314	314	1
<input type="checkbox"/>	2018-33-14	33	1
<input type="checkbox"/>	2018-43-6	43	1
Protocol Type: Renewal			
<input type="checkbox"/>	2020-24-1	24	2
<input type="checkbox"/>	2021-31-5	31	2

The three dots next to each column header will allow you to filter and sort based on that specific header. Click on the three dots to reveal a filter box where you can set parameters based on your criteria.

Research Protocols

The following sections explain how to manage a research protocol in TOPAZ. The tutorials cover all of the submissions you will be required to submit throughout the lifetime of the study to include: an original protocol, annual renewal(s), and amendment(s).

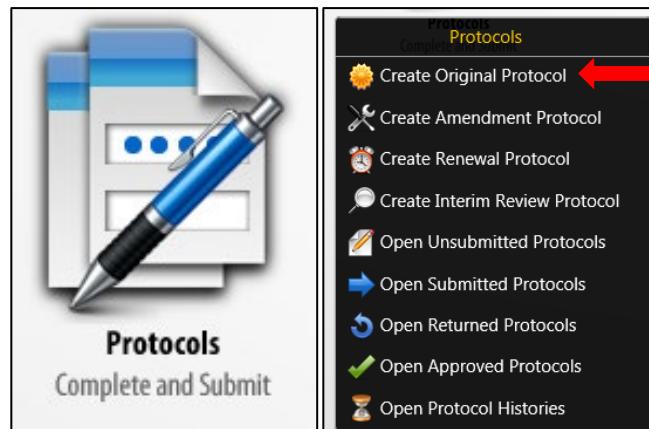
Definitions

1. **Original Protocol** – An Original Protocol is the first submission of your study. In an Original Protocol, you are submitting new research for its first approval period.
2. **Amendment** – An Amendment protocol must be submitted if you need to make changes to an approved study. You can submit an amendment at any time during the lifetime of the study.
3. **Interim Review** – An Interim Review protocol is submitted annually following initial approval and again annually after approval of renewal protocols. During review you can make amending changes to the original protocol, if desired. For IRB, annual Interim Reviews apply only to Full Committee-Reviewed protocols.
4. **Renewal** – A Renewal Protocol is submitted every three to five years following initial approval (program dependent). Most renewal protocols are sent to full committee review. During renewal, you can make amending changes to the protocol if work outlined in the protocol has changed. Upon approval, renewals extend the expiration of the protocol for another 3-5 years.

Creating an Original Protocol

An Original Protocol is the first submission for your study. In an Original Protocol, you are submitting new research for its first approval period.

1. Go to the TOPAZ login page at <http://www.montana.edu/orc/topaz/topaz.html>.
 - Bookmark this page for easy access.
 - Login with your MSU NetID and password.
2. Click the appropriate protocol module under the Compliance menu

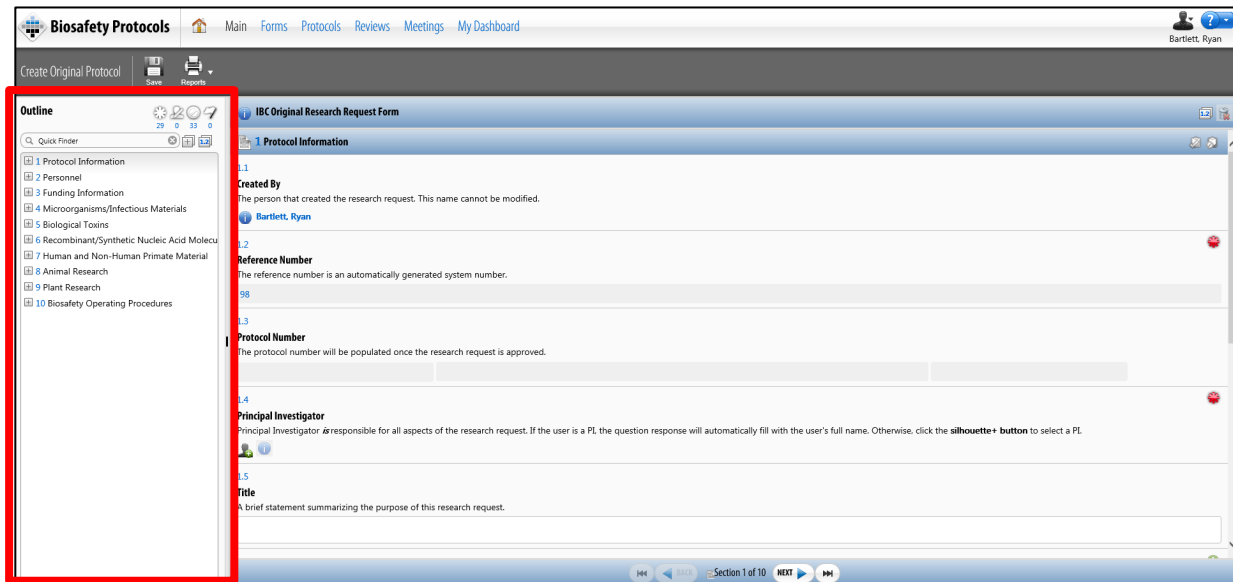


4. In the Select Form window, select the appropriate protocol for your research.

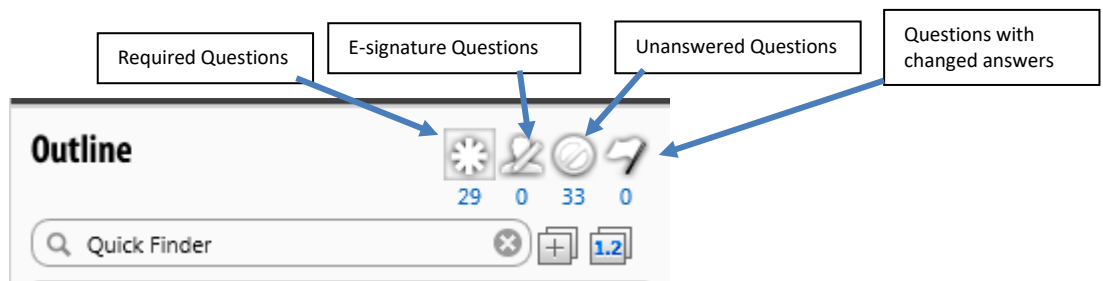
Name	Description	Type
IBC Original Research Request Form	IBC Original Research Request v. 01, Montana State University	Original
Radioactive Material Usage Form v.01	Radioactive Material Material Usage Form v. 01	Original
Laser Usage Form v. 01	Laser Usage Form v. 01	Original
X-Ray Usage Form v. 01	X-Ray Usage Form v. 01	Original

Navigating the Form

1. Once you have selected the form, the screen will display the protocol screen with an Outline of the sections and corresponding questions.
The Outline section is indicated below. Use this to quickly navigate between sections.



You may hover over each button in the Outline to see each function.








2. Answer each question of the sections and click Next at the bottom of the section. To return to a previous section, click the Back button at the bottom of the page.

Note: Do not use the browser's **Back** button to navigate to a previous section.

Reminder: Click the **Save** button at the top of the form often – before moving to a new section of the form is a good point to save.

Icons You Will See


-  Indicates a required question. The question must be completed prior to submitting the protocol.
-  Allows the user to see information about the staff member (e.g. training history).
-  Allows the user to view a list of available staff.
-  Allows the user to add rows to a table or choose information from a predefined list.
-  Allows the user to upload an attachment.

Completing the Form



Note: Many of the questions will expand after answering a 'Yes' or 'No' question. Be sure to answer all parts of the question.

1. Selecting PI/Personnel

When adding personnel to the protocol, utilize the  button to bring up the staff list. Select the correct staff from the list.

- You may filter by first or last name by clicking the 3 vertical dots next to the column header.
- Click on **Filter** and select the filter option.


Drag a column header and drop it here to group by that column

Last Name	First Name	Middle Name	Staff Number
PI	IBC		

↑ Sort Ascending
↓ Sort Descending
Columns
Filter

Show items with value that:
Contains
And
Contains
Filter Clear


- Enter the desired filter parameters and click **Filter**
- Select the role for each staff based on the description in the section.
 - Co-Investigators have the same privileges as the PI.
 - Key Associate does not have any editing privileges but will receive email notifications.
 - If no role is selected, associates are able to view the approved protocol only.
- **Do not** fill in the Responsibilities or Comments boxes.

 **PI, IBC**


Co-Investigator Key Associate


Responsibilities: DO NOT FILL IN THIS SECTION

Comments: DO NOT FILL IN THIS SECTION

- You can click the  to bring up the staff's information. Click on the **Staff Competency** tab to show current training records. These records are automatically uploaded to TOPAZ and the PI/Lab Manager does not need to input training dates.

2. Pre-Populated Lists

Many questions of the protocol will have the ability to select responses from a pre-populated list. Use the  to add rows to the table. In each cell with a drop down, select the proper response. Other cells in each row will need manual input.

4.1.1.1 

Microorganisms/Infectious Agents to be Used

List all the microorganisms that will be used in the research. Click the **green +** to add additional microorganisms/infectious agents. Select the center of the column for the drop-down list.


Complete each field:

- Genus species
- Strain
- Use

Microorganism	Strain	Use	

If the pre-populated list does not contain your required answer, the following questions will allow for manual input of information.



4.1.1.2.1 

Unlisted Microorganisms/Infectious Agents to be Used

List all the microorganisms that are not available to select from the pick list that will be used in the research. Click the **green +** to add additional microorganisms/infectious agents.

Complete each field:

- Genus species
- Type
- Risk Group
- Biosafety Level
- Strain
- Use


Genus species	Type	Risk Group	Biosafety Level	Strain	Use	

3. Required Questions

Many questions throughout the form are required to be answered. These questions are marked by



1.4 *
Principal Investigator

Ensure that all required questions are answered as you progress through the form. You can use the button in the Outline panel to navigate to all required questions. The number below the  in the Outline panel changes as you answer questions and save the form.



Once you have answered all of the required questions, the form has now been completed and is ready to be submitted. See the “Submitting a Protocol” section for next steps.

Opening a Saved Protocol

After saving an unsubmitted protocol, you can access it at a later time by following the steps below.

1. Go to the TOPAZ login page at <http://www.montana.edu/orc/topaz/topaz.html>.
 - Login with your MSU NetID and password.
2. Click the appropriate protocol module under the Compliance menu.
3. Hover (with your cursor) over **Protocols** and a menu will appear. Select Open Unsubmitted Protocols.



4. Click on the protocol that you wish to open.

Select Draft Protocol		Filter: Not Set...				
Drag a column header and drop it here to group by that column						
<input type="checkbox"/>	Reference #	Principal Investigator	Protocol Type	Title	Author	Modified
<input type="checkbox"/>	100144	Test1, Test1	Original		Test1, Test1	2/19/2020

5. The protocol will open, and you can continue to edit the form.

Creating an Amendment Protocol

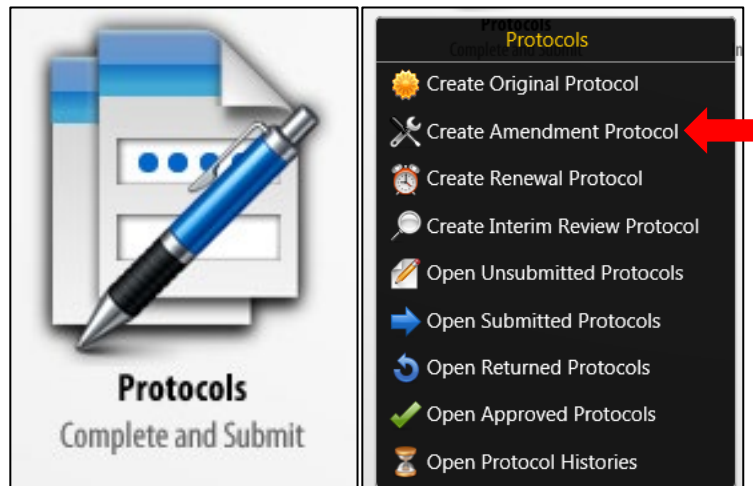
The steps below outline how to create an Amendment Protocol. An Amendment Protocol is used to add new information to a previously approved protocol.

- Go to the TOPAZ login page at <http://www.montana.edu/orc/topaz/topaz.html>.
 - Bookmark this page for easy access.
 - Login with your MSU NetID and password.

Note: To access TOPAZ from **off-campus**, you must sign into the **VPN** (i.e. Cisco AnyConnect).
- Click the appropriate protocol module under the Compliance menu



- Hover (with your cursor) over **Protocols** and a menu will appear. Select Create Amendment Protocol.



- In the Select Protocol for Amendment window, select the protocol you wish you amend.

Select Protocol For Amendment					Filter:
					Not Set...
Drag a column header and drop it here to group by that column					
Protocol #	Reference #	Protocol Type	Principal Investigat...	Title	
2020-225	225	Original	Test, PI	Test Protocol	

- In the Select Form for Amendment window, select the appropriate form for your research.

Select Form for Amendment		
Quick Finder		
Drag a column header and drop it here to group by that column		
Name	Description	Type
IBC: Amendment Form v. 01	IBC: Amendment Form v. 01	Amendment

6. Provide a brief description of the Amendment in section 1.1.
7. Add information to applicable sections of the protocol as needed.
8. After adding all applicable information, Save and Submit.

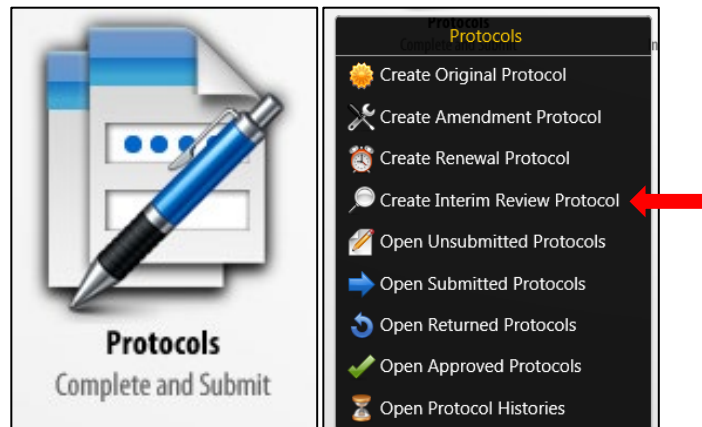
Creating an Interim Review Protocol

The steps below outline how to create an Interim Review Protocol.

1. Go to the TOPAZ login page at <http://www.montana.edu/orc/topaz/topaz.html>.
 - Bookmark this page for easy access.
 - Login with your MSU NetID and password.
2. Click the appropriate protocol module under the Compliance menu



3. Hover (with your cursor) over **Protocols** and a menu will appear. Select Create Interim Review Protocol.



4. In the Select Protocol for Interim Review window, select the protocol you wish you renew.
5. In the Select Form for Interim Review window, select the appropriate form for your research.
6. Answer question 1.1.
7. Update required sections (i.e. annual equipment certification dates).
9. If the protocol does not require changes, save and submit.

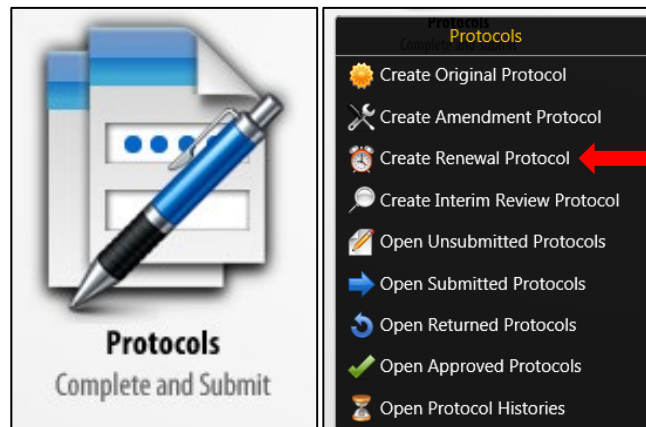
Creating a Renewal Protocol

The steps below outline how to create a Renewal Protocol.

1. Go to the TOPAZ login page at <http://www.montana.edu/orc/topaz/topaz.html>.
 - Bookmark this page for easy access.
 - Login with your MSU NetID and password.
2. Click the appropriate protocol module under the Compliance menu



3. Hover (with your cursor) over **Protocols** and a menu will appear. Select Create Renewal Protocol.



4. In the Select Protocol for Renewal window, select the protocol you wish you renew.

Select Protocol For Renewal					Filter: Not Set..
Drag a column header and drop it here to group by that column					
Protocol #	Reference #	Protocol Type	Principal Investigator	Title	
2020-225	225	Amendment	Test, PI	Test Protocol	

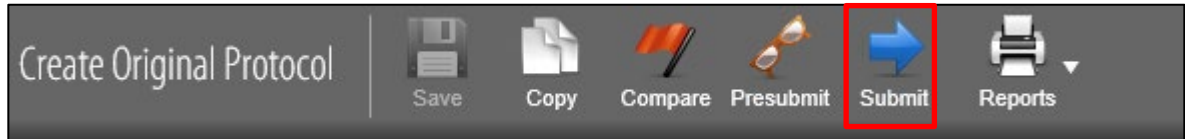
5. In the Select Form for Renewal window, select the appropriate form for your research.
7. Update required sections (i.e. annual equipment certification dates).
8. If the protocol requires changes, edit the applicable sections, save, and submit
9. If the protocol does not require changes, save and submit.

Submitting a Protocol

You can submit a protocol that is currently open and being worked on, or you can submit a previously saved protocol.

If submitting a previously saved protocol, open the desired protocol by following Steps in the “Opening a Saved Protocol” section.

Once the desired protocol is open and is ready to be submitted, click the **Submit** button at the top of the protocol.



This will open the E-Signature Information window. Click **Sign** at the bottom of the window. This will open a second window for you to enter your NetID and Password.

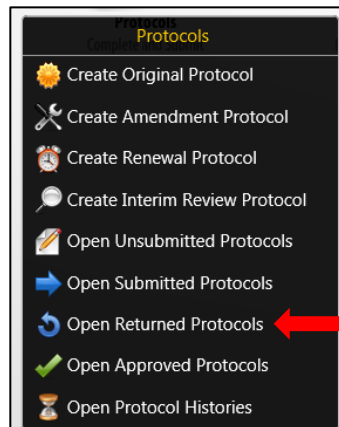
Editing a Protocol: Returned for Modification

This section will outline how to address comments on a protocol that has been returned for modification. The protocol may be returned after a pre-review, or after committee review.

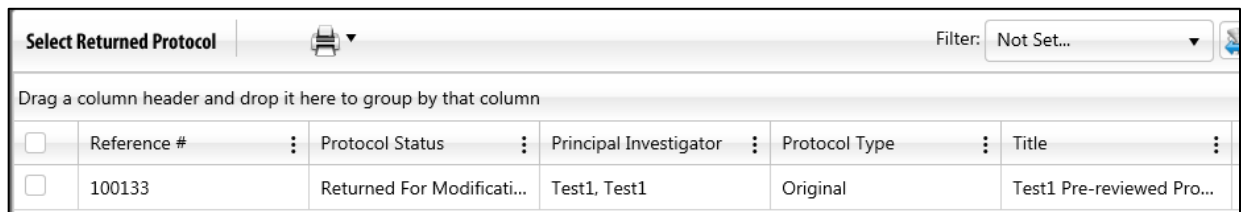
The investigator will receive an email that the protocol has been returned for modification. Follow the link in the email to log in and open the protocol directly.

The protocol may also be accessed by:

1. Logging into Topaz and selecting the appropriate protocol module under the Compliance menu.
2. Hover over **Protocols** and a menu will appear. Select **Open Returned Protocols**.



3. Click the protocol that you wish to open.

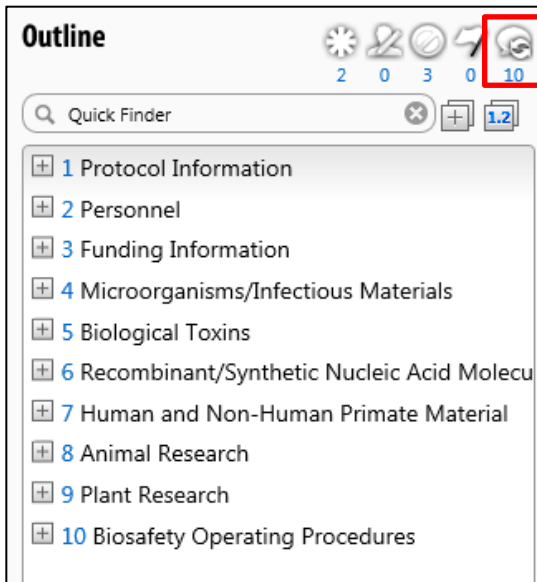


Select Returned Protocol						Filter: Not Set...
Drag a column header and drop it here to group by that column						
<input type="checkbox"/>	Reference #	Protocol Status	Principal Investigator	Protocol Type	Title	
<input type="checkbox"/>	100133	Returned For Modificati...	Test1, Test1	Original	Test1 Pre-reviewed Pro...	

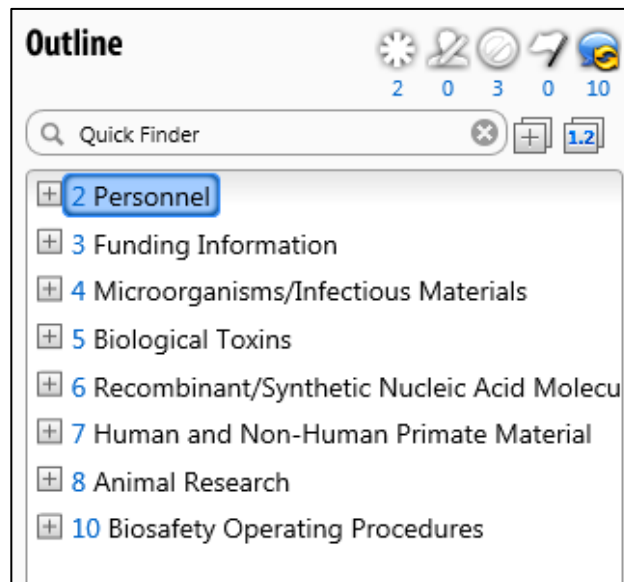
4. The protocol will open and can be edited to address the comments.

Once the protocol has been opened, address the comments by using the Outline panel. The Outline will show how many comments have been left for the protocol and will allow you to quickly navigate to the specific sections.

1. Click on the **Questions with Previous Submission Summary Comments** button in the Outline.



2. This will narrow down the Outline panel to only those sections with comments. Click on a section to open it and view the comments.



3. The comments will appear on the right side of the protocol. Each comment will show the specific section number and will have a text comment that needs to be addressed. You may address comments directly in the section by editing your answers, or if no edits are necessary, reply to each comment by clicking the **Reply** button next to the time stamp in the comment.

100133

2 Personnel

2.1

PI Responsibilities

The PI is responsible for providing adequate training and supervision of staff in microbiological techniques and practices to ensure laboratory safety and following MSU accident reporting procedures. The PI is responsible for enforcing federal, state, and local regulations, and ensuring compliance regarding laboratory safety for all personnel associated with this protocol.

The PI is responsible for correcting work errors and conditions that may result in the release of recombinant/synthetic nucleic acid materials, microorganisms, or infectious materials.

2.2

Protocol Associates

2.2 Protocol Associates

Comments From Last Submission

2/14/2020 11:34:08 AM

Indicate which associate is designated as the Co-Investigator.

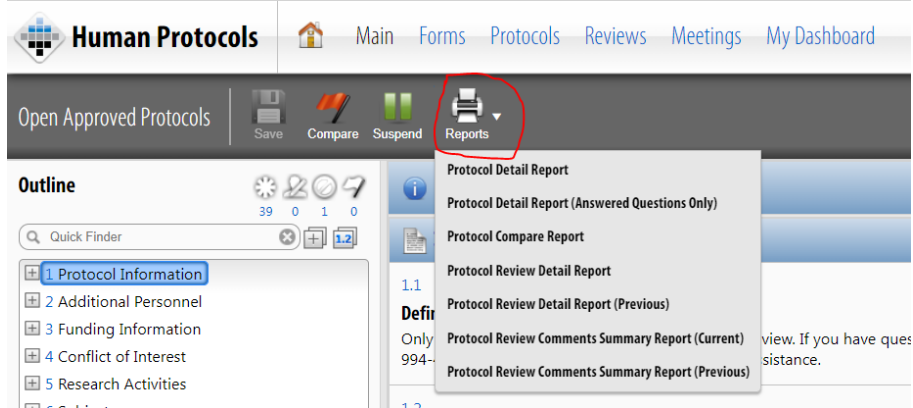
Section 2 of 8

BACK NEXT

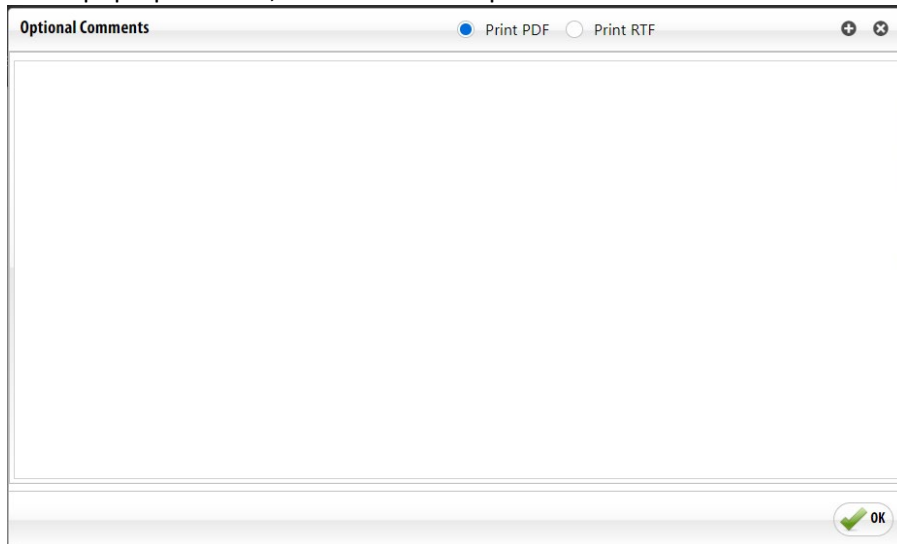
4. Use the **Outline** panel to navigate to the next section with comments. Address all comments, remembering to **Save** often.
5. After all comments have been addressed, select **Submit** and apply the E-signature.

How to Create a Protocol Report

1. Login to [TOPAZ](#)
2. Under **Compliance**, click **Human Protocols**
3. Hover over the **Protocols** menu; then select **Open Approved Protocols**
4. Locate and click your protocol to open the record.
5. In the top gray menu, click **Reports**; then select **Protocol Detail Report** (top option)



6. In the pop-up window, **Print PDF** will be preselected. Click **OK**.



7. Your Protocol Detail Report will generate in a new web browser window. This report can be downloaded as a pdf and shared. At this time, any protocol attachments (such as questionnaires and consent forms) are *not* pulled into the report, so those must be downloaded from your TOPAZ protocol separately. (We have submitted a request to our software vendor for this feature to be added.)



Protocol Detail Report

Printed By: Beiswanger, Kelly
2/8/2023 10:17:34 AM

Report Comments

Protocol Information

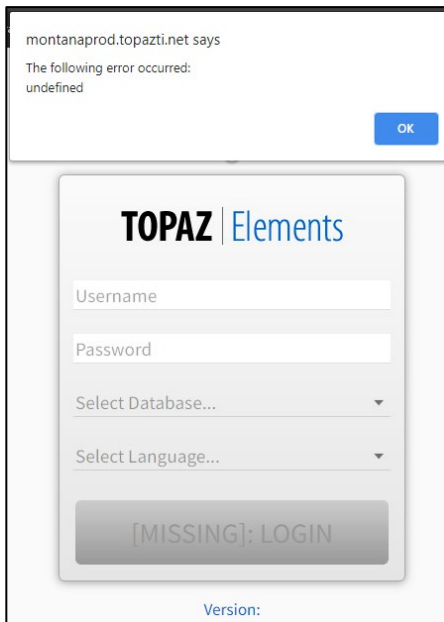
Version # 1

Reference Number:	420		
Protocol Number:	2022-420-EXEMPT		
Protocol Title:	Travel Impacts for Oncology Patients Living in the Rural Mountain West		
Protocol Type:	Original		
Principal Investigator:	Hammersla, Margaret	Approval Date:	1/6/2023
Submittal Date:	1/6/2023	Effective Date:	1/6/2023
Author:	Hammersla, Margaret	Renewal Date:	1/6/2028
Status:	Approved	Next Review Date:	1/6/2028
Inactive Date:		Expiration Date:	1/6/2028

Common Errors/FAQs

Q: Why can't I log in to TOPAZ?

A1: If you are directed to the TOPAZ login screen and not to the MSU Single Sign-On page:



- Clear your browser's cache
- Close your browser window
- Re-open browser and go to TOPAZ link
- Log in to TOPAZ

A2: If you are directed to the MSU Single Sign-On page and cannot access TOPAZ:

- Submit a 'Request to be Added into TOPAZ' form at the [bottom of this page](#)

Q: Why can't I find my personnel in the staff search box?

[bottom of this page](#)

Q: Why can't I create an Amendment/Interim Review/Renewal protocol?

A: Your protocol already has one of the above protocol forms in process. To find the started form:

- Hover over the Protocols icon and select Open Unsubmitted Protocols
- OR
- Hover over the Protocols icon and select Open Returned Protocols
- OR
- If your protocol is not in either of the locations above, it has been submitted and is in review
 - You can hover over the Protocol icon and select Open Protocol Histories to see the history of all associated protocols.

Q: Where is my protocol?

A: TOPAZ has multiple protocol modules (e.g. Animal Protocols, Biosafety Protocols, Human Protocols). In order to access specific protocols, you must be in the correct module. If you need to switch modules, click the TOPAZ symbol in the top left of the screen. Then select the appropriate module for the protocol you are seeking.