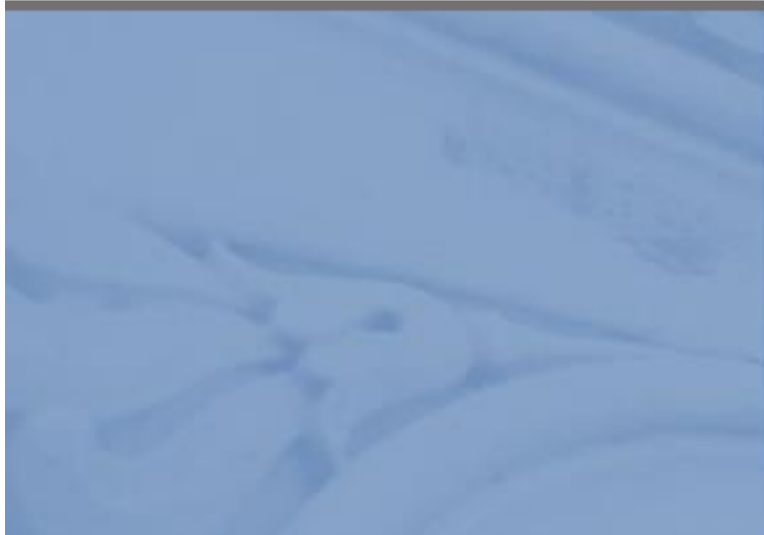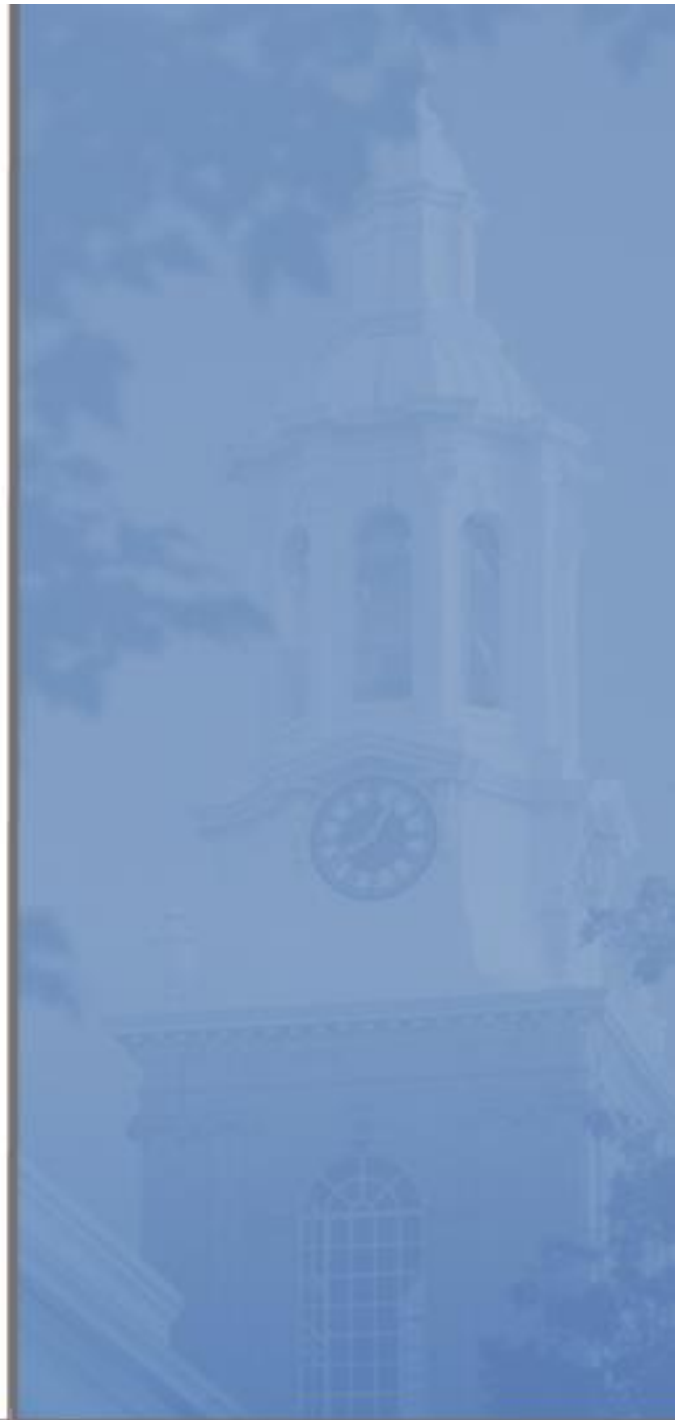# Click Portal

Safety Module
Training Exercises

September 2016

University at Buffalo
The State University of New York

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Safety Module Training Exercises

Contents

Logins Required for Exercises

You will be assigned users that you will log in as to perform the training exercises. For example, if you are assigned the number 1, for exercises that require you to log in as the Principal Investigator, you log in as pi1.

Role/User	User Name	Password
Principal Investigator	pi1 – pi25	1234
Safety Administrator Safety Specialist	safety1 – safety25	1234
Biosafety Officer	bso1 – bso25	1234
Committee Member	chair1 – chair25 (chairperson) comm1 – comm25 (committee member)	1234
Ancillary Reviewer	anc1 – anc25	1234

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Navigation Exercises

Exercise 1: Log into the Click Safety Module	
Steps	**Questions**
1. Go to: https://pacsstg1.rfsuny.org/SponsoredPrograms/login 2. Log in as the *Principal Investigator* with the number you were assigned. 3. Click **Enter**.	

Exercise 2: Explore the Inbox	
Steps	**Questions**
1. In the navigation menu, click the **Safety** tab to go to the module.	
2. Click the **Help Center** link to see the types of user assistance available to you.	What guides are available in the Help Center?
3. Click the **Submissions** link to access protocols in various stages of the review process.	What protocols can you access from the Submissions shortcut?
4. Click the **Reports** link to see the types of reports available.	What types of reports are available on the Standard and Custom Reports tabs?
5. Click the **Library** link to see what information is available for the different types of protocols.	What kind of information can you access from the Library?

6. Click the **My Inbox** link to return to the Inbox (There is also a My Inbox link at the top right).	

Exercise 3: Explore the Protocol Workspace	
Steps	**Questions**
1. From the Inbox, click the **Name** of a protocol to open it.	When you first open a protocol: • Where do you find the state of the protocol? • Where do you find the Principal Investigator of the protocol? • Where do you find the type of protocol?
2. On the **History** tab, review the activities that have already occurred for this protocol.	When was this protocol created and by whom?
3. Click the other tabs to see the types of information available.	On which tab can you find the following information? • Other protocols related to the Safety protocol • The documents attached to the protocol

	• The protocol team members
	• Snapshots of the protocol in a particular state
	• Reviews the protocol has gone through
	• Follow-on submissions for the protocol

Exercise 4: Explore the SmartForm Pages

Steps	Questions
1. From the protocol Workspace, click the **Edit Protocol** button. 2. On the navigation bar (at the top or bottom), click the **Jump To:** menu to see the list of pages making up the protocol. **Note:** Different pages appear depending on the type of protocol. 3. On the navigation bar, click the **Continue** button to move through all the pages. 4. On the last page, click **Finish** to return to the protocol Workspace.	

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Pre-Submission Exercises

Exercise 5: Create a Safety Protocol	
Steps	**Questions**

You should still be logged in as the *Principal Investigator* from the previous exercises.
 	
1. In the navigation menu, click the **Safety** tab to go to the module.
2. Click the **Create Safety Submission** button.
3. Complete the pages by entering the sample Safety protocol.
 	
    Note: Save time by cutting and pasting text from the sample document to the protocol SmartForm pages.
 	
4. When you get to the last page of the protocol, click **Hide/Show Errors** on the navigation bar to check for errors.
 	
    a. If an error appears on the Error/Warning Messages pane, click the **Jump To:** link and update any required fields that were missed. Next, go to the last page and click **Finish**.
 	
    b. If no errors were found, on the last page, click **Finish**.	

Exercise 6: Assign Additional Staff to a Protocol	
Steps	**Questions**
You should still be logged in as the *Principal Investigator* assigned to your protocol from the previous exercise and on the protocol Workspace. 1. From the protocol Workspace, click the **Assign PI Proxy** button. 2. Click the **Add** button and place a checkmark next to your name. **Note:** The **PI Proxy** must be selected from the individuals that were added to the Study Team.	In what instances would it be useful to have a PI Proxy?

Steps	Questions
3. Click **OK**, and then click **OK** once more. **Note:** The **PI Proxy** can perform all of a PI's duties, with the exception of assigning PI Proxies. 4. From the protocol Workspace, click the **Assign Primary Contact** button. 5. Click the **Select** button, and select an individual to serve as the Primary Contact. 6. Click **OK**, and then click **OK** once more. **Note:** The **Primary Contact** will receive the same email notifications that the PI does, regarding the protocol. 7. From the protocol Workspace, click the **Manage Guest List** button. 8. Click the **Add** button, and select an individual to include on the Guest List. 9. Click **OK**, and then click **OK** once more. **Note:** Those on the **Guest List** can read the protocol and any follow-on submissions, but cannot edit them.	Who might serve as a Primary Contact for a given protocol? Who might be added to the Guest List for a given protocol?

Exercise 7:   Submit a Protocol to Specialist Review

Steps	Questions
1. On the protocol Workspace, click **Submit** on the left. 2. Read the statement and click the check box to agree with the statement. 3. Click **OK** to submit the protocol for review.	Why is it important that the protocol cannot be edited once it has been submitted to the Specialist?

Note: The protocol can be removed from review by clicking **Withdraw** on the left. This action will discontinue the review of the protocol.

The protocol moves to the **Specialist Review** state.

Note: The protocol that was created in this exercise will be the one you will move through the workflow in the following exercises.

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Specialist Review Exercises

Exercise 8: Assign a Specialist	
Steps	**Questions**
1. Log in as the *Safety Specialist*. 2. In the navigation menu, click the **Safety** tab to go to the module. 3. On the **In-Review** tab, click the name of the protocol your PI created to open it. 4. From the protocol workspace, click **Assign Specialist** on the left. 5. Select your *Safety Specialist* from the list. 6. Click **OK**. The protocol does not change states.	How do you determine which Safety Specialist to assign to a protocol (what is your policy)?
Exercise 9: Add Reviewer Notes and Request Clarifications	
Steps	**Questions**
This exercise goes through adding Reviewer Notes to a protocol. If a reviewer has comments about the protocol in general, rather than about answers on a particular page, the reviewer would start at step #7. 1. From the protocol Workspace, click the **View Protocol** button. 2. Use the **Continue/Back** and **Jump To:** buttons to move through the SmartForm pages. 3. Navigate to the Basic Information page in the protocol and click **Add** in the Reviewer Note bar. 4. Select **Specialist Draft Change Request (response required)** from the Type list. **Note:** Selecting **(response required)** necessitates that the PI respond to your request before the protocol can move forward in the workflow.	What is the benefit of adding Notes to specific pages in the protocol?

Steps	Questions
5. In the Note box, type a request to the PI to make a change to something on that page. Click **OK**. Your request appears at the top of the page. 6. On the navigation bar, click **Exit** to exit the protocol. 7. In the protocol Workspace, click **Request Clarification by Specialist** on the left. 8. In the text box, type "See the reviewer notes" or some other general comment. 9. Click **OK**. The protocol moves to the **Clarification Requested (Specialist Review)** state.	What types of Notes might get added as a general comment?

Exercise 10:   Respond to a Reviewer Request

Steps	Questions
1. Log in as the *Principal Investigator*. 2. From the **Inbox**, open the protocol. 3. On the **History** tab, find the "Clarification Requested…" activity and read the comments. 4. Click the **Reviewer Notes** tab and read the request. 5. Click the **Jump To:** link to go right to the protocol page with the Reviewer Note. > **Note:** If no changes were needed to the protocol, the PI would simply respond to the reviewer note from the **Reviewer Notes** tab. 6. Make and **Save** the requested change(s) as noted in the Reviewer Note field. 7. Click the *Click here to respond* link. 8. Select **Change Request Completed** from the list and type a response in the text box. Click **OK**. 9. On the protocol navigation bar, click **Save** and then **Exit** to return to the protocol Workspace.	

Note: If changes were needed to the protocol, Click will save both the original and updated version of the protocol.

10. On the protocol Workspace, click **View Differences**.

11. You can view changes made to the Basic Information page, along with the Reviewer Notes and your response.

Note: If changes were requested on multiple pages in the protocol, you could use the **Changed Steps** option at the bottom of the page to move between pages.

12. Click the **Close** button to return to the protocol Workspace.

13. On the protocol Workspace, click **Submit Response** on the left.

14. In the Submit Response window, click **OK**.

The protocol moves back to the **Specialist Review** state.

Exercise 11: Approve a Protocol Administratively	
Steps	**Questions**
In this exercise, you will learn where to go to approve a protocol administratively, but **you won't actually complete this step**. 1. Log in as the *Safety Specialist*. 2. In the navigation menu, click the **Safety** tab to go to the module. 3. Locate and open the protocol. 4. Click **Approve Submission (Admin)** on the left. 5. Review the form (you will not actually administratively approve this protocol). 6. Click **Cancel** to close the window.	Can you administratively approve the protocol without any reviews?

When you approve a protocol administratively, the protocol moves to the **Post-Review** state. See Post-Review Exercises for activities to perform in that state.	

BSO Review Exercises

Exercise 12:	Send Protocol to BSO Review
Steps	**Questions**
You should still be logged in as the *Safety Specialist* assigned to your protocol from the previous exercise and on the protocol Workspace. 1. From the protocol Workspace, click **Send to BSO Review** on the left. 2. Select your *Biosafety Officer* from the list. 3. Click **OK**. The protocol moves to the **BSO Review** state.	

Exercise 13:	Submit Biosafety Risk Assessment
Steps	**Questions**
1. Log in as the *Biosafety Officer*, and go to **Safety**. 2. From the **Inbox**, open the protocol. **Note:** During BSO Review, Biosafety Officers may also request clarifications from the PI. See Request Clarifications for steps (use the **Request Clarification by BSO** link on the Workspace to submit the request). 3. From the protocol Workspace, click **Submit Biosafety Risk Assessment** on the left. 4. Type a summary of your risk assessment. You can type anything in the text box. 5. Leave the risk assessment already selected from when the protocol was created. Click the **Biological Research Standards** link and then close the window that opened. 6. Click the **View** link for any of the Applicable NIH Guidelines to see what happens. Click **OK** to close the window. 7. Click **OK** to submit the review. The protocol moves back to the **Specialist Review** state.	From the Workspace, on what tab can you find the Biosafety Officer's review?

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Member Review Exercises

Exercise 14:	Send Protocol to Member Review
Steps	**Questions**
1. Log in as the *Safety Specialist*. 2. In the navigation menu, click the **Safety** tab to go to the module. 3. Locate and open the protocol. 4. From the protocol Workspace, click **Send to Member Review** on the left. 5. Select your *Safety Committee Member* as the member reviewer. 6. Click **OK**. The protocol moves to the **Member Review** state.	

Exercise 15:	Submit Member Review
Steps	**Questions**
1. Log in as the *Safety Committee Member*, and go to **Safety**. 2. From the **In-Review** tab, open the protocol. 3. Click the **Review** tab on the Workspace to see information from the BSO Review. **Note:** During Member Review, Committee Members may also request clarifications from the PI. See Request Clarifications for steps (use the **Request Clarification by Member** link on the Workspace to submit the request). 4. From the protocol Workspace, click **Submit Member Review** on the left. 5. Select **Yes** to indicate that you are ready to submit the review. 6. Type any comments you want about the protocol. 7. Click **OK** to submit the review. The protocol moves back to **Specialist Review**.	From the Workspace, on what tab can you find the Committee Member's review?

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Ancillary Review Exercises

Exercise 16:	Set Up Ancillary Reviews	
Steps		**Questions**
1. Log in as the *Safety Specialist*. 2. In the navigation menu, click the **Safety** tab to go to the module. 3. Locate and open the protocol. 4. From the protocol Workspace, click **Manage Ancillary Reviews** on the left. 5. Click **Add** to add an ancillary reviewer. 6. Click the **Select** button for Person and select your Ancillary Reviewer. Click **OK**. 7. Select **Yes** to indicate a response is required. 8. Click **OK**, and then click **OK** again in the next window to add the ancillary reviewer. The protocol does not change states.		Which tab on the Workspace lists the ancillary reviewers assigned to the protocol?

Exercise 17:	Submit an Ancillary Review	
Steps		**Questions**
1. Log in as the *Ancillary Reviewer*. 2. From the Inbox, open the protocol. 3. From the protocol Workspace, click **Submit Ancillary Review** on the left 4. Select your *Ancillary Reviewer* in the table. 5. Select **Yes** to accept the proposed protocol. 6. Click **OK** to submit the ancillary review. The protocol does not change states.		STOP

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Committee Review Exercises

Exercise 18:	Send Protocol to Safety Committee Review
Steps	**Questions**
To send a protocol to committee review, the assigned Safety Specialist first has to submit a review. 1. Log in as the *Safety Specialist*. 2. In the navigation menu, click the **Safety** tab to go to the module. 3. Locate and open the protocol. 4. From the protocol Workspace, click **Submit Specialist Review** on the left. 5. Select the *Biosafety Committee Meeting*. 6. Do not change the assigned *Safety Specialist*. 7. Select **Yes** to indicate the review is complete. 8. Click **OK** to send the protocol to committee review. The protocol moves to the **Committee Review** state.	

Exercise 19:	Submit the Committee Review
Steps	**Questions**
You should still be logged in as the *Safety Specialist* assigned to the protocol from the previous exercise and on the protocol Workspace. 1. From the protocol Workspace, click **Submit Committee Review** on the left. 2. Select the **Approved** determination. 3. Leave the last day of continuing review. The system automatically populates this to be a year minus a day from now. 4. Select any approval date (this would typically be the committee meeting date.) 5. Click **OK** to submit the Committee Review. The protocol moves to the **Post-Review** state.	From the Workspace, on what tab can you find the committee's determination?

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Post-Review Exercises

Exercise 20:	Prepare and Send Determination Letter	
Steps		**Questions**
For the following exercises, you should still be logged in as the *Safety Specialist* assigned to the protocol from the previous exercise and on the protocol Workspace. 1. From the protocol Workspace, click **Prepare Letter** on the left. 2. Select the **Biosafety - Approved** letter template from the list and then click **Generate**. 3. Click the draft letter link to review the letter. Close the document when done. > **Note:** You can also upload a letter document in the **Prepare Letter** window. 4. In the Prepare Letter window, click **OK**. 5. Click **Send Letter** on the left. 6. In the Send Letter window, click **OK**. The protocol moves to the **Approved** state.		

Exercise 21:	Suspend an Approved Protocol	
Steps		**Questions**
1. From the protocol Workspace, click the **Submissions** shortcut to access all protocols. 2. Click the **Active** tab to find the approved protocols. 3. Find and open your protocol (created by your PI). 4. From the protocol Workspace, click **Suspend** on the left. 5. Type a reason for the suspension, for example, "Safety violation. Protocol suspended." 6. For the suspension start date, select the current date or a date in the past. 7. Click **OK**. The protocol moves to the **Suspended** state.		What is your policy for suspending protocols?

Exercise 22:	Lift Suspension of a Protocol
Steps	**Questions**
1. From the protocol Workspace, click **Lift Suspension** on the left. 2. Type a description of the corrective action taken that justifies lifting the suspension. 3. For the suspension end date, select the current date or a date in the past. 4. Click **OK**. The protocol moves back to the **Approved** state.	

Committee Meeting Management Exercises

A Committee Administrator can only perform the following activities for the committees on which he/she is the committee administrator. Committees may have different Committee Administrators.

Exercise 23: Create a New Meeting	
Steps	**Questions**
1. Log in as the *Safety Specialist*. 2. In the navigation menu, click the **Safety** tab to go to the module. 3. Click the **Meetings** shortcut. 4. From the meetings Workspace, click the **Create New Meeting** button. 5. Select a committee from the ones already set up in the system. 6. Click the calendar and select any date in the future. 7. Complete the form and click **OK**. 8. From the meeting Workspace, click **My Inbox** (at the top right). As protocols are assigned to this meeting (see exercise Send Protocol to Safety Committee Review above) they will show up as agenda items on this meeting's Workspace.	
Exercise 24: Run a Meeting	
Steps	**Questions**
You should still be logged in as the *Safety Specialist* from the previous exercise. 1. From the Inbox, click the **Meetings** shortcut (on the Safety menu) on the left. 2. Click a meeting name (one with agenda items) to open that meeting's Workspace. **Remove an Agenda Item** 3. From the meeting's Workspace, click the agenda item name. You will see **Remove from Agenda** on the left. (Do not perform this action.)	

4. Click the **Meetings** shortcut to return to the Meetings Workspace and then open the previous meeting.

Send Agenda to Committee Members

5. From the meeting's Workspace, click **Prepare Agenda** and generate an agenda from a template or add one to the meeting.

> **Note:** You can create an agenda from a template, save it, update it manually, and then upload the revised agenda via the Prepare Agenda action.

6. Click **Send Agenda** to email the agenda to committee members.

Create Meeting Minutes

You can create a Minutes document that you can update during the meeting.

7. From the meeting's Workspace, click **Prepare Minutes**.

8. Select the template and click **Generate**.

9. Save the document and update it during the meeting.

10. After the meeting, from the meeting's Workspace, click **Prepare Minutes** again and then **Add** to find (**Browse** button) and upload the updated document.