**TOPAZ Enterprise** *Biosafety Application*

Quick Reference Sheet: **Biosafety Application Request**

**Creating an Original Biosafety Application**

1. On the **Start Page,** go to **Protocols** under ‘Biosafety header (Can also click on the drop down menu in the upper right hand corner and choose **Biosafety Protocols**)
2. Choose **Create Original Protocol** (under the ‘Protocols’ header).
3. Click on the appropriate **Form**.
4. Populate required information for each section of the protocol request. (**Principal Investigator** and **Reference Number** must be populated before the first save).
5. The ‘Required Question’ filter icon () on the Protocol Outline indicates the questions that must be completed prior to submission of the application.
6. The ‘Unanswered Question’ filter icon () on the Protocol Outline indicates the questions which are incomplete; these are updated after completion and save.
7. Look for the *View Help* icon () in select questions. Clicking on this icon will provide helpful information while you complete your form
8. Selected questions may require you to choose information from a predefined list. Click on the Add icon () in the upper right hand corner of the question.
9. Selected questions may require you to add staff from a predefined list. Click on the () icon and a list of staff will appear. Be sure to designate a ‘Key Associate’ if you want personnel other than the PI to receive correspondence.
10. Throughout the request, there may be conditional questions which are indicated by a in the outline and numbering sequence in either the outline or main panel (i.e.).
11. Click the*Save*icon (). Make sure to **save often**.
12. On select questions, you may see an *E-signature* icon (). Once this question has been populated and saved, a signature box will appear. The ‘Assurance Statement’ e-signature question **must** be completed by the Principal Investigator (PI). If another person has completed this form, the PI must open the protocol, read all the proposed procedures and verify that the information is accurate and reflects the work to be done, then unclick the “I agree” button in section 8 for new protocol or section 1 for amended protocol, then click **Save**. Then, the PI must click the “I agree” button, click **Save** again, then complete the *E-signature* information.
13. Click on the ‘Submit/Withdraw’ icon ().
14. Click the ‘Set Status’ button ().

**Application Request Returned for Modification**

1. **My Dashboard**, click on a protocol request with **status of “Returned for Modification.”**
2. Click the ‘Questions with Summary Comments’ filter icon () in the Protocol Outline. Click to select a question.
3. Each question needing attention will have a yellow field containing the comment below the question. After viewing the *Comment Summaries,* make the recommended modifications and click **Save**.
4. To resubmit the protocol request, click on the ‘Submit/Withdraw’ icon (). Click the ‘Set Status’ button ().

**Amending a Biosafety Application**

1. On the **Start Page,** go to **Protocols** under ‘Biosafety’ header (Can also click on the drop down menu in the upper right hand corner and choose **Biosafety Protocols**).
2. Choose **Create Amendment Protocol**.
3. Select the protocol to be amended.
4. Choose appropriate form.
5. Amend the protocol as needed – include your intention and justification in the ‘Amendment’ section. Remember to refer to all the items in other sections that are being modified.
6. If another person has completed this form, the PI must open the protocol, read all the proposed procedures and verify that the information is accurate and reflects the work to be done, then unclick the “I agree” button in section 1 for amended protocol, then click **Save**. Then, the PI must click the “I agree” button, click **Save** again, then complete the *E-signature* information.
7. Click on the ‘Submit/Withdraw’ icon (). Click the ‘Set Status’ button ().

**Creating a Resubmission Biosafety Application or to Copy Answers from Another Protocol**

1. On the **Start Page,** go to **Protocols** under ‘Biosafety’ header (Can also click on the drop down menu in the upper right hand corner and choose **Biosafety Protocols**)
2. Choose **Create Original Protocol** (under the ‘Protocols’ header).
3. Populate the Principal Investigator and click **Save**.
4. Click on **Copy**. To proceed with the copying process, click the **OK** button.
5. Be sure to make the appropriate changes to the protocol to reflect the new protocol or the resubmission. For example, if you are resubmitting a protocol to a different funding agency, be sure to put the new funding agency information. Read all the answers before submitting to be sure that all information reflects the new submission information.
6. Click **Save**.
7. Click on the ‘Submit/Withdraw’ icon ().
8. Click the ‘Set Status’ button ().

\*\*Quick Reference Guides are created with the assumption that users have completed TOPAZ training prior to using this tool.

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