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| [Type the company name] |
| Safety Reviewers Reference Guide |

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| October 2016 |

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| Navigation and Basic Tasks | |
| When you first log in, you will be on the My Inbox page. This topic lists where to find Safety submissions and the basic tasks you will perform. | |
| 1        4      **3**        2      **6** | Where do I find? |
| From My Inbox, you can find:   1. **Submissions** that require you to take action. 2. **Shortcuts** to other itemssuch as all submissions in the system. |
| What do I do? |
| 1. Review the state of submissions in My Inbox. The state gives a clue as to what to do next. For example, “Specialist Review” means the submission is currently ready for review or being reviewed by a Safety specialist. |
| Open a Submission |
| 1. From My Inbox, click the submission name. 2. The submission workspace opens. |
| View Submission History |
| 1. From the submission workspace, click the **History** tab.   The history lists the actions performed on a submission to date, including any comments, attachments, or correspondence added.  (This t*opic continues on the following page.*) |

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| **7**      8        **9**      **10**      **11**      **13**      **12** | Find All Submissions |
| 1. Under My Current Actions, click **Submissions**. 2. Click the appropriate tab to see all submissions you have permissions to view:  * **In-Review:** All submissions undergoing Safety review * **Active:** All approved submissions * **Archived:** All discarded and closed submissions * **Suspended or Lapsed:** All submissions that have been suspended or whose continuing review deadline has passed * **All Submissions:** All submissions, in any state |
| Filter Data in a Table |
| To find a specific item in a table, use the Filter by feature:   1. Select the column to  filter by. 2. Type the beginning characters for the items you want to find. You can also type a % symbol as a wildcard before the characters. For example:  * 71 shows all items  beginning with 71 * %71 shows all items containing 71  1. For a list of operators you can type in the text box, click the Help icon. 2. Click **Go** to apply the filter. 3. To combine multiple filter criteria, click **Advanced** and then click **Add Another Row**. |

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| Review a Safety Submission | |
| When a protocol, amendment or continuing review is submitted, the submission appears in the Inboxes of users authorized to perform the next step in the review process. | | |
| 2        3      4          1      **1**    **OR** | Prerequisites for this task | |
| * You are logged in as a role that has privileges to view the submission in its current state. | |
| Review submission details | |
| 1. Click the e-mail link to open the submission workspace.   If you no longer have the e-mail message, find the submission on the **My Inbox** tab, and click its name.   1. Click **View Protocol** and add reviewer notes to specific pages of the submission as needed.    * To print out the submission, click **Printer Version**.    * To see what changed between this and a previous version, click **View Differences** and select the version to compare against. 2. To see details about other reviews, click the **Reviews Tab**. 3. To see notes added by other reviewers, click the **Reviewer Notes** tab. (It appears only if reviewer notes have been added.)   To request changes, see Request Clarification on a Submission on page 5. | |

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| Request Clarification on a Submission | |
| At nearly every stage of the review process, it is possible to request clarifications or modifications to a submission. You can do this by adding reviewer notes to specific pages or by making a general change request. | |
| **2**      **7**      **3**      **4**        **8**      9      **10**      **11** | Prerequisites for this task |
| * You are assigned to review the submission in its current state. (The submission appears in your Inbox.) |
| Add Reviewer Notes to Protocol |
| 1. Open the submission workspace and view the protocol (see Review a Safety Submission on page 4). 2. Navigate to a page that you want to comment on and click **Add** in the Reviewer Note bar. 3. Select whether a response is required or not. 4. Type your change request in the **Note** box and click **OK**.  Your comment appears at the top of the page. 5. Repeat steps 2–4 for all the pages you want to comment on. 6. When done adding notes, exit  the submission. |
| Send Change Requests to the PI |
| 1. In the submission workspace, click **Request Clarification by Specialist**. 2. If desired, assign a different user as the safety specialist for this submission. 3. To make a general request or alert the research team about reviewer notes within the submission, type a comment in the text box. 4. Add any supporting documents. 5. Click **OK**. |

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| Submit a Biosafety Risk Assessment | |
| This activity is a response to a request for a risk assessment made during specialist review. | |
| **2**        **4**      **5**      **6**        **7**      **3**      **8** | Prerequisites for this task: |
| * The submission is in the **BSO Review** state. * You are logged in as a user with the Biosafety Officer role. |
| Where do I start? |
| 1. Open the submission workspace. 2. From the submission workspace, click **Submit Biosafety Risk Assessment**. |
| Characterize your assessment and Submit. |
| 1. Select the inspection date if applicable. 2. Select your determination. 3. Type details about the determination in the **Summary of risk** box. 4. If applicable, add any supporting documents. 5. To submit your review, click **Yes.** 6. Click **OK**.   The protocol reverts to the Specialist Review state. |

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| Submit a Member Review | |
| A safety specialist can request reviews by individual members of the Safety Review Committee. This procedure shows committee members how to supply a review. | |
| **2**      **5**      **4**      **3**      **6** | Prerequisites for this task: |
| * The submission is in the **Member Review** state. * You are logged in as a user with the Committee Member role. |
| Where do I start? |
| 1. Open the submission workspace. 2. Click **Submit Member Review**. |
| Characterize your review and submit |
| 1. Select **Yes** to submit the review. 2. Supply any comments you have about the submission. 3. Add any supporting documents if applicable. 4. Click **OK**. |