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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**.
 |