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| Safety Staff Reference Guide |
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| October 2016 |

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| Overview of Click® Safety |
| The Click® Safety solution enables protocol teams to submit safety protocols and follow-on submissions (amendments and continuing reviews) for review by the Safety committee and other personnel with safety-related roles. The Click Safety system shepherds protocols through a series of states based on the actions of personnel participating in the review cycle.   1. A member of the protocol team enters a new protocol into the system, which puts it into the **Pre-Submission** state. When the PI submits it for review, its state changes to **Specialist Review**. 2. During **Specialist Review**, the Safety specialist assigned to oversee this process reviews the protocol and determines which additional reviews (if any) are needed—biosafety officer review (for biosafety protocols only), member review, and/or committee review. If the protocol goes through a biosafety review or member review, the protocol returns to the assigned specialist when that review is complete so the specialist can determine the next course of action. When a protocol is in the **Specialist Review** state, the specialist can decide to administratively approve the protocol thereby bypassing committee review and moving it directly to the **Post-Review** state.   At any point during a specialist, biosafety, or member review, a reviewer can request changes to the protocol resulting in a back and forth exchange between the PI and reviewer before the reviewer submits a review.   1. After all the requested biosafety and member reviews are complete, if the specialist determines a committee review is needed, the specialist submits a review and the protocol moves to the **Committee Review** state. The appropriate Safety committee reviews the protocol during a committee meeting. The committee can also request clarification from the protocol team as needed to come to a determination. 2. Generally, the specialist enters the committee determination in the system, which moves the protocol to the **Post-Review** state. During Post-Review, the specialist prepares the decision letter and sends it to the protocol team.   If the protocol is approved, the submission moves to the **Approved** state. If not approved, depending on the determination, the protocol might cycle back through some part of the review process again.   1. Once the protocol is approved, the protocol team can submit amendments as needed and continuing reviews as required by the institution. Amendments and continuing reviews follow the same review process as the original protocol submission. An approved protocol can have only one outstanding amendment or continuing review at a time.   The Click Safety workspace displays the high-level view of the review process shown below, highlighting the stage of the process the protocol is currently in.  High-Level View of the Safety Review Process |

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| Workflow States and Transitions |
| This diagram shows some of the more common states and transitions a safety protocol might go through during the review process. The workflow a submission actually follows depends on the actions, choices and data entered at different junctures. Though most actions can be performed by multiple roles, this diagram shows the roles that typically perform certain actions. When the submission is in an editable state (highlighted in yellow below), a member of the protocol team edits it as needed and submits or resubmits it. |
| **Approval Withheld**  **Approved**  **Modifications Required**  **Pre-Submission**    Lorem ipsum dolor sit amet, consecte  Lorem ipsum dolor sit amet,  Lorem ipsum dolor sit amet, consectetur  Lorem ipsum dolor sit amet  Lorem ipsum dolor  Lorem ipsum  Protocol team member creates a protocol.  PI submits the protocol.  Specialist administratively approves the submission.  Specialist submits  a review.  **Clarification Requested**  **Legend**  Regular submission state  States in which submission can be edited  Submit or approve  Request an optional review or verification  Request or require clarification or modification  Specialist submits the committee review.  Specialist sends a determination letter.  **Clarification Requested**  **Determination from Committee Review**  Modifications Required  Approved  Approval Withheld  Specialist administratively verifies that the required changes have been made.  **Clarification Requested**  **Post-Review**  **Specialist Review**  **Chair Letter Review**  **Committee Review**  **Member Review**  **BSO Review**  **Clarification Requested**  **Modifications Review by Member**  Specialist sends submission to member review.  Committee member sends submission to specialist review.  **Modifications Review** |
| The table on the next page lists all actions that change the state of the submission and the roles that can perform them. (For role definitions, see Roles in Click Safety on page 6.) |

| Actions and State Transitions | | | | |
| --- | --- | --- | --- | --- |
| **In this state…** | **These roles…** | **Can perform these actions…** | **Changing the submission state to…** | |
| **(No State)** | Any registered user | Create a new safety protocol | Pre-Submission | |
| **Pre-Submission** | Principal Investigator or PI Proxy | Submit | Specialist Review | |
| **Specialist Review** | Safety Specialist | * Send to BSO Review | BSO Review | |
| Send to Member Review | Member Review | |
| Approve Submission (Admin) | Post-Review | |
| Safety Specialist, Safety Administrator | Request Clarification by Specialist | Clarifications Requested (Specialist Review) | |
| Safety Specialist | Submit Specialist Review | Committee Review | |
| **Clarification Requested  (Specialist Review)** | Principal Investigator or PI Proxy | Submit Response | Specialist Review | |
| **BSO Review** | Biosafety Officer | Submit Biosafety Risk Assessment | Specialist Review | |
| Request Clarification by BSO | Clarification Requested (BSO Review) | |
| **Clarification Requested (BSO Review)** | Principal Investigator or PI Proxy | Submit Response | BSO Review | |
| **Member Review** | Committee Member,  Safety Specialist,  Safety Administrator | Submit Member Review | Specialist Review | |
| Committee Member | Request Clarification by Member | Clarification Requested (Member Review) | |
| **Clarification Requested (Member Review)** | Principal Investigator or PI Proxy | Submit Response | Member Review | |
| **Committee Review** | Safety Specialist, Safety Administrator, Committee Chair | Submit Committee Review | Post-Review | |
| **Clarification Requested (Committee Review)** | Principal Investigator or PI Proxy | Submit Response | Committee Review | |
| **Post-Review** | Safety Specialist,  Safety Administrator | Forward Letter for Review. (A determination letter must be prepared beforehand.) | Chair Letter Review | |
| Committee Chair, Safety Specialist, Safety Administrator | Send Letter (A determination letter must be prepared beforehand.) | A state reflecting the committee decision entered during the Submit Committee Review action: | |
| * Approved * Approval Withheld | * Modifications Required * Deferred |
| **Chair Letter Review** | Safety Specialist,  Safety Administrator,  Committee Chair | Send Letter (A determination letter must be prepared beforehand.) | A state reflecting the committee decision entered during the Submit Committee Review action: | |
| * Approved * Approval Withheld | * Modifications Required * Deferred |
| Committee Chair | Request changes to Letter | Post-Review | |
| **Modifications Required** | Principal Investigator or PI Proxy | Submit Response | Modifications Review | |
| **Modifications Review** | Safety Specialist | Send to Member Review | Modifications Review by Member | |
| Request Clarifications by Modifications Reviewer | Modifications Required | |
| Verify (Admin) | Post-Review | |
| **Modifications Review by Member** | Committee Member | Submit Modifications Review Findings | * Specialist Review (if committee review is required) * Post-Review (if committee review is not required) | |
| **Approval Withheld** | Principal Investigator or PI Proxy | Submit Response | Specialist Review | |
| **Approved** | Principal Investigator, Protocol team members | Request Closure | Closure Requested | |
| Safety Specialist,  Safety Administrator | Suspend | Suspended | |
| Close Protocol | Closed | |
| **Closure Requested** | Safety Specialist,  Safety Administrator | Close Protocol | Closed | |
| Request Clarification from Specialist | Clarification Requested (Closure Requested) | |
| **Clarification Requested (Closure Requested)** | Principal Investigator or PI Proxy | Submit Response | Closure Requested | |
| Withdraw Closure Request | Approved | |
| **Deferred** | Principal Investigator or PI Proxy | Submit Response | Specialist Review | |
| **All states before Post-Review** | Assigned Principal Investigator, Protocol team members | Discard | Discarded | |
| **All states before Post-Review except Pre-Submission** | Assigned Principal Investigator, Protocol team members | Withdraw | Pre-Submission | |

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| Terms Used in This Quick Reference | |
| **Term** | **Definition** |
| **Protocol** | A “safety protocol.” Documents the aspects of a research project that pose a potential safety risk to humans or animals and the precautions that will be taken to mitigate those risks. In this Quick Reference, “protocol” also refers to the representation of a safety protocol in the Safety solution. |
| **Submission** | A protocol, amendment or continuing review defined in the Safety solution that has been submitted for review. |

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| Roles in Click Safety | |
| Some of the Safety roles defined below are fundamental, predefined user roles, but others are secondary, contextual roles that must be explicitly assigned in Click Safety. For example, ”Study Staff” is a fundamental user role, whereas “PI” is a contextual role; a user with the Study Staff role must be explicitly assigned the role of “PI.” For additional information on roles, see the *Safety Deployment Guide*. | |
| **Position** | **Typical Activities** |
| **PI** | The Principal Investigator (PI) listed on the submission. While others assist the PI in developing and editing the submission, only the PI (or designated PI proxies) can submit the protocol or follow-on submission to start the review process. |
| **Protocol Team** | Individuals involved in developing the submission and listed on the submission as *protocol team members*. The protocol team always includes a PI but can also include a PI proxy, other co-investigators, science contributors, and administrative staff. |
| **Safety Specialist** | Individuals who guide submissions through the review process. The specialist reviews a newly submitted protocol for completeness, determines the level of review it needs, and ensures correspondence with the PI is completed in a timely manner. |
| **Biosafety Officer** | Individuals responsible for reviewing biosafety protocols and follow-on submissions. |
| **Committee Member** | Individuals on a Safety committee. |
| **Committee Chair** | A Safety committee member assigned to chair the committee. |
| **Safety Administrator** | An individual with Safety oversight responsibilities. Can perform the same actions as specialists, but is typically less involved in the day-to-day processing of submissions. |
| **Committee Administrator** | An individual responsible for managing committee meetings. See Manage Committee Meetings on page 21 for tasks this person performs. |
| **Site Manager** | An individual who has system-wide access. This includes full access to security and system settings, and all data, workspaces, activities, and actions in the system. |

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| Navigation and Basic Tasks | |
| When you first log in, you will be on the My Inbox page. This topic shows where to find Safety submissions and the basic tasks you will perform. | |
| **Submission Workspace**    2        4      **3**      5          7    **1**    **My Inbox page**    6 | Where do I find? |
| 1. From My Inbox, you can find: **Submissions** that require you to take action. 2. **Shortcuts** to other itemssuch as the Help Center. |
| 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. If the **History** tab is not already displayed in the submission workspace, click it. 2. The history lists the activity taken on a submission including any comments, attachments, or correspondence added. |

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| **Navigation and Basic Tasks (Continued)** | |
| **8**        **10**      **12**      **14**      **13**      9      11 | Find All Submissions |
| 1. On the left, click **Submissions**. 2. Click the appropriate tab to see all of your submissions:  * **In-Review:** All submissions undergoing Safety committee review * **Active:** All approved submissions * **Archived:** All discarded and closed submissions * **Suspended or Lapsed:** All submissions that have been suspended or whose annual review due dates have passed * **All Submissions:** All submissions, in any state |
| Find specific entries in a table |
| To find one entry or set of entries in a table, use the **Filter by** feature:   1. Select the column to filter by. 2. Type the beginning characters for the entries 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 special search 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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| Assign a Safety Specialist | |
| After the PI submits a protocol or follow-on submission for review, it appears in the Inbox of all Safety specialists for the administrative office specified in the protocol. The first step is to assign a specialist to handle the submission. Any user with the specialist or administrator role can do this. | |
| 1      2      3      4 | Where do I start? |
| 1. From My Inbox or the In Review submission tabs, click the submission name. |
| Assign a Safety specialist |
| 1. From the submission workspace, click **Assign Specialist** on the left. 2. Select a Safety specialist from the list. 3. Click **OK**. |
| **Note**: You can also assign a specialist on the page that appears when you submit a specialist review or administratively approve a submission. |
| Once you assign a specialist, when the submission enters a state requiring specialist attention, it appears only in the assigned specialist’s Inbox. |

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| Initiate a BSO or Member Review | |
| As the assigned specialist, you might decide that you want a review performed by the biosafety officer or a particular committee member. | |
| 2      3      4      **1** | Where do I start? |
| 1. From My Inbox or the In Review submissions tab, click the submission name. |
| Send Submission to BSO or  Member Review |
| 1. From the submission workspace, click **Send to BSO Review** or **Send to Member Review**. 2. Select the biosafety officer or committee member. 3. Click **OK**.   The submission returns to the assigned specialist’s inbox. |

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| Send Submission into Committee Review | |
| As the assigned specialist, you can send a submission that is in the Specialist Review state into committee review. Alternatively, you can send the submission to a biosafety officer or committee member for review first, or approve it administratively instead. See Initiate a BSO or Member Review on page 10 or Approve a Submission Administratively on page 12. | |
| **1**      2        **4**      3      **5**      **7**      **6** | Where do I start? |
| 1. From My Inbox or the In Review submissions tab, click the submission name. |
| Submit specialist’s review to the Safety committee |
| 1. From the submission workspace, Click **Submit Specialist Review**. 2. Select a committee meeting. 3. If not already assigned, select yourself or another specialist to handle this submission. 4. Select **Yes** to indicate you completed the review. 5. Add any comments or supporting documents. 6. Click **OK** to send the submission to committee review.   See Manage Committee Meetings on page 21 to set up meetings and perform meeting related tasks. |

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| Approve a Submission Administratively | |
| If you determine a committee review is not necessary, as the assigned specialist, you can administratively approve a submission that is in the Specialist Review state, sending it directly into Post-Review. | |
| 2      **3**        4      **8**      **7**      **5**      **6** | Where do I start? |
| 1. From My Inbox or the in Review submissions tab, click the submission name. |
| Approve the Submission |
| 1. After any reviews you requested have been submitted, in the Submission workspace, click **Approve Submission (Admin)**. 2. If not already assigned, select yourself or another specialist to handle this submission. 3. Selectthe committee to acknowledge that the submission has been approved. 4. The last day of the continuing review period populates automatically, but you can override this date. 5. Select the date you are approving the submission. 6. Add any comments or supporting documents. 7. Click **OK**.   The submission enters the Post-Review state, which enables you to manage the approval letter. |
| Submit the Committee Review | |
| Once the Safety committee has reviewed a submission and determined how to handle it, a specialist typically records the committee’s decisions by submitting the committee review. | |
| **2**        **3**        **5b**    (If needed)    **6**      **5a**      **7**      **4** | Prerequisites for this task |
| * The submission is in the **Committee Review** state. * You are logged in with the safety administrator, safety specialist or committee chair role. |
| Where do I start? |
| 1. Open the submission. 2. Click **Submit Committee Review**. |
| Characterize the review and submit |
| 1. Select your determination. 2. The last day of the continuing review period populates automatically. However, if necessary, you can modify this date. 3. If the committee…    1. **Approved the submission:** Select the approval date (typically the committee meeting date).    2. **Withheld approval or required changes:**  Type those details in the **Identify**... box. 4. If desired, you can also document the committee’s vote, supply additional comments, and attach supporting documents. 5. Click **OK** to submit the committee review.   The submission enters the Post-Review state, which enables you to notify the PI of the review decision. |

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| Manage the Determination Letter | |
| When a submission enters the Post-Review state, Safety staff or the committee chair can prepare and send the determination letter. If a staff person prepares the letter, he or she can forward it for review by the committee chair. | |
| **2**      **13**      **7**      **6**      **14**      **3a**    b  **3b**      **4**    b  **5**      **9**      8        **10** | Where do I start? |
| 1. From My Inbox, click the submission. |
| Prepare the determination letter |
| 1. From the submission workspace, click **Prepare Letter**. 2. To create a letter from a template:    1. Select a letter template.    2. Click **Generate**. 3. Alternatively, click **Add,** then navigate to a prepared document. 4. Click **OK**. |
| If needed, have the letter reviewed |
| 1. Click **Forward Letter for Review**. 2. Click **OK**. The state changes to Chair Letter Review and the submission appears in the chair’s Inbox. |
| Make any changes requested |
| 1. Read the change request on the **History** tab. 2. Click the letter name to open. 3. Revise the letter and save it. 4. Repeat 4–5 to upload the letter. 5. Repeat 6–10 for another review. |
| When ready, send the letter to the PI |
| 1. Click **Send Letter**. 2. Click **OK**. Depending on the determination selected in Committee Review, the state changes to Approved, Modifications Required, Approval Withheld or Deferred. |

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| Review the Determination Letter | |
| As committee chair, you might receive determination letters to review before they are sent. | |
| **2**        3      **5**      **8**      **6′**      4    Committee  Chair changes      **9**      **7**      **6**      **5′**      **7′**      **8′**      **9′**      **10** | Where do I start? |
| 1. From My Inbox click the submission. |
| Review the determination letter |
| 1. On the History tab, under Letter Forwarded for Review, click the name of the letter. 2. On the resulting query, click **Open.** 3. Examine the letter. |
| Request any needed changes |
| **5**. From the workspace, Click **Request Changes to Letter**.  **6**. Describe the requested changes.  **7**. Click **OK**. The state changes to Post-Review and the submission reappears in the specialist’s Inbox.  **8**. From the submission workspace, click **Send Letter**.  **9**. Click **OK**. Depending on the determination selected in Committee Review, the state changes to Approved, Modifications Required, Approval Withheld or Deferred. |
| Alternatively, make changes yourself |
| **5′**. Make the needed revisions to the determination letter and save it.  **6′**. Click **Prepare Letter**.  **7′**. Click **Upload Revision**.  **8′**. Upload the revised letter.  **9′**. Click **OK**.  **10**. Click OK on the Prepare Letter page.  **11**. Send the letter as described in 8a–9a. |

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| Verify Required Modifications | |
| When a PI resubmits a protocol with modifications that the Safety committee required for approval, the submission moves to the **Modifications Review** state. The Safety specialist then verifies the modifications as described below. | |
| **11**      **8**      **5**      **6**      **7**      **2**      **4a**      **4b**      **4c**      4d        **3**      **9**      **10**      **12** | Where do I start? |
| 1. From My Inbox or the In Review submissions tab, click the submission name. |
| View and comment on modifications |
| 1. From the submission workspace, click **View Differences**. 2. Click the directional buttons to page through the modifications. 3. To comment on a modification:    1. In the Note bar click **Add**.    2. Select the type of note to add.    3. Type your question or comment.    4. Click **OK**.   Based on your assessment, perform one of the following three tasks. |
| Request committee member review |
| 1. From the submission workspace, Click **Send to Member Review**. 2. Select the committee member. 3. Click **OK**. The state changes to Modifications Review by Member. |
| Request clarification or changes |
| 1. From the submission workspace, click **Request Clarification by Modification Reviewer**. 2. Describe the required changes. 3. Click **OK**. |
| Send the submission to Post-Review |
| 1. From the submission workspace, click **Verify (Admin)**. 2. Click **OK**. The determination changes to “Approved,” and the submission returns to **Post-Review**. |

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| Set Up Ancillary Reviews | |
| Principal Investigators can set up ancillary reviews when a submission is in any editable state, and Safety staff can do so anytime from protocol creation through Post-Review). Ancillary reviews occur in parallel with other activities and do not block them. All ancillary reviewers receive notifications stating they have been assigned. In addition, the submission appears in required reviewers’ Inboxes, where it remains until they accept or reject it (see Submit an Ancillary Review on page 18). If a protocol is in the Pre-Submission state, notifications and Inbox updating do not occur until the protocol gets submitted. | |
| **2**      **4**        **5**      **6**        7      **3**      **9**        **8** | Where do I start? |
| 1. From My Inbox or the In Review submissions tab, click the submission name. |
| Set up the review |
| 1. From the submission workspace, click **Manage Ancillary Reviews**. (Depending on the state of the submission, it may be farther down in the list.) 2. Click **Add**. 3. Optionally type comments and upload supporting documents 4. Select reviewers by organization or by person. 5. Optionally select the type of review. 6. Select whether a review is optional or required for the specified reviewers. 7. In Add Ancillary Review, click **OK** or **Ok and Add Another**. 8. When you finish adding reviewers, Click **OK** in Manage Ancillary Reviews.   The newly added reviewers receive notifications, and if they are required reviewers, the submission appears in their Inboxes. |

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| Submit an Ancillary Review | |
| If you are assigned as an ancillary reviewer for a submission, you will receive an email notification. If your review is required for approval, the submission appears in your Inbox and remains there until you accept or reject the submission. | |
| **2**          **4**      **3**      **5**        **6** | Where do I start? |
| 1. From My Inbox or the In Review submissions tab, click the submission name. |
| Submit the review. |
| 1. Click **Submit Ancillary Review**. 2. Select the review you want to submit. 3. Accept or reject the submission. 4. Optionally type a comment and add supporting documents. 5. Click **OK**. |

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| Suspend a Protocol | |
| In some circumstances, for example a safety violation, the committee might vote to suspend all activity on a project until the problem is resolved. In such cases, a specialist or the Safety administrator suspends the approved submission. | |
| **3**      **4**      **5**      **2**        **6** | Where do I start?: |
| 1. From My Inbox or the Active submissions tabs, click the name of the submission that you want to suspend. |
| Suspend the protocol. |
| 1. From the submission workspace, click **Suspend**. 2. Type the reason for the suspension. 3. Select the effective date of the suspension (must be the present date or a date in the past). 4. Optionally type additional comments or upload supporting documents. 5. Click **OK**.   The submission changes to the **Suspended** state. (See Lift Suspension from a Protocol on page 20.) |

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| Lift Suspension from a Protocol | |
| When the situation that warranted suspending a protocol has been addressed sufficiently to resume the project, the specialist or Safety administrator can lift the suspension. | |
| **3**      **5**      **2**      **6**      **4** | Where do I start? |
| 1. From My Inbox or the Suspended or Lapsed tab, click the name of the submission whose suspension you want to lift. |
| Lift the suspension. |
| 1. From the submission workspace, click **Lift** **Suspension**. 2. Type a description of the corrective action taken that justifies lifting the suspension. 3. Select the date the suspension ended (must be the present date or a date in the past). 4. Optionally type additional comments or upload supporting documents. 5. Click **OK**.   The protocol returns to the **Approved** state.  **Note**: If a submission passes the last day of the continuing review period while suspended, when you lift the suspension, the submission enters the Lapsed state instead of Approved. |

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| Manage Committee Meetings | |
| If you are a committee administrator or oversee committee meetings, you will perform the following activities. | |
| 1      4    **6a**      **6b**      5    7      2    3 | Open a Meeting |
| 1. From My Inbox, click **Meetings**. 2. On the Upcoming Meetings tab, click the name of the meeting to open it. |
| Create a New Meeting |
| 1. From the meetings workspace, click **Create New Meeting**. 2. Complete the form and click **OK**.   The meeting workspace appears. |
| Run a Meeting |
| From the meetings workspace, open the meeting. See Open a Meeting above.  **Before the Meeting:**   1. To remove an agenda item, click the agenda item name and then **Remove from Agenda** on the left of the workspace. 2. When ready to send out the agenda to committee members:    1. Click **Prepare Agenda** and generate an agenda or add one to the meeting.    2. Click **Send Agenda** to e-mail the agenda to committee members. 3. To create a minutes document to update during the meeting, click **Prepare Minutes** and generate the minutes from a template. Save the document and update it during the meeting.   **Tip:** Use Track Changes in Word so later you can copy your notes into the final minutes document. |