I. VIEWING UPCOMING IRB MEETING AGENDA

From the IRB Assistant Home page, select the applicable committee.

II. COMPLETING THE APPLICABLE FIELDS WITHIN IRB MEETING AGENDA SCREEN

1. Click on "Meeting Agenda" to see the most current agenda. Once the agenda screen opens, you may use the arrows surrounding the date to navigate to the IRB agenda you wish to view.

   Be sure to complete the fields highlighted below:

2. From this screen, you may also upload any documents the Board should consider during the IRB meeting. Typically, the IRB Analyst includes the Expedited Actions Report, the final draft minutes from the previous IRB meeting, and any other informational items (pertinent human subject protections articles, policies, miscellaneous documents).
To upload these documents, click on “Review Documents”

Click on the screen that opens up.

Enter the title of the document you are uploading.

Providing a description of the document is optional. Then click .

The upload document pop-up box will open. Click .

Choose the file you wish to upload from your computer. Once you have located it, click
Click to upload the file. Then click .

The document has now been uploaded. From here, more documents may be uploaded if needed.

If a document needs to be deleted, simply click on the box next to the item and then click .

In the event a revised version of a currently uploaded document needs to be included, click on the box next to the item and then click . You will then follow the same steps as above to upload a new/revised version.
3. Whenever a protocol action is scheduled for a particular meeting date, it will appear on the agenda under the appropriate action type and in no particular order (each automatically defaults to position “1”). The IRB Analyst has the ability to set the order of each action under each action type by resetting the number in the “Order” column.

In the “Order” column next to each action, click in the field and type in the desired number to re-sort the order. Then click **Save Changes**.

### III. ENABLING REVIEWER NOTIFICATIONS

For any action that requires a Primary or Secondary Reviewer, you will first need to ensure that reviewer notifications are actually enabled before making any reviewer assignments.

1. From the IRB Assistant Home page, click on **Meeting Manager** and locate the meeting date and click on it to open.
2. Click “Yes” to enable reviewer notifications. Then click **Back** to return to the Meeting Manager. Click **Back** again to return to IRB Assistant Home page.

### IV. ASSIGNING PRIMARY REVIEWERS

1. Click on "**Meeting Agenda**" and scroll to any action that requires primary reviewer assignment.

2. Open the action and click on "**Pre-review Screening**".

---

**Commented [KL(1)]:** NHLBI does not assign Secondary Reviewers. However, the same process is used for assigning Secondary Reviewers as it is for Primary Reviewers.

**Commented [KL(2)]:** NHLBI assigns Primary Reviewers to CRs only. Generally, the same PR is assigned year after year.
3. Click to open the reviewer to activate the dropdown menu then select “Reviewer Role” (in this case, “Primary Reviewer”).

4. Click on the dropdown menu under “Reviewer” to select the individual to be assigned.

5. Click . The “Date Notified” field will now show that the reviewer has been alerted to the new assignment.
6. Click the \( \text{Back} \) button and proceed to the next agenda item that requires assignment of a reviewer.

V. FINALIZING AND GENERATING AGENDA

Once all agenda items have been scheduled and all reviewers have been assigned, the agenda in iRIS is ready to be finalized.

1. From the IRB Assistant Home page, click on “Meeting Manager” and locate the meeting date. Click on it to open.

2. Next to Meeting Status, click “Finalized”
3. A new option will appear, which will allow for a finalized agenda to be generated. Click on

```
Generate A Finalized Agenda Document
```

The menu will expand to include more options.

4. To customize the agenda in a Word format, select the second option.

Commented [KL[13]]: NHLBI prefers to create and edit the agenda in Word to make a more customized document. We add in information and highlighted text to help convey additional information to the Board members.
5. A new screen will open. After a few seconds, a pop-up will appear at the bottom of the screen. Click **Open**.

6. The agenda will open in Word in a separate window. If you are not quite ready to finalize your agenda in iRIS, click **Cancel**. However, if you are ready to finalize it, click **Complete Checkout**.

Either way, you may edit the Word generated agenda and save it on your desktop.
7. Once you have saved all changes to the Word version of the agenda, it is ready to be “checked in” to iRIS. Select “Check-In Finalized Agenda”

8. A pop-up window will appear. Click to upload the agenda document.

9. Choose the document you wish to upload, then click .
10. Click **Save selected file** to complete the upload into iRIS.

11. The agenda is now ready to publish. Click **"Publish The Finalized Version Of The Agenda"**
A message will appear indicating that the agenda has been published.

VI. **SENDING FINAL AGENDA TO BOARD MEMBERS**

Using Outlook, send the final agenda to the Board members and copy any other applicable individuals (OHSRP, Protocol Navigation, etc.).