I. COMPLETION OF THE OUTCOME PAGE FOR AGENDA ITEMS

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

2. 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 will be working from.

3. Scroll to the first action on the agenda and click on Open icon.

4. The action will open to the “General Information” page. Click on “Outcome”

5. Enter the “Review Outcome” as listed for this action in the meeting minutes. If the action was approved at the IRB meeting, select “Approved” from the dropdown menu. Then enter the
“Submission Approval” date, which will be the date of the IRB meeting. Click.

If the action received a different outcome during the IRB meeting, select the applicable outcome from the dropdown menu and enter the “Follow-up Due” date.

Click.

II. ENTRY OF MINUTES INTO iRIS

Generally, the IRB minutes writer enters the approved draft minutes into iRIS and alerts the IRB Analyst once this is done. However, on occasion the IRB Analyst may need to enter draft minutes into iRIS (i.e., CR expires same day as the IRB meeting, etc.). Below are the steps for entering IRB minutes into iRIS, which will then be used to generate outcome letters.

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 will be working from.

2. Scroll to the first action on the agenda and click on Open icon.

3. Click on “Submission Discussion” to open the free text field. Copy the applicable text from the approved Word version of the draft minutes and paste into the Submission Discussion field. Then click .
4. To enter stipulations, click on “Stipulations” to open the “Stipulations to be sent for Response” screen. Click on + Add New for each stipulation that needs to be entered.

5. The “Stipulation Content” screen will open. Copy the applicable text from the approved Word version of the draft minutes and paste into the “Stipulations to be sent for Response” field. Then click .

Add any remaining stipulations one at a time.

**Helpful Hint:** When copying stipulations from the Word document, do not include the number. iRIS automatically numbers stipulations in the order in which they are entered.

Commented [KL[1]: NHLBI has opted to add steps one at a time instead of using “Add Multiple” because we historically experienced problems. Not sure if this will be the case with the NIH instance.
6. To enter recommendations, click on "Recommendation" to open the "Recommendations" screen. Click + Add a new Recommendation.

7. Copy the applicable text from the approved Word version of the draft minutes and paste into the "Recommendation Editor". Then click OK.

Add any remaining recommendations one at a time.

Helpful Hint: When copying recommendations from the Word document, do not include the number. iRIS automatically numbers stipulations in the order in which they are entered.
III. GENERATING OUTCOME LETTERS

1. Click on “Outcome Letter” and select the applicable Notification Letter from the menu. Click to import the template.

2. Once the template opens, be sure to review it for accuracy and appropriate formatting. Provide any edits prior to saving the letter. When done, click .

3. When ready to send the letter, click “Send”
4. Select the recipients to whom you wish to send the Outcome Letter. Click after making all of your selections.

The “Status” section will update to show that the letter has been sent.

IV. POST MEETING ROUTING/ACTION RETURN

There are 2 different scenarios for how actions are handled post-IRB meeting:

- Actions approved without stipulations/recommendations
- Actions that were deferred, tabled, disapproved, or approved with stipulations

1. If an action was approved without any stipulations or recommendations, then the action can be routed for final signatures (IRB Chair or designee, Clinical Director if not yet captured).

Commented [KL12]: I believe the CD routing workflow will change with the PNs routing ahead of IRB submission. So CD routing may not be necessary for the IRB Analyst.
Once final signatures are applied, the action is now ready to be sent to OPS for final processing, OHSRP if it’s a problem report that requires reporting, or simply closed out if it’s a Miscellaneous Submission or similar administrative action type.

2. Actions that were reviewed but did not receive full IRB approval will be sent back to the PI/study team for formal response.

To ensure the action goes back to the PI’s queue, go to the “Submission Complete” page. Click the box next to “Submission processing complete” and then click

The action is now back with the team awaiting their formal response and resubmission.