I. NIH PROBLEM FORM SUBMISSION VIA iRIS

1. Once the problem form is submitted via iRIS, it will appear on the “Not Assigned” Submission page. Click on “Open.”

2. Click on “Pre-review Screening” to assign yourself as the analyst (or the appropriate analyst). Then click

II. PRE-IRB REVIEW SCREENING PROCESS

1. Click on “Submission Components” to review the form and any attachments submitted with the action.

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2. Review all components to ensure they can be opened and are complete and consistent.

3. If everything appears to be complete and accurate, go back to “Pre-review Screening” and determine the correct review process (i.e., “Assign to Review Committee Agenda” or “Process Administratively”).

   If pre-review changes are required before moving forward for IRB review, go to SECTION VII. RETURNING THE NIH PROBLEM FORM FOR CORRECTION AND/OR CLARIFICATION within this guide for additional instructions.

III. ASSIGNING REVIEW PROCESS

1. If no further changes/corrections are required, select “Process Administratively”

   Click to save your selection.

   You will immediately see the left menu expand to include further options.

   ![Screen Shot]

   2. Now begin routing the action for IRB Chair and Clinical Director review.

IV. ROUTING PROBLEM REPORT FORMS FOR REVIEW/APPROVAL SIGNATURES

Forward the problem report form to the appropriate signatories for immediate review.

If the action meets the criteria for an Unanticipated Problem (UP) or Serious and Continuing Non-Compliance (NC), then this event will be scheduled for IRB review at a convened
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meeting. In the interim, be sure to route to the IRB Chair for confirmation. Then route to the Clinical Director and the designated individual in OHSRP following the steps below.

Helpful hint: Go to the General Information page to check if the IRB Chair/Designee or appropriate Clinical Director/Designee is already an investigator on the study. If so, you will need to route it to a different signatory due to conflict of interest rules.

1. Click on “Internal Submission Routing” to navigate to the screen where you can complete signature routing. To route to the IRB Chair, click on [Add Review Board Routing].

From the drop-down menu, select the individual who will sign off as IRB Chair.

2. Now select the role in which that person will sign off (in this case, IRB Chair).

NOTE: You may leave a comment for a signatory by clicking on [Assignment Comments]. However, this is not usually necessary. Comments come in handy if you want to convey additional information that may not be readily available in iRIS.

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3. You are now ready to route to the Clinical Director. This time, you will click on (since the Clinical Director is not on the Board). The “Directory Browse/Find” screen will open and allow you to search for the appropriate signatory. In this case, you will type in the name of the Clinical Director (or Acting Clinical Director, if applicable), then click to search the directory.

4. After selecting the proper signatory, assign the role for which they will be signing off. In this case, select “Clinical Director” from the drop-down menu.

5. Route to the OHSRP designated reviewer by clicking on . The “Directory Browse/Find” screen will open and allow you to search for the appropriate signatory. In this case, you will type in the name of the OHSRP designated reviewer (usually Margaret “Peg” Sanders), then click to search the directory. Assign the role for which they will be signing off. In this case, select “Protocol Specialist” from the drop-down menu.

Commented [KL(1)]: Wondering if we can change this role to reflect “OHSRP” or something similar?
V. IRB CHAIR COMPLETION OF THE REVIEW BOARD SECTION OF THE PROBLEM REPORT FORM

The IRB Chair will make the determination as to the type of problem for which this event should be classified by completing pertinent fields within the Review Board Section of the form.

If the IRB Chair determines this event does not meet the criteria for a UP or serious or continuing NC, the appropriate fields will be completed and the event does not need to be scheduled on a convened IRB agenda and can be administratively reviewed. The Chair will apply their signature and the IRB Analyst will send the report with this determination back to the study team.

*If full Board review is not required, go to Section IX. PROCESSING OF PROBLEM REPORT FORM AFTER IRB REVIEW/APPROVAL within this guide for additional instructions.*
However, if the Chair refers the action to be reviewed by the FULL BOARD, the applicable fields will be completed and the IRB Analyst will schedule it for the next available IRB meeting.

**NOTE:** The IRB Analyst will need to preliminarily send a PDF of the form to the OHSRP designee via Correspondence. In doing so, be sure to complete the “Date Sent to OHSRP” field.
VI. SCHEDULING PROBLEM REPORT FORM FOR FULL BOARD REVIEW

1. On the “Pre-review Screening” page, click “Assign to Review Committee Agenda.” Select the appropriate Committee Name from the drop-down list, the Upcoming Meeting Date, and the Agenda Category. Then click .

2. Now the action is scheduled for the assigned meeting.
VII. SENDING CORRESPONDENCE TO THE STUDY TEAM

When a problem report is referred for review at a convened IRB, the PI/study team needs to be made aware. Often, the Board will request that the PI attend the meeting to discuss the event.

1. Click on “Correspondence.”

2. Click on . A new screen will open, which will allow you to select the proper correspondence template. Then click .

3. The template will load into the content window and allow for editing.

4. Be sure to complete the Subject field.
Select your recipients. The page listing study personnel will open and you will click in the box next to each name you wish to include in the correspondence. Once you have made your selections, click

5. Click

The status will update to show that the correspondence is pending delivery or will show the date and time the correspondence finally posted.
VIII. RETURNING PROBLEM REPORT FOR CORRECTION AND/OR CLARIFICATION

In the event a submission is incomplete or requires correction or further clarification, the analyst should return it back to the study team.

1. Click on “Pre-Review Screening,” then select “Pre-Review changes requested.” Click to save your selection.

2. Click on “Recommendation” if revisions are being requested by the IRB Analyst. Click on “Stipulation” if revisions are being requested by IRB Chair or Clinical Director.
NOTE: During the pre-review screening phase, the analyst treats requests for additional documentation, correction, or clarification as a recommendation as opposed to a formal stipulation.

The following screen will open.

3. Click on the + button and enter your first request. The recommendation editor will open to allow entry into the free text space. Once you have entered your first item, click on the button to save it.

Continue to add as many new recommendations as necessary, being sure to click on the button after each one.
NOTE: It's important to enter recommendations and stipulations one at a time so that the PI can respond in a point-by-point fashion when resubmitting.

4. You will now need to generate an Outcome Letter to alert the study team that changes are required before the action can move forward for IRB review. Click on “Outcome Letter” to navigate to the next screen.

5. From the drop-down menu next to “Notification Letter,” select the appropriate outcome letter template.

6. Once selected, click on . The outcome letter will open in Word and allow for editing. It is advised that you scroll through the document to ensure that the recommendations/stipulations and any other information were pulled into the text of the letter appropriately.
If everything appears to be correct, click . The outcome letter is now ready to be sent to the appropriate recipients.

7. Click to bring up the page of project personnel to whom you wish to send the letter. Click in the box next to each name you wish to include in the notification. At a minimum, you should always include the Principal Investigator, anyone listed as a Study Contact, and yourself.
The letter has now been sent to the selected recipients and the status column below confirms that this is complete.

8. To ensure that the action goes back into the study team’s queue, you will need to click on “Submission Complete.” This brings you to the last page in iRIS. Click the box next to “Submission processing complete” and then

IX. PROCESSING OF PROBLEM REPORT FORM AFTER IRB REVIEW/APPROVAL

After IRB and Clinical Director review and final approval, the outcome will need to be recorded in iRIS.

- If the Problem Report Form underwent full Board review, an outcome letter will need to be generated.
- If it was administratively reviewed and approved, a PDF of the Problem Report Form will be sent back to the PI/study team and the action will be closed out.

Below are the steps for both scenarios:
A. **Administratively Reviewed and Approved Problem Report Forms**

1. Once the appropriate signatories have signed off, the action will appear in your queue on your home screen under the “**Internal Submission Routing Complete**” section. Click on “**Open**.”

![Image](image_url)

2. Click on “**Submission Components**” and then click on the NIH Problem Form submission form to open it. Once open, click on the “**Review Board Sections**” tab to ensure that the IRB Chair recorded the IRB determination.
3. If the IRB Determination is complete, click on "Internal Submission Routing" to verify the date that the IRB Chair signed off on the action.

4. Now, click on "Outcome" and choose "Approved" from the "Review Outcome" drop-down menu and enter the Submission Approval date (which should match the IRB Chair approval date found in the "Internal Submission Routing" section). Click to save.
5. Go back to “Submission Components” and click on the NIH Problem Form submission form to open it. From here, you will need to create a PDF of the NIH Problem Form by clicking on .

A pop-up box will appear asking you to select the print friendly method. Select “NIH Problem Form – NHLBI IRB.” Then click .

6. After a few seconds, the PDF will open. Save it to your desktop and create a unique file name (e.g., “09-H-0199 Problem Report Form (Ref 371083) – IRB Determination”). Then click to return to the form and to exit the form.

7. Click on “Correspondence” and then . (You may follow the same steps as you did in Section VII. SENDING CORRESPONDENCE TO THE STUDY TEAM).
In this case, you will select the following template: “**Expedited Administrative IRB Review and Approval of Problem Report Form**.” Click **Import template**.

A pop-up window will appear indicating that the Template inserted. Click **OK**.

8. In the Subject Line, add the file name (“**09-H-0199 Problem Report Form (Ref 371083) – IRB Determination**”) and then click on **Add Material**.

9. Add the file name to the Title field and click **Save selected file**.

10. A pop-up window will appear. Click “Browse” to locate the PDF of the Problem Report that you previously saved on your desktop. Once you have selected the file, click **Save selected file**.

11. Select your recipients. The page listing study personnel will open and you will click in the box next to each name you wish to include in the correspondence.

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NOTE: For Problem Reports, it’s important to include the following recipients: PI, Accountable Investigator, Study Contacts and the PI’s Branch Chief.

Once you have made your selections, click [Save Changes].

12. Click [Send Correspondence] to send to the selected recipients.

The status will update to show that the correspondence is pending delivery or will show the date and time the correspondence finally posted.

13. Click on “Submission Complete.” On this screen, check the box next to “Submission processing complete,” then click [Save the Submission Complete].

The action is now closed out and will no longer appear in your assigned queue.

B. Problem Report Forms Reviewed and Approved by the Convened IRB without Stipulations
1. The IRB Analyst who is assigned to cover the IRB meeting during which the problem form is reviewed will be responsible for completing the rest of the Problem Report Form, which includes filling out the following fields:
   - Date Reviewed by the IRB
   - Date sent to the IC Clinical Director
   - Date Sent to OHSRP (if applicable)
   - IRB Determination
   - IRB Meeting Minutes
   - Indicate the IRB’s actions in response to this event

   Once all required fields are completed, click .

2. Click on “Outcome” and choose “Approved” from the “Review Outcome” drop-down menu and enter the “Submission Approval” date (which should match the IRB meeting date). Click .

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3. Generate a formal Outcome Letter to send back to the PI/research team and OHSRP (if applicable), by clicking on “Outcome Letter” to navigate to the next screen.

4. From the drop-down menu next to “Notification Letter,” select the appropriate outcome letter template.

5. Once selected, click on . The outcome letter will open in Word and allow for editing. It is advised that you scroll through the document to ensure that the recommendations/stipulations and any other information were pulled into the text of the letter appropriately.
If everything appears to be correct, click **Save Letter Changes**. The outcome letter is now ready to be sent to the appropriate recipients.

6. Click **Send** to bring up the page of project personnel to whom you wish to send the letter. Click in the box next to each name you wish to include in the notification. Be sure to select the PI, Accountable Investigator, Study Contacts and the PI’s Branch Chief.
The letter has now been sent to the selected recipients and the status column below confirms that this is complete.

7. The IRB Analyst will also route the action for final signature by the IRB Chair through “Internal Submission Routing”.

8. If the final IRB determination requires OHSRP reporting, then the IRB Analyst will generate a PDF of the problem report form and send to OHSRP via correspondence.

9. The action is now ready to close out on the “Submission Complete” page.
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