IRB Analyst Review Process
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Shortcut to protocol

1. Open Workflow Message received in Outlook from a POC
2. Open *Analyst Pre-Review* Action Item from inside Workflow Message

Option to Re-Assign Analyst

3. To Re-Assign Analyst (this is optional; skip to step 7 if bypassing)
    a. Next Status = “Re-Assign Analyst”
    b. Assign to = name of analyst you want to do Pre-Review instead of you
    c. Click “I am Done,” and close window
4. If you receive a Workflow Message for *Re-Assign Analyst*
    a. If you accept the re-assignment
        i. Choose yourself from dropdown
        ii. Click “I am Done”
        iii. Add comment
        iv. Close window
    b. If you do not accept the re-assignment
        i. Choose someone else from dropdown
        ii. Click “I am Done”
        iii. Add comment
        iv. Close window
5. Open Workflow Message for *Analyst Pre-Review*
6. Open *Analyst Pre-Review* Action Item from inside Workflow Message
7. Open Protocol from inside Action Item
8. Ensure your name appears in the Coordinator dropdown on General page. If it does not, choose your name and Save the screen

Add Personnel

9. Add Personnel based on Research Personnel eForm
    a. View Research Personnel eForm, move form to other screen
    b. Open a Word document, making a section for Provisions and a section for Comments; set aside Word document
        i. Provisions = messages to the PI
        ii. Comments = message for IRB eyes (PI cannot see these)
    c. Open the Certifications Database, set aside
    d. Navigate to Personnel within submission
    e. For each personnel member
        i. Check that the personnel member has satisfied all education requirements
            1. If no:
                a. Make a note in the Provisions section of Word doc
                b. Do not add personnel to InfoEd
            2. If yes:
                a. Click Add Personnel, choose from picklist
                b. Choose Role, either *Co-Inv* or *Research Coordinator*
                c. Ensure radial button for Primary Investigator is set to the PI
                d. Save screen
    f. Close Research Personnel eForm, close Certifications DB

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Pre-Review

10. Navigate to Reviews
11. Conduct tasks for Pre-Review
    a. Create Review Method for Pre-Review
        i. Add "IRB Pre-Review"
        ii. Set Board = "IRB Analysts"
        iii. Add Assignment = your name
        iv. If InfoEd enters a reviewer by default without you having to click Assign and this reviewer is correct, you still must click Assign, remove the reviewer, and then add the reviewer again.
    b. Review eForms and Uploads
        i. Open Reviewer Dashboard
        ii. View each eForm and/or Upload
        iii. Type Provisions and/or Comments in Word document as you review each form
        iv. Choose a Reviewer Action for each form
        v. Click Save after choosing each Reviewer Action
        vi. When finished, click "Completed," "Save," and close window
        vii. Enter the appropriate Review Category (Expedited, Exempt, or NHSR) when known
        viii. Scroll to bottom and paste (from Word) Provisions in Provisions box and Comments in Comments box
    c. Choose a Review Decision for Pre-Review
        i. If any form is "Action Required" choose Review Decision = *Modification Requested*
        ii. If all forms are "Ok As-Is" and submission is <u>Exempt:</u>
            1. Choose Review Decision = *Approved – Exempt*
            2. Enter Approval Date and Period Start. **Do not enter an End Date.**
            3. **Enter Risk Level**
            4. Save Screen
            5. OPTIONAL – If you are a Junior Analyst, follow these steps for Senior Analyst Review:
                a. Return to the Action Item
                b. Select "Senior Analyst Review" in Next Status, select Lori or Suzanne in "Assign To"
                c. Enter a comment to the effect of "Please take a look at this and make sure it can be approved as Exempt (or NHSR)"
                d. Click "I am Done"
                e. Wait for a response in the form of a new WF message / Action Item
                f. Open the protocol from the Action Item and follow the instructions from the Senior Analyst (if necessary)
                g. When finished, go to step 12

Pre-Review *(continued)*

iii. If all forms are "OK As-Is" and submission is <u>Not Human Subjects Research</u>:
   1. Choose Review Decision = *Approved – NHSR*
   2. **Enter Approval Date only. Do not enter Period Start or Period End Date.**
   3. **Do not Enter Risk Level**
   4. Save Screen
   5. OPTIONAL – If you are a Junior Analyst, follow these steps for Senior Analyst Review:
      a. Return to the Action Item
      b. Select "Senior Analyst Review" in Next Status, select Lori or Suzanne in "Assign To"
      c. Enter a comment to the effect of "Please take a look at this and make sure it can be approved as Exempt (or NHSR)"
      d. Click "I am Done"
      e. Wait for a response in the form of a new WF message / Action Item
      f. Open the protocol from the Action Item and follow the instructions from the Senior Analyst (if necessary)
      g. When finished, go to step 12

iv. If all forms are "OK As-Is" and submission is <u>Expedited</u> choose Review Decision = *Chair/Designee Review*

v. Save screen

Send Communication

12. Send Communication
   a. Navigate to Reviews > IRB Pre-Review > Communication
   b. If decision was "*Modification Requested,*" send Modification Requested letter to PI
      i. Remember to CC the Contact Person from Research Personnel if listed (then go to 15)
   c. If decision was an Approval, send Approval letter to PI
      i. The Not Human Subjects Decision approval can be used as-is. Build this letter from the "Form Letter" dropdown.
      ii. Exempt and Expedited approval letters must be generated in Word from the IRB template folder called InfoEd under IRBdocs and then replaced into the template. Do this by building the appropriate approval letter from the "Form Letter" dropdown (either Exempt or Expedited). Then click the replace icon and upload the Word version.
      iii. Remember to CC the Contact Person from Research Personnel if listed (then go to 15)
   d. If decision was "*Chair/Designee Review*," send Chair Review Letter to Chair

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Create Review Method for Chair (if necessary)

13. Create Review Method for Chair
    a. Navigate to Reviews
        i. Add "Chair/Designee Review"
        ii. Review Category = "Chair Review"
        iii. Set Board = "Chair/Designee"
        iv. Add Assignment = [the appropriate chair]
        v. if InfoEd enters a reviewer by default without you having to click Assign and this reviewer is correct, you still must click Assign, remove the reviewer, and then add the reviewer again.
14. Click "Done," (then go directly to 16)

Update Summary (only for *Mods Req* or *Approved*)

15. Update Summary – only for *Modification Requested* or *Approved – NHSR or Approved – Exempt*
    a. Navigate to Reviews > IRB Pre-Review > General
        i. If Decision = "*Modification Requested*" or "*Approved – NHSR* or *Exempt*," click Update Summary
        ii. Check that appropriate items will be updated
        iii. Uncheck any item that should not be updated
        iv. Cancel update if something looks incorrect and go fix
        v. Click Continue Update if everything looks correct

End *Analyst Pre-Review* status

16. Return to *Analyst Pre-Review* Action Item
    a. If Decision = "*Modifications Requested*," simply Close the Action Item
        i. Open the corresponding Action Item that says "Review Submission" and click "I am Done" | **STOP HERE**
    b. If Decision = "*Approved – NHSR or Approved – Exempt*," simply Close the Action Item
        i. Open the corresponding Action Item that says "Review Submission" and click "I am Done" | **STOP HERE**
    c. If Decision = "*Chair/Designee Review*"
        i. Next status = "*Scheduled for Chair/Designee Review*"
        ii. Assign to = yourself
        iii. Click "I am Done," and close window
        iv. Open the corresponding Action Item that says "Review Submission" and click "I am Done"

Monitor Chair Review (if Expedited)

17. Open new Workflow message
    a. Read instructions—this is the status to monitor the Chair
    b. Delete this Workflow message
18. Monitor the Chair, bother him/her if the review is not being completed in a timely manner
    a. If Chair review is not being done, re-send the Chair Review Letter in Communication (navigate to IRB Pre-Review > Communication and follow step 12d)
19. When you receive an email from the Chair that he/she is done, go to 20
20. Return to *Scheduled for Chair/Designee Review* Action Item
    a. Assign To = yourself
    b. Click "I am Done," and close window

21. Delete email from Chair
22. Open new Workflow message

Determine the Chair's decision

23. Open *Analyst Re-Review* Action Item from WF Message
24. Open Protocol from inside Action Item
    a. Examine Chair/Designee Review Method
        i. If any form is red and has the status "Action Required"
            1. Click (i) icon next to the form and view Chair's message
            2. If part of message is a Provision to the PI, copy and paste that information into the Provisions section of Word doc
            3. If part of message is a Comment for IRB eyes only, copy and paste that information into the Comments section of Word doc (go to 24b)
        ii. If all forms are green and have the status "Ok As-Is"
            1. Check to see if there are any optional checkboxes under "Include Comments in Response"
                a. If yes, click the (i) icon next to the form and view the Chair's message
                b. If message is a Comment for IRB eyes only, copy and paste that information into the Comments section of Word doc (go to 24b)

    Carry-out Chair's decision (if Mods Requested)

    b. Follow instructions based on Chair/Designee Review
        i. If any form is red and has the status "Action Required"
            1. Choose Review Decision = "*Modification Requested*"
            2. Paste all Provisions and Comments from Word doc into Provisions and Comments boxes at bottom of screen
            3. Save screen
            4. Click Update Summary
                a. Check that appropriate items will be updated
                b. Uncheck any item that should not be updated
                c. Cancel update if something looks incorrect
                d. Click Continue Update if everything looks correct
            5. Navigate to Communications within Chair/Designee Review
                a. Send "Modification Requested" built letter to PI
                    i. Remember to CC the Contact Person from Research Personnel if listed
            6. Return to Analyst Re-Review Action Item
                a. Close window | **STOP HERE**

Carry-out Chair's decision (if Approved)

ii. If all forms are green and have the status "Ok As-Is"
1. Enter the appropriate Review Category (presumably, Expedited)
2. Choose Review Decision = "*Approved - Expedited*"
3. Double check that all messages from Chair are in Comments box
4. Enter Approval Date, Period Start, Period End, and Risk Level
5. Save screen
6. Click Update Summary
    a. Check that appropriate items will be updated
    b. Uncheck any item that should not be updated
    c. Cancel update if something looks incorrect
    d. Click Continue Update if everything looks correct
7. Navigate to Communications within Chair/Designee Review
    a. Send "Approved" built letter to PI
        i. Remember to CC the Contact Person from Research Personnel if listed
8. Return to Analyst Re-Review Action Item
    a. Close window | **STOP HERE**