RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

eIRB

eIRB User Manual for IRB Staff (Router and IRB Administrator)

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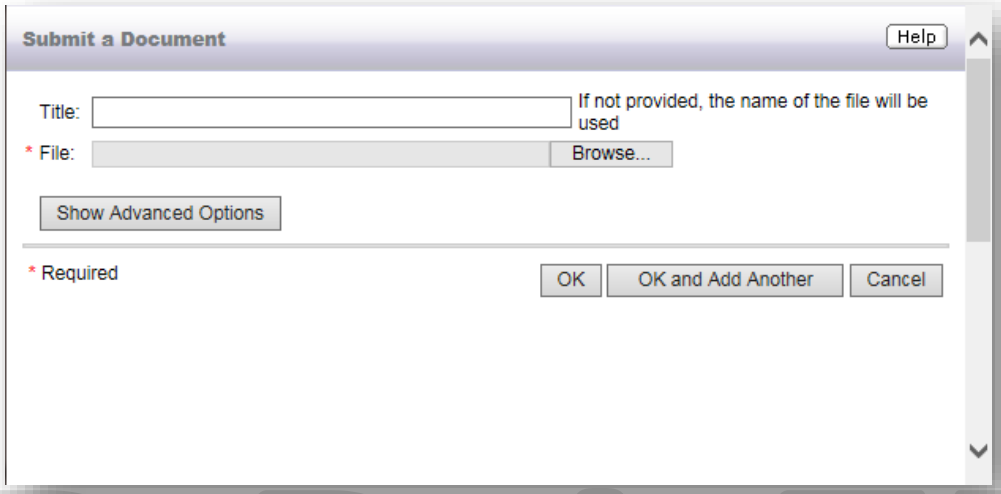


A. eIRB Access

This user manual outlines the steps and procedures necessary for IRB staff to fully utilize eIRB.

The Live site is at http://eirb.rutgers.edu using any Internet connection anytime with a supported browser.

The sandbox is located at http://test-eirb.rutgers.edu/ for netid log ins. This link is also on the live site.

The link for eIRB training and test accounts is https://test-eirb.rutgers.edu/eIRB/login/login

Here are the test accounts; the password is 1234 for all accounts:

Principal Investigator	Training	trainingpi1
Committee Member	Training	irbcm
Department Approver	Training	rudr
School of Nursing	Student	snstudent
IRB	Administrator	irba

B. Confidentiality

eIRB contains study designs, ideas, methodology, and other proprietary information for which IRB staff are responsible for safeguarding.

Precautions should be taken to protect RUTGERS information in eIRB. Please protect this information in the following ways:

B.1. Do not select the "Remember Me" feature on the eIRB log in page from your laptop or home computers, as this may compromise the security of confidential information.
B.2. Do not share your eIRB password.
B.3. Do not leave your computer unattended while working in eIRB.
B.4. If possible, do not print the Investigator's Brochure, the protocol, or other study materials.
B.5. If you do print from eIRB, take precautions to destroy the paper upon completion of your pre-review and processing of the study application in accordance with University Policy.
B.6. Do not disclose, in whole or in part, protocol-specific confidential information to individuals not listed on the study team

C. Getting Help

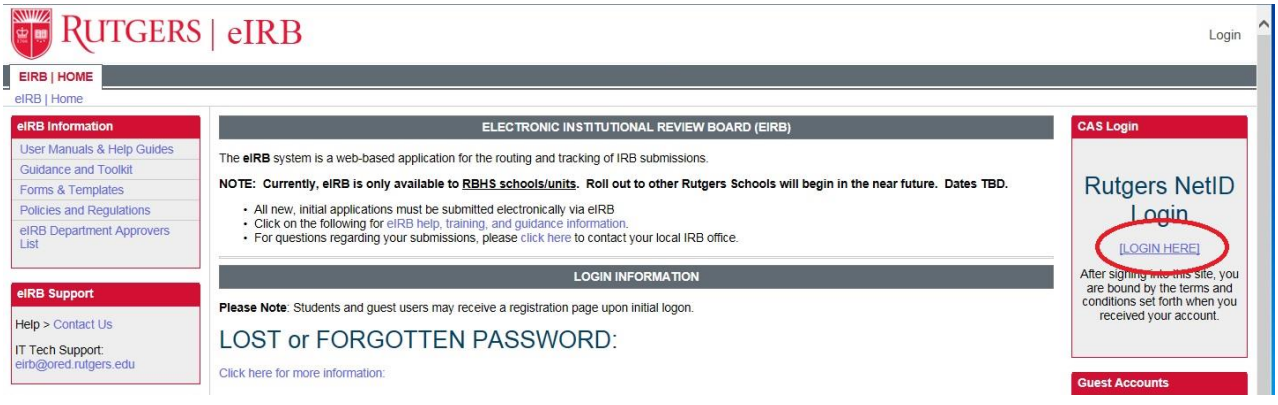
If you have technical problems, need help, or have technical questions about eIRB please contact IST eIRB Help Desk at eirb@ored.rutgers.edu, cc'ing the IRB Director (IRBD) and IRB Assistant Director (IRBAD).

D. Using eIRB website, you can:

D.1. Conduct a completeness check of an electronic application
D.2. Conduct a preliminary administrative review (PAR) of an electronic application
D.3. Return the application to the study staff (SS) and principal investigator (PI)
D.4. Assign a submission to an IRB committee member (CM) for review
D.5. Log comments to IRB CMs about a study (private) and log comments to the PI and study staff SS about a study (public)
D.6. Send Email to Reviewer
D.7. Send Committee Correspondence (full IRB)
D.8. Send Email to Study Team
D.9. Stamp PDF, Word, and Excel documents after the study is approved
D.10. Track the progress of the submission as you route it for review and signoff before processing approval
D.11. Send correspondence review (determination notice, and notice of approval) for appropriate signoff before releasing notification to the PI and SS
D.12. Download notice of approval and stamped approved research documents, such as consent forms, protocol, and data collection forms
D.13. View a time stamped log of all changes made to the application and any correspondence sent between the IRB and the study team.
D.14. Access committee rosters
D.15. Generate IRB reports

E. Login to eIRB

You can log into the eIRB website using your NetID username and password. Do not share your NetID username and password with anyone.



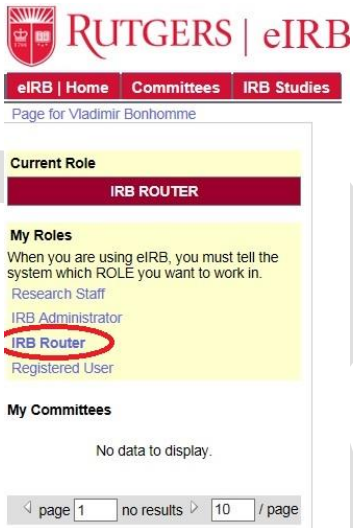
F. IRB Staff Workflow

eIRB enables IRB staff to conduct a PAR, assign reviews to CMs, coordinate a full IRB committee meeting, and process new study, modification (Mod), continuing review (CR), and reportable event (RE) submissions in an electronic environment that improves record-keeping and reduces environmental impact.

G. Overview of processing a submission:

G.1. Login to eIRB

G.2. Select IRB Router under Current Role



G.9.1. Browse the Router inbox for submissions from assigned departments/schools/centers/institutes

G.9.2. Click the application Name to navigate to the submission workspace

G.9.3. Click re-assign owner under the My Activities menu to select your name and then route the application to your IRB Administrator (IRBA) inbox

G.3. Click My Inbox in the top right corner of the page

G.4. Select IRBA under Current Role. Applications that you routed to yourself or that have been routed to you by your assigned Management Assistant (MA) will appear in **My Inbox**

G.5. Select the submission you will PAR. Click **Edit Study** or **Print Version** to view the study

G.6. The MA will complete the MA Completeness Checklist under the **My Activities** menu for all **new study** submissions

G.7. The Program Assistant (PA)/ Program Support Specialist (PSS) will complete the MA-PA Checklist activity under the **My Activities** menu and upload the Pre-Review checklist for all **new study** submissions

G.8. Although the PAR checklist activity is not currently available for Mod, CR, and RE submission types, the IRBA is still expected to complete a PAR of all submission types

G.9. Refer to the PAR Policy and Procedure and related addenda located in S:\2018\Newark IRB SOP\IRB Office Policy and Procedures

G.9.1. If section 1 findings (show stoppers), add notes to each page in the application using the **Edit Study** view, and then click the **Request Changes or Clarifications** activity to send the submission back to the PI and SS

G.9.2. If section 2 findings (e.g. eCOI), then the IRBA has the option to inform the PI and SS using the **Send Email to Study Team** activity; also inform the CM in text box during the Forward to Expedited/ Full Board Review activity

G.9.3. If no PAR findings, then inform CM of no findings in comment box during the Forward to Expedited/ Full Board Reviewer activity

G.10. Place study on meeting agenda (when applicable)

G.11. Assign study to IRB CM(s) for review

G.12. Ensure IRB CM(s) completed all applicable reviewer checklists associated with the submission

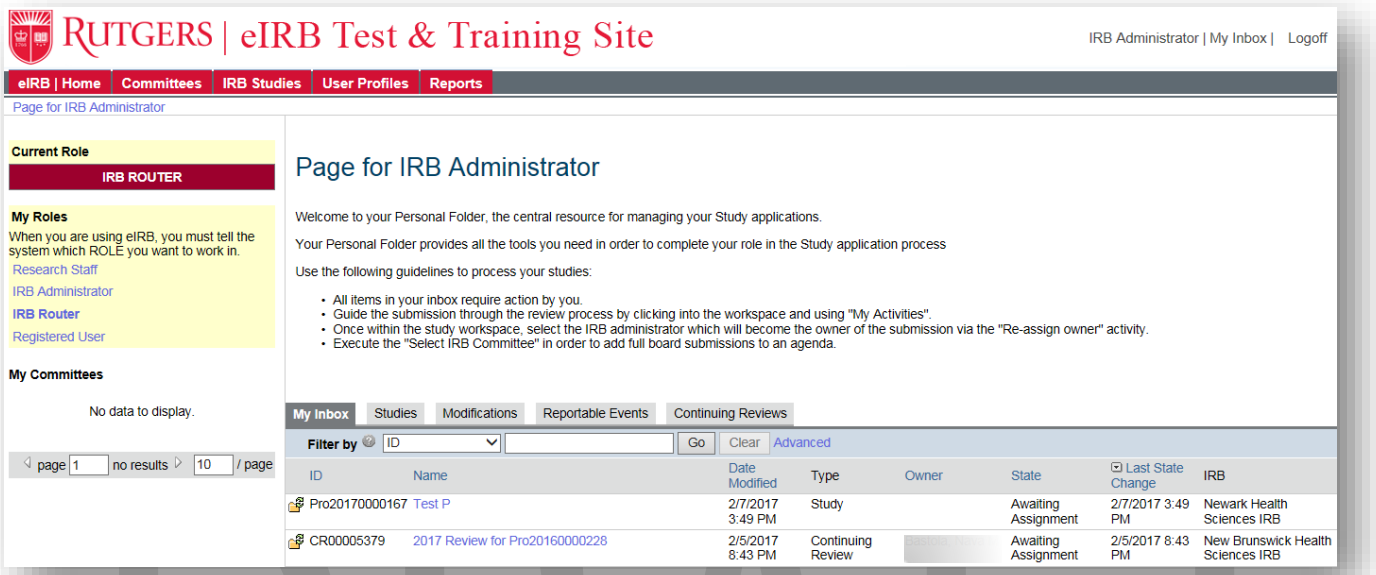
G.13. Prepare correspondence review based on reviewer notes and/ or PARM findings

G.14. Submit correspondence review (determination notice or notice of approval) to IRBAD or IRBD for review

G.15. If a determination notice is sent, then continue to process application until approved after receiving response from the PI

G.16. If notice of approval is issued, then ensure that applicable study documents are stamped with current approval and expiration dates

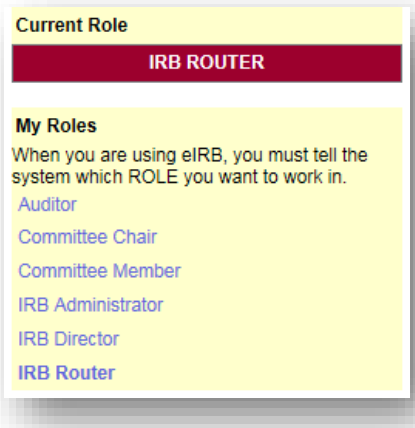
1. Personal Folder: My Inbox



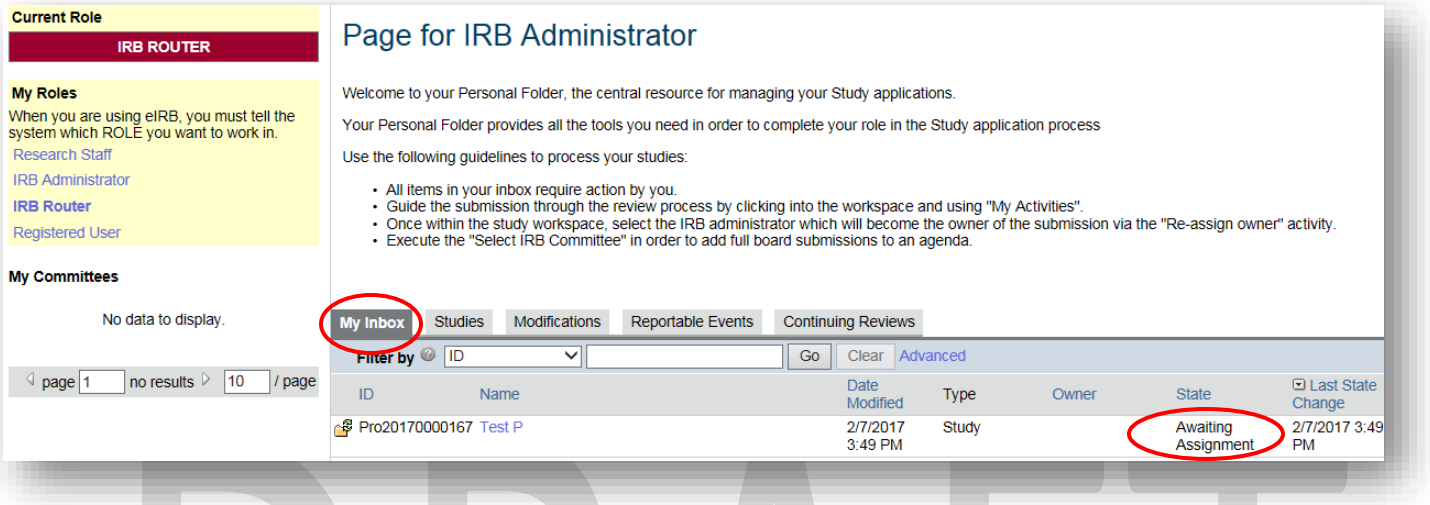
Your Personal Folder is the default welcome page after you log in. Click **My Inbox** in the upper right corner of the page at any time to return to your default welcome page.

1.1. Current role

- Determines access level
- Multiple roles will be listed here (if applicable)
- Select correct role
- Each role has its own inbox (remember to check each inbox for submissions)



1.2. Router (Management Assistant and Program Assistant)



Check eIRB for new submissions every 2-3 hours on the hour between 8:30am-5pm Monday-Friday.

All submission types will be under the **My Inbox** tab. The Router will assign **new study** submissions to an IRBA for processing.

Each PA is responsible for taking ownership/ re-assigning ownership of department specific modification and continuing review submissions.

The PSS is responsible for taking ownership/ re-assigning ownership of department specific modification and continuing review submissions and all reportable event submissions regardless of department.

1.3. MA-PA Checklist

eIRB MA completeness checklist is available for **new study** submissions only. The following function is listed under **My Activities:**

1. MA takes ownership of a new **study submission** and then completes MA-PA checklist
2. If there are any section 1 items then the MA must request the clarifications and send the study back to the PI. Section 1 items will appear as orange sections as seen below:

3. MA will re-assign ownership to PA/ PSS when there are no section 1 items or when the investigator responds to all section 1 items that were requested by the MA.

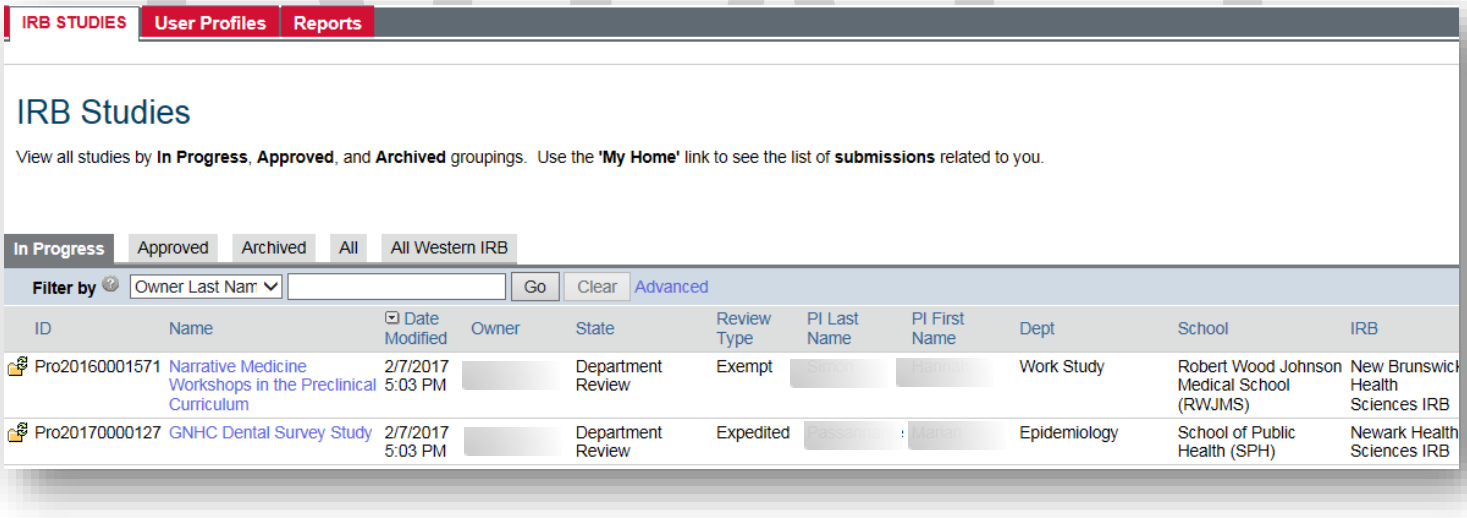
4. If the MA identifies items that he/ she knows are orange section items from the Preliminary Administrative Review (PAR) checklist before re-assigning ownership to PA/ PSS, then the MA is encouraged to send the study back to the PI.
5. Once the MA checklist is complete then it will appear in the history as seen below:

In the event that an assigned IRB administrator is out of the office than the assigned MA must follow the steps listed below for their assigned IRB administrator action items and send an email to the IRBD/ IRBAD of any outstanding items that requires further processing. The IRBD/ IRBAD will inform the MA via email to reassign the items to the designated floater:

For new submissions:

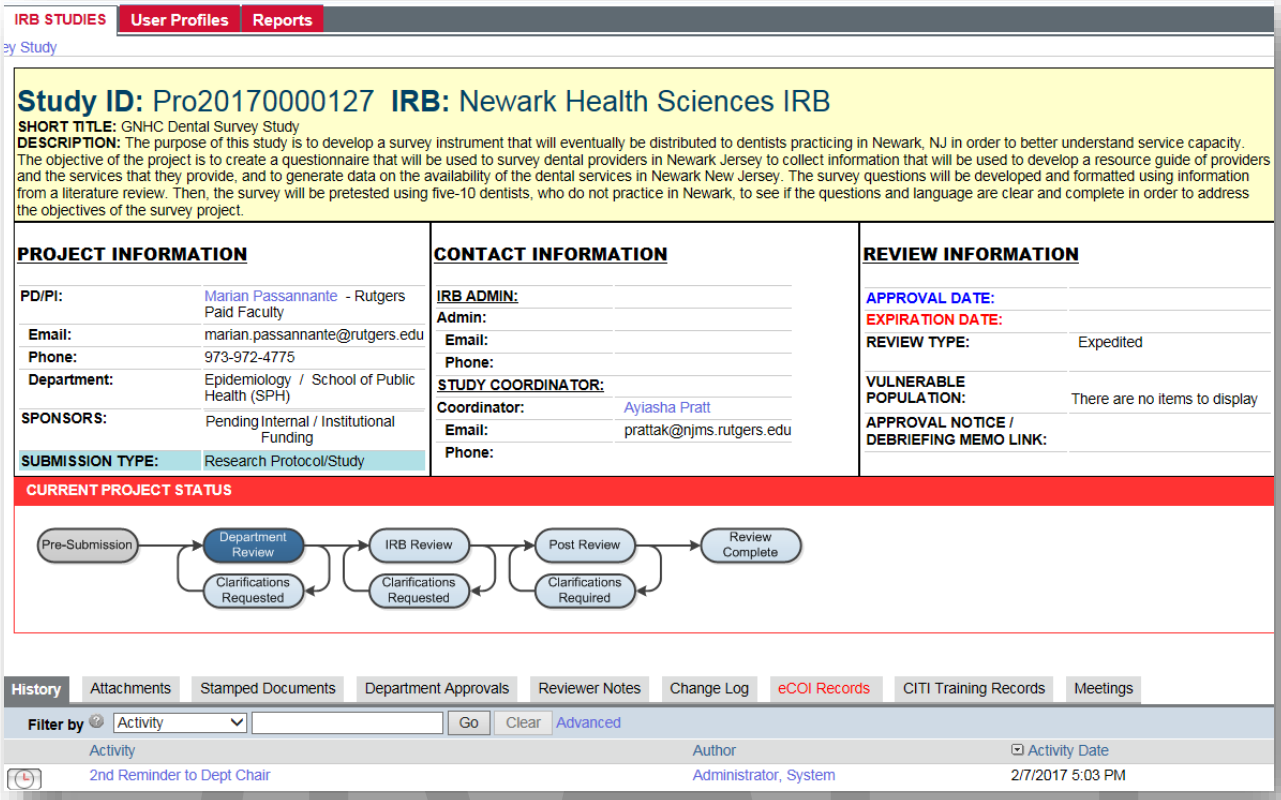
- Check the IRB Router Inbox
- Assign ownership of the submission to the designated IRBA covering for the absent PA/PSS

For reviewer notes and investigator's response:



- Click the IRB Studies tab at the top of your home screen
- Click the In Progress tab
- Select Filter by Owner Last Name/ First Name (your choice)
- Type IRBA's last/ first name
- Click Go
- Click on each of the protocol titles listed to navigate to the study workspace

- In the study workspace, you will find the current History for the study



- If IRB Administrator action is required based on the most recent action under the History tab or an item has exceeded the acceptable task timeline of three business days, then the MA will assign ownership of the study to the designated IRB administrator covering in the absence of the administrator.
- If the IRB administrator is expected to return prior to the acceptable task timeline then the item will not be reassigned. Upon return, the administrator must prioritize the items that were not reassigned.

1.4 Submission Types

1.4.1. New Study - **Pro**

- Full board
- Expedited
- Exempt
- Non-human
- Facilitated

1.4.2. Continuing Review- **CR**

- Full board
- Expedited
- Facilitated

1.4.3. Reportable Event- **RE**

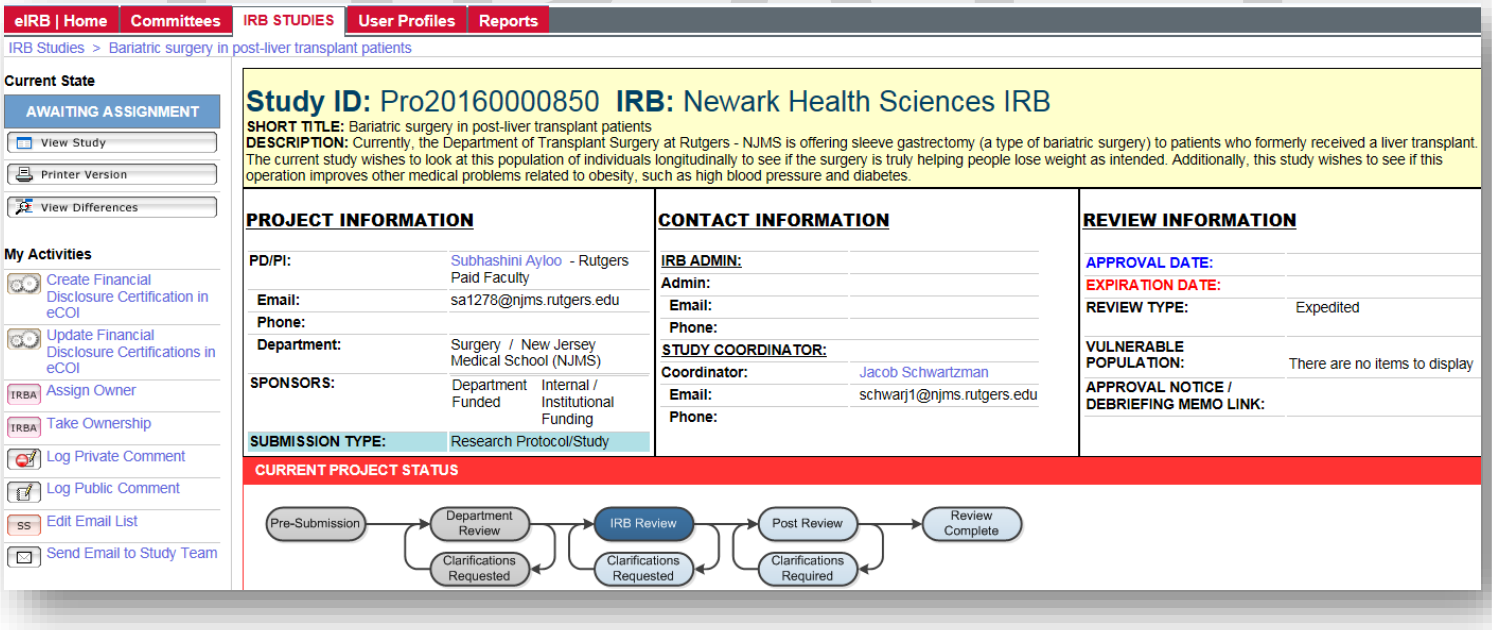
- Unanticipated Problem
- Adverse Event
- Deviation
- Violation

1.4.4. Modification- **Mod**

- Substantive (full board)
- Non-substantive (expedited)

2. Study Workspace

Click the study name to access the study workspace.



2.1. Current State

Current State specifies where the study is in the IRB review process

2.2. History and other tabs

History lists all of the study activities throughout the submission, review, and approval process
Attachments lists supporting documents included with the submission
Stamped Documents lists documents with IRB approval stamp (If applicable)
Department Approvals lists approval or pending approval for departments
Reviewer Notes lists comments added by IRBA and each CM and the location of the note in the submission
Reviews lists the assigned CM, motion, and comments for the submission
Change Log displays all changes made to the submission and supporting documents
Approval/Memo Notices lists all debriefing and approval notices from IRBA

IRB Only lists internal correspondence between IRBA and CM
Meetings includes the meeting minutes for the submission
CITI Training Records lists completion report status for all study personnel
eCOI go to https://ecoi.rutgers.edu/eCOI to access current status of conflict of interest (COI) disclosures for all study personnel

2.3. Log Private Comment

Only use the **Log Private Comment** activity in the following instances:

2.3.1. Email Sent to IRBA (Outlook) - Study team and/ or committee member sends an email to IRBA through Outlook requesting information and/or providing information and/ or documents
2.3.2. Forward to Full IRB Review (Continuing Review) - Paste comment box text because it does not appear under the History tab when the Forward to Full IRB Review activity is completed for the CR submission type
2.3.3. Email Sent to Reviewer (Outlook) - IRBA sends an email to one of two committee members through Outlook as a reminder to complete his/ her full IRB review assignment
2.3.4. Grant congruency/ endorsement - Grants and Contracts confirm with IRBD that protocol and award match and then MA uploads applicable documentation
2.3.5. Re-assign ownership of full IRB review submission when meeting is canceled - IRBA indicates submission is being re-assigned because team meeting was canceled due to lack of quorum or minimal submissions
2.3.6. Change Review Type - IRBA sends an email to IRBAD/ IRBD to confirm proposed change to review type and IRBAD/ IRBD replies
2.3.7. Email Sent to IRBD (Outlook) - IRBD forwards an email to IRBA through Outlook providing information and/ or documents
2.3.8. Audit Request (Outlook) - IRBA sends an email to HSPP audit team through Outlook requesting a for-cause audit

2.3.9. Processing a Mod with revised study documents (for an expired study or a linked continuing review) - Refer to the section titled ***Processing a Mod or RE for an expired study*** in this manual

2.3.10. Email Sent to IST (Outlook) - IRBA sends and email to IST through Outlook regarding technical difficulties with a submission and IST replies

2.3.11. Full IRB submission approved (with stipulations), pending COIC determination – Refer to the section titled ***Study pending a determination from the Conflict of Interest Committee (COIC)*** in this manual

2.4. Send Email to Study Team

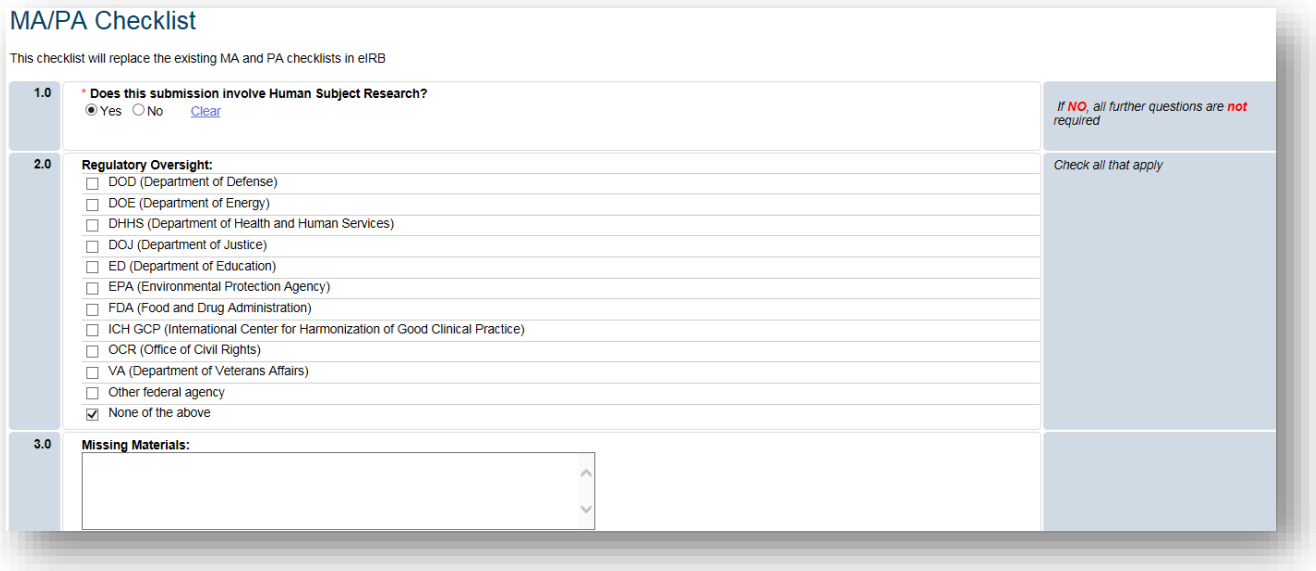
Use the **Send Email to Study Team** activity to communicate with the study team about submission related information, documents, phone conversations, in-person meetings, and other relevant study related discussions, interactions, and communications. The **Send Email to Study Team** activity is a supplement to the **Prelimenary Administrative Review (PAR)**, **Add Notes**, **Request Changes or Clarifications**, and **Edit Action Letter** (determination notice) activities.

Include the following text at the bottom of your message in the **Send Email to Study Team** activity window:

> "Do not click Reply in Oulook to respond to this email. Click the ID link above to navigate to the study workspace. Click Send Email to IRBA to provide a response."

2.5. Completeness Check

In addition to the (orange) section 1 items noted in the MA checklist - in order to assist the PA/ PSS with the administrative review of the study - the MA is encouraged to request any (orange) section 1 items from the PAR checklist that are identified at the time the MA checklist is being completed.


MA/PA Checklist

This checklist will replace the existing MA and PA checklists in eIRB

1.0 * **Does this submission involve Human Subject Research?**
◉ Yes ○ No Clear

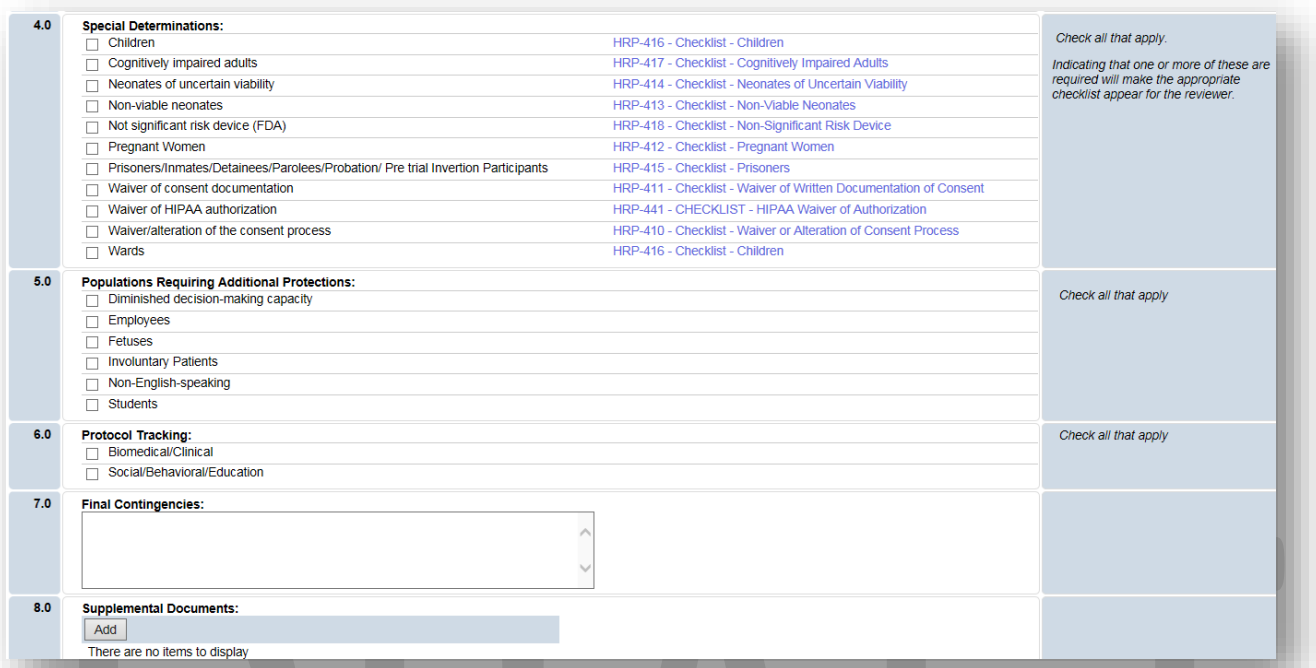
If NO, all further questions are not required

2.0 **Regulatory Oversight:**

Check all that apply

- ☐ DOD (Department of Defense)
- ☐ DOE (Department of Energy)
- ☐ DHHS (Department of Health and Human Services)
- ☐ DOJ (Department of Justice)
- ☐ ED (Department of Education)
- ☐ EPA (Environmental Protection Agency)
- ☐ FDA (Food and Drug Administration)
- ☐ ICH GCP (International Center for Harmonization of Good Clinical Practice)
- ☐ OCR (Office of Civil Rights)
- ☐ VA (Department of Veterans Affairs)
- ☐ Other federal agency
- ☑ None of the above

3.0 **Missing Materials:**



4.0	**Special Determinations:**		*Check all that apply.* *Indicating that one or more of these are required will make the appropriate checklist appear for the reviewer.*
	☐ Children	HRP-416 - Checklist - Children	
	☐ Cognitively impaired adults	HRP-417 - Checklist - Cognitively Impaired Adults	
	☐ Neonates of uncertain viability	HRP-414 - Checklist - Neonates of Uncertain Viability	
	☐ Non-viable neonates	HRP-413 - Checklist - Non-Viable Neonates	
	☐ Not significant risk device (FDA)	HRP-418 - Checklist - Non-Significant Risk Device	
	☐ Pregnant Women	HRP-412 - Checklist - Pregnant Women	
	☐ Prisoners/Inmates/Detainees/Parolees/Probation/ Pre trial Invertion Participants	HRP-415 - Checklist - Prisoners	
	☐ Waiver of consent documentation	HRP-411 - Checklist - Waiver of Written Documentation of Consent	
	☐ Waiver of HIPAA authorization	HRP-441 - CHECKLIST - HIPAA Waiver of Authorization	
	☐ Waiver/alteration of the consent process	HRP-410 - Checklist - Waiver or Alteration of Consent Process	
	☐ Wards	HRP-416 - Checklist - Children	
5.0	**Populations Requiring Additional Protections:**		*Check all that apply*
	☐ Diminished decision-making capacity		
	☐ Employees		
	☐ Fetuses		
	☐ Involuntary Patients		
	☐ Non-English-speaking		
	☐ Students		
6.0	**Protocol Tracking:**		*Check all that apply*
	☐ Biomedical/Clinical		
	☐ Social/Behavioral/Education		
7.0	**Final Contingencies:**		
8.0	**Supplemental Documents:**		
	Add		
	There are no items to display		

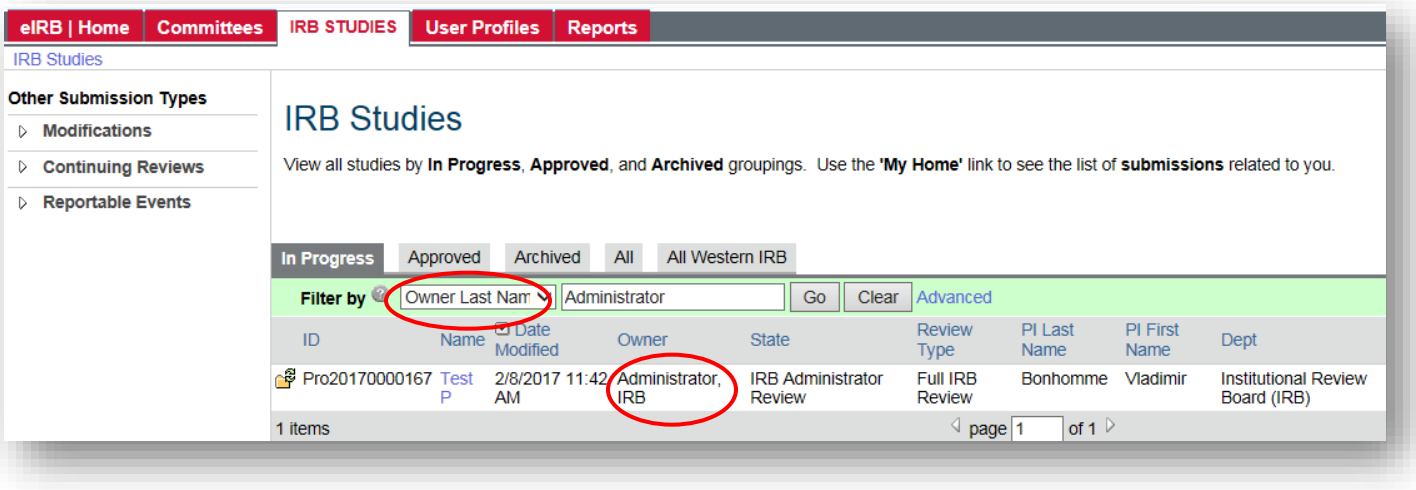
The MA will reassign ownership of full IRB new study submissions to the PA/PSS assigned to the principal investigator's department. This will give the department PA/PSS an opportunity to verify that the submission meets the criteria for full IRB review before they reassign it to the PA/PSS assigned to the upcoming IRB team meeting.

2.6. Re-assign Owner

2.6.1. If the router is a MA, then the router will complete the MA completeness checklist. Once the checklist is completed, the router will IRBA Request Changes or Clarifications or IRBA Assign Owner to assign the application to the IRBA, i.e. PA/ PSS if all MA and/ or PAR orange section 1 items are resolved.

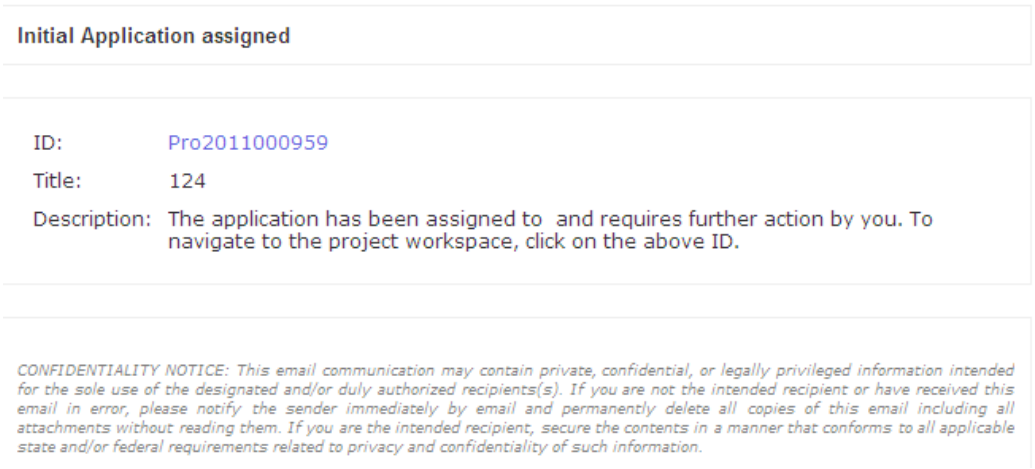
2.6.2. If the router is a PA/ PSS, then the router will IRBA Assign Owner to assign the application to himself/ herself. The PA/ PSS will complete the MA completeness checklist first and then complete the PAR checklist.

2.6.3. In the event an IRBA is unavailable to continue processing a submission, the assigned MA for the absent PA/ PSS will re-assign ownership to another PA/ PSS/ MA based on current work volume.



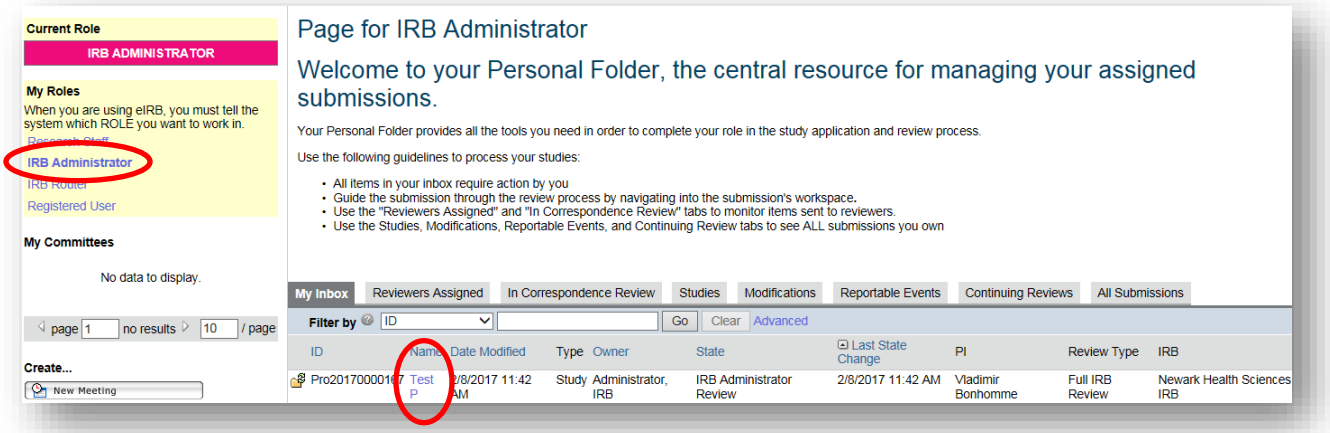
a. Click on IRB Studies
b. Sort by Owner or Filter by owner
c. Select study Name
d. Click Re-assign Owner in study workspace

3. IRBA (MA, PA, and PSS)



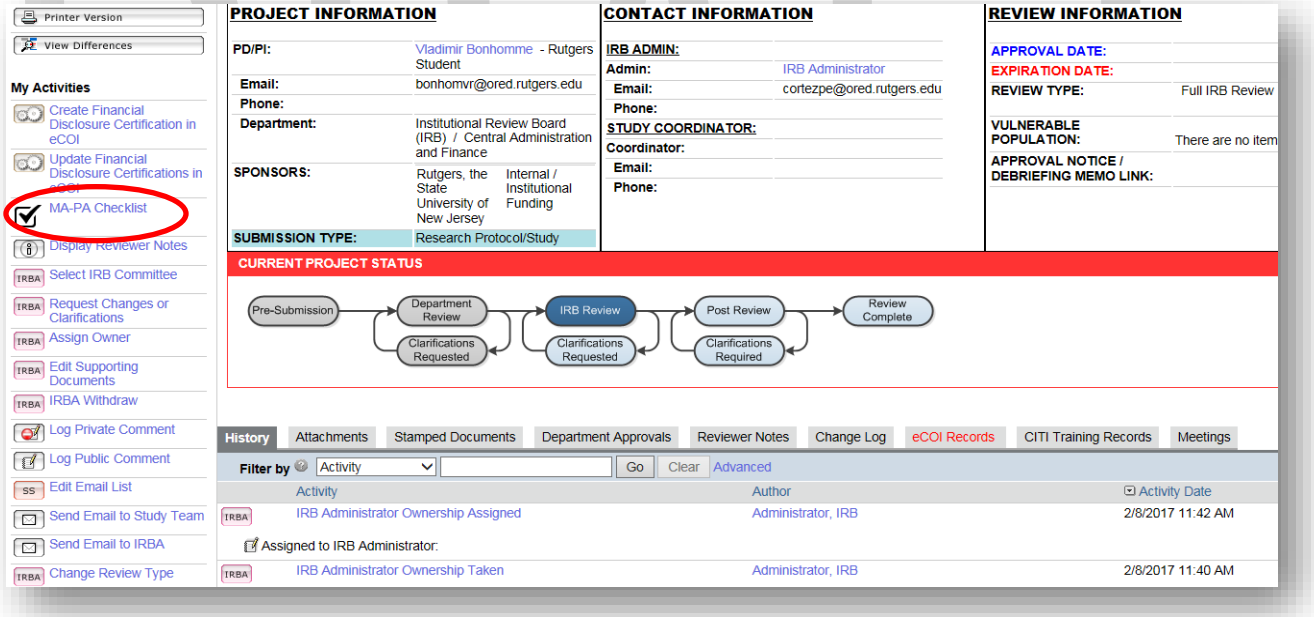
1. The IRBA will receive an email notification in Outlook after the Router assigns the submission. Click on the ID number to access the eIRB website.
2. Login to eIRB

3.1. Preliminary Administrative Review (PAR)



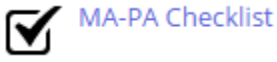
3.1.1. Select **IRB Administrator** under **My Roles** menu on the left navigation bar.

3.1.2. Click Name to access the submission workspace



3.1.3. Click **Display MA-PA Checklist** to view the MA findings.

3.1.4. Select **MA-PA Checklist** and perform a thorough PAR check in accordance with the PAR policy and procedures:



3.1.5. Click **View Study/ Edit Study** to conduct a PAR of the application by cross-referencing with the PAR checklist. Add notes on each page and identify the specific section(s) in the note.

3.1.6. Click the **Attachments** tab or **Edit Supporting Documents** to pre-review protocol, consent, and other research documents

3.1.6.1. Download documents to your computer.

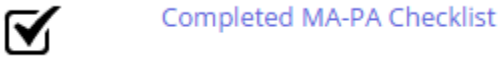
3.1.6.2. Add notes, comments, and suggestions in track changes. Save revised document on your computer.

3.1.6.3. Track Changes function is not available in the Pre-submission state, i.e. before the research staff submits the application for department review. Track changes is programmed to initiate tracking in WORD documents after the department approves the study and it is submited to the IRB

3.1.7. If the PAR finds that the submission requires substantive revisions before it can move forward to the CM, then click **Request Changes or Clarifications** to send application back to the investigator.

3.1.8. If the PAR finds that the submission requires minor revisions, then it can move forward to the CM.

3.1.9. Once the PAR Checklist is complete it will appear in the history of the study workspace as displayed below:



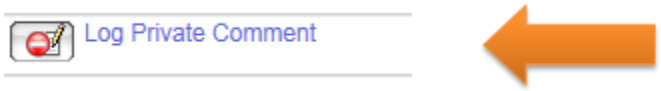
NOTE! Perform a thorough PAR in accordance with the PAR policy and procedures for all submission types. IRBA is encouraged to use his/ her discretion/ judgment in requesting additional section 1 items from the principal investigator even if those items are not among the orange section in the PAR checklist. For example, recruitment flyer.

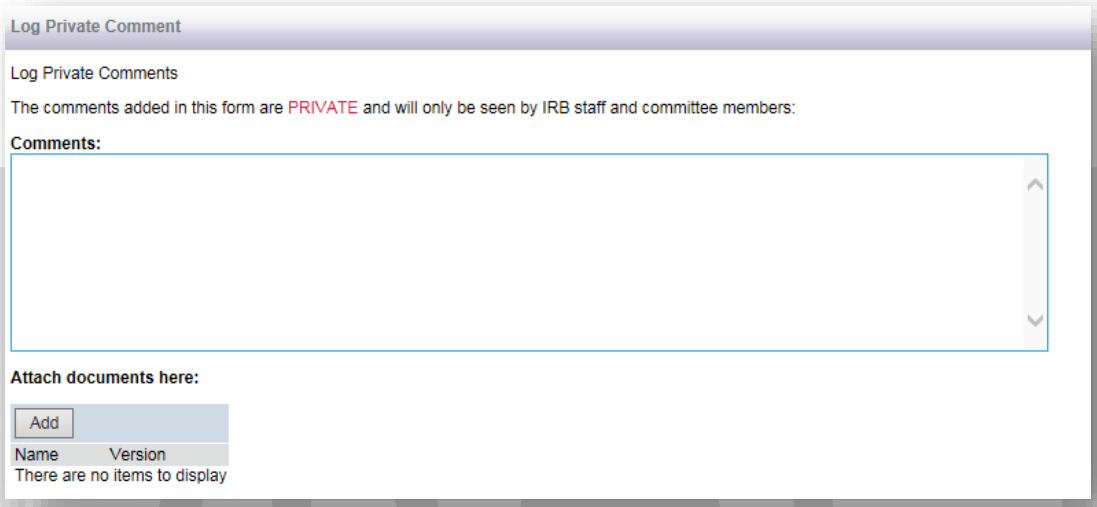
The department PA/PSS will reassign ownership of the new study submission to the full IRB team PA/PSS after the PAR checklist activity is completed, the principal investigator has responds to PAR section 1 items, and full IRB review is verified.

3.2 Change Review Type activity (Expedited to Exempt)

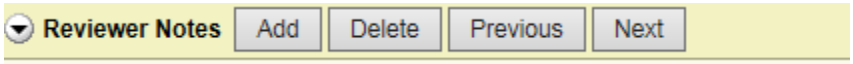
3.2.1. Send an Outlook email to the Assistant Director requesting confirmation of the change in review type

3.2.2. Complete the **Log Private Comment** activity specifying change in review type from Expedited to Exempt. Click **Add** in **Log Private Comment** activity window to attach the email confirmation and then click **OK**



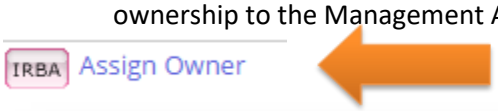


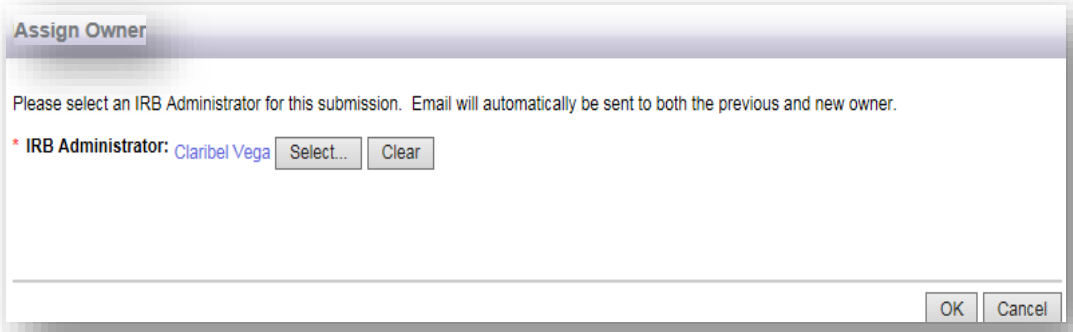
3.2.3. Navigate to page **1.5 Review Type** (page **1.4 Review Type** for studies 2017 and on) be in the new study submission and then add a note to request the PI change the review type to Exempt. Refer to the Standard Language Document for appropriate language



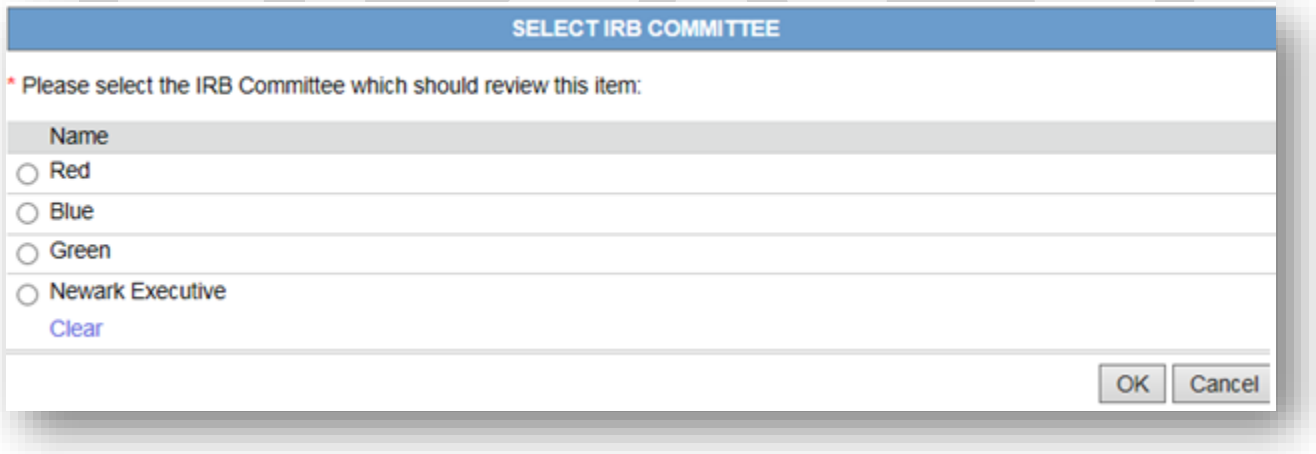
1.5 Review Type

3.2.4. Complete **Re-assign Owner** activity after the PI makes all applicable changes to assign ownership to the Management Assistant processing Exempt submissions





3.3. Committee Assignment

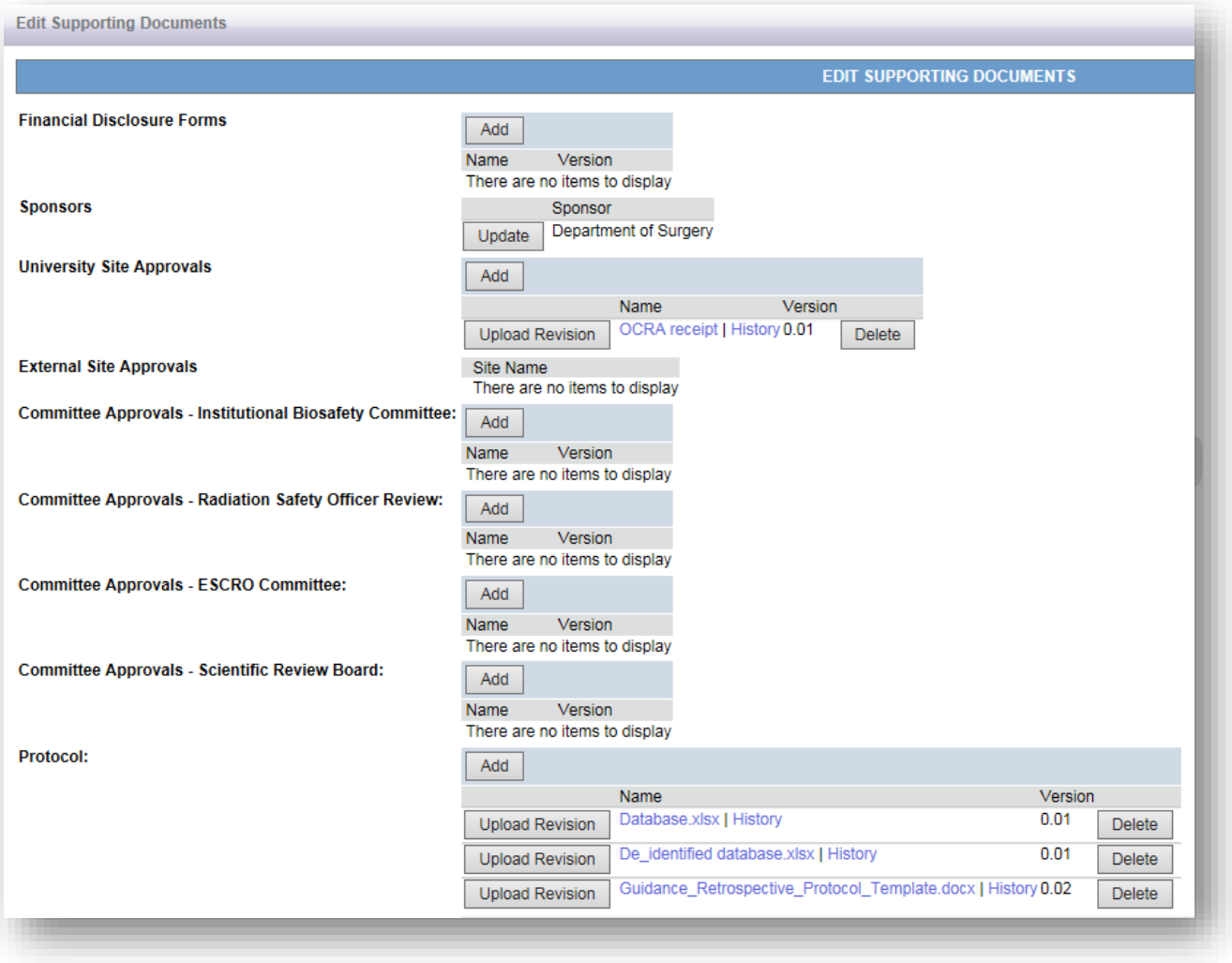


3.3.1. Click **Select IRB Committee** under the **My Activities** menu in the left navigation bar in the study workspace

3.3.2. Select your assigned IRB team name

3.3.3. Click OK

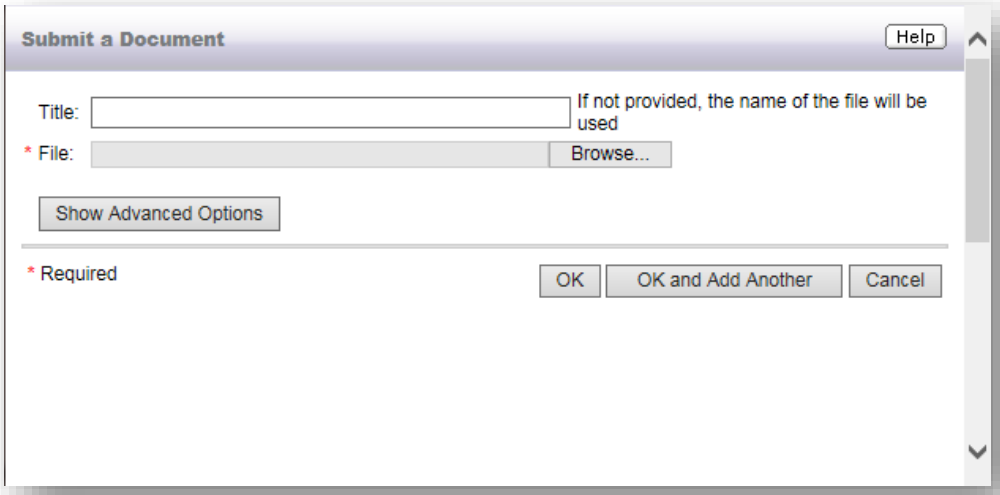
3.4. Edit Supporting Documents



The IRBA Edit Supporting Documents activity allows the IRBA to Add or Upload Revision for study documents listed under the **Attachments** tab.

This activity is useful when the investigator and/ or IRBA make changes to study documents and a previous version of the document needs to be replaced by the current version.

3.4.1. New Study



The IRBA edits a study document with track changes and/ or comments and saves it on her/ his computer.

3.4.1.1. Click **Edit Supporting Documents** activity in the new study workspace
3.4.1.2. Locate the applicable section, i.e. **Draft Consent Forms** in the **Edit Supporting Documents** activity window shown above
3.4.1.3. Click **Add**
3.4.1.4. Click **Browse**
3.4.1.5. Click OK to return to the **Edit Supporting Documents** activity window
3.4.1.6. Click OK to return to the new study workspace

NOTE! Click **Edit Study** in the new study workspace to navigate to the page where the document was uploaded. Add a note on the page when offering a revised study document with track changes and/ or comments to the PI.

Here is suggested language for the note:

The IRB office revised the consent form on behalf of the PI. Please see the track changes and comments in the document titled "Adult_ICF_V1.0_IRB Office_Revised 12-5-2015." Please confirm the changes are acceptable.

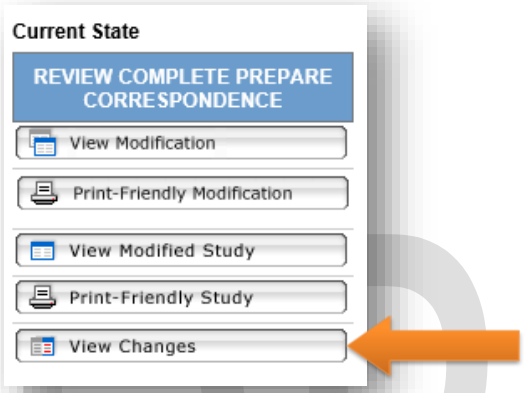
The IRB office revised the consent form on behalf of the PI. Please accept the track changes and respond to the comments in the document titled "Adult_ICF_V1.0_IRB Office_Revised 12-5-2015." Please upload a clean version of the revised document.

3.4.2. Modified Study

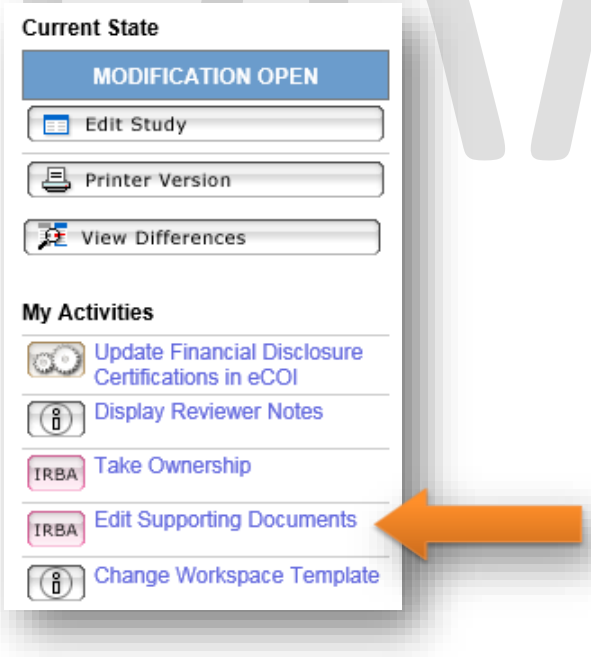
If you need to complete the **Edit Supporting Documents** activity for a Mod then those documents need to be added to the Mod.

To do this. You have to go to the Mod workspace.

Then click on the **View Changes** button

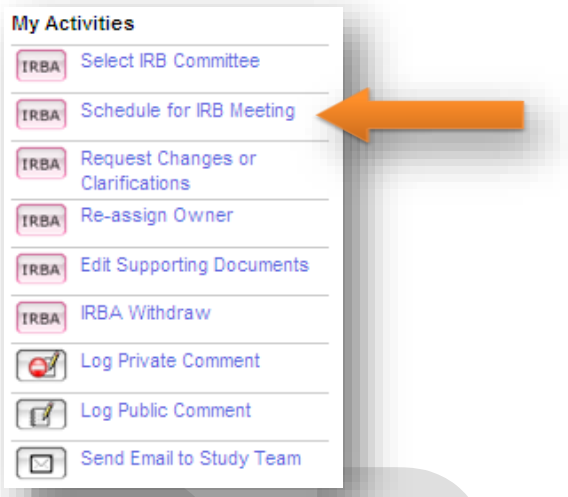


That will open up a new workspace , from there you will see the **Edit Supporting Documents** for that Mod:

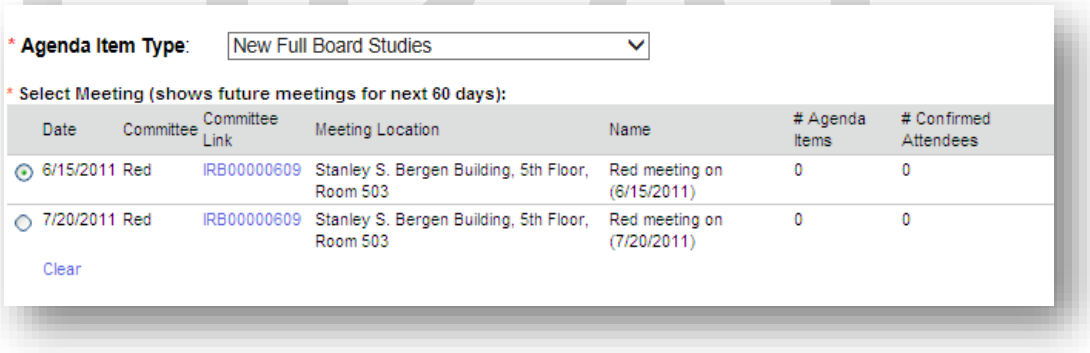


Upload them from there and you will then be able to stamp them from the Mod workspace.

3.5. Schedule for IRB Meeting (Full IRB Review only)



Click **Schedule for IRB Meeting** for full board study



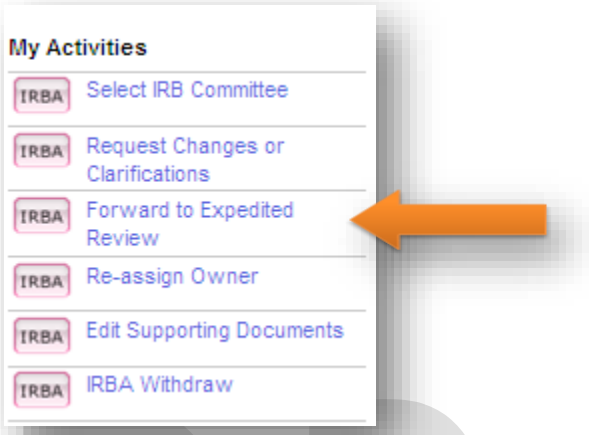
3.5.1. Select the **Agenda Item Type** from the drop down menu

3.5.2. Select the upcoming meeting date. Agenda Item Notes will appear on the meeting agenda

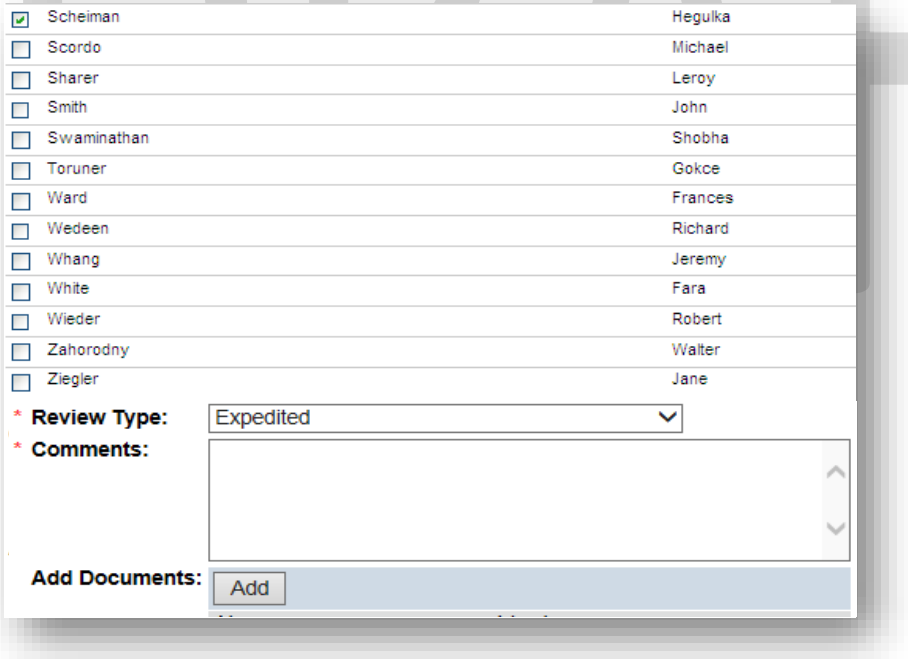
3.5.3. Click Ok

3.5.4. Click **Forward to Full Board Review** to assign a CM

3.6. Forward to Expedited Reviewer (Non-Human, Exempt, and Expedited)



Click **Forward to Expedited Reviewer** for all other review types



For full or expedited review, select CM from the list that appears after you click forward review activity

3.6.1. Select your CM
3.6.2. Click Add to upload any suggested revised documents with tracked changes
3.6.3. Enter any additional or clarifying comments in the space provided
3.6.4. Click Ok

3.7. Comment Box

When an item is being forwarded for review, the IRBA is to enter a comment within the comment box providing the reviewer with information regarding the administrative pre-review that has been conducted.

The language used must be similar to the following statements in the comment box to alert the CM of your preliminary administrative review (PAR) findings:

1. A preliminary administrative review (PAR) was completed; no findings to display.
2. Click the "Display Reviewer Notes" activity to access the preliminary administrative review (PAR) findings.
3. Click the "Display Reviewer Notes" activity to access the preliminary administrative review (PAR) findings. A response to the following PAR findings is pending: {list page number(s) and heading}
4. Click the "Display Reviewer Notes" activity to access the preliminary administrative review (PAR) findings and response from the principal investigator (PI).
5. Click the "Display Reviewer Notes" activity to access the preliminary administrative review (PAR) findings and response from the principal investigator (PI). A response to the following PAR findings is still pending: {list page number(s) and heading}

Full IRB Review

Add the following text before the PAR findings statements listed above for full IRB review submissions:

"A [new study/ modification/ continuing review/ reportable event/ final report/ acknowledgment request] has been assigned to you for Full IRB review. Kindly complete the checklist(s) and then submit your review by 12:30 P.M. on [insert meeting date]."

Continuing Review

In addition to the PAR findings statments listed above, use the comment box to list the expedited review category, funding information (if applicable), vulnerable population code(s), linked modification, and other supplemental information that the IRBA deems appropriate and necessary for the CM to complete the review and applicable checklists.

Modification/ Reportable Event

In addition to the PAR findings statement listed above, use the comment box to provide recommendation for approval based on PAR findings, e.g. approved with stipulations and other supplemental information the IRBA deems appropriate and necessary for the CM to complete the review and applicable checklists.

Once the comments are entered and the submission is forwarded for review, the comments entered appear under the History tab in the submission workspace (except for Full IRB review CR submission type).

3.7.1. Follow-up with Committee Members (CM)

The IRBA will receive an email if the CM **Acknowledges** or **Defers** the review assignment.

The IRBA will re-assign review if the CM has not acknowledged review by the morning of the 4th business day. To reassign a study, click the **Manage Reviewers** activity under **My Activities**. Choose another reviewer.

NOTE! Click the **Remove** button to remove the initial CM and then click the **Add** button to select the backup CM.

Expedited

If the CM **Acknowledges** the review assignment, then s/he has 10 business days from date acknowledged to complete the checklist(s) and submit review

Full IRB

The CM has until the day of the full IRB meeting to complete the checklist(s) and submit review

NOTE! IRBA will send an email (Outlook or **Send Email to Reviewer** activity) to the CM(s) the morning of the full IRB meeting if the review has not been submitted.

4. IRB Full Board Meeting

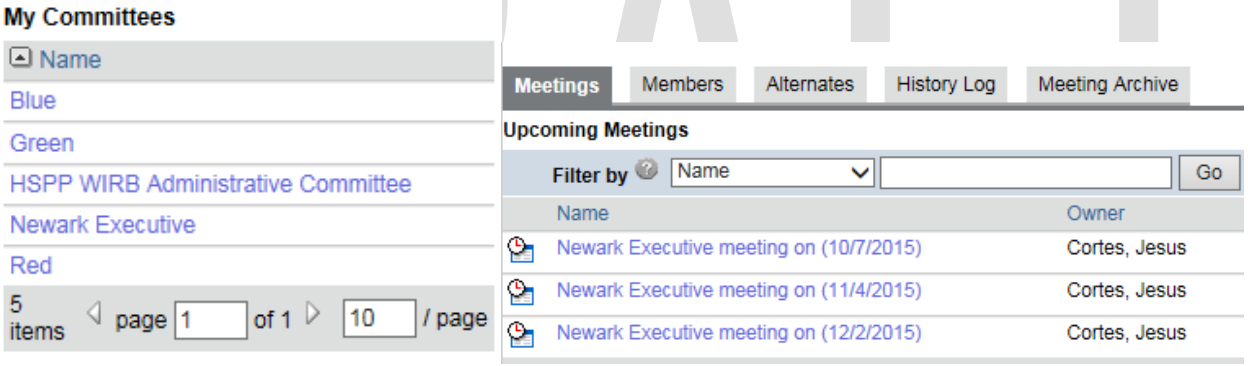
The meeting schedule and submission deadlines are available under HealthSci Newark at https://orra.rutgers.edu/deadlines

The pre-meeting and pos-meeting checklists are available in S:\2018\Newark IRB SOP\Full Board Meeting SOP

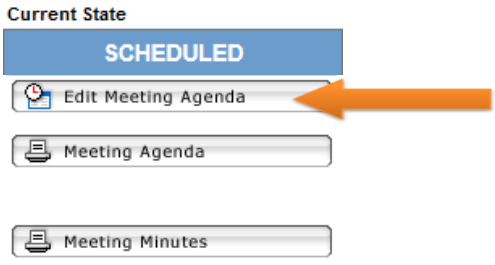
Full board paper submissions will be added on to the electronic agenda.

The MA processing the FB submission will scan a PDF version of the submission onto a newly created Full Board Meeting folder (Team specific) on the J-Drive. The original paper application will be placed in the protocol file and the copy paper application will be placed in the IRBA's inbox. The Full Board Meeting folder will remain on the J-Drive until the Thursday following the Full Board Meeting, and then the folder will be deleted.

4.1. Before the full board meeting



4.1.1. Navigate to your welcome page
4.1.2. Click Committee Name hyperlink as shown above
4.1.3. Click Meeting Name hyperlink as shown above
4.1.4. Click Take Ownership activity in the meeting workspace
4.1.5. Complete Poll for Attendance and Poll for Attendance Alternates activities



4.1.6. Click **Edit Meeting Agenda** button
4.1.7. Click **Continue** to proceed
4.1.8. Add any announcements

4.1.9. Add education item attachment and/ or URL

4.1.10. Add paper submissions that have been scanned onto the J-Drive for that Team's meeting

4.1.11. Attach electronic/paper minutes (PDF format)

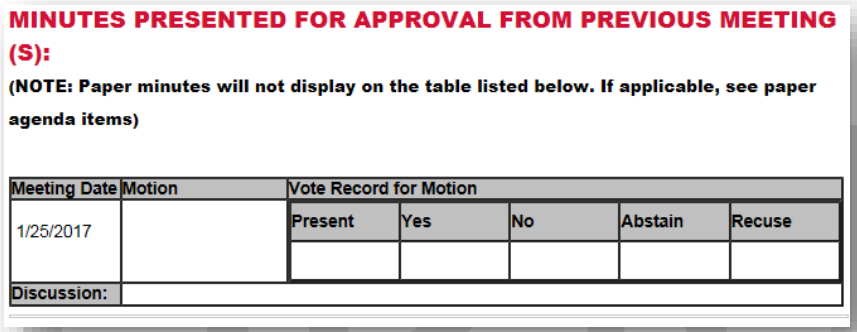
4.1.12. Include any new business

4.1.13. If there are any additional discussion items, it can be added on the 'additional discussion items' page

4.1.14. Save entries and then click Exit to return to the Agenda workspace

4.1.15. Click 

to open the print view version of the agenda



MINUTES PRESENTED FOR APPROVAL FROM PREVIOUS MEETING (S):

(NOTE: Paper minutes will not display on the table listed below. If applicable, see paper agenda items)

Meeting Date	Motion	Vote Record for Motion				
		Present	Yes	No	Abstain	Recuse
1/25/2017						
Discussion:						

4.1.16. Navigate to the meeting workspace if the **Link to Minutes** hyperlink is not visible under the previous meeting date as shown above

4.1.17. Click on the' Edit Meeting Agenda' button

4.1.18. Navigate to "Prepare Past Meeting Minutes" page

4.1.19. Click on the 'Delete' option for the past meeting minutes that are not being displayed properly

4.1.20. Click on the 'Add' option to "re-add" the appropriate meeting minutes

4.1.21. Save and Exit

4.1.22. Click on the 'Print Agenda' button

4.1.23. This will refresh the link between the two items.

4.1.24. IRBA (PA/ PSS) assigns reviewers

4.1.25. Once members have confirmed attendance, they will have access to the agenda

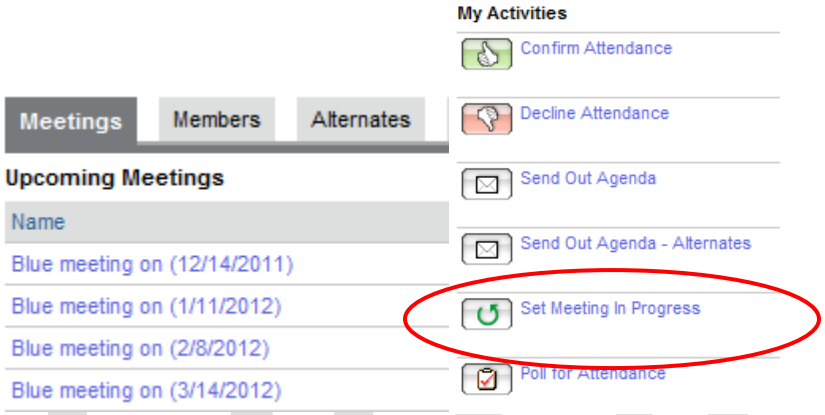
4.1.26. IRBA sends agenda to confirmed attendees

4.1.27. IRBA will send the PAR/ review submitted email to the IRB Chair, cc'ing AMA, IRBD, and IRBAD in accordance with the Task Timeline, unless otherwise specified by the IRB Chair, e.g. Monday/ Tuesday before the meeting. Refer to J:\2015\Newark IRB SOP\Full Board Meeting SOP for sample email

4.2. During the full board meeting

The Chair/ Vice Chair will call the meeting to order

If two IRBAs coordinate a meeting, then two laptops will be connected to the projector (*computer 1* and *computer 2*). Each IRBA is responsible to navigate their submission workspace as it is projected overhead. Press the *Source Search* button on the projector to switch between laptops. Press Ctrl +/- to adjust the font size projected overhead. IRBA will inform the Chair before switching between laptops.



4.2.1. IRBA will ask members to sign into eIRB and direct the committee members to the agenda

4.2.2. IRBA will make the following announcement before quorum is achieved

- If you have not confirmed your attendance in eIRB, please take a moment to do that now in order to have an accurate count for the minutes
- Direct the members to the left side of the screen under to confirm attendance under **My Activities**

4.2.3 IRBA will set meeting in progress in the meeting workspace

4.2.4 IRBA will display agenda on overhead screen in **print** version

4.2.3. Instruct committee members to navigate between agenda and other screens by placing cursor over the internet explorer “e” icon at the bottom of the task bar and then select desired screen

4.2.4. If quorum for previous meeting minutes has not been met after call to order, then IRBA will recommend to the Chair/ Vice Chair to defer the previous meeting minutes for email vote

4.2.5. IRBA will move through agenda items

- Take notes and document meeting as usual
- Stop periodically to make sure all members are on the same screen

4.2.6. IRBA will set meeting in progress for each submission before discussion starts and then display application on overhead screen in view study version

4.2.7. The IRBA will make the following announcement after the reviewer completes his/her presentation

- If you have not submitted your review prior to the meeting, then please do so before you exit eIRB, by clicking "Submit Review" (no further actions, such as

minutes, debriefing memos, approvals, can take place without your submitted review)

- Advise members if they need help submitting their review at the meeting, then another IRBA will be around to assist them

4.2.8. IRBA navigates through application as reviewer(s) discuss application and as requested by Chair/other members present at the meeting

4.2.9. Chair will move to close the meeting

4.2.10. IRBA will end the meeting by double checking that all reviewers have submitted their review in eIRB before the Chair ends the meeting

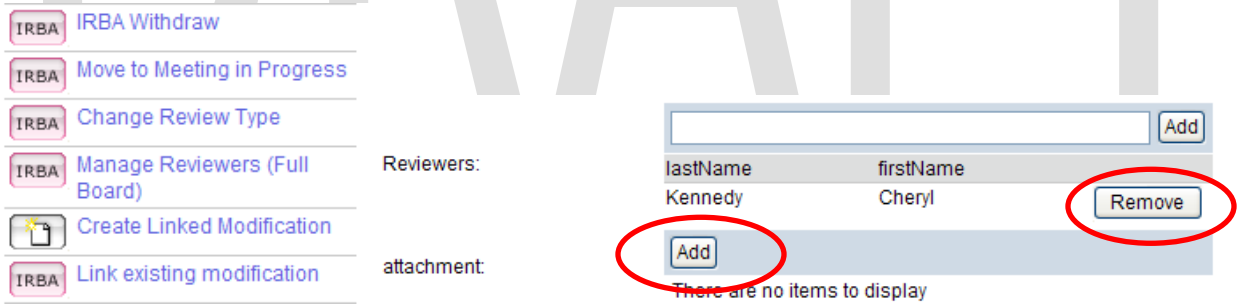
- Advise members if they need help submitting their review at the meeting, then another IRBA will be around to assist them

4.2.11. IRBA will ensure the draft minutes are saved on the laptop and then added to the meeting workspace. Verify draft minutes are uploaded under the History Log in the meeting workspace

4.2.12. IRBA instruct committee members to log out of eIRB and then shut down laptops before leaving the conference room

4.3. After the full board meeting

If a committee member with an assigned full board review does not attend the meeting nor submit his/her review in eIRB prior to the meeting, then do the following after the meeting is adjourned, but before the Chair/ Vice Chair departs:



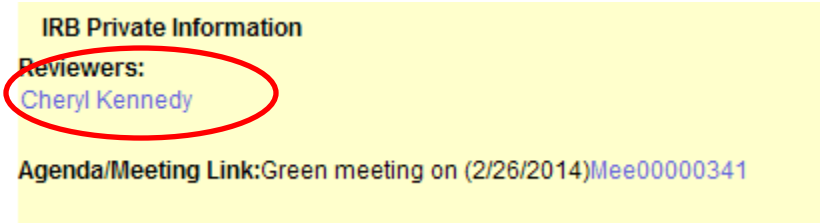
4.3.1. Navigate to the submission workspace

4.3.2. Click Manage Reviewers (Full Board) under the My Activities menu as shown above

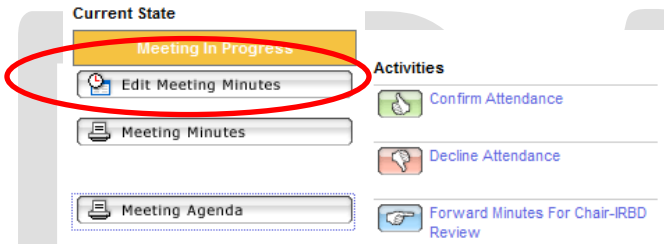
4.3.3. Click the **Remove** button as shown above to delete the assigned but absent CM

4.3.4. Click the **Add** button as shown above to reassign the action to the Chair

4.3.5. Click Ok to finalize the reassignment



4.3.6. Verify in the action workspace that the Chair is listed under Reviewers as shown above
4.3.7. Sit with the Chair to complete all applicable checklists and submit review for the specific action
4.3.8. The submitted review must coincide with the motion made at the meeting
  4.3.8.1. For new study submission: if one of the assigned CM is absent and did not submit his/her review in eIRB, then follow the steps above to reassign review to the Chair after the meeting is adjourned, but before the Chair departs
  4.3.8.2. For initial protocol submission: If both committee members assigned to a full board initial review do not attend the meeting nor submit their review in eIRB prior to the meeting, then Chair is advised to defer the protocol to the next full board meeting
4.3.9. For all other actions (e.g. CR, MOD, RE): if the assigned committee member is absent and did not submit his/her review in eIRB, then follow the steps above to reassign review to the Chair after the meeting is adjourned, but before the Chair departs
4.3.10. Edit Meeting Minutes



  4.3.10.1. IRBA will click **Edit Meeting Minutes** to enter vote counts for paper and electronic agenda items, ensure quorum count and meeting attendance is accurate, and prepare action letters for paper and electronic agenda items
  4.3.10.2. When responsibility for meeting minutes is shared, each IRBA will assume ownership for the studies for which minutes will be generated by IRBA.
  4.3.10.3. Navigate to the study workspace and click the “Take Ownership” button to reassign ownership of the study for which you will generate minutes.
  4.3.10.4. IRBA will convert paper minutes (if applicable) to PDF. Move the PDF minutes to the “Other Discussion Items” section of the corresponding eIRB minutes. Navigate to the meeting workspace, click ‘Edit Meeting Minutes”, jump to “Record Other Business” and then click “Add” to upload the PDF minutes. Naming convention is “[Team] IRB meeting minutes [meeting date]”. For example, **Blue Team IRB meeting minutes 5-9-2012**.
4.3.11. IRBA will **forward minutes** in eIRB to the IRB Chair (upon request), IRBD, or IRBAD for review
4.3.12. IRBD/ IRBAD will Request Changes or Accept as submitted through eIRB
4.3.13. IRBA will make changes and then click "Release for committee review"
4.3.14. The minutes will be placed on the next team agenda for review and approval the full board meeting

Collection and Documentation of Electronic Approval of Meeting Minutes

When the IRB Chair defers the approval of IRB minutes to electronic vote due to lack of quorum, the IRB will:

1. Send an email via Outlook with a PDF attachment of the minutes to all team specific IRB committee members on the roster (attending and non-attending). The following language must be included in the body of the email:

Good Afternoon IRB Committee Members,

Please review the attached minutes for the August 17, 2016 Red Team IRB Meeting. The minutes were reviewed at the Red Team IRB meeting on September 18, 2016, but were deferred by the Chair due to lack of quorum.

Please REPLY to this email with your vote of approval, disapproval, or abstention.

PLEASE: Select 'Abstain' if you were not in attendance for the August 17, 2016 Red Team IRB Meeting.

****

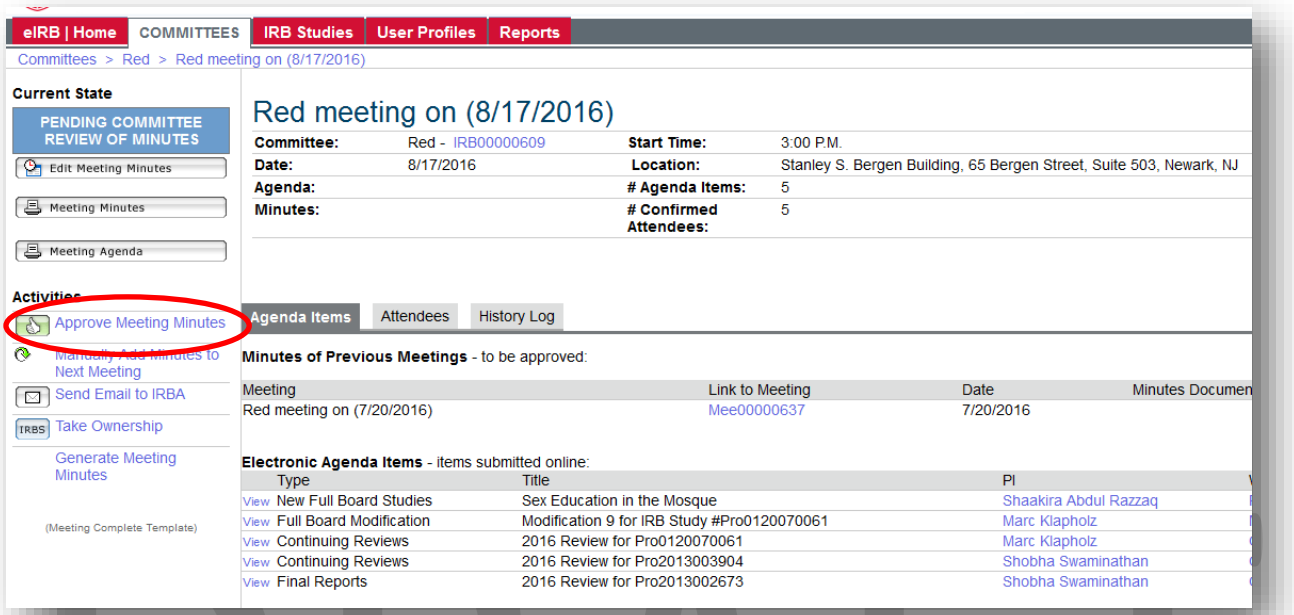
_____ Approval

_____ Disapproval

_____ Abstain (Not in Attendance)

Thank you for your prompt attention and cooperation.
Sincerely,
IRBA

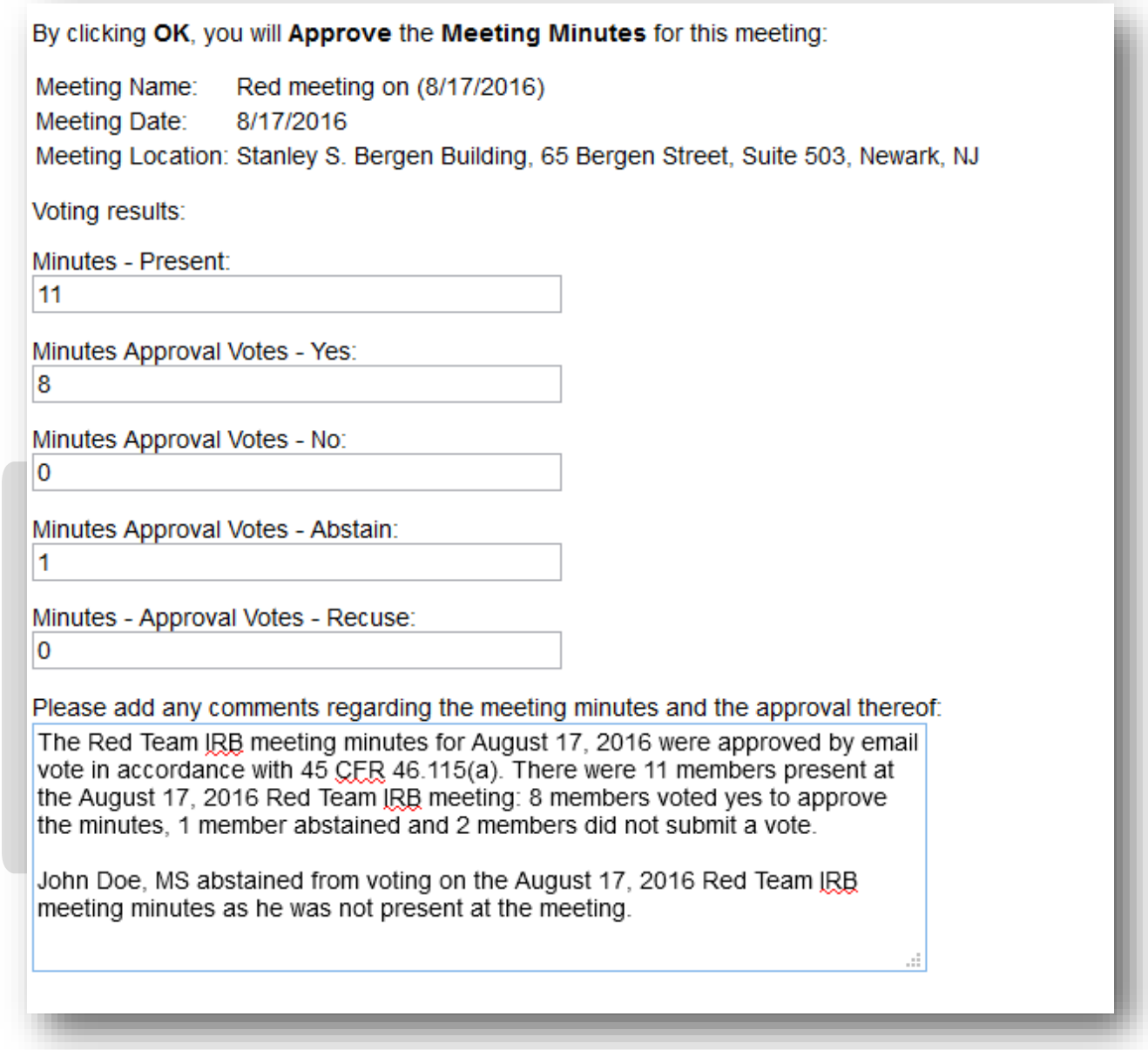
2. Record the incoming votes from the committee until the desired number of approvals are obtained. The IRBA will remind members not in attendance to enter their vote as an abstention, as needed.
3. Navigate to the eIRB meeting workspace for the meeting for which minutes were electronically approved.



4. Click on **Approve Meeting Minutes** and enter the number of committee members present at the meeting of the deferred minutes, the number of 'Yes' votes, the number of 'No' votes, the number of abstentions and the number of recusals.
5. Use the comment box to describe the vote as follows:
   The Red Team IRB meeting minutes for August 17, 2016 were approved by email vote in accordance with 45 CFR 46.115(a). There were 11 members present at the August 17, 2016 Red Team IRB meeting: 8 members voted yes to approve the minutes, 1 member abstained and 2 members did not submit a vote.

   John Doe, MS abstained from voting on the August 17, 2016 Red Team IRB meeting minutes as he was not present at the meeting.

The members who abstained must be mentioned by name and credentials.



6. Click **Ok**.

The electronically approved minutes will appear under the **History Log** tab for that meeting.

Electronically approved minutes must be announced by the IRB Chair at the next convened meeting for that team.

The IRBA conducting the next meeting will add the following language to the **New Business** section of the agenda:

Minutes for the August 17, 2016 Red Team IRB meeting were approved via electronic vote on 1/20/2017.

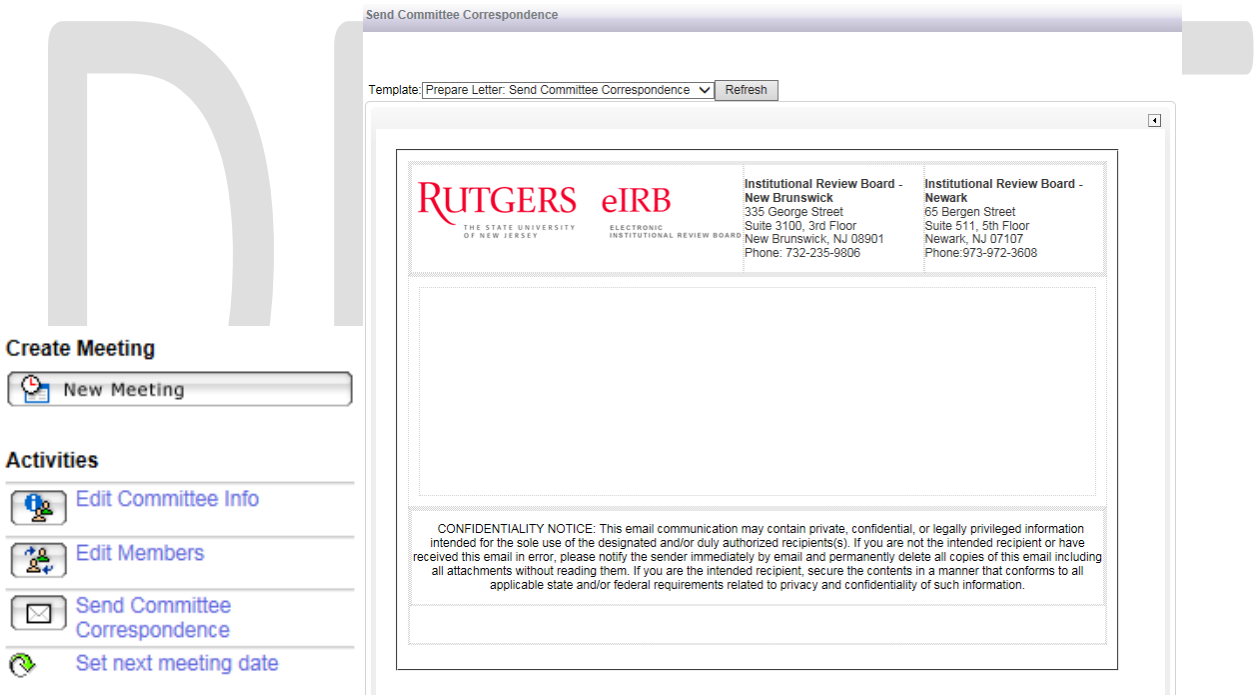
The Red Team IRB meeting minutes for August 17, 2016 were approved by email vote in accordance with 45 CFR 46.115(a). There were 11 members present at the August 17, 2016 Red Team IRB meeting: 8 members voted yes to approve the minutes, 1 member abstained and 2 members did not submit a vote.

John Doe, MS abstained from voting on the August 17, 2016 Red Team IRB meeting minutes as he was not present at the meeting.

This coincides with the *Draft Meeting Minutes* template.

4.4. Full Board Meeting is cancelled

IRBA will navigate to his/her assigned committee workspace and then click the **Send Committee Correspondence** activity to notify the IRB members that a specific meeting is canceled. Please select the users that will receive emails after entering applicable text in the template.



IRBA will send an email to IST (eIRB Help Desk), cc'ing IRBAD and IRBD in Outlook informing them of the cancelled meeting , request that they remove the meeting from eIRB and any Exempt/Expedited Report items be moved to the next scheduled committee meeting for that team.

If there are any submissions scheduled for/ assigned to the cancelled meeting, the IRBAD or IRBD will direct the IRBA to re-assign ownership of those submissions to the IRBA of the upcoming scheduled meeting. The IRBA of the cancelled meeting will navigate to each submission workspace and then take the following steps:

1. Remove from Agenda
2. Re-assign Owner

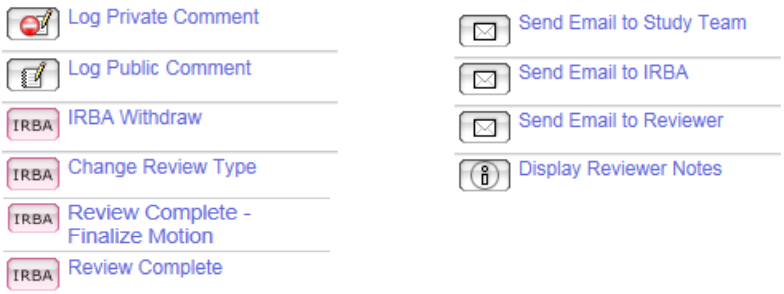
3. **Log Private Comment** (indicate why the above listed activities were completed, e.g. the [Blue/ Red/ Green/ Executive] team committee meeting was cancelled due to lack of quorum or submissions; this [Mod/ CR/ Study/ RE] is being moved to the upcoming [Blue/ Red/ Green/ Executive] team committee meeting)

5. Processing Submitted Reviews

IRBA will receive a **Rutgers University eIRB: Submit Review Activity** email indicating that a review has been submitted

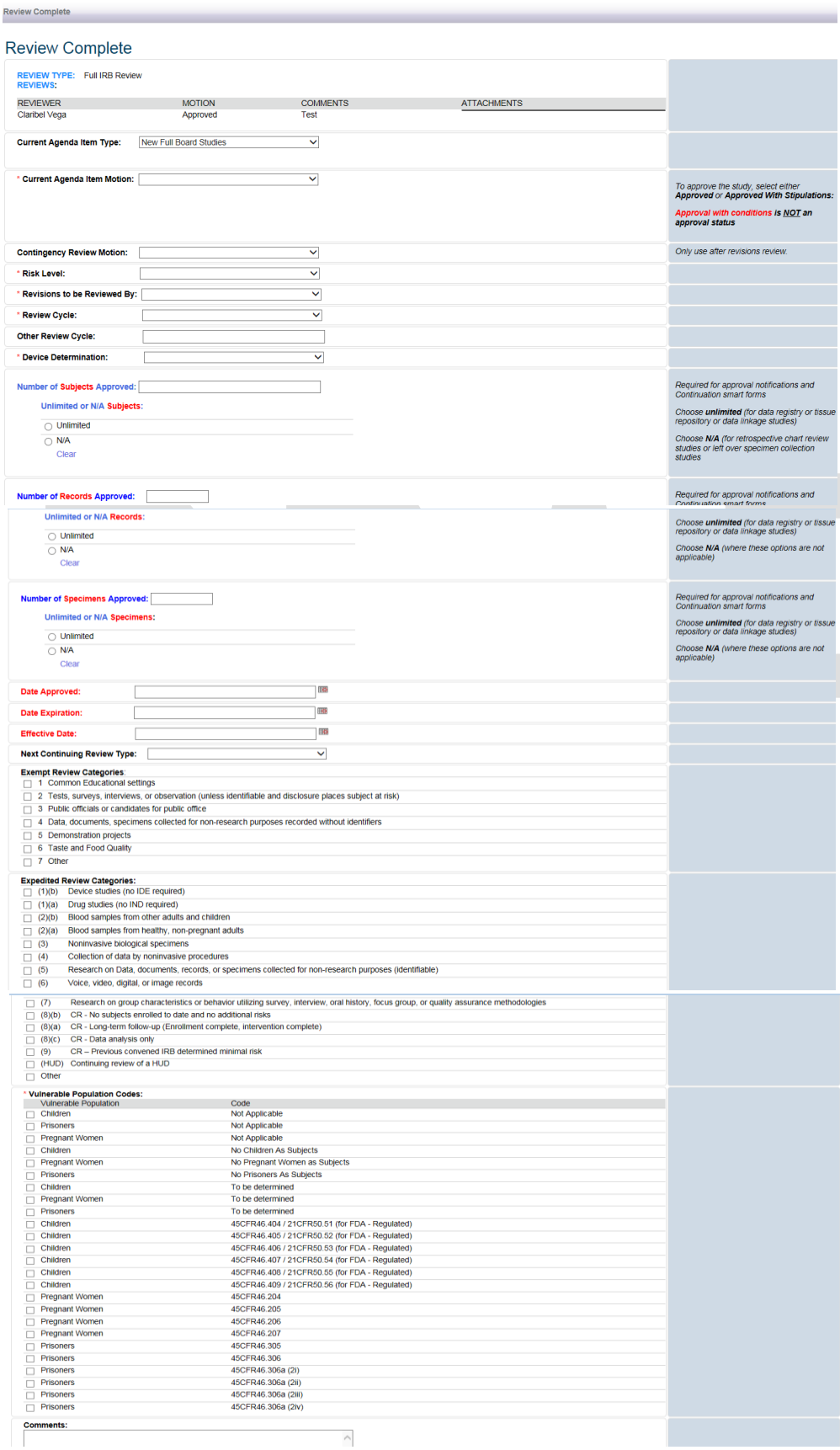
- Click on the ID number in the email to access the submission
- Login to eIRB
- Navigate to the submission workspace
- Click on the **Designated Review Submitted** hyperlink under the **History** tab shown above
- Click on the **Reviewer Notes** tab shown above.
- Complete **Display Reviewer Notes** activity

NOTE! IRBA will read the contents of each CM activity hyperlink for comments and consistency.



Once the CM has completed the **Designated Submit Review** activity, he/she is unable to make changes in the **Submit Review** activity window; the CM can complete the **Send Email to IRBA** activity or **Log Private Comment** activity shown above to alert the IRBA to make any changes; the IRBA will make the change on behalf of the CM using the **Review Complete** activity shown above.

The IRBA will process the submitted review as follows when review motion is **Approved**:



Review Complete

Review Complete

REVIEW TYPE: Full IRB Review
REVIEWS:

REVIEWER	MOTION	COMMENTS	ATTACHMENTS
Claribel Vega	Approved	Test	

Current Agenda Item Type: New Full Board Studies

*** Current Agenda Item Motion:**

*To approve the study, select either **Approved** or **Approved With Stipulations:***

***Approval with conditions** is **NOT** an approval status*

Contingency Review Motion: *Only use after revisions review.*

*** Risk Level:**

*** Revisions to be Reviewed By:**

*** Review Cycle:**

Other Review Cycle:

*** Device Determination:**

Number of Subjects Approved: *Required for approval notifications and Continuation smart forms*

Unlimited or N/A Subjects:

- ○ Unlimited
- ○ N/A

Clear

*Choose **unlimited** (for data registry or tissue repository or data linkage studies)*

*Choose **N/A** (for retrospective chart review studies or left over specimen collection studies*

Number of Records Approved: *Required for approval notifications and Continuation smart forms*

Unlimited or N/A Records:

- ○ Unlimited
- ○ N/A

Clear

*Choose **unlimited** (for data registry or tissue repository or data linkage studies)*

*Choose **N/A** (where these options are not applicable)*

Number of Specimens Approved: *Required for approval notifications and Continuation smart forms*

Unlimited or N/A Specimens:

- ○ Unlimited
- ○ N/A

Clear

*Choose **unlimited** (for data registry or tissue repository or data linkage studies)*

*Choose **N/A** (where these options are not applicable)*

Date Approved:

Date Expiration:

Effective Date:

Next Continuing Review Type:

Exempt Review Categories:

- ☐ 1 Common Educational settings
- ☐ 2 Tests, surveys, interviews, or observation (unless identifiable and disclosure places subject at risk)
- ☐ 3 Public officials or candidates for public office
- ☐ 4 Data, documents, specimens collected for non-research purposes recorded without identifiers
- ☐ 5 Demonstration projects
- ☐ 6 Taste and Food Quality
- ☐ 7 Other

Expedited Review Categories:

- ☐ (1)(b) Device studies (no IDE required)
- ☐ (1)(a) Drug studies (no IND required)
- ☐ (2)(b) Blood samples from other adults and children
- ☐ (2)(a) Blood samples from healthy, non-pregnant adults
- ☐ (3) Noninvasive biological specimens
- ☐ (4) Collection of data by noninvasive procedures
- ☐ (5) Research on Data, documents, records, or specimens collected for non-research purposes (identifiable)
- ☐ (6) Voice, video, digital, or image records
- ☐ (7) Research on group characteristics or behavior utilizing survey, interview, oral history, focus group, or quality assurance methodologies
- ☐ (8)(b) CR - No subjects enrolled to date and no additional risks
- ☐ (8)(a) CR - Long-term follow-up (Enrollment complete, intervention complete)
- ☐ (8)(c) CR - Data analysis only
- ☐ (9) CR – Previous convened IRB determined minimal risk
- ☐ (HUD) Continuing review of a HUD
- ☐ Other

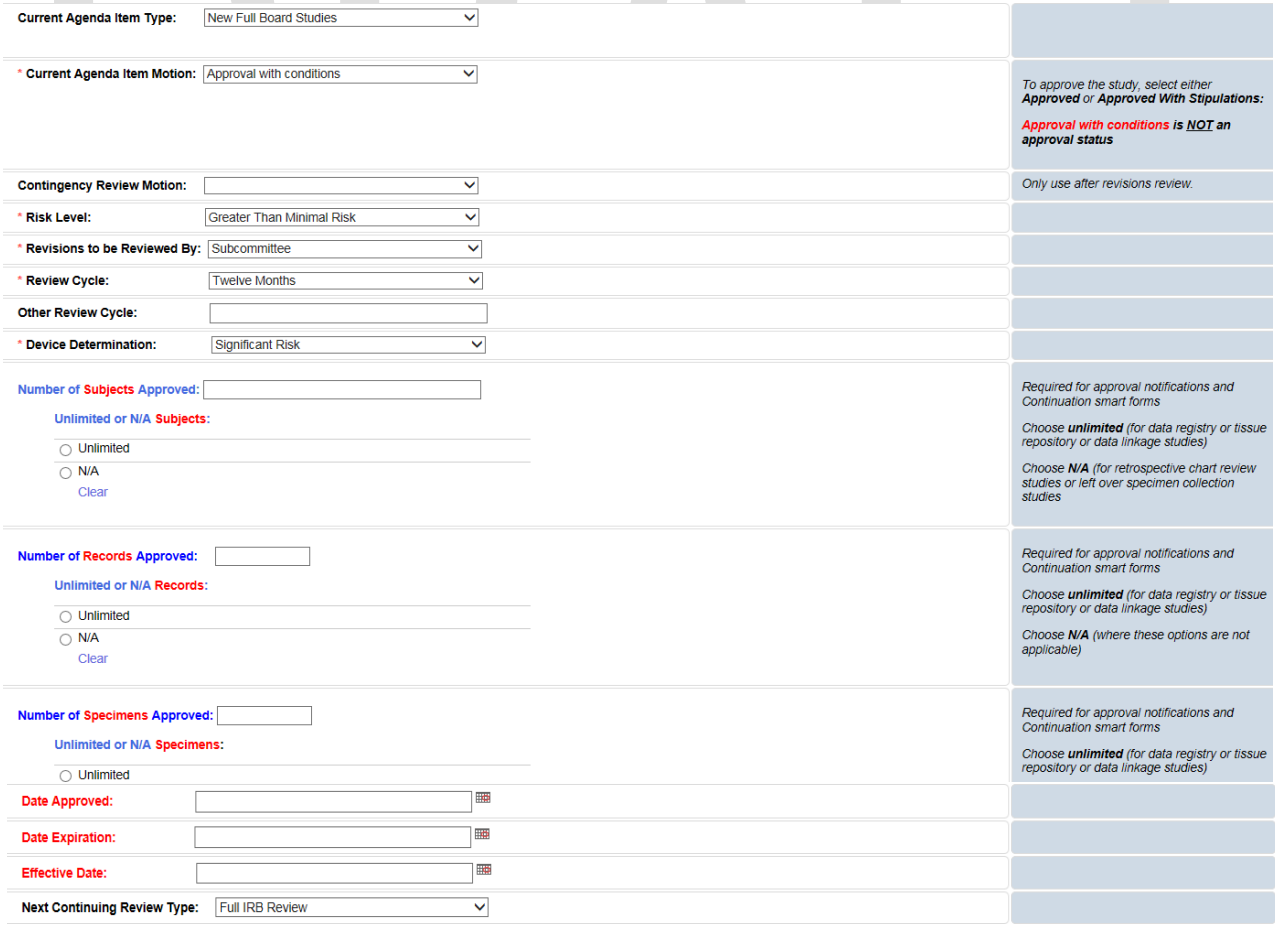
*** Vulnerable Population Codes:**

Vulnerable Population	Code
☐ Children	Not Applicable
☐ Prisoners	Not Applicable
☐ Pregnant Women	Not Applicable
☐ Children	No Children As Subjects
☐ Pregnant Women	No Pregnant Women as Subjects
☐ Prisoners	No Prisoners As Subjects
☐ Children	To be determined
☐ Pregnant Women	To be determined
☐ Prisoners	To be determined
☐ Children	45CFR46.404 / 21CFR50.51 (for FDA - Regulated)
☐ Children	45CFR46.405 / 21CFR50.52 (for FDA - Regulated)
☐ Children	45CFR46.406 / 21CFR50.53 (for FDA - Regulated)
☐ Children	45CFR46.407 / 21CFR50.54 (for FDA - Regulated)
☐ Children	45CFR46.408 / 21CFR50.55 (for FDA - Regulated)
☐ Children	45CFR46.409 / 21CFR50.56 (for FDA - Regulated)
☐ Pregnant Women	45CFR46.204
☐ Pregnant Women	45CFR46.205
☐ Pregnant Women	45CFR46.206
☐ Pregnant Women	45CFR46.207
☐ Prisoners	45CFR46.305
☐ Prisoners	45CFR46.306
☐ Prisoners	45CFR46.306a (2i)
☐ Prisoners	45CFR46.306a (2ii)
☐ Prisoners	45CFR46.306a (2iii)
☐ Prisoners	45CFR46.306a (2iv)

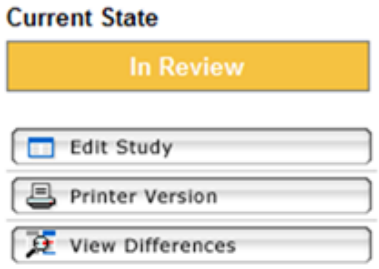
Comments:

- Complete **Display Reviewer Notes** activity
- Complete **Review Complete** activity
- Enter the applicable information in the **Review Complete** activity window shown above
- Complete **Stamp Supporting Documents** activity
- Check all the documents under the **Stamped Documents** tab to ensure the stamp is clear and current approval and expiration dates are listed
- If the stamp is obstructed partially or fully, then refer to the "eIRB how to stamp using PDF and JPEG" document in S:\2018\Newark IRB SOP\IRB Office Policy and Procedures\eIRB for instructions to stamp the document(s) outside of eIRB
- Complete **Edit Action Letter** activity
- Complete **Request Correspondence Review** activity
- Complete **Release Action Letter to Study Staff** activity after the IRBD confirms correspondence content

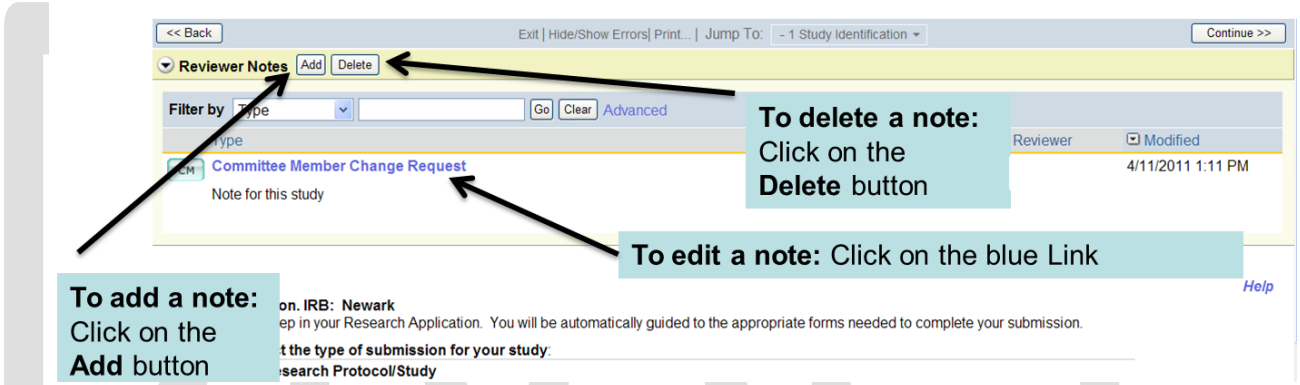
The IRBA will process the submitted review as follows when revew motion is **Approval with Conditions**:



- Complete **Display Reviewer Notes** activity
- Add all comments from the CM if applicable
- Complete **Review Complete** activity
- Enter the applicable information in the **Review Complete** activity window shown above
- Click on **Edit Study/ Edit Continuing Review/ Edit Modification** under **Current State**.



- Add notes on applicable pages in each submission (including **Modified Study** for a modification)

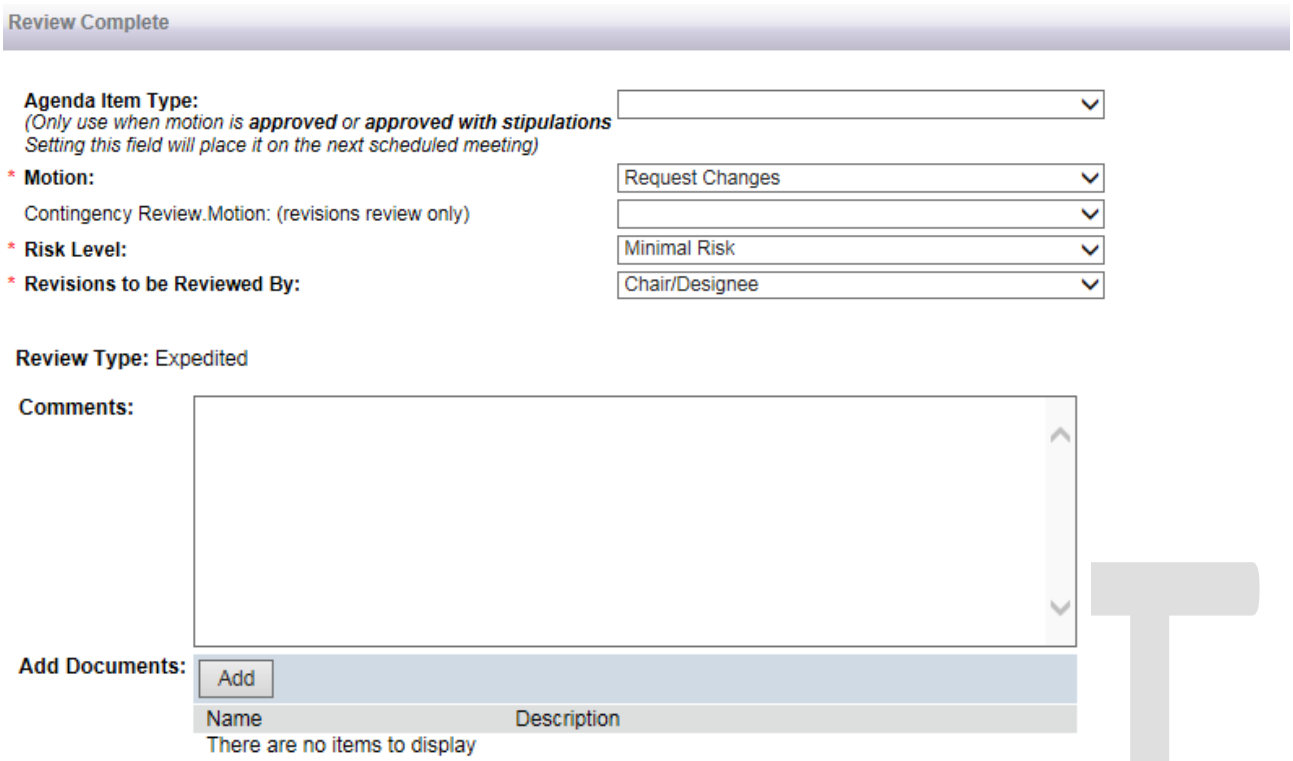


- Complete **Edit Action Letter** activity
- Complete **Request Correspondence Review** activity
- Complete **Release Action Letter to Study Staff** activity after the IRBD confirms correspondence content

5.1. Expedited Review only

If a CM submits a motion of **Approved**, but there are PAR findings that must be addressed, then the IRBA may select the motion **Request Changes** in the **Review Complete** activity window. This includes PAR findings identified prior to **Forward to Expdited Review** and/ or after **Submitted Review** activities.

If a CM submits a motion of **Approved**, but the IRBAD/ IRBD requires clarification/ additional information/ changes from the investigator after the IRBA completed **Request Correspondence Review** activity, then the IRBA may select the motion **Request Changes** in the **Review Complete** activity window.



The IRBA will request changes as follows:

5.1.1. Click **Review Complete** under **My Activities** menu
5.1.2. Select motion **Request Changes** in the **Review Complete** activity window shown above
5.1.3. Make applicable selections for required fields with a red *
5.1.4. Enter notes in the **Comments** box shown above indicating that the *PAR findings are pending and the approval will be processed after acceptable response from the PI is received*
5.1.5. Click Ok
5.1.6. Return to submission workspace
5.1.7. Click **Edit Study/ Continuing Review/ Modification** under **Current State** menu
5.1.8. Navigate to each page of the submission (including **Modified Study** for modification submisisons) to add notes (if not previously done)
5.1.9. Exit submission
5.1.10. Complete **Display Reviewer Notes** activity
5.1.11. Complete **Edit Action Letter** activity
5.1.12. Select **Determination notice (debriefing memo)** template
5.1.13. Verify that **Request Changes** is reflected in the **Submission Status** field in the determination notice
5.1.14. Remove cells that that contain *Not Applicable* and *There is no information to display*

5.1.15. Delete *The IRB considered your Initial Application and moved to issue an Approval with Conditions, pending re-review by the IRB and satisfactory resolution of the action item(s) below*

5.1.16. Delete the following cells:

Approval Date:			**Expiration Date:**		
Subjects:	0	**Specimens:**	0	**Records:**	
Committee:	Newark Executive	**Meeting/Determination Date:**	12/2/2015		

5.1.17. Delete *#6. Letter* Comments: There *are no additional comments*

5.1.18. Click OK

5.1.19. Click View Letter under the History tab

5.1.20. Complete **Request Correspondence Review** activity

5.1.21. Complete **Release Action Letter to Study Staff** activity after IRBD confirms correspondence content

5.2. Full IRB Review only

If the CM **review motion** is **Deferred** or if the IRB Vice/ Chair decides to **Defer** a submission:

5.2.1. Navigate to the submission workspace

5.2.2. Add CM and/ or IRBA notes on each applicable page in **View/ Edit Study/ Continuing Review/ Modification**

5.2.3. Click **Display Reviewer Notes** activity, click **OK** in the activity window

5.2.4. Navigate to the meeting workspace

5.2.5. Click **Edit Meeting Minutes**

5.2.6. Jump to page **Record/Review Agenda Items**

- 5.2.6.1. Click **Update**
- 5.2.6.2. Select **Yes** in response to **Item Processed (step1 & 2)?:**
- 5.2.6.3. Select **Deferred** for the applicable submission type
- 5.2.6.4. Complete all other fields in the **Update** window and then click **OK**

5.2.7. Navigate to the submission workspace

5.2.8. Click **Review Complete – Finalize Motion**, enter **Deferred** in the text box and then click **OK**

5.2.9. Click **Record Action Minutes-Edit Action Letter**, specify the reason the submission was deferred in the *Deferred action letter template*, verify the record action minutes information is accurate, and then click **OK**

5.2.10. Click **Request Correspondence Review**

5.2.11. Click **Release Action Letter to Study Staff** after IRBD/ IRBAD confirms content

5.2.12. Click the **Request Changes or Clarifications** activity to send the submission back to the study team

5.2.13. Re-assign ownership to the IRBA responsible for the future meeting.

5.2.14. Newly assigned IRBA will PAR the response fromPI. Follow PAR procedure.

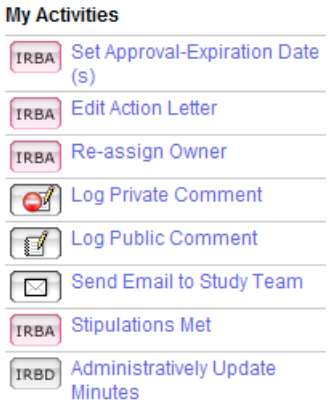
5.2.15. Select the committee that the submission will be deferred to.

5.2.16. Schedule submission for upcoming meeting.

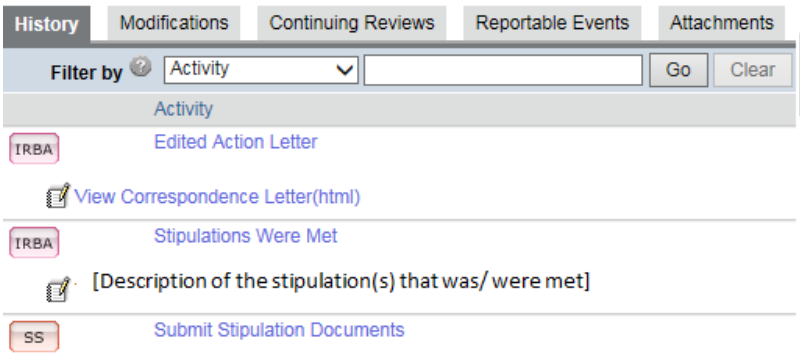
5.3. Expedited Review and Full IRB Review

If the full IRB or expedited CM **review motion** is **Approved with Stipulations**, then the submission will remain in the IRBA's inbox until the stipulations are met.

The **Submit Stipulations Documents** activity will appear under the investigator's **My Activities** menu in the submission workspace



The **Stipulations Met** activity will appear under the IRBA's **My Activities** menu in the submission workspace after the investigator has submitted the stipulation document(s)



The IRBA will process the stipulation(s) as follows:

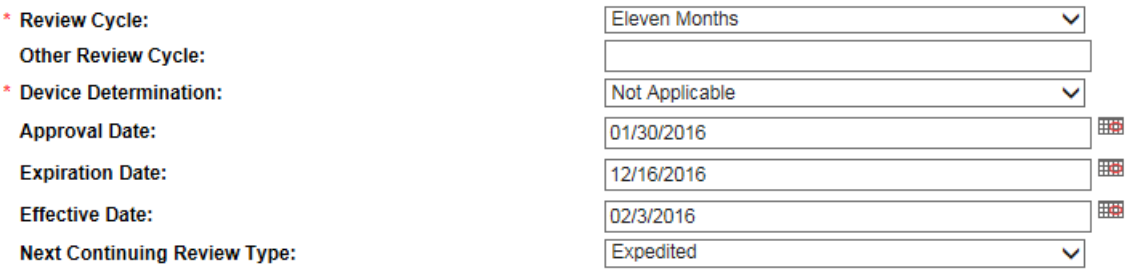
5.3.1. Complete **Stipulations Met** activity
5.3.2. Describe the stipulation(s) that was met in the text box provided
5.3.3. Complete **Edit Action Letter** activity
5.3.4. Type REVISED after the Pro#
5.3.5. Replace **Approved with Stipulations** with **Approved** in **Submission Status:**
5.3.6. Delete the section * IRB APPROVAL IS GRANTED SUBJECT TO THE STIPULATION(S) THAT:

5.3.7. Add # 10. **Revision:** [describe the stipulation(s) that was met and the changes made to the notice of approval as a result]

5.3.8. If external (non-Rutgers) site approval document(s) was pending, then list the document name(s) in **Other Materials:**

5.3.9. Click OK

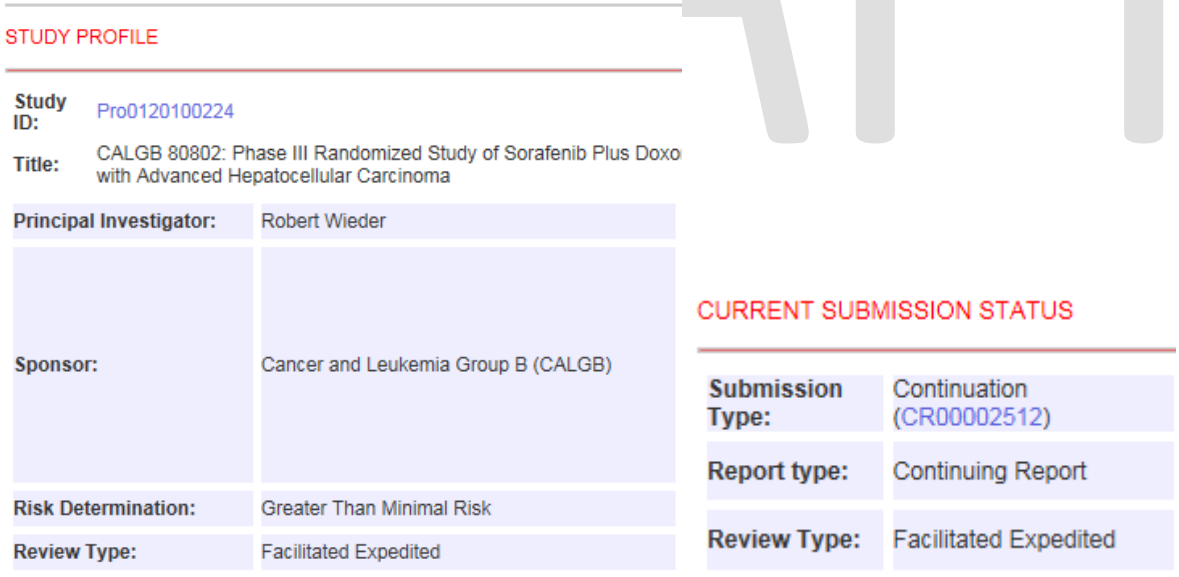
5.4. Facilitated Review



Use the expiration date listed on the central IRB approval letter in the **Review Complete** activity window for Facilitated Review or NCI-CIRB Independent Review submissions.

The central IRB approval letter is accessible under the **Attachments** tab.

The **Review Cycle** in the **Review Complete** activity window must be consistent with the approval and expiration dates.



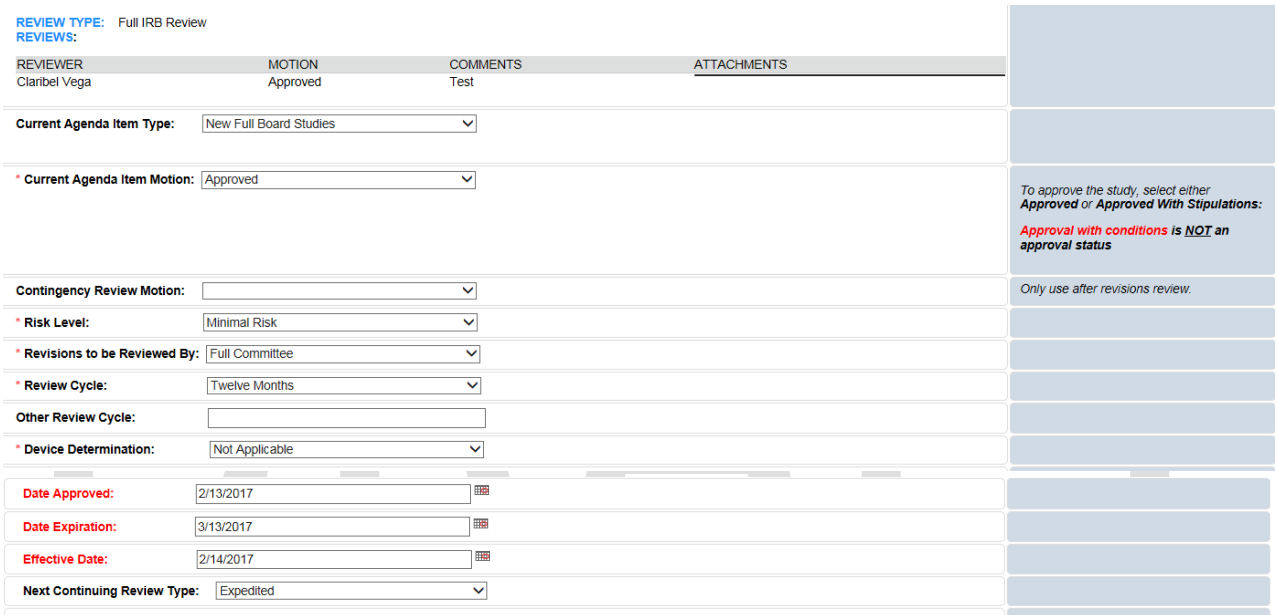
Type “Faciliated Expedited” in the cell next to **Review Type:** under the STUDY PROFILE and CURRENT SUBMISSION STATUS sections in the action letter as shown above

6. Processing Submitted Changes

The study staff (SS) or principal investigator (PI) will use the **Submit Changes** activity to respond to a Determination notice. Revisions review by the Chair/ Designee (IRBA or CM) for Expedited and revisions review by Full Committee/ Subcommittee for Full IRB is required to determine if the changes are acceptable.

6.1. Revisions Review by: Chair/Designee(IRBA)

If the CM selects "revisions review by Chair/Designee (IRBA)" in the **Submit Review** activity window or the IRBA requested changes because PAR findings are pending, then the IRBA will:



6.1.1. Click the **Submit Administrative Review** activity to select the **Contingency Review Motion**.

6.1.2. Click the **Review Complete** activity to verify the contingency review motion and all other pertinent fields in the activity window are filled and accurate.

6.1.3. If contingency review motion is **Approved** or **Approved with Stipulations**, then

6.1.4. Fill **Agenda Item Type**, **Effective Date**, and **Next Continuing Review Type** fields shown above in the **Review Complete** activity window.

6.1.5. Click OK.

6.1.6. Click on **Stamp Supporting Documents**, **Edit Action Letter**, and then **Request Correspondence Review** activities.

NOTE! Fields in the **Review Complete** activity window are filled based on the submission type. For example, do not fill the **Expiration Date** field for Exempt and Non-Human submissions; select "Not Applicable" in the **Review Cycle** field and do not change/ fill the **Next Continuing Review Type** field for

Modifications (unless the modification is changing the review type, which is rare, but has happened); select "Not Applicable" in the **Device Determination** field if the submission does not include a device.

6.2. Revisions Review by: Chair/Designee(CM)

If the CM indicated revisions review by Chair/ Designee (CM), Full Committee, or Subcommittee, then the IRBA will:

6.2.1. Click **Display Reviewer Notes** activity
6.2.2. Click **View Differences** to PAR the response
6.2.3. Click **Edit Study** to add notes (if necessary)
6.2.4. Click **Display Reviewer Notes** activity
6.2.5. Click **Forward to Revisions Review** activity

6.3. Contingency Review Motion

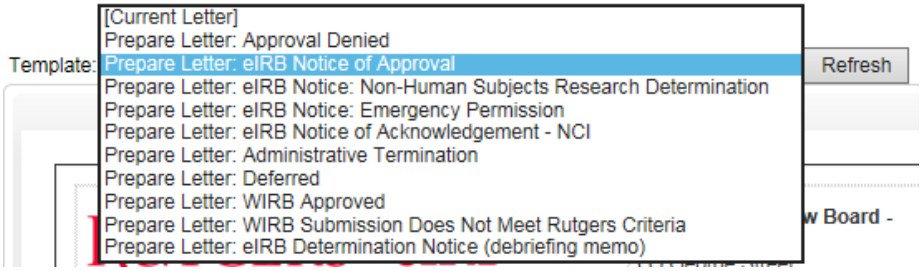
If contingency review motion is **Request Clarification**, **Request Changes**, or **Approval with Conditions**, then:

6.3.1. Click **Display Reviewer Notes** activity
6.3.2. Click **Edit Study** under **Current State** menu
6.3.3. Navigate to each section of the application to add notes (if not previously done)
6.3.4. Exit application
6.3.5. Click **Display Reviewer Notes** activity and then click OK in the activity window
6.3.6. Click **Request Changes or Clarifications** activity

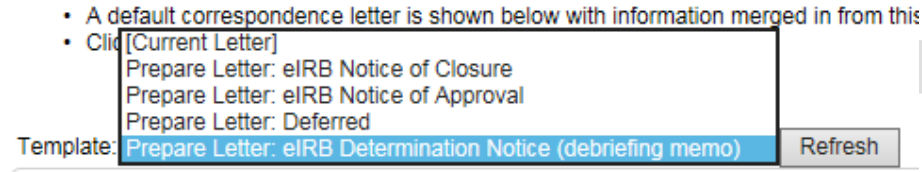
NOTE! Click Schedule for IRB Meeting activity for the submissions requiring Full Committee revisions review.

7. Edit Action Letter

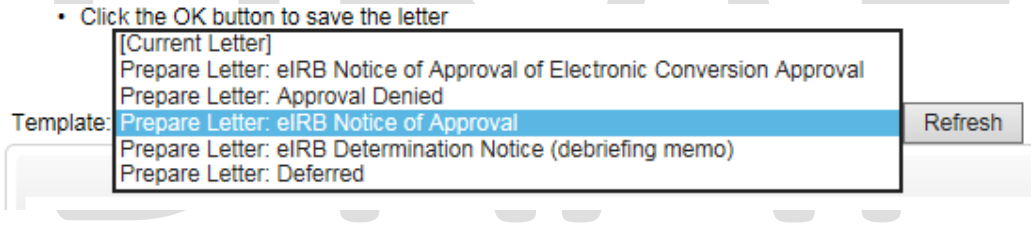
New Study



Continuing Review



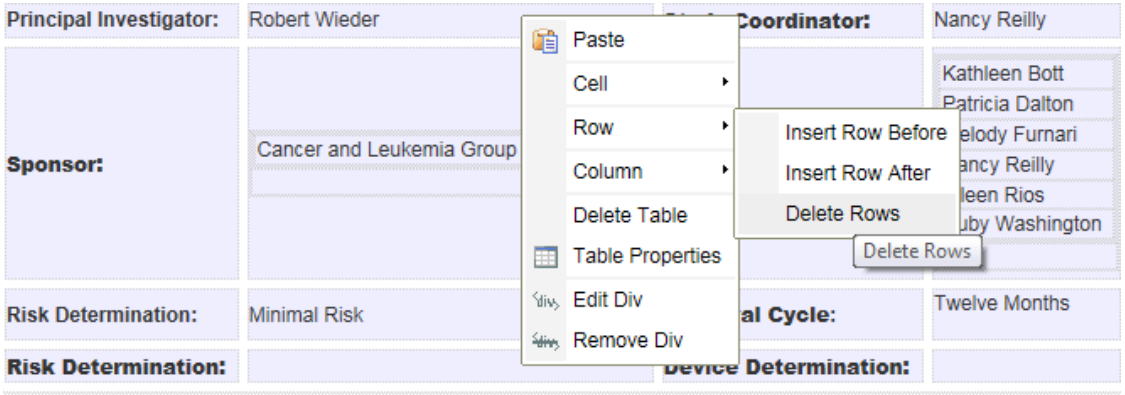
Modification

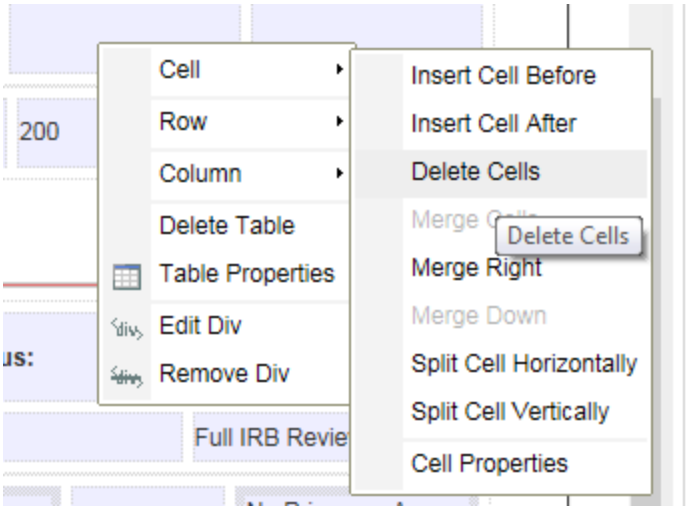


Select the applicable template shown above based on the submission type and review motion.

7.1. Clean up cells

Clean up the action letter before completing the **Request for Correspondence Review** activity shown below.

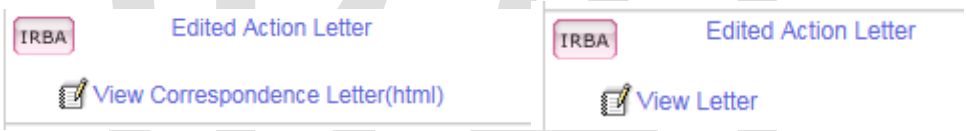




7.1.1. Right click a cell as shown above to delete empty cells/ rows/ columns or same containing "There are no items to display"

7.1.2. Right click a cell with acceptable text, select “Merge Right” to consolidate empty cells.

7.1.3. Delete cells/ rows/ columns containing protocol, consent, and other materials if such were not approved with the submission type.



7.1.4. Click View Correspondence Letter or View Letter hyperlink shown above after completing the **Edit Action Letter** activity and beware of floating “??”

- Repeat **Edit Action Letter** activity to remove floating “??”

7.1.5. Refer to section **7.3.** below for **Determination Notice** formatting

- If the **Submission Status** is Tabled, Request Changes, or Request Clarifications, then delete *“The IRB considered your Initial Application and moved to issue an Approval with Conditions, pending re-review by the IRB and satisfactory resolution of the action item(s) below”*

7.1.6. Refer to the *eIRB and Paper Stamping guidance* in S:\2018\Newark IRB SOP\IRB Office Policy and Procedures\eIRB

7.2. Replace or Remove text

7.2.1. New study Notice of approval, delete 10. Letter Comments: *There are no additional comments.*

7.2.2. Mod Notice of approval, replace 10. Letter Comments: *There are no additional comments.* with “10. **Modification:** [Briefly describe the changes].”

7.2.3. Refer to the study approval or previous CR approval for applicable text in “7. **Consent/Assent:** “ except when the **Study Status** is **Closed to Enrollment** or **Closed to Chart/Specimen/Record Collection**. For example: “7. **Consent**: Closed to Enrollment: Data analysis only (data analysis being performed by or on behalf of Rutgers Investigators).”

7.2.4. Refer to the study approval or previous CR approval for applicable vulnerable population codes (you will need to redo the **Review Complete** activity to change the vulnerable population codes)

7.2.5. Refer to the *Standard Language Document* in S:\2018\Newark IRB SOP

7.2.6. The **Effective Date** listed on the action letter changes when the content of the action letter changes; the **Effective Date** in the **Review Complete** activity window and on the action letter changes when you redo the **Review Complete** activity

Here is an example of acceptable formatting under the STUDY PROFILE section in a **Notice of Approval**:

Study ID: Pro#

Title: Study Title

Principal Investigator:	Name	**Study Coordinator:**	Name
Co-Investigator(s):	Name(s)	**Sponsor:**	Funding Source(s)
Risk Determination:	Risk Level	**Approval Cycle:**	Months

Review Type:	Expedited	**Expedited Category:**	2	**Subjects:**	1000
Records:	1000	**Specimens:**	1000		

The takeaway from the example above: ID and title remain unchanged; study personnel and sponsor in close proximity; risk and cycle in the same row; review, category, and records/ subjects/ specimens in close proximity.

NOTE! The MA must ensure that the PA/PSS has completed the review once submitted via eIRB according to the Rutgers-Newark Campus IRB Task Timeline. If no action is completed as indicated in the Rutgers-Newark Campus IRB Task Timeline than the assigned MA must send an email to the IRBD/IRBAD informing them of the outstanding item(s).

7.3. Determination Notice

Remove cells that contain “Not Applicable” and “There is no information to display”

Delete the following cells:

Approval Date:			**Expiration Date:**		
Subjects:	0	**Specimens:**	0	**Records:**	
Committee:	Newark Executive	**Meeting/Determination Date:**	12/2/2015		

Verify that the **Submission Status** is consistent with the motion selected in the **Review Complete** activity

Delete “shown above” in #4. Continuing Review

Delete *#6. Letter* Comments: There *are no additional comments*

7.4. Revised Notice of Approval (NOA)

Principal Investigators (PI) may request the language in the NOA to be revised. If request was sent in Outlook, than log a private comment with PDF of email attached. If request was sent using **Send Email to IRBA** activity in the related submission workspace, than it will already appear under the history tab.

1. Click **Edit Action Letter** activity in the submission workspace
2. Udate the **Effective Date**
3. Make the change(s)
4. Add the standard language
5. Verify information is accurate
6. Click OK
7. Click **Send Email to Study Team** activity to notify the PI and Study Coordinator that the NOA has been revised as requested

NOTE! Refer to the Standard Language document for specific text and section to include in the revised NOA.

8. Continuing Review

8.1. Study Status

Continuing Review / Final Report

Study ID: Pro2011001068

Study Name: The Use of Customizable Implants in Orthopaedic Oncology Patients

1.0 * **Type of Report**:
Continuing Report

2.0 * **Please indicate which of the following applies to your study.**
(Check all that apply)

- [x] Records
- [x] Specimens
- [x] Subject Interaction or Intervention

If an investigator selects, Subject Interaction or Intervention, Specimens, and Records (e.g. accessing charts/records to collect data for research purposes using a data collection/abstraction form) on page **1.0 Study Status** of the Continuing Review/Final Report and the protocol document is approved for prospective review of records (but the initial/ subsequent notice(s) of approval did not include number of records approved) then please advise the investigator of the following option:

- Submit a linked Modification where the **Modified Study** shows "Other" selected under section **2.0 Study type** on page **7.0 Study Summary** and the specification "Prospective review of [insert #] charts/records" in the space provided under "If other, please specify"

The aformentioned instruction is an option, not a requirement. Some investigators, at the behest of their Sponsor, want the notice of approval to include number of records approved. Please also consider the selection made on page **1.10 Continuing review study status** when assessing the applicability of the aformentioned instruction.

NOTE! If you see that the protocol document in a **new study** submission describes prospective data collection from charts/ records in addition to Subject Interaction or Intervention and/or Specimen collection, then feel free to query the investigator about the option to select "Other" under section **2.0 Study type** on page **7.0 Study Summary** and specify "Prospective review of [insert #] charts/records" in the space provided under "If other, please specify"

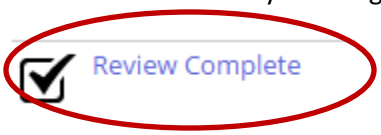
The future notice of approval will include number for subjects, specimens, and records approved.

8.2. Study pending a determination from the Conflict of Interest Committee (COIC)

8.2.1. Full IRB Review only

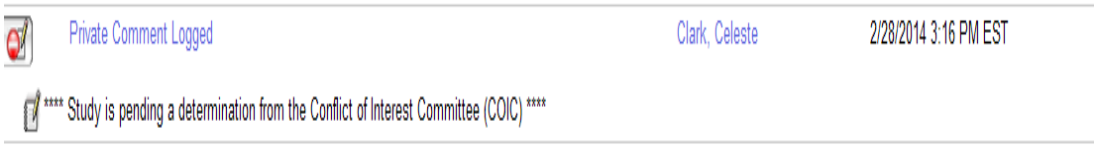
When an eIRB **Continuing Review (CR)** application is reviewed and given a motion of **Approved** or **Approved with Stipulations**, but a determination is pending from the Conflict of Interest Committee (COIC); the study must be updated and documented indicating that it is pending a determination from the COIC as follows:

1. Confirm with your assigned MA that no determination has been received from the COIC



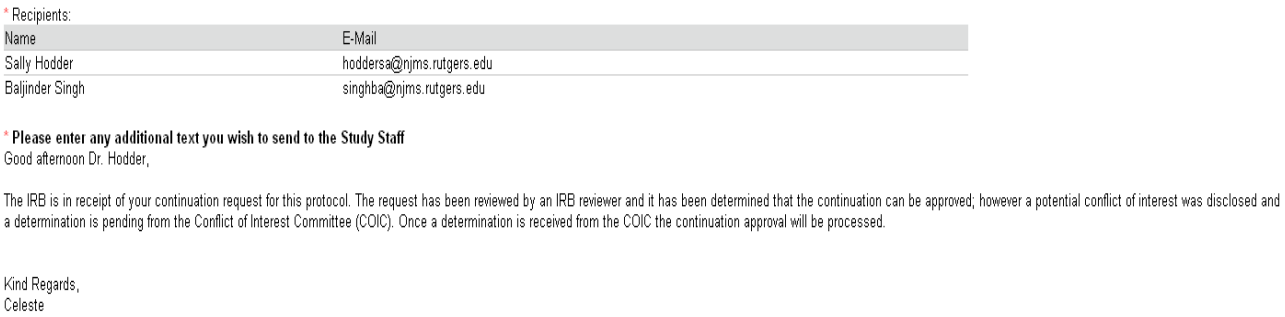
2. Click **Review Complete** under My Activities menu
3. Select motion **Approved or Approved with Stipulations**
4. Fill out the Review Complete screen in its entirety, with the exception of the **effective date**
5. Return to the study workspace
6. The study should now be in the state "Review Complete Prepare Correspondence"

7. Log a Private comment indicating that the study is pending a determination from the COIC



8. Click 'Send Email to Study Team'

9. Inform the principal investigator that the study has been reviewed and is ready for approval; however the study is pending a determination from the COIC. Once a determination is received from the COIC, the approval will be processed.



* Recipients:

Name	E-Mail
Sally Hodder	hoddersa@njms.rutgers.edu
Baljinder Singh	singhba@njms.rutgers.edu

* **Please enter any additional text you wish to send to the Study Staff**

Good afternoon Dr. Hodder,

The IRB is in receipt of your continuation request for this protocol. The request has been reviewed by an IRB reviewer and it has been determined that the continuation can be approved; however a potential conflict of interest was disclosed and a determination is pending from the Conflict of Interest Committee (COIC). Once a determination is received from the COIC the continuation approval will be processed.

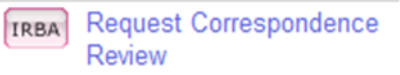
Kind Regards,
Celeste

Note! Do not complete the **Edit Action Letter** activity because a draft Action Letter will become available and accessible to the study team

An eIRB **New Study** application pending a determination from the COIC must receive a motion of **Approval with Conditions**. The study workspace must be updated and documented indicating that it is pending a determination from the COIC as shown in steps 1-6 listed above.

8.2.1.1. The IRBA will add a note to the applicable conflict of interest page requesting eCOI status update or COIC paper determination

8.2.1.2. IRBA will 

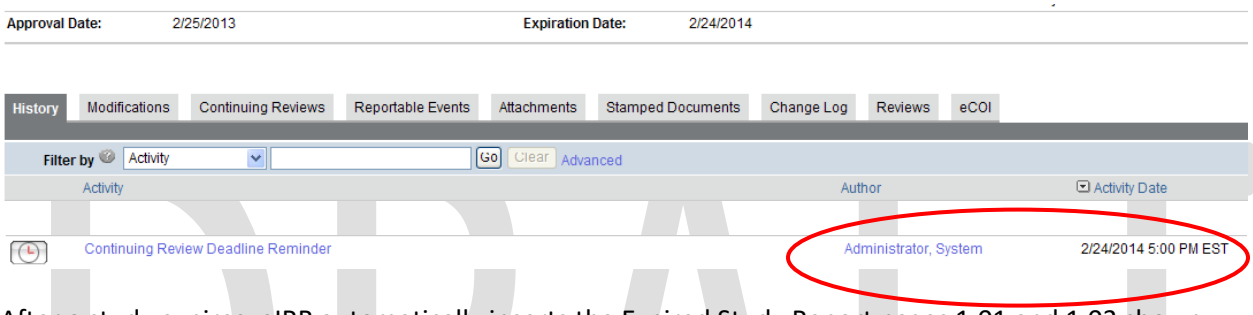
8.2.1.3. IRBA will 

8.2.1.4. Action Letter will be released to the principal investigator after the correspondence is reviewed and approved by the IRBD/ IRBAD

8.2.1.5. In the event that a determination notice (debriefing memo) will be processed to request clarification/ changes on other pages in the submission, then add a note on the Conflict of Interest page

8.3. Study Expired during IRB review

Investigators are advised to submit a CR to the IRB office at least four to eight weeks before the study expiration date. Four weeks for expedited protocols and eight weeks for full board protocols. There are instances when the investigator follows this advice, but a delay in approval occurs during the IRB review process resulting in a lapse in approval. Delays include, but are not limited to lack of PI response to a determination notice (debriefing memo), unresponsive committee member(s) to a review assignment, or awaiting other committee determinations (e.g. IBC, COIC). Regardless of the reason for the delay, eRB will automatically send an **IRB Study Expiration Notice** to the PI at the close of business on the date of expiration as shown below under the **History** tab in the study workspace.



After a study expires, eIRB automatically inserts the Expired Study Report pages 1.01 and 1.03 shown below in the CR application. A response from the PI is required before generating the Notice of Approval. Complete the following steps to send the CR application back to the PI to respond to these additional sections:

8.3.1. Click **Review Complete** under **My Activities** menu

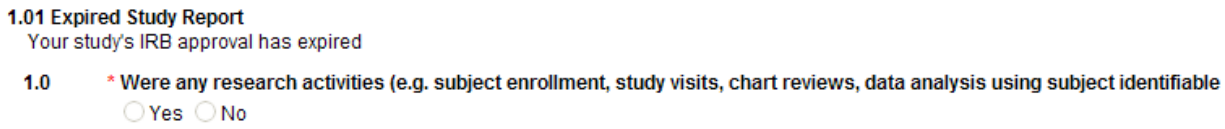
8.3.2. Select motion **Request Changes** in the **Review Complete** activity window

8.3.3. Enter notes in the **Comments** box indicating that the "PAR findings are pending and the approval will be processed after acceptable response from the PI is received."

8.3.4. Click Ok

8.3.5. Return to the submission workspace

8.3.6. Click **Edit Study** under My Activities menu



8.3.7. Navigate to **1.01 Expired Study Report** (shown above) add note

8.3.8. Navigate to **1.03 Expired Study Report** (shown below) add note(s)

1.03 Expired Study Report
Your study's IRB approval has expired

1.0 * **Provide an explanation as to why a timely Continuing Review Application was not submitted prior to expiration date:**

2.0 * **Provide a corrective action plan describing how this will be prevented from occurring in the future:**

8.3.9. If a timely (at least four [expedited] to eight weeks [full board] before the study expiration date) CR application was submitted to the IRB, then the note on **1.03** will explain to the PI that the IRB office acknowledges that timely CR application was submitted and instructs the PI to enter "N/A" in response to **1.0** and **2.0** on this page.

8.3.10. **Please note:** PA/PSS judgment is imperative in this circumstance. For example, if the PI submitted the CR application two days before the study expiration date, then the PI must provide a detailed response to **1.0** and **2.0** on this page.

8.3.11. Exit submission

8.3.12. Complete **Display Reviewer Notes** activity

8.3.13. Complete **Edit Action Letter** activity

8.3.14. Select **Determination notice** template

8.3.15. Verify that **Request Changes** is reflected in the **Submission Status** field in the determination notice

8.3.16. Remove cells that that contain *Not Applicable* and *There is no information to display*

8.3.17. Delete *The IRB considered your Initial Application and moved to issue an Approval with Conditions, pending re-review by the IRB and satisfactory resolution of the action item(s) below*

8.3.18. Delete the following cells:

Approval Date:			**Expiration Date:**		
Subjects:	0	**Specimens:**	0	**Records:**	
Committee:	Newark Executive	**Meeting/Determination Date:**	12/2/2015		

8.3.19. Delete *#6. Letter* Comments: There *are no additional comments*

8.3.20. Click OK

8.3.21. Click *View Letter* hyperlink under the History tab

8.3.22. Complete **Request Correspondence Review** activity

8.3.23. Complete **Release Action Letter to Study Staff** activity after IRBD confirms correspondence

8.4. Processing a Mod or RE for an expired study

A Mod/RE can be linked or unrelated to a CR. If linked, then the Mod Name and ID will appear under the **Related Modifications** section in the CR workspace. The **Link existing modification** activity allows the IRBA to link a related Mod to the CR. The study staff also has the option to link a related Mod to a CR.

A related Mod is associated with page **4.00 Proposed Modifications/Amendments/Changes to the research** in the CR or as a result of findings made during the IRB review of the CR.

A related RE is associated with page **3.0 Progress Report - Unanticipated Problems** in the CR or as a result of findings made during the IRB review of the CR.

When a CR is submitted for an **expired** study or study approval expires during IRB review of the CR, then the Mod/ RE must be processed prior to completing the **Edit Action Letter** activity in the **expired** CR workspace.

8.4.1. If the MOD/RE requires additional information, changes, and clarifications, then the IRBA will **Request Changes or Clarifications** (PAR section 1 findings) or prepare a determination notice after CM review is complete (PAR section 2 findings + any CM findings).
NOTE! Not all Mod/ RE submissions are linked to a CR. Those that are linked are not always submitted because of findings during the IRB review of a CR.

8.4.2. If the MOD/RE is acceptable as submitted and the CM approves/ acknowledges the submission, then the IRBA will:

8.4.2.1. Process the Mod/RE before completing the **Edit Action Letter** activity for the **expired** CR

8.4.2.2. If study documents, i.e. protocol, consent, flyer, survey, etc. were revised as a result of the Mod, and then include the following language in #10. **Modification** on the action letter:
"The modified stamped documents will accompany the Continuing Review notice of approval."

8.4.2.3. Remove the expiration date from the Mod/RE action letter

8.4.2.4. Submit the Mod/RE action letter to the IRBD/ IRBAD for correspondence review before you complete the **Edit Action Letter** activity for the CR.

NOTE! Please keep in mind, the Mod/RE action letter **must** be submitted on the same day as the CR to maintain timely processing and approval of the MOD/RE and CR.

8.4.3. The IRBA will **Log a Private Comment** in the CR workspace to reflect the current status of the pending CR approval based upon the MOD or RE status. The MOD approval or RE acknowledgement will be issued upon receiving satisfactory requirements based on the CR determination notice (if applicable).

9. Modification (Mod)

When processing Modifications, any additional changes the IRBA or CM request from the principal investigator (PI) must be shown on the **Modification Request** page, section (2.0) and (3.0), in **Edit/View Modification**.

For example, IRBA asks the PI to revise the consent documents/ IRBA revises the consent documents on behalf of the PI; in this instance, IRBA would add notes on the **Modification Request** page, (2.0) Please select Consent Form(s); (3.0) Please specify the changes made to the consent forms.

NOTE! For full IRB submissions, the **Modification Request** cannot be revised at the time of Correspondence Review because changes made to the **Review Complete** activity impact the minutes.

9.1. Processing an Expedited Mod for a full board Study/ Continuing Review

The Mod review type defaults to the review type of the parent study, i.e. full IRB review.

If the principal investigator selected "Minor, Non-Substantive Change" as the **Degree of Change**, then PAR the Mod to verify that the "risk to subjects are not increased; the revision is not a significant alteration of the study design"

9.1.1. Send an email to the IRBAD/ IRBD requesting confirmation to change review type; provide justification

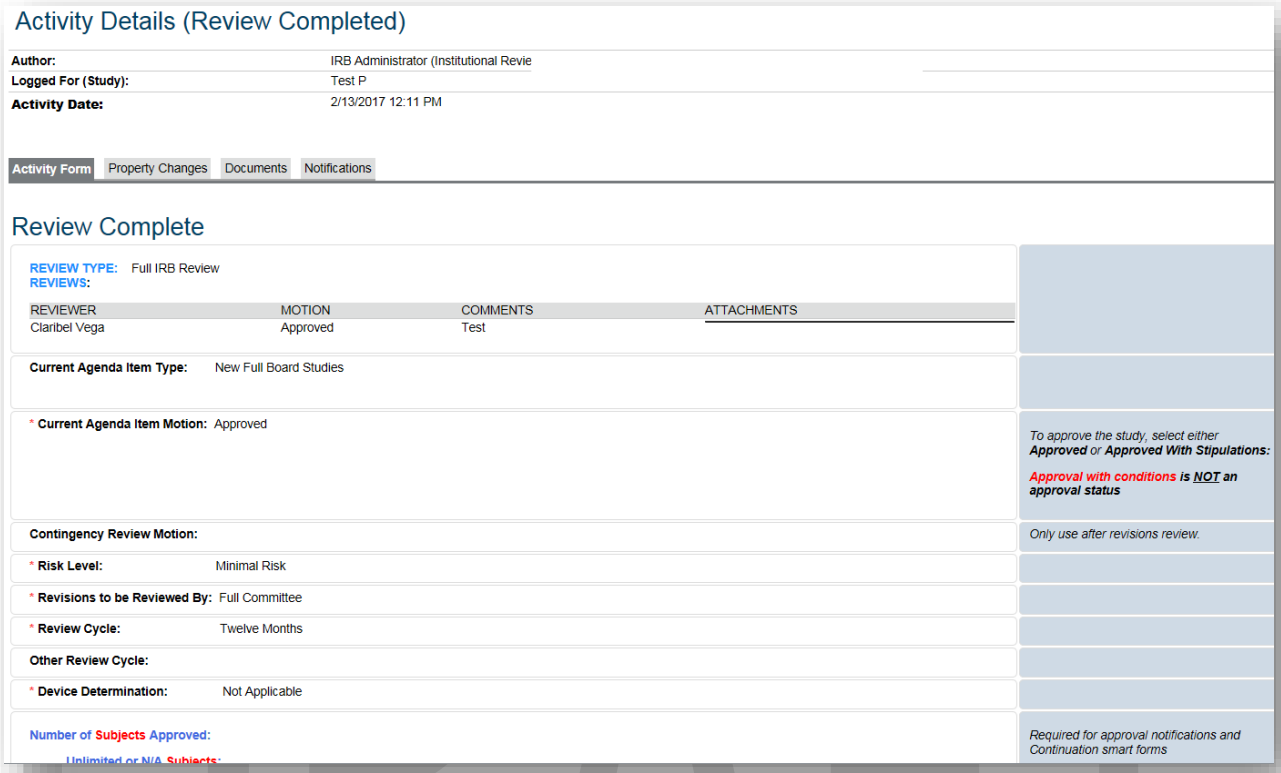
9.1.2. Log Private Comment "Email Sent to IRBD" with a PDF version of the email attached

9.1.3. Log Private Comment "Email Sent to IRBA" with a PDF version of the email reply attached

9.1.4. Click the **Change Review Type** activity, select **Expedited**, enter "risk to subjects are not increased; the revision is not a significant alteration of the study design" in the text box, and then click OK

When processing an expedited Mod for a full IRB review Study or CR make sure that the **Next Continuing Review Type** field lists full IRB, not expedited.

NOTE! If the next **review type** is changed to **expedited** in the review complete activity window, then the **review type** for the study or CR will also change to **expedited**.


Activity Details (Review Completed)

Author: IRB Administrator (Institutional Revie
Logged For (Study): Test P
Activity Date: 2/13/2017 12:11 PM

Activity Form | Property Changes | Documents | Notifications

Review Complete

REVIEW TYPE: Full IRB Review
REVIEWS:

REVIEWER	MOTION	COMMENTS	ATTACHMENTS
Claribel Vega	Approved	Test	

Current Agenda Item Type: New Full Board Studies

* Current Agenda Item Motion: Approved — To approve the study, select either Approved or Approved With Stipulations: Approval with conditions is NOT an approval status

Contingency Review Motion: — Only use after revisions review.

* Risk Level: Minimal Risk

* Revisions to be Reviewed By: Full Committee

* Review Cycle: Twelve Months

Other Review Cycle:

* Device Determination: Not Applicable

Number of Subjects Approved: — Required for approval notifications and Continuation smart forms

Unlimited or N/A Subjects:

9.2. Mod notice of approval template

eIRB will populate the **Modifications** field on the Notice of Approval with generic modification description as shown below. Maintain this format for this field, but add a numbered Modification field with a description of the change under the template section ALL APPROVED INVESTIGATOR(S) MUST COMPLY WITH THE FOLLOWING as shown below.

Modifications:	Changes to Consent Form(s) Changes to Protocol Document(s)

10. **Modification:** Submission of the Sponsor's Letter of Amendment (LOA) # 1 dated November 25, 2013. The LOA # 1 is for Protocol A5314, Version 1.0, 7/11/13. The English and Spanish consent forms have both been updated to reflect the changes listed within the LOA.

9.3. Mod adding investigator-on-probation

For a Mod adding one study staff and that person is an investigator-on-probation, use the 'IRBA Withdraw' activity and include the text '{Name} is an investigator-on-probation. Investigators-on-probation may not be added by modification to existing protocols.'

For a Mod adding more than one investigator to the study but not all are on probation, inform the PI of the investigator(s)' status with the IRB office and request that the PI remove the investigator(s) from the Mod application, in order for it to be processed.

10. Reportable Event (RE)

Please refer to the Reporting requirements in section 8.2.1 in the Human Subjects Protection Program (HSPP) Standard Operating Procedures available at https://orra.rutgers.edu/policies-and-guidance

Reportable events are used to report any of the following to the IRB:

- Acknowledgement Request
- Unanticipated Event
- Data Safety Monitoring Report
- Protocol Deviation

10.1. Emergency Permission

In addition, the IRB requires investigators to submit follow-up reports for an Emergency Permission (EP) submission type. Please refer to the Emergency Use guidance available at https://orra.rutgers.edu/emergency-use

The following procedure is for investigators to submit a follow-up report to the IRB after EP is granted. Advise the investigator to do the following:

10.1.1. Please navigate to the study workspace and then click the **Create a New Reportable Event** activity under the **My Activities** menu.

10.1.2. The submission type for this RE is an **Acknowledgement Request**.

10.1.3. Please complete all required sections, upload the report (PDF or WORD document), and then the PI must submit the RE.

Note! The RE **Acknowledgment Request** containing a follow-up report for an EP submission will be scheduled for an upcoming IRB Executive Committee meeting.

11. Stamp Supporting Documents

Pleaser refer to the *eIRB and Paper Stamping guidance* in S:\2018\Newark IRB SOP\IRB Office Policy and Procedures\eIRB

11.1. Study Status

Active – Closed to Enrollment - Data analysis only; Active - Closed to Chart/Specimen/Record Collection - Data analysis only

- Stamp current version of the protocol document (check recent Modification(s) to verify current version)

Active – Closed to Enrollment – Long term follow-up (survival)

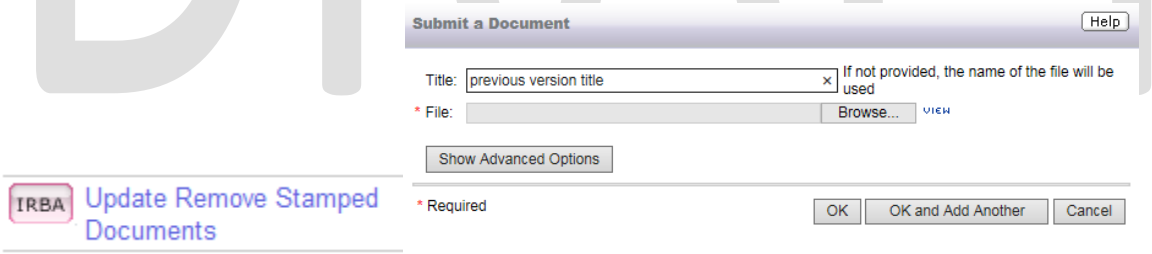
- Stamp current version of the protocol document (check recent Modification(s) to verify current version) and any research instruments, e.g. follow-up questionnaires
- If follow-up involves children reaching age of majority during the study, then stamp applicable consent document(s)

Active – Closed to Enrollment – Treatment/ Active follow-up

- Stamp current version of the protocol document (check recent Modification(s) to verify current version) and any research instruments, e.g. follow-up questionnaires
- If follow-up involves children reaching age of majority during the study, then stamp applicable consent document(s)

11.2. Update Remove Stamped Documents

Below is the process to Update and/ or remove stamped documents.



11.2.1. Click **Update Remove Stamped Documents** activity

11.2.2. Click on the **Name** hyperlink of the current version and then save it to your computer

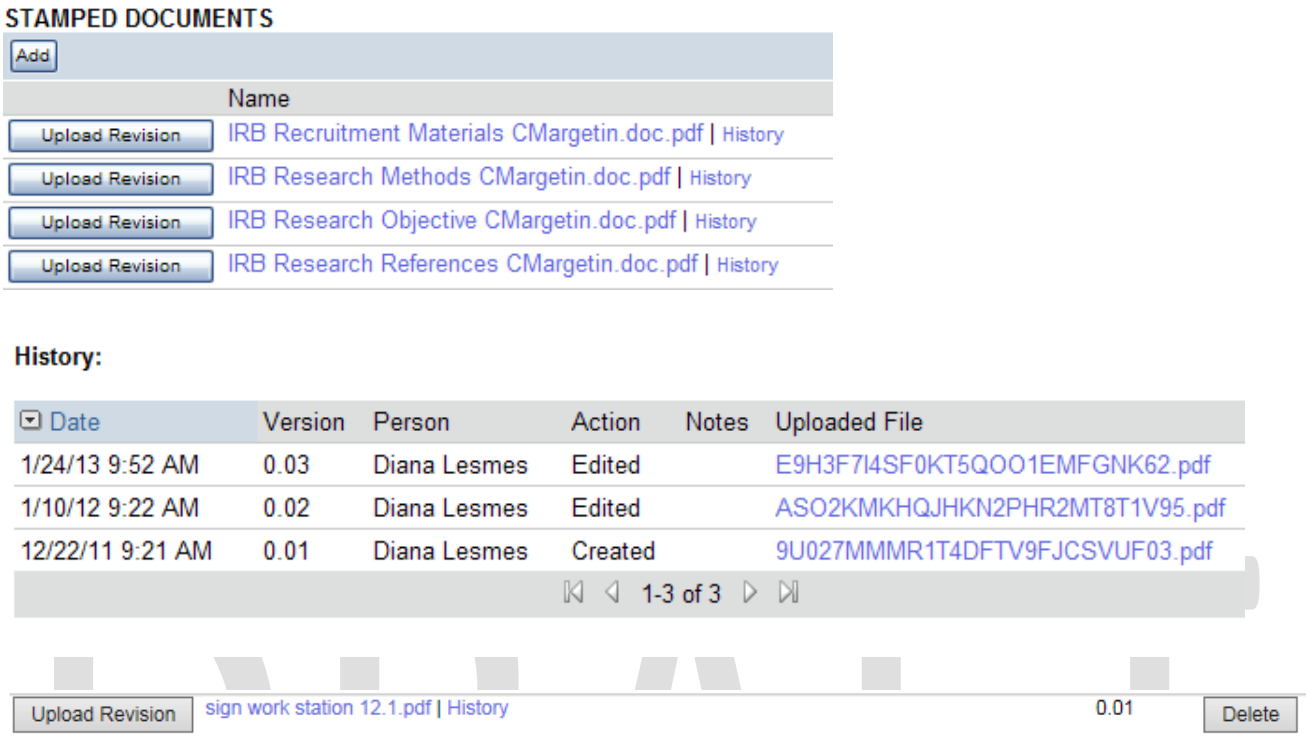
11.2.3. Click on the **Upload Revision** button next to the **Name** hyperlink of the previous version

11.2.4. Click the **Browse** button to locate the current version that was saved on your computer

11.2.5. Enter the **Title** of the current version

11.2.6. Click the OK button to return to the **Update or Remove Stamped Documents** activity window

11.2.7. Click on the **History** hyperlink next to the current version **Name** hyperlink to see previous versions of the same document:



11.2.8. Click the **Delete** button next to the duplicate current version **Name** hyperlink; make sure the current version has been uploaded before you delete the duplicate

11.2.9. Click the OK button in the **Update or Remove Stamped Documents** activity window after **Upload Revision** and **Delete** is completed for all applicable stamped documents.

11.2.10. Click **Stamped Document**s tab to make sure all versions of the stamped documents are available by clicking the **History** hyperlink next to the **Name** hyperlink

NOTE! A principal investigator (PI) may submit a modification request asking the IRB office to clean up documents listed under the **Stamped Documents** tab. Advise the PI to include in the modification which documents s/he wants to keep and which s/he wants removed.

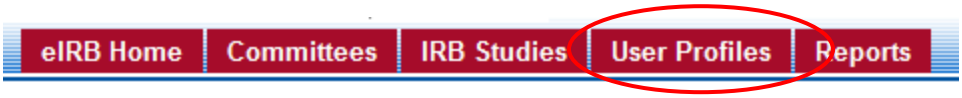
12. Investigators on Probation

The IRBA assigned to the IRB Executive Committee is responsible for updating an investigator's standing in eIRB.

12.1. Administratively Closed

An investigator is placed on probation after their study is **administratively closed** by the IRB Executive Committee. Refer to the Continuing Review Compliance (CRC) Policy in S:\2018\Newark IRB SOP\IRB Office Policy and Procedures

To place an investigator on probation:

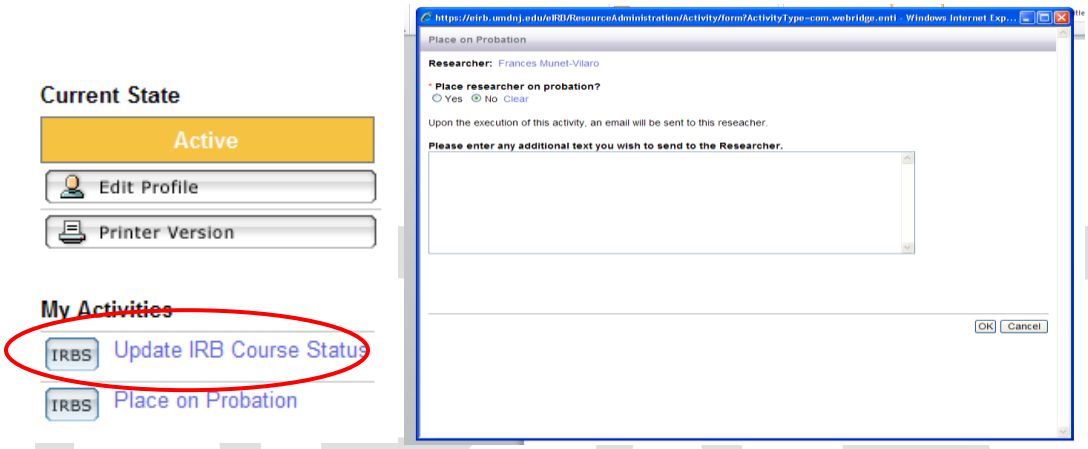


12.1.1. Log in to eIRB

12.1.2. Navigate to the investigator's user profile by clicking the **User Profiles** tab as shown above and then search for the investigator by last name.

12.1.3. Click on the investigator's name hyperlink.

12.1.4. Select the "Place on Probation" activity as shown below

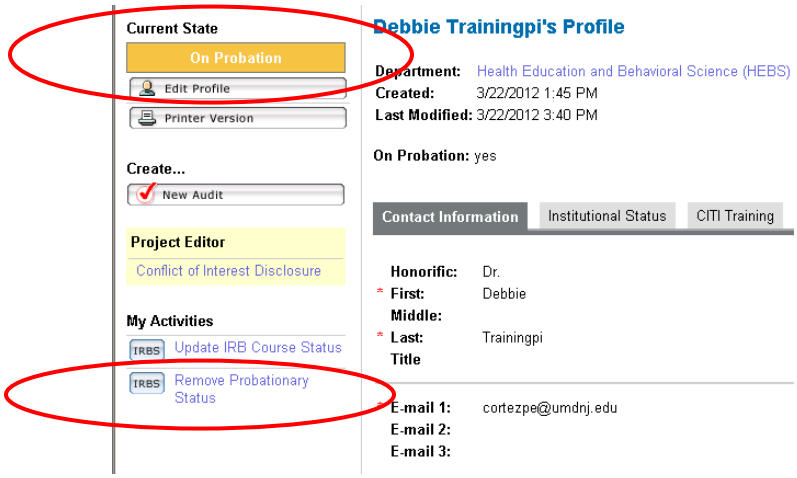


12.1.5. The **Place on Probation** window as shown above will come up to confirm the investigator is on probation.

12.1.6. Refer to the *Place on Probation activity_additional text box template* available in S:\2018\Executive IRB 2017\Exec IRB Admin Closed Correspondence for the applicable language in the "additional text" box:

12.1.7. The system will generate an email to the investigator indicating they have been placed on probation and request they submit a final report for all studies that have been administratively closed.

12.1.8. The investigator's profile will be updated to reflect the following:



12.1.9. The IRB Executive Committee will return an investigator to good standing after satisfactory review of their final report and corrective action plan.

12.1.10. The investigator's profile must be updated to "Remove Probationary Status" shown above.

12.1.11. The system will generate an email to the investigator indicating they have been returned to good standing.

NOTE! An investigator on probation:

- may not submit a new for review to the Rutgers IRB or Western IRB
- may not be listed as study personnel on other new study submissions or be added by modification to an existing study
- may submit continuing reviews for their own studies; continuing reviews should not be suspended nor should the approval be delayed because the IRB does not want to prevent the investigator from renewing any ongoing research or closing any completed research

13. Investigators Separated from RUTGERS

Request to Department Chairs to Modify/Close Studies When PI has left RUTGERS:

The MA is informed by IST via email that the PI has left the University or a Separation Report is received by the IRBD. The MA must filter each PI's eIRB User Profile to assure the number of active studies listed within the study listing tab. If the PI has active studies or is a co-investigator on a study then the following email(s) is sent to the Department Chair or the PI of the study where they are listed as a co-investigator:

Dear Department Chair:

Principal Investigator _____ has left without closing or replacing the Principal Investigators for the following study(ies).

- *Protocol Number – Title – expiration date, List co-investigators, if any*

Please contact the co-Investigators for the/these studies to submit a modification to change the PI if there is interest in continuing the studies. If not, please submit a final study report form for the study (ies) you wish to close. Once, a modification or Final Study Report has been created and completed kindly send an email request to the IRB Director, Carlotta Rodriguez, at rodrigcm@ored.rutgers.edu requesting that the item be administratively submitted for further processing.

Thank you in advance for assisting us to comply with our IRB regulations.

Dear PI:

Principal Investigator _____ has left the University. Please submit a modification at your earliest convenience to remove them as a co-investigator from the study (ies) listed below:

- *Protocol Number – Title, expiration date*

If a Principal Investigator has left the university and no other study personnel are listed on the study. The following actions should be followed to close out the study:

1. The IRBA must contact the assigned IT administrator by email
2. The IT administrator will add the designated department chair as a co-investigator in eIRB
3. Once the designated chair is added as a co-investigator, the IRBA will contact the designated department chair to create the final study report in eIRB
4. Once the application is completed, the assigned IRBA will email the IRBD to administratively submit the final study report

14. Review Motions

Project Type	Review Type	Review Motion	DEFINITION
Study	Full Board	Deferred	Moved to next convened meeting due to insufficient information
Study	Full Board	Tabled	Moved to upcoming convened meeting due to insufficient information
Study	Full Board	Approved	Approved as submitted
Study	Full Board	Approved with Stipulations	The IRB has approved the proposed research or changes as submitted with **stipulations.** Stipulations mandated by the IRB may prohibit the investigator(s) from conduction or initiating certain aspects of the study. Stipulations may only be removed by submitting the required documents for review by the IRB.
Study	Full Board	Approval with conditions	At the time the IRB reviews a research study, the IRB requires that before research can be approved, the investigator make changes specified in the action letter/debriefing memo.
Study	Full Board	Approval Denied	Not approved as submitted due to insufficient information or potential risks to human subjects outweighs potential benefit

Project Type	Review Type	Review Motion	DEFINITION
Study	Non-Full Board	Request Changes / Clarifications	Approved pending additional information and then re-review by IRB Chair or a designee, IRB subcommittee, or convened IRB.
Study	Non-Full Board	Approved with Stipulations	The IRB has approved the proposed research or changes as submitted with **stipulations.** Stipulations mandated by the IRB may prohibit the investigator(s) from conduction or initiating certain aspects of the study. Stipulations may only be removed by submitting the required documents for review by the IRB.
Study	Non-Full Board	Approve	Approved as submitted
Study	Non-Full Board	Send to Full Committee	Deferred due to risk determination may be greater than minimal and does not qualify for non-full board/ expedited review procedure
Project Type	**Review Type**	**Review Motion**	**DEFINITION**
Study WIRB	Non-Full Board	WIRB – Denied	Not accepted as submitted
Study WIRB	Non-Full Board	WIRB - OK to Process	Accepted as submitted

Project Type	Review Type	Review Motion	DEFINITION
Modification	Full Board	Deferred	Moved to next convened meeting due to insufficient information
Modification	Full Board	Tabled	Moved to upcoming convened meeting due to insufficient information
Modification	Full Board	Approved	Approved as submitted
Modification	Full Board	Approved with Stipulations	The IRB has approved the proposed research or changes as submitted with **stipulations.** Stipulations mandated by the IRB may prohibit the investigator(s) from conduction or initiating certain aspects of the study. Stipulations may only be removed by submitting the required documents for review by the IRB.
Modification	Full Board	Approval with conditions	At the time the IRB reviews a research study, the IRB requires that before research can be approved, the investigator make changes specified in the action letter/debriefing memo.
Modification	Full Board	Approval Denied	Not approved as submitted due to insufficient information or potential risks to human subjects outweighs potential benefit

Project Type	Review Type	Review Motion	DEFINITION
Modification	Non-Full Board	Request Changes / Clarifications	Approved pending additional information and then re-review by IRB Chair or a designee, IRB subcommittee, or convened IRB.
Modification	Non-Full Board	Approve	Approved as submitted
Modification	Non-Full Board	Approval with conditions	At the time the IRB reviews a research study, the IRB requires that before research can be approved, the investigator make changes specified in the action letter/debriefing memo.
Modification	Non-Full Board	Approved with Stipulations	The IRB has approved the proposed research or changes as submitted with **stipulations.** Stipulations mandated by the IRB may prohibit the investigator(s) from conduction or initiating certain aspects of the study. Stipulations may only be removed by submitting the required documents for review by the IRB.
Modification	Non-Full Board	Send to Full Committee	Deferred due to change may be substantive and risk determination may be greater than minimal and does not qualify for non-full board/ expedited review procedure

Project Type	Review Type	Review Motion	DEFINITION
Continuing Review	Full Board	Deferred	Moved to next convened meeting due to insufficient information
Continuing Review	Full Board	Tabled	Moved to upcoming convened meeting due to insufficient information
Continuing Review	Full Board	Approved	Approved as submitted
Continuing Review	Full Board	Approved with Stipulations	The IRB has approved the proposed research or changes as submitted with **stipulations.** Stipulations mandated by the IRB may prohibit the investigator(s) from conduction or initiating certain aspects of the study. Stipulations may only be removed by submitting the required documents for review by the IRB.
Continuing Review	Full Board	Approval with conditions	At the time the IRB reviews a research study, the IRB requires that before research can be approved, the investigator make changes specified in the action letter/debriefing memo.
Continuing Review	Full Board	Approval Denied	Not approved as submitted due to insufficient information or potential risks to human subjects outweighs potential benefit

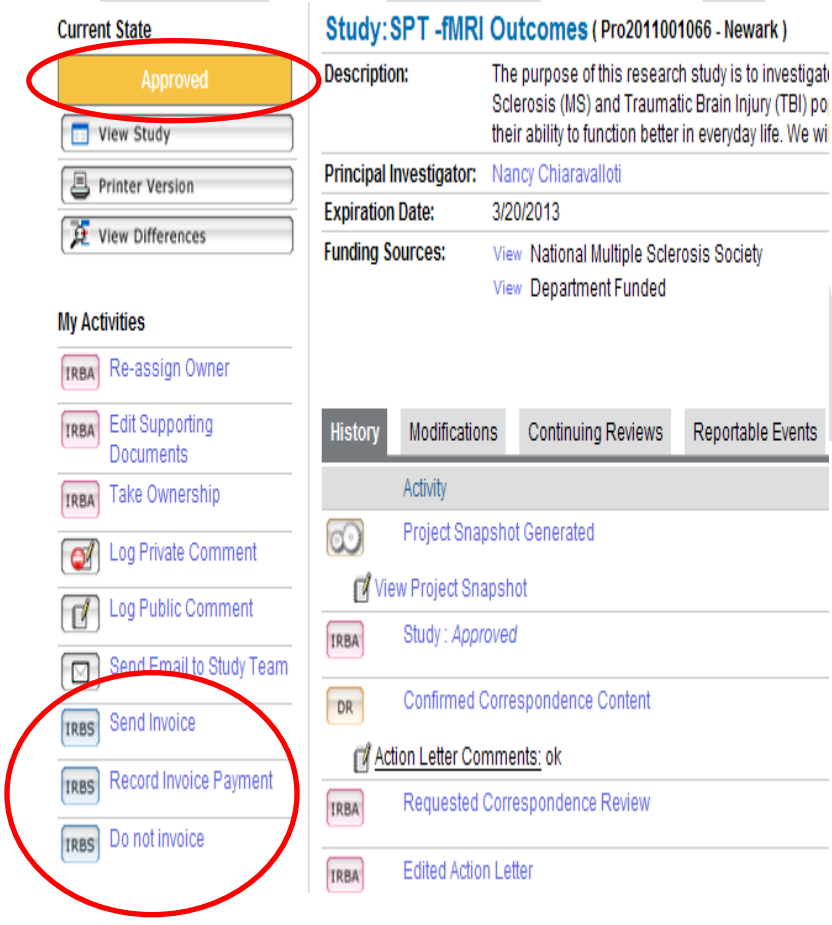
Project Type	Review Type	Review Motion	DEFINITION
Continuing Review	Non-Full Board	Request Changes / Clarifications	Approved pending additional information and then re-review by IRB Chair or a designee, IRB subcommittee, or convened IRB.
Continuing Review	Non-Full Board	Approve	Approved as submitted
Continuing Review	Non-Full Board	Approved with Stipulations	The IRB has approved the proposed research or changes as submitted with **stipulations.** Stipulations mandated by the IRB may prohibit the investigator(s) from conduction or initiating certain aspects of the study. Stipulations may only be removed by submitting the required documents for review by the IRB.
Continuing Review	Non-Full Board	Send to Full Committee	Deferred due to risk determination may be greater than minimal and does not qualify for non-full board/ expedited review procedure

Project Type	Review Type	Review Motion	DEFINITION
Reportable Event	Full Board	No further action required	Accepted as submitted
Reportable Event	Full Board	Action required	Additional information or follow-up report needed prior to issuing a determination and then re-review by Chair or a designee, IRB subcommittee, or convened IRB
Reportable Event	Full Board	External action required	Reportable to FDA or OHRP
Reportable Event	Full Board	Suspend Study	All research activity, i.e. study visits, data analysis, enrollment, and etc. except when the intervention is in best interest of subject, must stop because of potential harm to subjects
Reportable Event	Full Board	Deferred	Moved to next convened meeting due to insufficient information
Project Type	**Review Type**	**Review Motion**	**DEFINITION**
Reportable Event	Non-Full Board	Request Changes / Clarifications	Additional information or follow-up report needed prior to issuing a determination and then re-review by Chair or a designee, IRB subcommittee, or convened IRB
Reportable Event	Non-Full Board	Acknowledged	Accepted as submitted
Reportable Event	Non-Full Board	Send to Full Committee	Deferred due to nature of even and potential for greater than minimal risk to potential human subjects
Reportable Event	Non-Full Board	No further action required	Accepted as submitted
Reportable Event	Non-Full Board	Action required	Additional information or follow-up report needed and then re-review by Chair or a designee, IRB subcommittee, or convened IRB

15. Invoicing

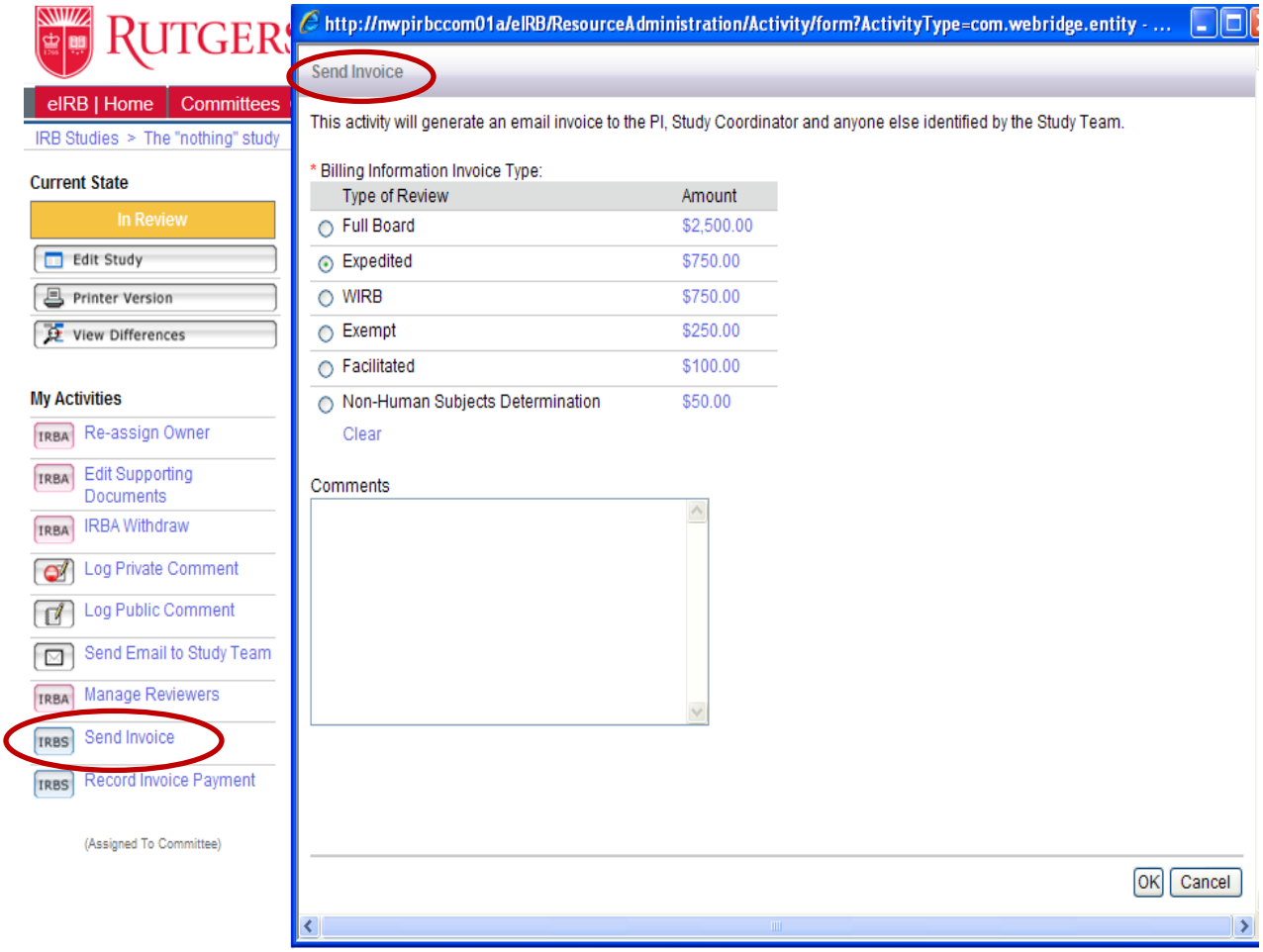
The three invoicing activities shown below will become visible to the IRBA/ IRB Router after a study is approved and whenever one or all of the following 3 criteria are met:

- Study is Industry Sponsored and Sponsor is covering costs
- PI is listed as unaffiliated or affiliated through a contractual agreement
- Western IRB (WIRB) is the IRB of record



15.1. Send Invoice

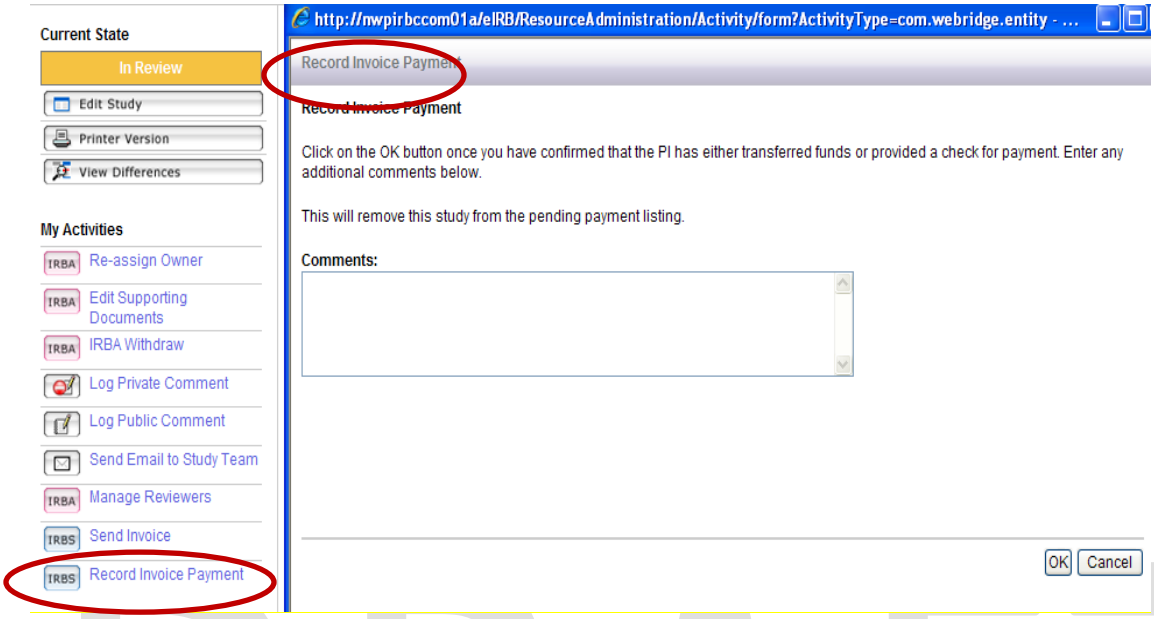
Click **Send Invoice** and then an email will be sent to the PI, Study Coordinator, and anyone else on the Study Team. Please note, **a copy** of the invoice is sent to the IRBA.



Enter relevant invoice notes, i.e. 'awaiting check'/ 'funds transfer' to document expected method of payment in the Comments text box. Click OK in the **Send Invoice** window shown above and the action will be documented in the **History** tab as shown below:

15.2. Record Invoice Payment

Click **Record Invoice Payment** after the IRB office/ HSPP Administrator receive payment. HSPP Administrator will collect and transfer funds to the appropriate accounts (NB, NWK, ST) in Banner/ the IRB office will receive a check.



Enter notes in the Comments text box indicating check number/ transfer of funds confirmation number for payment received. Click OK in the **Record Invoice Payment** window shown above and the action will be recorded in the **History** tab as shown below:

15.3. Do not Invoice

Click **Do not Invoice** when an invoice is not required.

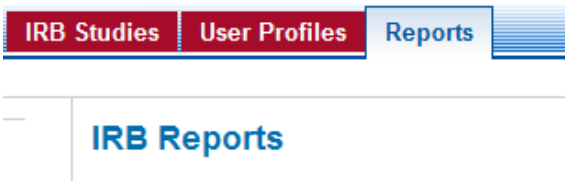
15.3.1. Include in the comment section the reason for not sending an invoice

15.3.2. Upload a document in support of not invoicing, i.e. email from investigator/ Research Dean

15.3.3. The system will automatically remove the **Send Invoice** function from any future submissions related to the study. (i.e. CRs and Mods).

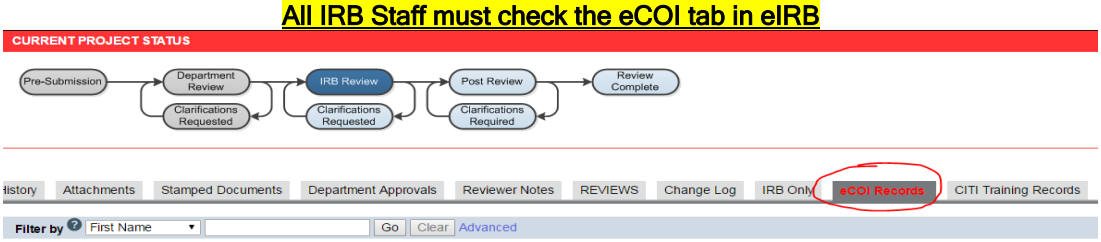
16. Reports

IRB Directors and HSPP Administrator have access to several different reports under the **Reports** tab.



How to Handle eCOI in all States

All IRB Staff must check the eCOI tab in eIRB



- Every Investigator must abide by the University Policy on Investigator Conflict of Interest.
- The policy requires all university faculty and staff (including students) or other individuals engaged in a research project to complete the disclosure through eCOI.
  - For non-Rutgers personnel, they must complete a paper-based form Non-Rutgers Investigator Attestation Form and uploaded into eIRB under Section 15.
  - The form has two certifications:

Certifications (Check one)

☐ **Researcher's Institution does follow a PHS-Compliant FCOI Policy which abides by the following:**
(1) all significant financial interests (SFI) related to the Researcher's Institutional responsibilities have been disclosed;
(2) any new SFI acquired or discovered altering any previous disclosure will be reported within 30 days of identification or acquisition;
(3) all identified COI have or will be satisfactorily managed, reduced, or eliminated **prior** to the expenditure of any funds under any resulting grant or agreement **and**, as required, by Rutgers University, any identified financial conflict of interest (FCOI) information shall be provided to the Rutgers University Office of Research and Regulatory Affairs.

☐ **Researcher's Institution does not have an active and/or enforced COI policy and hereby agrees to:**
(1) Abide by Rutgers University's Conflicts of Interest policy 90.2.5 and procedures, available at http://policies.rutgers.edu/view-policies/research-section-90#2
(2) Complete their FCOI disclosure online, available at http://ecoi.rutgers.edu , at the time of proposal submission, to disclose any SFI

  - For non-Rutgers personnel at an institution with an existing COI policy: They DO NOT need to complete Rutgers COI disclosure requirements. Instead, they need to complete the attestation form by checking the first box stating that their institution has an existing COI policy. No further actions required.
  - For non-Rutgers personnel at an institution WITHOUT an existing COI policy: They need to complete the attestation form by checking the second box stating that their institution does not have a COI policy and follow the remaining instructions.
  - This process must be re-completed at every continuing review period, where applicable.
- If it doesn't include any eCOI disclosures from the PI and listed personnel. It must be noted in your previews and on a debriefing memo.

  - Please click under "My Activities"
  - By clicking the "Create Financial Disclosure", you can select all names associated with the project. This will allow eIRB to send personnel a notification with a link for their COI disclosures.
- No Approvals can be issued without eCOI disclosures* (*see chart below).
- Investigators might be unaware of Rutgers' financial conflict of interest (eCOI) requirements. Encourage them to find out more information online at www.ecoi.rutgers.edu. You can also provide the link to eCOI FAQs.
- Encourage investigators with specific eCOI/ financial conflict of interest inquiries to reach out directly to the COI Administrator (sa1273@ored.rutgers.edu).Consequently, if investigators have been under eCOI review for some time, please advise them to reach out directly to their department's COI Monitor, which is also available online.

Certification Status	Required Actions
No Review Required	COI Monitor review has been completed. IRB Staff can process the IRB approval.
Review Complete	COI Monitor review has been completed. IRB Staff can process the IRB approval.
Schedule for Meeting	IRB staff must speak with eCOI Administrator about Outcomes regarding financial conflicts. Effective 9.25.18: If the eCOI tab lists "Schedule for Meeting" or "Committee Meeting" for any person, IRB staff must email the eCOI Administrator for a pre-review. The eCOI Administrator will perform pre-eCOI meeting review and inform IRB staff whether or not there are any COI issues pending review by the COI Committee. Currently, this committee meets every other week.
Administrative Review	IRB staff must speak with eCOI Administrator about Outcomes regarding financial conflicts.
Under COI Monitor Review	IRB staff cannot provide IRB approval until the COI review has been completed. Effective 9.25.18: Any eIRB submissions where there is an automatic trigger listing any personnel under COI Monitor Review, IRB staff must immediately email the eCOI Administrator indicating the submission number and name(s) under COI Monitor Review. The eCOI Administrator will perform an initial COI review and email IRB staff within 48 hours with her final review (i.e., disclosure does not require a management plan with consent changes). Following the eCOI Administrator's email, IRB staff should process and release the notice of approval through eIRB.

Under Management Plan	IRB staff must speak with eCOI Administrator regarding financial conflicts that might need to be disclosed in the consent process/form.
Withdrawn	The COI submission has been withdrawn in the eCOI system for a variety of reasons. IRB staff should speak with eCOI Administrator to find out why BEFORE processing approvals.

Non-Rutgers Investigator Attestation Form

Protocol Information

All Researchers (Principle Investigators and all Key Personnel) who are not employees must complete this form when applying for any extramural project. It provides provisions and certifications required by Public Health Service Agencies, NSF, other sponsors, and Rutgers University.

Rutgers University's is committed to assuring objectivity in research in accordance with federal requirements, to preserve the public trust and to promote the integrity of research. Its policies and practices are based on the applicable federal regulations: 42 CFR Section 50, Subpart F and 45 CFR Part 94.

Researcher's Name	Rutgers University Principal Investigator	
Project Title	Protocol / Log Number	
Sponsor / Funding Source	Start Date	End Date (optional)

Certifications (Check one)

☐ **Researcher's Institution does follow a PHS-Compliant fCOI Policy which abides by the following:**
(1) all significant financial interests (SFI) related to the Researcher's Institutional responsibilities have been disclosed;
(2) any new SFI acquired or discovered altering any previous disclosure will be reported within 30 days of identification or acquisition;
(3) all identified COI have or will be satisfactorily managed, reduced, or eliminated **prior** to the expenditure of any funds under any resulting grant or agreement **and**, as required, by Rutgers University, any identified financial conflict of interest (FCOI) information shall be provided to the Rutgers University Office of Research and Regulatory Affairs.

☐ **Researcher's Institution does not have an active and/or enforced COI policy and hereby agrees to:**
(1) Abide by Rutgers University's Conflicts of Interest policy 90.2.5 and procedures, available at http://policies.rutgers.edu/view-policies/research-section-90#2
(2) Complete their FCOI disclosure online, available at http://ecoi.rutgers.edu , at the time of proposal submission, to disclose any SFI

For Researcher

By signing this form, the Researcher certifies that the statements provided on this form are accurate and complete; The Researcher understands the continuing obligation to disclose any change(s) to significant financial interests and other conflicts of interests that may arise after submission of this form.

Signature of Researcher	Address
Email	Phone

For Researcher's Authorized Official

By signing this form the Authorizing Official of the Researcher and/or proposing Institution certifies that the statements in this document are true and complete to the best of his/her knowledge.

Signature of Authorized Official	Title of Authorized Official	Date
Name of Organization/Institution	Phone	E-mail
Federal Employer Identification Number (EIN)		