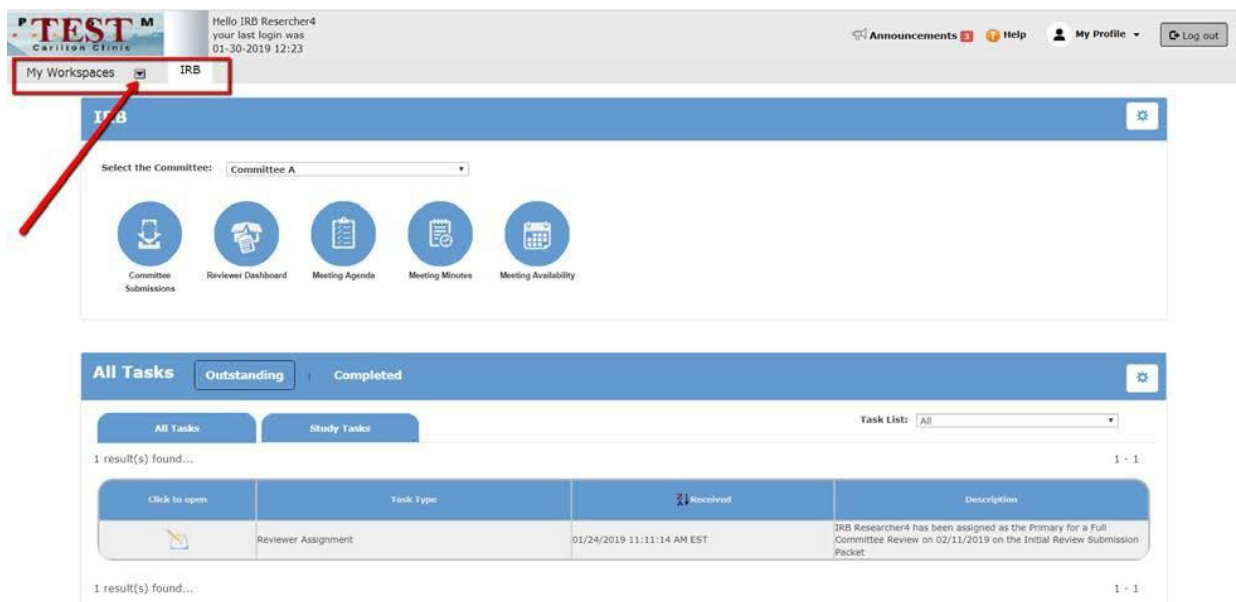


# User Guide: *IRB Members*

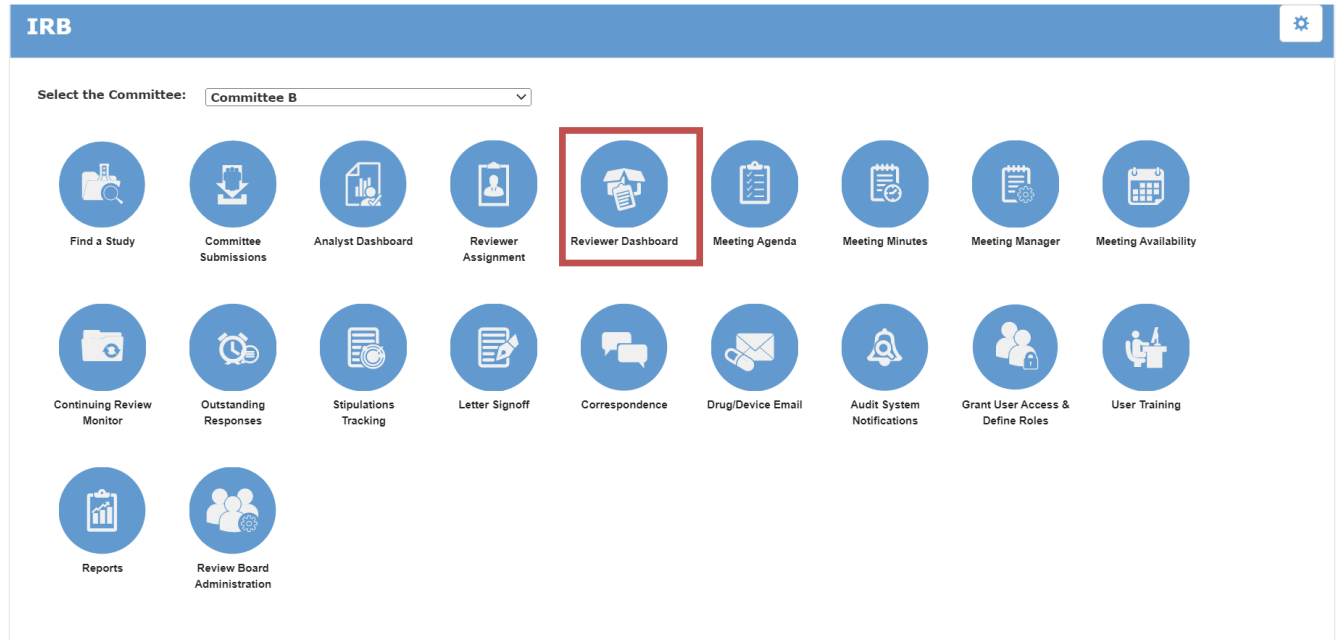
Last Update	08/01/2022
Intended Audience	IRB Members
Purpose	To provide IRB Members with step-by-step instructions on how to conduct a review of a study for the Full Committee Meeting

Follow the steps below to review the agenda and protocols for an upcoming meeting:

- STEP 1. Close all open web browsers.
- STEP 2. Open a new browser and go to: <https://carilionclinic.imedris.net/>
- STEP 3. Login using your Carilion ID and password.
- STEP 4. Ensure you are in the Review Board Workspace in the **IRB Assistant** Workspace by hovering the pointer over **"My Workspaces"** on the left of the page and clicking on **"IRB Assistant"** if necessary. You will know you are in the correct workspace if you see IRB at the top of the page in the blue bar.



**STEP 5.** Click the **Reviewer Dashboard** button in order to access the protocol and supporting documents for review, even if you have not been asked to be a Primary or Secondary Reviewer.



**STEP 6.** You are now in the **Reviewer Dashboard**. Select the correct meeting date under **Upcoming Committee Meeting**. You will then be able to see all the items on the agenda. Click on the **pencil and paper icon** to access each separate study submission.

Switch View

Task List

Internal Submission Routing

Upcoming Committee Meeting

July 28, 2022 @ 11:30 AM

August 25, 2022 @ 11:30 AM

September 22, 2022 @ 11:30 AM

October 27, 2022 @ 11:30 AM

October 27, 2022 @ 11:30 AM

Past Committee Meeting

May 26, 2022 @ 11:30 AM

June 23, 2022 @ 11:30 AM

July 2022

Su	Mo	Tu	We	Th	Fr	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

Agenda Status: Closed

Reviewer Notification

Items to be Reviewed

Review Documents

No documents have been associated with this agenda

Meeting Start Time: Meeting End Time

Initial Reviews - 0 Submissions

0 Items for review in this category.

Continuing Reviews - 2 Submissions

Order	Click to open	★	IRB Number	Ref Num	COI	Letters	Outcome	Type	Principal Investigator	Reviewer(s)	Date Board Received
1		★						Submission Correction for Carilion Clinic - Continuing Review Form			07/14/2022 9:40:52 AM EDT
1		★						Submission Correction for Carilion Clinic - Continuing Review Form			07/20/2022 3:56:26 PM EDT

Research Change / Update - 1 Submissions

Order	Click to open	★	IRB Number	Ref Num	COI	Letters	Outcome	Type	Principal Investigator	Reviewer(s)	Date Board Received
1								Carilion Clinic - Research Change / Update Form			06/23/2022 2:46:33 PM EDT

Promptly Reportable Information - 0 Submissions

0 Items for review in this category.

Others - 0 Submissions

0 Items for review in this category.

Save Changes

1: Select the correct meeting date

2: Click on pencil and paper icon to select the study

**STEP 7.** You will then be taken to the Initial Review Submission Packet for the study. You can view a summary and the study personnel on the **General Information** tab. To start **reviewing the study**, click on the gray **Submission Components** tab on the left.

If you wish to make a PDF packet of all study documents, you can click the boxes in the PDF packet column for the documents you want to include, then click “Create PDF Packet” button on the right side.

The screenshot shows the 'Display Submission Components' window. At the top, there are buttons: 'Compare Item(s)', 'Items in List View', 'Add New Component', 'Create PDF Packet', and 'Approve Attachment(s)'. Below these is a table with columns: 'Compare', 'Include in PDF Packet', 'Compare to Last Approved', 'View in Separate Window', 'Unattach', 'Revise/Attach', 'Revisions', 'Current Submission Components (All Rounds)', and 'More Details'. The table lists two 'Submission Form(s)': 'Carilion Clinic IRB - Pre-Review Correction Form - (Version 2.0)' and 'Carilion Clinic - Continuing Review Form - (Version 2.1)'. A red box labeled '1: Select documents' points to the 'Include in PDF Packet' column for the first form. Another red box labeled '2: Select create PDF packet to save to your computer' points to the 'Create PDF Packet' button.

**STEP 8.** If you do not create a PDF with all the documents included, you can then review the individual submission component you wish to review. For the IRB application, you can see the entire application at once using the scroll bar on the right side, or you can view the application section by section. You can use the **Print Friendly** button on the top right to create a **PDF copy** of the application to save it to your computer.

The screenshot shows the 'Display Submission Components' window with a sidebar on the left. The sidebar has a 'Submission Details' section with a red box around 'Submission Component(s)'. A red box labeled 'Click on a component to view' points to the 'Carilion Clinic - Continuing Review Form - (Version 2.1)' row in the table. Another red box labeled 'Click here to open in a new window to allow for side-by-side comparison' points to the 'View in Separate Window' icon in the same row. A third red box labeled 'Click on a component to view' points to the 'FW\_19\_488 Enrollment Update CR 2022 - (Version 1.0)' row. The table also shows a 'Document(s)' section with 'Category : Email correspondence'.

If there are additional components to view (such as consent documents or other supplemental materials), use the back button right above the Print Friendly button to get back to the list of components.

**STEP 9.** When you are finished reviewing the application and supporting documents, if you have a major concern with the application or supporting documents, you can navigate back to the Initial Submission Packet page by clicking the back button. You will click the **Submission Review** tab on the left of the page an additional drop-down menu will appear. You can select what you would like to do next or just click and it will take you to the next page, which has all of the options on one page.

On this page, you can add comments by clicking on the **Add Member Comments** button and make your comments in the text box, then clicking **Save**. Please reference the specific section/question that your comment applies to so it is easy for the IRB staff to reference.

Member Comments

Add Member Comments

Delete	Member Name	Comment
No Comments entered		

My Workspaces

IRB Number: **IRB-19-346**

PI: Emerson, Carley

IRB: Committee A

Member Comments

Back

Save the comments

Testing workflow email notifications - Comments for IRB Researcher3

☒ Display my comments on the review
 ☒ Display my name with the comments

Format

Font

Size

test

enter comments

You can select if you want your name linked to your comments and if you would like to share them with the other members.

## SELECTED PRIMARY OR SECONDARY REVIEWERS:

For protocols in which you were not selected as a Primary or Secondary Reviewer, you will review the study documents as described above.

If you were notified that you have been selected as a Primary or Secondary Reviewer for a protocol, please first review the above instructions on navigating to the meeting agenda. To conduct your review and complete the required checklists, follow the below instructions. Please complete your review and enter your comments as soon as possible after you receive the request so that the IRB can communicate with the PI regarding any issues that may otherwise result in the study being tabled.

**STEP 1.** When in the **Reviewer Dashboard**, click on Task List at the top left of the screen. You will then see any studies for which you were assigned as the reviewer. Click on the PDF icon so you have a PDF of the entire submission packet. Review the documents, and keep this open to review while you complete the checklist under Step 2.

Click here to show studies assigned to you as a reviewer

Upcoming Committee Meeting

PDF	Details	Click to open	IRB Number	Ref Number	Type	Study Classification	Review Process	Date Board Received	Expiration Date	Principal Investigator	Submission Assigned Analyst
			TEST BIOREPOSITORY	IRB-21-559	000705	Initial Review Submission Packet	Expedite	06/03/2022 11:25:54 AM EDT		Emerson, Carley	

- This is the only study for which you have to complete a checklist
- You can click on the PDF icon to PDF the entire submission packet so you can review it while you complete the reviewer checklist
- To access the reviewer checklist, click the paper and pencil icon

vascript:OpenItems (558, 276, 'OPEN\_INCOMPLETE\_ITEM')

## STEP 2:

To open the **Reviewer's Checklist**, you will click on the pencil and paper icon. The checklist that you need to complete will automatically display. If you wish to use the **Reviewer Panel**, which will show you the application and attached documents in a separate window, select the **Reviewer Panel button**. This is for your convenience only. If you have PDF'd the application, you will likely not need to open the Reviewer's Panel.

The screenshot shows a web form titled "General Info" with sections for "1.0 General Info", "1.2 Study Title:", and "1.3 IRB #:". At the top right, there are buttons: "Print Friendly", "Reviewer Panel", "Refresh Constant Fields", "Save Section", and "Save and Continue to Next Section". A red box highlights the "Reviewer Panel" and "Save and Continue to Next Section" buttons. A red arrow points from the "Reviewer Panel" button to a text box containing the following instructions:

- If you wish to have the application open while you review the checklist, click the reviewer panel button
- This is the cover page to the checklist, click *save and continue to next section* to proceed to the checklist

The screenshot shows a web browser window displaying the "Submission Review Panel". The URL is [https://carilionclinic-test.imedris.net/30880423/RB\\_Components\\_Review.jsp?windowName=Review\\_Panel\\_1659107010816&rand=1659107010881](https://carilionclinic-test.imedris.net/30880423/RB_Components_Review.jsp?windowName=Review_Panel_1659107010816&rand=1659107010881). The interface includes a header with "Study Status: Pending - Submitted for I...", "Ref Number: 000705", "IRB Number: IRB-21-559", "Study Title: TEST BIOREPOSITORY", and a "Close Panel" button. Below the header is a "Submission Components" section with a "Submission Form(s)" bar and an "Application" bar. The "Submission Form(s)" bar contains "Initial Review Submission Package (Version 1.0)" and the "Application" bar contains "Carilion IRB Application (Version 1.0)". A red box highlights the "Submission Form(s)" and "Application" bars. A red arrow points from the "Submission Form(s)" bar to a text box containing the following instructions:

**Welcome to Submission Review Panel**  
Click on the submission components you would like to review from the left-side menu.

This is the reviewer panel that opens as a separate window. Click on the blue bar (submission forms or application), then you can click on the bar that shows up underneath.



**Submission Components**

**Submission Form(s)**

- Initial Review Submission Package (Version 1.0)
- Application**
- Carilion IRB Application (Version 1.0)

**5.0**

**5.1 Select the application type**

☐ Human Subject Research Study  
☐ Determination of Human Subject  
☒ Establishing a prospective Data  
☐ Humanitarian Use Device (non-  
☐ Expanded Access or Compassionate Use  
☐ Single Patient Emergency Use  
☐ Preparatory to Research Application  
☐ IRB Grant Review ONLY for preliminary approval if required by funder  
☐ Requesting Carilion Clinic RELY on another IRB of Record (WIRB, CIRB, VT, UVA, Advarra etc.)  
☐ Conversion of a paper application due for Continuing Review or Annual Check-In

**Reviewer Comments Editor**

Author: [Redacted] Comments: [Redacted]

No reviewers share comments for this question.

The R&D Application Department Level Review eCRAF Form must be signed by the R&D Application Department Chair or signatory through RedCap BEFORE you may proceed with this application. Please read the below bullet points carefully and ensure you have completed all steps in the above order will result in a denial of your application.

- The R&D Application Department Level Review eCRAF Form must be signed by the R&D Application Department Chair or signatory through RedCap BEFORE you may proceed with this application.
- The R&D Application Department Level Review eCRAF Form must be signed by the R&D Application Department Chair or signatory through RedCap BEFORE you may proceed with this application.
- You must submit a copy of the signed R&D Application Department Level Review eCRAF Form with your supplemental document section.
- Failure to complete the steps in the above order will result in a denial of your application.

☒ Acknowledged

**6.0**

**Funding Information**

**6.1 Select the applicable funding source(s).**

☒ None (no money, equipment, supplies, and/or services will be provided by the sponsor)  
☐ No monetary funding BUT equipment, supplies, and/or services will be provided by the sponsor  
☐ Federal Government  
☐ Foundation or Non-profit  
☐ Industry/Commercial Sponsor  
☐ State or Local Government  
☐ Investigator or Departmental/Unit Funds

☐ Display my comment to other reviewers

Cancel Save Comment

**Be sure to select Save Comment when you have finished. You can return to these and edit as necessary, prior to your final decision.**

### STEP 3:

Complete the **Reviewer's Checklist** by answering the questions and making notes regarding any concerns under the applicable Criteria for Approval. Be sure to click the **Save Section** button if you are entering long responses. When you click **Save and Continue to Next Section** button, your responses will also be saved.

Please make sure you reference the specific application section and question number if it applies to the application. You can also add general comments at the end and select the applicable section of the application or the supplemental document. Indicate that you have completed your review by clicking **Yes** under the final question "**Have you completed your review?**". If you have not completed your view, you can come back to this form and data you entered and saved will be there when you return.

1. Proceed through the checklist sections by clicking *Save and Continue to Next Section*

Section view of the Form | Entire view of the Form

Print Friendly | Reviewer Panel | Refresh Constant Fields | Save Section | Save and Continue to Next Section

1.0 General Info  
2.0 Minimal Risk Determination and Checklist  
3.0 Approval Recommendation  
4.0 Indication of Completion

4.0 Indication of Completion

4.1 Comments:

Add any comments

Add a new comment

Rank | Item Number (or name)

No Comments have been entered.

4.2 Have you completed your review?

☐ Yes ☒ No

Date Completing Form: 07/29/2022

Once you have completed your review, it will be returned to the IRB and you will not be able to make any other edits.

Switch View  
Task List  
Internal Submission Routing  
Upcoming Committee Meeting  
February 04, 2019  
February 04, 2019  
February 11, 2019  
February 18, 2019  
February 25, 2019

[ Close Search ]

Submissions Type: All Committee Types: All -- Search

Process Type: All Status: Incomplete

ID#	Details	Click to open	IRB Number	Ref Number	Type	Study Classification	Review Process	Date Board Received	Expiration Date	Principal Investigator	Assigned Analyst
No Items To Review											

Once your review is closed, it will no longer appear in the task list

**STEP 4:** Once you have completed the **Reviewer's Checklist** and selected that you have completed your review, the IRB staff member will be notified. You will be contacted if there are any questions about your review.

**STEP 5:** If you wish to get back to the Reviewer Dashboard to review other studies, click the Back button in the system (not your computer back button) and select the applicable meeting agenda.