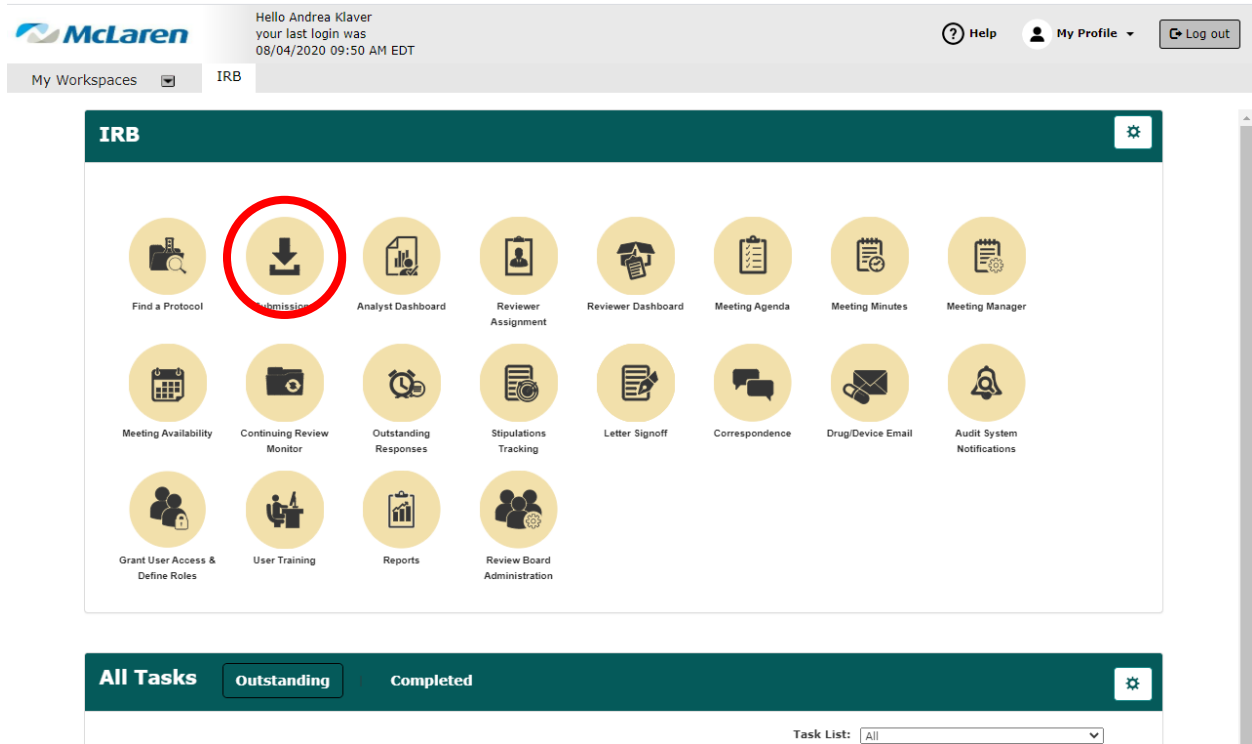


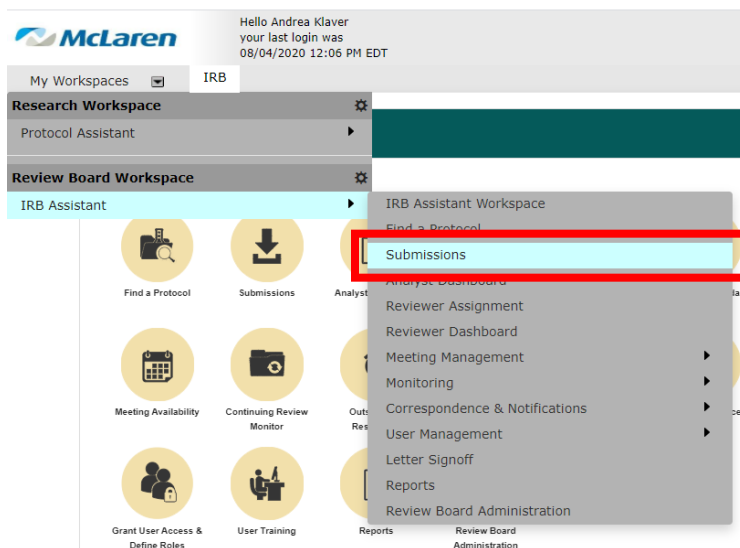
IRB iRIS TRAINING MANUAL

Article I. NAVIGATION

Welcome to iRIS! After you log in to iRIS, this is your homepage.



Click Submissions (red circle). The Submissions icon allows you to view and process submissions sent to the IRB. You can also find links to the icons in the My Workspaces drop-down menu.



Submissions are divided into tabs, including Not Assigned, Assigned, Completed, Agendas, and Outstanding Board Tasks. iRIS automatically defaults to Not Assigned. Information pertaining to each submission populates in sortable columns to make it easier to locate a submission.

Close Search

Submission Type: All	Assigned Analyst:
Active Principal Investigator:	IRB Expiration Date:
Date Board Received:	
IRB Number: All	
Ref Number:	

- Not Assigned
- Assigned
- Completed
- Agendas
- Outstanding Board Tasks

8 result(s) found...

Open	IRB Number	Ref Number	Type	Date Board Received
	<i>Pre-Review Correction Test</i> IRB-2020-0018	000827	Protocol Violation/Exception Report	04/07/2020 05:02:59 PM
	<i>Question link</i> IRB-2020-0025	000839	Initial Review Submission Packet	04/17/2020 10:12:02 AM

You may always click on the McLaren logo in the upper left corner of the screen to return to your homepage.

Hello Andrea Klaver
your last login was
08/04/2020 09:50 AM EDT

Help My Profile Log out

My Workspaces IRB

IRB
⚙️

Find a Protocol

Submissions

Analyst Dashboard

Reviewer Assignment

Reviewer Dashboard

Meeting Agenda

Meeting Minutes

Meeting Manager

Meeting Availability

Continuing Review Monitor

Outstanding Responses

Stipulations Tracking

Letter Signoff

Correspondence

Drug/Device Email

Audit System Notifications

Grant User Access & Define Roles

User Training

Reports

Review Board Administration

All Tasks
Outstanding
Completed
⚙️

Task List: All

0 result(s) found... 0 - 0

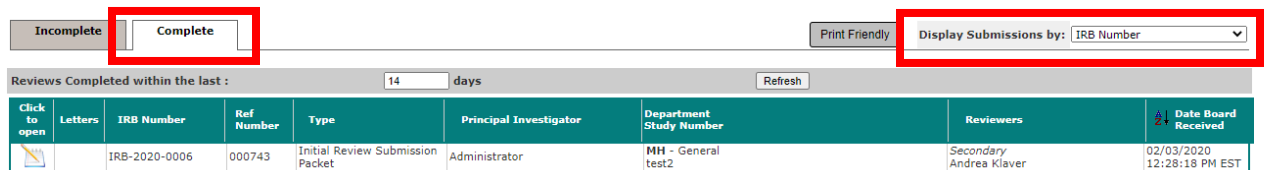
Click to open	Task Type	Received	Description
No Studies match the search criteria			

Click Reviewer Assignment. The Reviewer Assignment area of IRB Assistant allows you to view and open your current Incomplete and Complete reviewer assignments. By default, the Reviewer Assignment screen opens to the Incomplete tab.




Click to open	IRB Number	Ref Number	Type	Review Process	Date Board Received	Expiration Date	Principal Investigator	Assigned Reviewers	Assigned Analyst
	IRB-2020-0018	000827	Protocol Violation/Exception Report	Full Committee Review	04/07/2020 5:03:00 PM EDT	03/25/2021	Mott, Donna	Primary Andrea Klaver	Klaver, Andrea

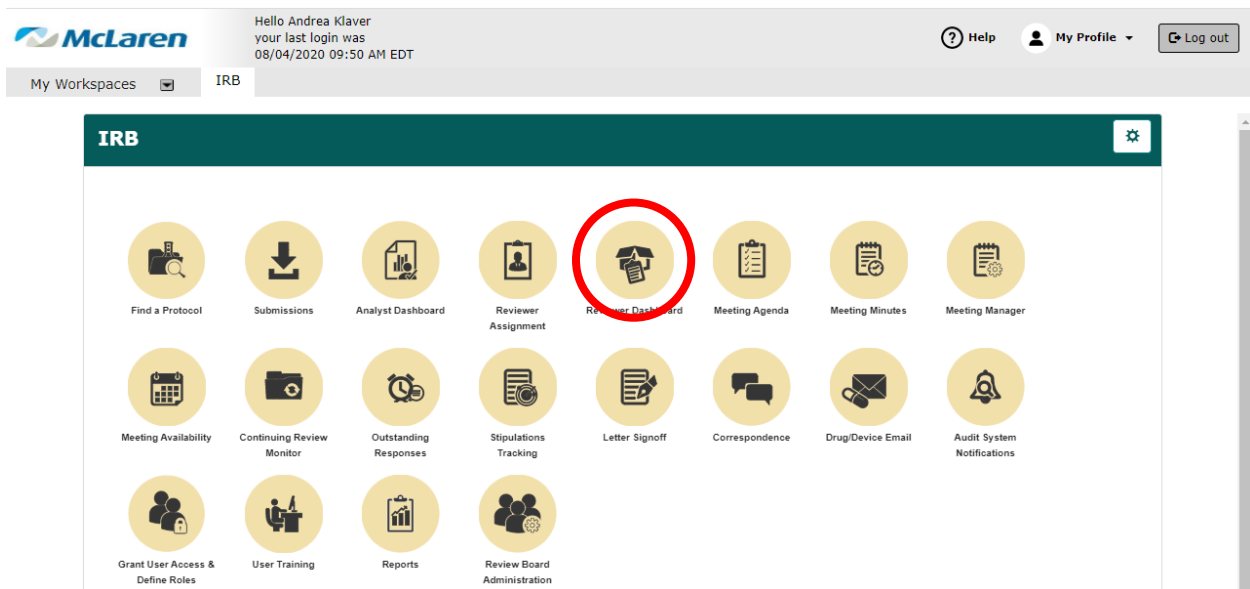
On the Complete tab, you can enter a number in the "Reviews Completed within the last:" text box. This will determine how far back your completed review assignments will display. Opening an assignment will take you to your completed form.




Click to open	Letters	IRB Number	Ref Number	Type	Principal Investigator	Department Study Number	Reviewers	Date Board Received
		IRB-2020-0006	000743	Initial Review Submission Packet	Administrator	MH - General test2	Secondary Andrea Klaver	02/03/2020 12:28:18 PM EST

By clicking the  icon in the "Click to open" column, you will be directed to your reviewer assignment(s). You can choose to display submissions by IRB Number or by another type of study numbering using the "Display Submissions by:" drop-down menu.

Click on the McLaren logo in the upper left corner of the screen to return to your homepage.



 Hello Andrea Klaver
 your last login was 08/04/2020 09:50 AM EDT

My Workspaces IRB

? Help My Profile Log out

IRB

- Find a Protocol
- Submissions
- Analyst Dashboard
- Reviewer Assignment
- Reviewer Dashboard**
- Meeting Agenda
- Meeting Minutes
- Meeting Manager
- Meeting Availability
- Continuing Review Monitor
- Outstanding Responses
- Stipulations Tracking
- Letter Signoff
- Correspondence
- Drug/Device Email
- Audit System Notifications
- Grant User Access & Define Roles
- User Training
- Reports
- Review Board Administration

Click Reviewer Dashboard. The Reviewer Dashboard allows you to access any submission you have been assigned to review, access internal submission routing assignments, and review submissions for both upcoming and past committee meetings.

Article II. REVIEWER DASHBOARD

Within the Reviewer Dashboard, you can access any submission you have been assigned to review, access internal submission routing assignments, and review any upcoming meetings.


Any of your incomplete Reviewer Assignments will populate in the main page in your Task List.

At page left, you can switch screen views and view the agenda for different meeting dates. The Switch View area contains links to the Task List and Internal Submission Routing. The Upcoming Committee Meeting and Past Committee Meeting areas will display different meeting dates.

The closest meeting is shown in red. Click on any meeting date to open the Agenda. From this view, you can access submissions placed on a particular meeting date. You can click on any of the dates in the Past Committee Meetings area to open the agenda for that meeting, as well.




Section 2.01 TASK LIST

The Task List contains search and view options for you to manage your review assignments. The search criteria at the top of the queue will allow you to search for specific assignments. You can click the Close Search link to hide the search criteria.

[Close Search] 


Submissions Type: All Committee Type: -- All -- Search



Process Type: All Status: Incomplete

PDF	Details	Click to open	IRB Number	Ref Number	Type	Review Process	Date Board Received	Expiration Date	Principal Investigator	Assigned Analyst
Pre-Review Correction Test										
			IRB-2020-0018	000827	Protocol Violation/Exception Report	Full Committee Review	04/07/2020 5:03:00 PM EDT	03/25/2021	Mott, Donna	Klaver, Andrea


Click Close Search.



[Open Search] 

PDF	Details	Click to open	IRB Number	Ref Number	Type	Review Process	Date Board Received	Expiration Date	Principal Investigator	Assigned Analyst
Pre-Review Correction Test										
			IRB-2020-0018	000827	Protocol Violation/Exception Report	Full Committee Review	04/07/2020 5:03:00 PM EDT	03/25/2021	Mott, Donna	Klaver, Andrea

The  icon will hide the menu on the left, allowing the Task List to display on the entire page.

My Workspaces ▾ IRB **Reviewer Dashboard** 

Switch View

Task List

Internal Submission Routing

Upcoming Committee Meeting

August 06, 2020 @ 09:00 AM

September 03, 2020 @ 09:00 AM

October 01, 2020 @ 09:00 AM

November 05, 2020 @ 09:00 AM


December 03, 2020 @ 09:00 AM

Past Committee Meeting

May 07, 2020 @ 09:00 AM




June 04, 2020 @ 09:00 AM

July 02, 2020 @ 09:00 AM

[Close Search] 


Submissions Type: All Committee Type: -- All -- Search


Process Type: All Status: Incomplete




PDF	Details	Click to open	IRB Number	Ref Number	Type	Review Process	Date Board Received	Expiration Date	Principal Investigator	Assigned Analyst
Pre-Review Correction Test										
			IRB-2020-0018	000827	Protocol Violation/Exception Report	Full Committee Review	04/07/2020 5:03:00 PM EDT	03/25/2021	Mott, Donna	Klaver, Andrea


Click the  icon.



My Workspaces ▾ IRB **Reviewer Dashboard** 

[Open Search] 

PDF	Details	Click to open	IRB Number	Ref Number	Type	Review Process	Date Board Received	Expiration Date	Principal Investigator	Assigned Analyst
Pre-Review Correction Test										
			IRB-2020-0018	000827	Protocol Violation/Exception Report	Full Committee Review	04/07/2020 5:03:00 PM EDT	03/25/2021	Mott, Donna	Klaver, Andrea

Click on the  icon to review or print the submission form in PDF.

My Workspaces ▾ IRB **Reviewer Dashboard** Back

Switch View

Task List

Internal Submission Routing

Upcoming Committee Meeting

August 06, 2020 @ 09:00 AM

September 03, 2020 @ 09:00 AM

October 01, 2020 @ 09:00 AM




November 05, 2020 @ 09:00 AM

December 03, 2020 @ 09:00 AM

[Close Search]

Submissions Type: All Committee Type: -- All -- Search

Process Type: All Status: Incomplete

PDF	Details	Click to open	IRB Number	Ref Number	Type	Review Process	Date Board Received	Expiration Date	Principal Investigator	Assigned Analyst
			IRB-2020-0018	000827	Protocol Violation/Exception Report	Full Committee Review	04/07/2020 5:03:00 PM EDT	03/25/2021	Mott, Donna	Klaver, Andrea

The new window allows you view the PDF version of the submission components and the Reviewer Dashboard screen at the same time. This enables you to continue with your review or switch back to the submission form as needed. When you are finished, click the Close button.

My Workspaces ▾ IRB **Reviewer Dashboard** Back

Switch View

Task List

Internal Submission Routing

Upcoming Committee Meeting

August 06, 2020 @ 09:00 AM

September 03, 2020 @ 09:00 AM

October 01, 2020 @ 09:00 AM

November 05, 2020 @ 09:00 AM

December 03, 2020 @ 09:00 AM

Past Committee Meeting

May 07, 2020 @ 09:00 AM

June 04, 2020 @ 09:00 AM

July 02, 2020 @ 09:00 AM

August 2020

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

iris - Document - Google Chrome

mclaren-test.imedris.net/System_Dispatch_Document.jsp?FORM_MODE=PRINT_COMP_PDF&ID=811&noprnt=Yes

[Close Search]

Submissions Type: All Committee Type: -- All -- Search

Process Type: All Status: Incomplete

Close **Save**

Protocol Violation/Exception Report (Version 7.0)

1.0 IRIS Protocol Violation/Exception Report

1.1 Protocol VIOLATIONS must be reported to the MHC IRB within 10 working days of the study team's knowledge of the occurrence.
 Protocol VIOLATIONS are those that:(1) affect the rights, safety, or welfare of study subjects;(2) change the risk/benefit ratio;(3) affect the scientific design of the study; or(4) violate an ethical principle.
 Protocol EXCEPTION is a one-time enrollment of an individual who does not meet current IRB approved criteria for inclusion in the research study as outlined in the protocol. Protocol Exceptions require prior approval of the MHCIRB and the study sponsor, if applicable, prior to the enrollment of the subject.
 Protocol DEVIATIONS are to be recorded by the investigator and submitted to the MHC IRB at the time of continuing review.(See MHC SOP, MHC_RPD122, Protocol Deviations, Violations and Exceptions)

2.0 General Information


2.1 Form Completed by:

Administrator

2.2 Date Submitted:

04/07/2020

2.3 Protocol Number

Clicking the  icon will open additional details about the submission.

My Workspaces ▾ IRB **Reviewer Dashboard** Back

Switch View

Task List

Internal Submission Routing

Upcoming Committee Meeting

August 06, 2020 @ 09:00 AM

September 03, 2020 @ 09:00 AM

October 01, 2020 @ 09:00 AM

November 05, 2020 @ 09:00 AM

December 03, 2020 @ 09:00 AM




Past Committee Meeting

May 07, 2020 @ 09:00 AM

[Close Search]

Submissions Type: All Committee Type: -- All -- Search


Process Type: All Status: Incomplete

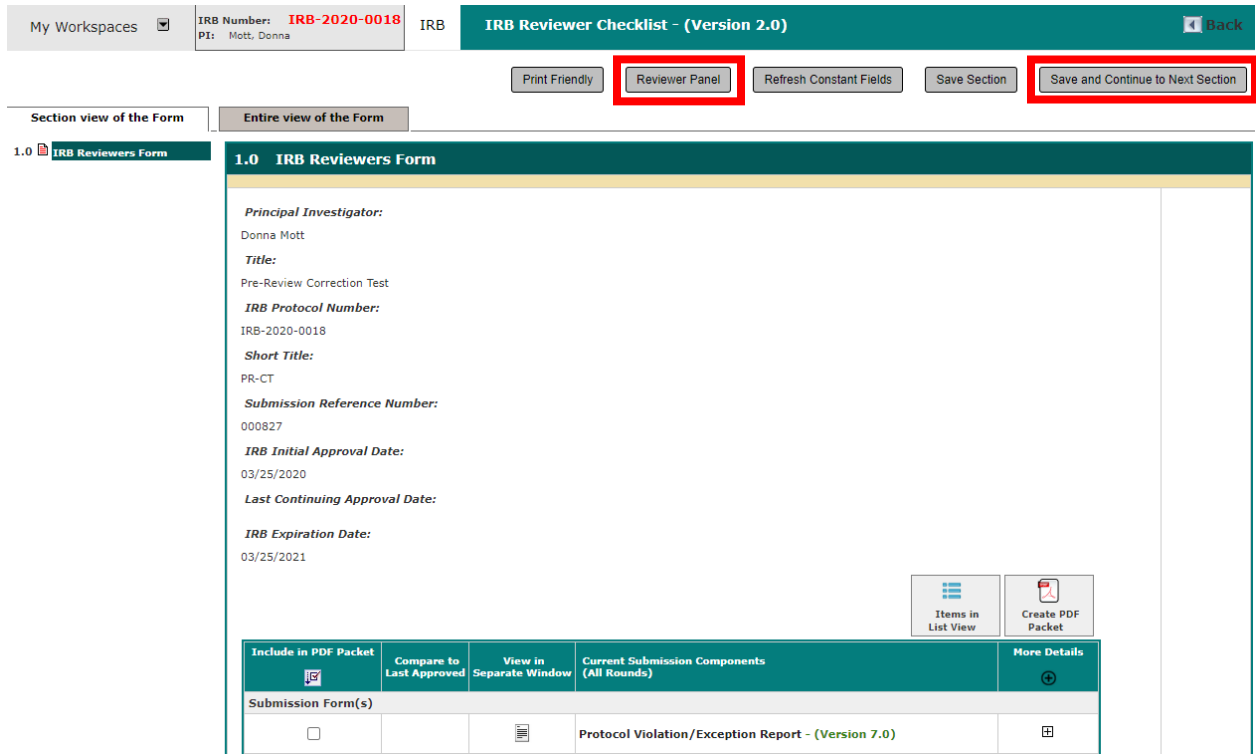
PDF	Details	Click to open	IRB Number	Ref Number	Type	Review Process	Date Board Received	Expiration Date	Principal Investigator	Assigned Analyst
			IRB-2020-0018	000827	Protocol Violation/Exception Report	Full Committee Review	04/07/2020 5:03:00 PM EDT	03/25/2021	Mott, Donna	Klaver, Andrea

Submission Details [X]

Ref Number	Study Classification	Date Board Received	Principal Investigator	Assigned Analyst
000827		04/07/2020 5:03:00 PM EDT	Mott, Donna	Klaver, Andrea

Section 2.02 REVIEWER CHECKLIST

Access your Reviewer Checklist by clicking the  icon. This will open the Reviewer Checklist form. Navigate through the form by completing the necessary questions and clicking the Save and Continue to Next Section button on the top right of the page.

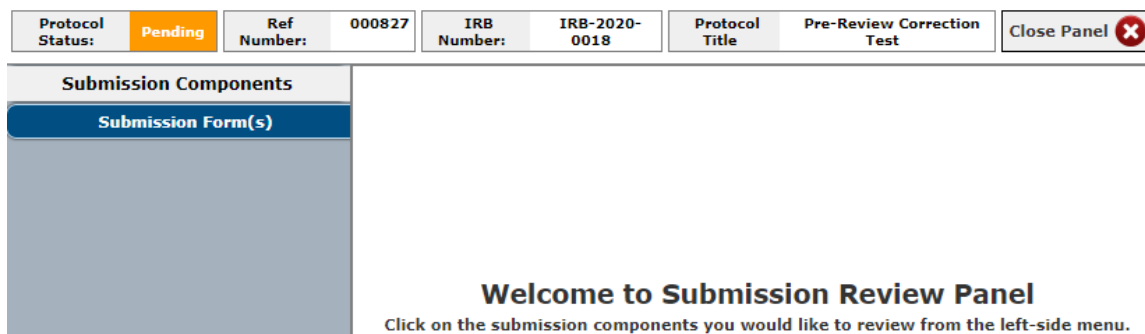


Include in PDF Packet	Compare to Last Approved	View in Separate Window	Current Submission Components (All Rounds)	More Details
<input type="checkbox"/>			Protocol Violation/Exception Report - (Version 7.0)	

Within your Reviewer Checklist, you also have the option to use the Reviewer Panel option located at the top of the page. The Reviewer Panel lets you to navigate through the submission components, view specific sections within each form, and make comments if necessary.

Section 2.03 REVIEWER PANEL

Click the Reviewer Panel button to open the submission review panel.



Protocol Status: Pending **Ref Number:** 000827 **IRB Number:** IRB-2020-0018 **Protocol Title:** Pre-Review Correction Test **Close Panel**

Submission Components


Submission Form(s)


Welcome to Submission Review Panel






Click on the submission components you would like to review from the left-side menu.

On the left-hand side of the screen, you will have all the submission components available for viewing access.


Click on the different submission components link(s) to view the associated forms within each corresponding section.

You can also view specific sections within each form by clicking on the  icon to expand section details. Once the sections are expanded, you can click on a specific section for review.

Protocol Status: Pending	Ref Number: 000827	IRB Number: IRB-2020-0018	Viewing: Protocol Violation/Exception Report (Version 7.0)	Close Panel 
---------------------------------	--------------------	---------------------------	--	---

Submission Components		General Information	
Submission Form(s)		Form Completed by:	
<input type="checkbox"/> Protocol Violation/Exception Report (Version 7.0)		Administrator	
Section Name		Date Submitted:	
IRIS Protocol Violation/Exception Report		04/07/2020	
General Information		Protocol Number	
Type of Report		IRB-2020-0018	
Humanitarian Device Protocol Violation/Except..			
Attachments			
		Protocol Title	
		Pre-Review Correction Test	
		Principal Investigator	
		Administrator	

Within each form, you will have the ability to make comments associated with specific questions.

To comment, click on the  icon next to the corresponding question. This will populate a comment window where you can enter comments and save them to the submission form.

Reviewer Comments Editor X

Author	Comments
	No reviewers share comments for this question.
<div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> ↶ B <i>I</i> <u>U</u> ABC x_2 x^2 Font Family 12 ↕ </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> ↴ ↵ ☰ ☷ ☰ ☷ ☰ ☷ 🔗 🖼️ Ω ✍️ 🖨️ 🔄 </div>	
<input type="checkbox"/> Display my comment to other reviewers	
Cancel Save Comment	

Once you are done entering comments and reviewing components, exit the review panel by clicking the Close Panel button at the top of the page. This will bring you back into the Reviewer Checklist.

Protocol Status: Pending	Ref Number: 000827	IRB Number: IRB-2020-0018	Viewing: Protocol Violation/Exception Report (Version 7.0)	Close Panel
---------------------------------	---------------------------	----------------------------------	---	--------------------

Submission Components	General Information																		
Submission Form(s)	Form Completed by:																		
<div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> ☰ Protocol Violation/Exception Report (Version 7.0) </div> <table border="1" style="width: 100%; border-collapse: collapse; font-size: small;"> <thead> <tr style="background-color: #008080; color: white;"> <th>Section Name</th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td>IRIS Protocol Violation/Exception Report</td> <td></td> <td></td> </tr> <tr style="background-color: #008080; color: white;"> <td colspan="3">General Information</td> </tr> <tr> <td>Type of Report</td> <td></td> <td></td> </tr> <tr> <td>Humanitarian Device Protocol Violation/Except..</td> <td></td> <td></td> </tr> <tr> <td>Attachments</td> <td></td> <td></td> </tr> </tbody> </table>	Section Name			IRIS Protocol Violation/Exception Report			General Information			Type of Report			Humanitarian Device Protocol Violation/Except..			Attachments			<div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> Administrator </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> Date Submitted: 04/07/2020 </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> Protocol Number IRB-2020-0018 </div>
Section Name																			
IRIS Protocol Violation/Exception Report																			
General Information																			
Type of Report																			
Humanitarian Device Protocol Violation/Except..																			
Attachments																			

At the end of the form, you will be asked for your recommendation and to indicate whether you have completed your review. When you indicate Yes and click Save and Continue to Next Section, the system will mark your review as complete.

My Workspaces ▾ IRB Number: **IRB-2020-0018** IRB PI: Mott, Donna **IRB Reviewer Checklist - (Version 2.0)** Back

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

Section view of the Form Entire view of the Form

1.0 IRB Reviewers Form
2.0 Reviewer Comments
3.0 **Reviewers Completion**


3.0 Reviewers Completion

3.1 Is your Review complete?

Yes No

Your assignment will move from Outstanding to Complete in the Task List on your homepage, and from Incomplete to Complete in Reviewer Assignment.

Article III. INTERNAL SUBMISSION ROUTING

This link contains any Internal Submission Routing tasks that you have been assigned. Click the  icon to open an assignment.


My Workspaces ▾ IRB **Reviewer Dashboard** Back

Switch View

Internal Submission Routing

Upcoming Committee Meeting

- August 06, 2020 @ 09:00 AM
- September 03, 2020 @ 09:00 AM
- October 01, 2020 @ 09:00 AM
- November 05, 2020 @ 09:00 AM
- December 03, 2020 @ 09:00 AM

Open	Task Type	Received	Tasks
	Internal Submission Routing Signoff	08/05/2020 11:01 AM EDT	<p>Andrea Klaver has been assigned to Administratively review the submission</p> <p>Study Title: Pre-Review Correction Test Principal Investigator: Mott, Donna Submission Type: Protocol Violation/Exception Report Reference Number: 000827 IRB Number: IRB-2020-0018 IRB Expiration: 03/25/2021</p>

The Internal Submission Routing page lists elements of the submission that allow you to access different areas of the study related to the submission.

My Workspaces ▾ IRB Number: **IRB-2020-0018** IRB PI: Mott, Donna **Submission validation** Back

Protocol Items Miscellaneous Submission Forms Additional Attached Forms

Ref Number: **000827** IRB Number: **IRB-2020-0018** Protocol Title: Pre-Review Correction Test
Protocol Status: Pending IRB Expiration Date: 03/25/2021


Submission components:

Items in List View Create PDF Packet

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Current Submission Components (All Rounds)	More Details
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Protocol Violation/Exception Report - (Version 7.0)	<input type="checkbox"/>

- Reviewer Assignment List
- Meeting Discussion
- Stipulations
- Submission Outcome
- Outcome Letters
- Internal Submission Routing

The Reviewer Assignment List section displays any reviewers associated to the submission. If you are assigned as the reviewer, you will be able to access your Reviewer Checklist from this section.

Reviewer Assignment List:						
View Form	Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed	
	Primary	Klaver, Andrea	Yes	08/05/2020	08/05/2020	

The Outcome Letters section lists any outcome letters created for the submission. If you have been assigned to sign off on a letter for this submission, you will be able to access your signoff task from this section. You can also create and send a letter from this section.

Outcome Letters:						
Delete	Send	Edit/View	Title	Signature Required	Status	Route Signoff Copy
No Letters have been created for this submission.						

Internal Submission Routing contains specific information about the internal submission routing task. This is where you can view assignment notes and indicate completion of the routing task.

Internal Submission Routing:						
Submission Routing.		Assigned Analyst :	Klaver, Andrea			
		Assignment notes :				
Assignment comments						
Assigned To	Assigned From	Date Notified	Completed ?	Date Completed		
User comments						
Assignment Comments:						
Klaver, Andrea	Klaver, Andrea	08/05/2020	Complete: <input checked="" type="radio"/> Yes <input type="radio"/> No			
User Comments:						

From this section, you can respond back to the Analyst by clicking User Comments to add comments regarding the submission.

When you are finished with your assignment, indicate that your assignment is complete by selecting Yes under the Completed column and click Save Routing.

If you return to the Reviewer Dashboard, the Internal Submission Routing task will no longer appear on this page.

Article IV. REVIEWER SPECIFIC TASKS

Section 4.01 REVIEWER ASSIGNMENT TASK

The Reviewer Assignment home screen task will populate when you have been assigned as a reviewer. The task will stay on your home screen until the assignment has been completed.

The screenshot shows the 'All Tasks' interface with the 'Outstanding' tab selected. There are 5 results found. The first task is highlighted with a red box:

Click to open	Task Type	Received	Description
<input type="checkbox"/>	Reviewer Assignment	08/05/2020 02:09 PM EDT	Andrea Klaver has been assigned as the Primary for a Full Committee Review on 08/06/2020 on the Initial Review Submission Packet
<input type="checkbox"/>	Analyst Assignment	08/05/2020 02:09 PM EDT	Andrea Klaver has been assigned as the analyst
<input type="checkbox"/>	Internal Submission Routing Complete	08/05/2020 12:41 PM EDT	Internal submission routing review completed by Andrea Klaver
<input type="checkbox"/>	Analyst Assignment	08/05/2020 08:26 AM EDT	Andrea Klaver has been assigned as the analyst
<input type="checkbox"/>	Analyst Assignment	08/04/2020 04:54 PM EDT	Andrea Klaver has been assigned as the analyst

Opening this task will navigate you into the Reviewer Checklist where you can complete the review for the submission round.

Section 4.02 Internal Submission Routing Signoff Task

The Internal Submission Routing Signoff home screen task will populate when you have been routed to complete a signoff. The task will stay on your home screen until you indicate that you are complete with your signoff task.

Opening this task will navigate you into the Submission Validation page, where you can verify the submission components and complete the signoff.

The screenshot shows the 'All Tasks' interface with the 'Outstanding' tab selected. The 'Task List' dropdown menu is open, and 'Internal Submission Routing Signoff' is selected and highlighted with a red box:

Click to open	Task Type	Received	Description
<input type="checkbox"/>	Internal Submission Routing Signoff	08/05/2020 02:23 PM EDT	Andrea Klaver has been assigned to Administratively review the submission