



# IRBManager User Guide

## REVIEWER DASHBOARD

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### Dashboard Overview

The screenshot shows the IRBManager Reviewer Dashboard. Key features are highlighted with callouts:

- Your Reviewer Due:** Points to the 'Due' column in the 'My Reviews' table.
- Reviewer Worksheet:** Points to the 'Full board review (optional)' row in the 'My Reviews' table.
- Access the Protocol:** Points to the 'IRB - Initial Expedited/FB Submission' row in the 'My Reviews' table.
- Filter what you see:** Points to the dropdown menu in the 'Events (2 Open)' section.

**My IRB**

**You have 1 reviews pending**

Type	Assigned	Due	Review Item
Full board review (optional)	07/12/2021	07/13/2021	IRB - Initial Expedited/FB Submission 2021-513-Childrens Hospital/DMC

**Projects (2 Active)**

- You are associated with **2 active** Projects and **2 total** Projects.
- You are the PI for **2 active** and **2 total** Projects.
- You are the Co-Investigator for **1 active** and **1 total** Projects.

**xForms (8 Active)**

- You have **4 unsubmitted** xForms.
- You have **4 xForms** being processed at a later stage.
- There are **2 xForms** awaiting your attention.

**Events (2 Open)**

Only show events where I am:

- You have **2 Single IRB Initial Submission** events.
- You have **2 Total Open** events

**Notices**

**CITI Training Re Human Subjects**

Investigators who utilize current CITI certification from a institution to satisfy training requirements at CMU required modification of, current expiration of, current contact the Office with any questions

**Update on Resur Subjects Research Person Interacti**

In consultation with

1. **Login to IRBManager to view your Dashboard**

2. **Starting a Review**

- If you have an assigned review pending, it will show at the top of the page.
- The protocols for review will be listed underneath in the section titled "My Reviews"
- The dates Assigned and Due are listed to the right.

The screenshot shows the IRBManager dashboard for Central Michigan University. At the top, a notification bar states "You have 1 reviews pending." Below this, the "My Reviews (1 Open)" section contains a table with the following data:

Type	Assigned	Due	Review Item
Full board review (optional)	07/12/2021	07/13/2021	IRB - Initial Expedited/FB Submission 2021-513-Childrens Hospital/DMC

The dashboard also includes sections for "Projects (2 Active)", "xForms (8 Active)", and "Events (2 Open)". A sidebar on the left contains navigation links for Actions, Recent Items, Messages, and Useful Links. A "Notices" section on the right provides information about CITI Training and Resur Subjects Research Person Interacti.

3. **Accessing the Reviewer Worksheet**

- Select the "Type" title of the protocol you have been assigned to review. (In this case, the title is "Full board review (optional)")

This screenshot is identical to the previous one, but a yellow arrow points to the "Type" column header in the "My Reviews (1 Open)" table, indicating the user should click on it to access the reviewer worksheet.

- The Reviewer Worksheet will open in another tab. This will allow you to open the protocol and view it separately as you complete the worksheet.

**Review Assignment**

Review Type: Full board review (optional)      Assigned: 07/12/2021 by Geasler, Gary  
 Reviewer: Geasler, Gary      Due: 07/13/2021  
 Review Item: **IRB - Initial Expedited/FB Submission**  
 2021-513-Childrens Hospital/DMC

**Review xForm**

Collaborators      Worksheet for Expedited Review of N...      Page 1 of 1

Reviewer Worksheet Expedited Review of New Application -- Worksheet for Expedited Review of New Application

Reviewer Add Note   View Audit

Geasler, Gary

Email: geaslerg@gmail.com      Phone:

➤ **Tip:** As in most IRBManager forms, you can use the dropdown box at the top to navigate to different parts of the form. (All required fields must be completed before it will allow you to do this.)

**Review Assignment**

Review Type: Full board review (optional)      Assigned: 07/12/2021 by Geasler, Gary  
 Reviewer: Geasler, Gary      Due: 07/13/2021  
 Review Item: **IRB - Initial Expedited/FB Submission**  
 2021-513-Childrens Hospital/DMC

**Review xForm**

Collaborators      Worksheet for Expedited Review of New...      Page 1 of 1

Reviewer Worksheet Expedited Review of New Ap...      Worksheet for Expedited Review of New Application      of New Application

Check & Submit Form

4. **Accessing the Protocol**

➤ From the Dashboard select the protocol link listed under "Review Item" column to view the protocol and access attachments related to the study.

Home      Find Project (Ctrl+Q)

My IRB      Help      Gary's Settings

**You have 1 reviews pending.**

**My Reviews (1 Open)**

Type	Assigned	Due	Review Item	Request Details
Full board review (optional)	07/12/2021	07/13/2021	IRB - Initial Expedited/FB Submission 2021-513-Childrens Hospital/DMC	

**Projects (2 Active)**

- You are associated with **2 active** Projects and **2 total** Projects.
- You are the PI for **2 active** and **2 total** Projects.
- You are the Co-Investigator for **1 active** and **1 total** Projects.

**Notices**

**CITI Training Requirement Reg; Human Subjects Research (IRB)**  
Investigators who have been allow utilize current CITI human subjects

➤ The protocol will open in the same tab. (You're Reviewer Worksheet should be open in another tab.)

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Home | Find Project (Ctrl+Q) | Event Details: IRB - Initial Expedited/FB Submission on 2021-513-Childrens Hospital/DMC | Help | Gary's Settings | Sign off

**Project-Site**

Project: 2021-513-Childrens Hospital/DMC | Site: Childrens Hospital/DMC - Childrens Hospital of Michigan  
 Title: A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group, Event-Driven, Grou (hover for more...) | Committee: CMU Pediatrics IRB  
 PI: Ross, Robert | Sponsor Id

**Event**

Type: IRB - Initial Expedited/FB Submission | Started: 05/03/2021  
 Instance: | Completed: |  
 Committee: CMU Pediatrics IRB | Assigned: |  
 Review Type: Full Board

**Reviews (5)**

Type	Reviewer	Outcome	Due	Complete
Full board review (optional)	Abdel-Haq, Nahed		05/11/2021	
Full board review (optional)	Blahunka, Stephen		05/11/2021	
Full board review (optional)	Geasler, Gary		07/13/2021	
Full board review (optional)	Heidemann, Sabrina		07/13/2021	
Full board review (optional)	Thomas, Ronald		05/11/2021	

**Emails (12)**

Subject	Date	Del	To/From	Int
IRB Determination of Conditional Approval for 2021-513	07/15/2021		lbourke@dmc.org; ross3rd@cmich.edu	No
Selexipag ICF Appendix	07/14/2021		czach1j@cmich.edu; lbourke@dmc.org	Yes

➤ **From this screen you should be able to view all protocol information:**

- Project Site Information: Project, Title, PI, Site, and Committee.
- As a Reviewer, you will not do anything with this section, but are welcome to view it.

**Project-Site**

★ **Project:** 2021-513-Childrens Hospital/DMC | ★ **Site:** Childrens Hospital/DMC - Childrens Hospital of Michigan  
 ★ **Title:** A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group, Event-Driven, Grou (hover for more...) | **Committee:** CMU Pediatrics IRB  
 ★ **PI:** Ross, Robert | **Sponsor Id**

- Event Information: Type of Submission, Committee, Review Typ, and data entry start date.
- As a Reviewer, you will not do anything with this section, but are welcome to view it.

**Event**

★ **Type:** IRB - Initial Expedited/FB Submission | ★ **Started:** 05/03/2021  
**Instance:** | **Completed:** |  
 ★ **Committee:** CMU Pediatrics IRB | **Assigned:** |  
 ★ **Review Type:** Full Board

- Reviews: All Reviewers' names and Review Types, Outcome, and Dates Due/Complete
- You may select any of the review type titles to see other Reviewer's Reviewer Worksheets.

**Reviews (5)**

Type ★	Reviewer ★	Outcome ★	Due ★	Complete ★
Full board review (optional)	Abdel-Haq, Nahed		05/11/2021	
Full board review (optional)	Blahunka, Stephen		05/11/2021	
Full board review (optional)	Geasler, Gary		07/13/2021	
Full board review (optional)	Heidemann, Sabrina		07/13/2021	
Full board review (optional)	Thomas, Ronald		05/11/2021	

- Email: All emails sent related to the study.

**Emails (12)**

Subject	Date	Del	To/From	Int
IRB Determination of Conditional Approval for 2021-513	07/15/2021		lbourke@dmc.org; ross3rd@cmich.edu	No
Selexipag ICF Appendix	07/14/2021		czach1j@cmich.edu; lbourke@dmc.org	Yes
Full Board Review Assignment for 2021-513	06/30/2021		jani1sm@cmich.edu; sanil1y@cmich.edu	Yes
Assign study to Convened Board	06/30/2021		stane1dm@cmich.edu	Yes

- **Steps:** All steps related to the protocol within IRBManager and indication of which step have been completed.
- As a Reviewer, you will not do anything with this section, but are welcome to view it.

Steps (11) <span style="float: right;">Hide Skipped</span>					
Step	Planned	Actual	Complete	Minutes	Micro Note
Receive Submission		04/28/2021	Yes		
Admin Review		06/30/2021	Yes		
Notify Board of Expedited Approval			No		
Assign to Full Board Reviewers		06/30/2021	Yes		
Assign to FB Agenda	07/13/2021	07/13/2021	Yes	05/11/2021, 07/13/2021	
Notify PI of Results		07/15/2021	Yes		
Notify PI of Approval			No		

## 5. Accessing the Protocol Forms & Attachments

### ➤ Actions Section

- All forms and attachments are located in the "Actions" section of the protocol.
- You may also send a protocol-related email through this section.

The screenshot shows the CMU IRBManager interface. On the left is the CMU logo and navigation menu. The 'Actions' menu item is highlighted with a yellow arrow. The main content area shows 'Event Details: IRB - Initial Expedited/FB Submission on 2021-513-Childrens Hospital/DMC' and 'Project-Site' information including Project, Title, and PI.

### ➤ Accessing the Protocol Application

- From the "Actions" section, select "xForms".




The screenshot shows the 'Actions' dropdown menu. The 'xForms (11)' option is highlighted with a yellow arrow. Other options include Attachments (37), Send EMAIL, and Done.

- A list of forms related to the protocol will show on the screen.

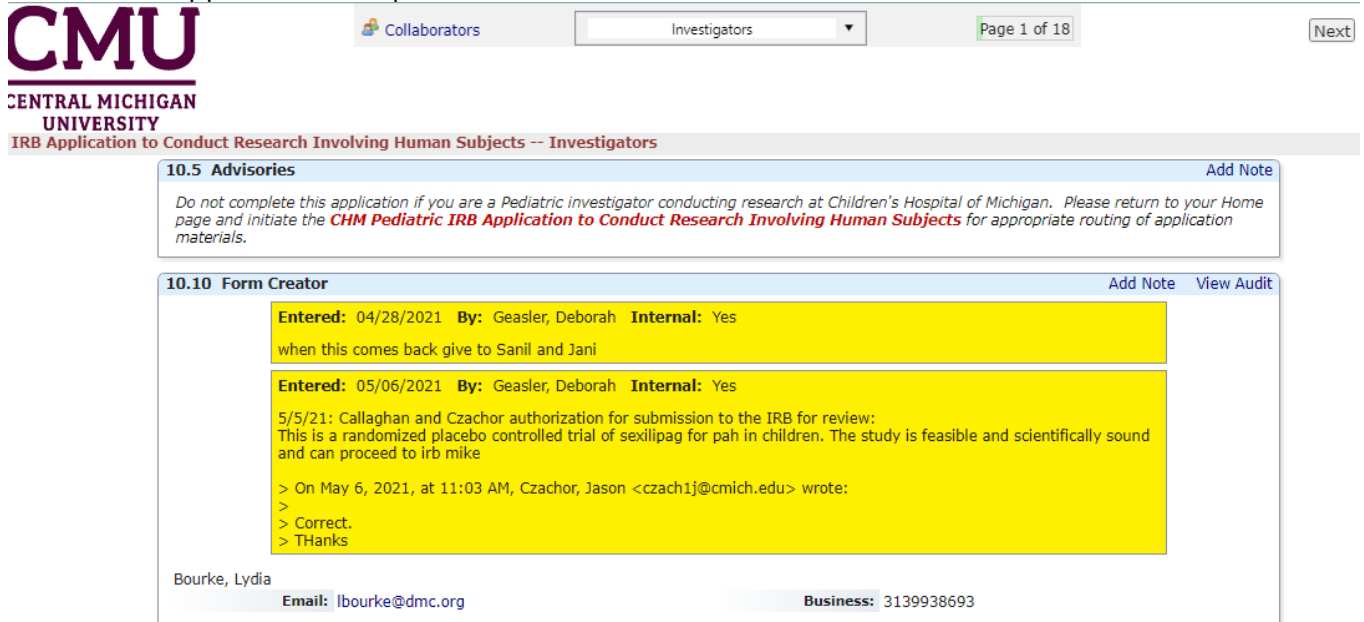
The screenshot shows the IRBManager interface displaying a list of forms. The table below represents the data shown in the screenshot.

Action	Form	Identifier	Stage/Status	Started	Submitted	By
✗	Reviewer Worksheet Expedited Review of New Application		Data entry	07/12/2021		Sanil, Yamuna
✗	Reviewer Worksheet Expedited Review of New Application		Data entry	07/12/2021		Jani, Sanket
✗	Reviewer Worksheet Expedited Review of New Application		Data entry	07/12/2021		Geasler, Gary
✗	Reviewer Worksheet Expedited Review of New Application		Data entry	05/11/2021		Jani, Sanket
✗	Reviewer Worksheet Expedited Review of New Application		Data entry	05/11/2021		Jani, Sanket
✗	Reviewer Worksheet Expedited Review of New Application		Data entry	05/11/2021		Blahunka, Stephen
✗	Reviewer Worksheet Expedited Review of New Application		Data entry	05/11/2021		Sanil, Yamuna
✗	Reviewer Worksheet Expedited Review of New Application		Data entry	05/10/2021		Sanil, Yamuna
✗	Reviewer Worksheet Expedited Review of New Application		Data entry	05/10/2021		Faraon, May
✗	Reviewer Worksheet Expedited Review of New Application		Data entry	05/08/2021		Abdel-Haq, Nahed
✗	IRB Application to Conduct Research Involving Human Subjects	Ross, Robert	Data Entry (6th time)	03/09/2021		Bourke, Lydia

- Scroll down until you see the Application title.
- Select the Title "IRB Application to Conduct Research Involving Human Subjects".

Welcome to IRBManager at Central Michigan University  Useful Links		Reviewer Worksheet Expedited Review of New Application		Data entry	05/10/2021		Faraon, May
		Reviewer Worksheet Expedited Review of New Application		Data entry	05/08/2021		Abdel-Haq, Nahed
		IRB Application to Conduct Research Involving Human Subjects	Ross, Robert	Data Entry (6th time)	03/09/2021		Bourke, Lydia

- The Application will open in a new tab.



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IRB Application to Conduct Research Involving Human Subjects -- Investigators

Collaborators | Investigators | Page 1 of 18 | Next

**10.5 Advisories** Add Note

*Do not complete this application if you are a Pediatric investigator conducting research at Children's Hospital of Michigan. Please return to your Home page and initiate the **CHM Pediatric IRB Application to Conduct Research Involving Human Subjects** for appropriate routing of application materials.*

**10.10 Form Creator** Add Note View Audit

**Entered:** 04/28/2021 **By:** Geasler, Deborah **Internal:** Yes  
when this comes back give to Sanil and Jani

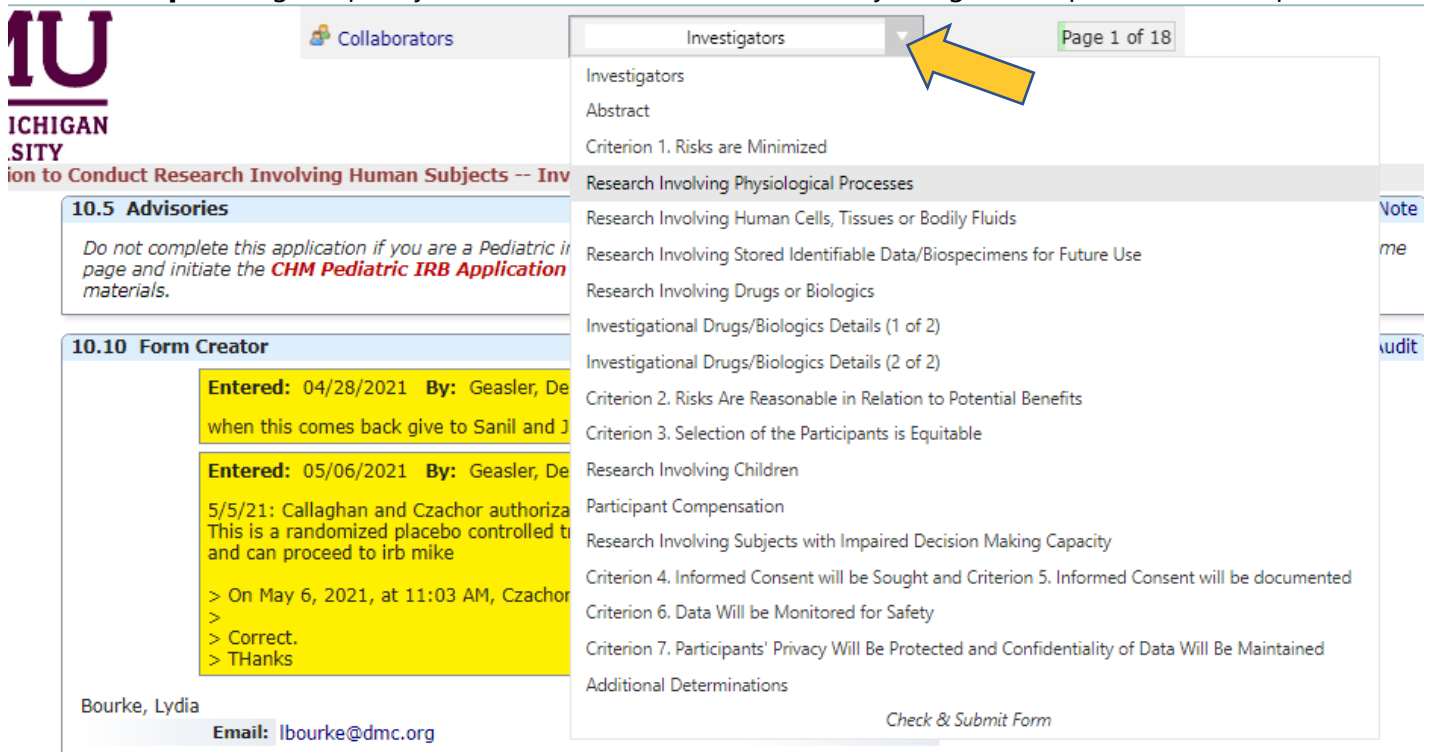
**Entered:** 05/06/2021 **By:** Geasler, Deborah **Internal:** Yes

5/5/21: Callaghan and Czachor authorization for submission to the IRB for review: This is a randomized placebo controlled trial of sexlipag for pah in children. The study is feasible and scientifically sound and can proceed to irb mike

> On May 6, 2021, at 11:03 AM, Czachor, Jason <czach1j@cmich.edu> wrote:  
> Correct.  
> Thanks

Bourke, Lydia  
Email: lbourke@dmc.org Business: 3139938693

- **Tip:** Navigate quickly to different sections of the form by using the dropdown at the top.



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IRB Application to Conduct Research Involving Human Subjects -- Inv

Collaborators | Investigators | Page 1 of 18

Investigators  
Abstract  
Criterion 1. Risks are Minimized  
Research Involving Physiological Processes  
Research Involving Human Cells, Tissues or Bodily Fluids  
Research Involving Stored Identifiable Data/Biospecimens for Future Use  
Research Involving Drugs or Biologics  
Investigational Drugs/Biologics Details (1 of 2)  
Investigational Drugs/Biologics Details (2 of 2)  
Criterion 2. Risks Are Reasonable in Relation to Potential Benefits  
Criterion 3. Selection of the Participants is Equitable  
Research Involving Children  
Participant Compensation  
Research Involving Subjects with Impaired Decision Making Capacity  
Criterion 4. Informed Consent will be Sought and Criterion 5. Informed Consent will be documented  
Criterion 6. Data Will be Monitored for Safety  
Criterion 7. Participants' Privacy Will Be Protected and Confidentiality of Data Will Be Maintained  
Additional Determinations

**10.5 Advisories**

*Do not complete this application if you are a Pediatric investigator conducting research at Children's Hospital of Michigan. Please return to your Home page and initiate the **CHM Pediatric IRB Application** materials.*

**10.10 Form Creator**

**Entered:** 04/28/2021 **By:** Geasler, Deborah  
when this comes back give to Sanil and Jani

**Entered:** 05/06/2021 **By:** Geasler, Deborah

5/5/21: Callaghan and Czachor authorization for submission to the IRB for review: This is a randomized placebo controlled trial of sexlipag for pah in children. The study is feasible and scientifically sound and can proceed to irb mike

> On May 6, 2021, at 11:03 AM, Czachor, Jason <czach1j@cmich.edu> wrote:  
> Correct.  
> Thanks

Bourke, Lydia  
Email: lbourke@dmc.org

Check & Submit Form



- **Attachments that were included in the application** will be accessible within the application in the corresponding sections. (You may also access all attachments, including those not included in the application in another area. Directions for this process are in the next section.)

Please provide name of new personnel to be added to this protocol if they are not CMU affiliated or if a contact is not appearing in the above table. Lydia Bourke

Role on Study Team Coordinator

Affiliation Other

Institutional Affiliation Other Institution

Training Attachments

Bourke Lydia CV 18MAR2020.pdf CVs

Bourke Lydia HSR training exp 17FEB2023.pdf Misc/Other

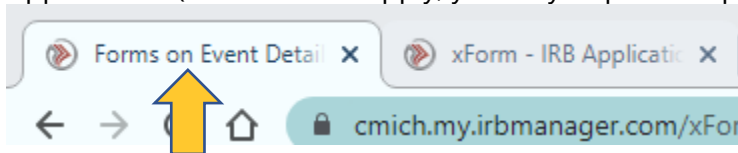
Bourke Lydia GCP training exp 19FEB2023.pdf Training Documentation

[Download All Attachments](#)

*Convert Word documents to PDF before uploading.*

➤ **Accessing Protocol ALL Attachments (including those NOT in the Application)**

- If you have just accessed the Application, Return to the previous tab from which you selected the Application. (if this doesn't apply, you may skip this step)



- Once you return to the list of forms, select "Done" to return to the Protocol Site. (if this doesn't apply, you may skip this step)

Action	Form
✗	Reviewer Worksheet Expedited Review of New Application
✗	Reviewer Worksheet Expedited Review of New Application
✗	Reviewer Worksheet Expedited Review of New Application
✗	Reviewer Worksheet Expedited Review of New Application
✗	Reviewer Worksheet Expedited Review of New Application
✗	Reviewer Worksheet Expedited Review of New Application

- From the Protocol Site page, in the "Actions" section select "Attachments."

**Actions**

Attachments (37) 

Send EMail

Start xForm

xForms (11)

Done

**Project-Site**

**Project:** 2021-513-Childrens Hospital/DMC

**Title:** A Randomized, Multicenter, Double-Blind, Place Controlled, Parallel-Group, Event-Driven, Group  
(hover for more...)

**PI:** Ross, Robert

**Event**

**Type:** IRB - Initial Expedited/FB Submission

**Instance:**

- A list of attachments related to the protocol will be listed in the same tab.
- Select the Name of any attachment to view.

**Project-Site** PI Ross, Robert

**Attachments on Event IRB - Initial Expedited/FB Submission Started 05/03/2021 on 2021-513-Childrens Hospital/DMC**

Attachments (35)	Name	Attached	Type	Internal
Generated Docs (2)	<a href="#">Rec_Mat_1.zip</a>	05/03/2021 4:46 PM ET	Questionnaire/Survey	No
	<a href="#">COVID-19 pROTOCOL aPPENDIX</a>	05/03/2021 4:46 PM ET	Protocol	No
	<a href="#">04.1 AC-065A310 IB Edition 15 Addendum 1.pdf</a>	05/03/2021 4:46 PM ET	Investigators' Brochure	No
	<a href="#">Bosentan Investigator Brochure v20 Jun2017.pdf</a>	05/03/2021 4:46 PM ET	Investigators' Brochure	No

- When finished reviewing attachments, select "Done" under the "Actions" section to return to the Protocol Site.

**Actions**

Export

Done 

Recent Items

**Project-Site**

PI Ross, Robert

**Attachments on Event IRB - Initial Expedited/FB Submission Started 05/03/2021**

Attachments (35)	Name	Attached
Generated Docs (2)	<a href="#">Rec_Mat_1.zip</a>	05/03/2021
	<a href="#">COVID-19 pROTOCOL aPPENDIX</a>	05/03/2021