



MedStar Health

It's how we **treat people.**

May 13, 2025

# How to Submit a Modification to Update a Study

# Who can submit modifications?

- Only the PI and PI proxies
  - Any approved team member may create edit modifications in pre-submission state but **cannot submit**.
  - Study team members, other than the PI, must be assigned as proxies to submit.



- 

Georgetown University



MedStar Health

# Georgetown-MedStar IRB System

Hello, [Timothy Rodriguez](#)

[Switch User](#)

Dashboard

erIC Archive

Admin

IRB

Create ▼

Enter search terms to filter list

Jan 4 2025 STUDY00005689:...STI Incidence  
CR: *none*  
Coordinator: *Kim*, 4 days ago

Jan 6 2017-0589: Con...or new parents  
CR: *none*  
Coordinator: *Brown*, 2 days ago

Jan 8 STUDY00003849:...ervical Cancer  
CR: *none*  
Coordinator: *Khawar*, 10 hours ago

2015-0110: TBC...erapy For Muta  
CR: *none*

Hello, Timothy Rodriguez ▾

Switch User

## My Inbox

## Assignments

In Process

## My Inbox







Filter by ?

ID 



[+ Add Filter](#) [✕ Clear All](#)




ID	Name	Date Created	Date Modified	State	Coordinator
 STUDY00008222	Test MSS_202407251046360430	7/25/2024 1:18 AM	8/29/2024 9:20 AM	Pre-Review	Timothy Rodriguez
 STUDY00008276	10.5.6 Item #2	8/28/2024 11:11 AM	8/28/2024 11:14 AM	Suspended	Timothy Rodriguez
 MOD00018431	Modification / Update #6 for Study CDC Polysubstance Surveillance	6/25/2024 9:36 PM	6/25/2024 9:39 PM	Pre-Review	Timothy Rodriguez
 STUDY00008150	Reading and Lifelong Learning by Academic Cardiologists	6/25/2024 11:43 AM	6/25/2024 11:47 AM	Pre-Review	
 STUDY00008146	Professional Female Lacrosse Observational Study	6/24/2024 3:24 PM	6/24/2024 8:46 PM	Pre-Review	
 STUDY00000662	test	5/8/2019 2:37 PM	4/26/2024 10:36 AM	Pre-Submission	

6 items


page 1 of 1

25 / page

- Select the **Active** tab to show your currently approved studies. Then use the search box to find the study you would like to modify.



Georgetown University



MedStar Health

# Georgetown-MedStar IRB System

Hello, Timothy Rodriguez ▾

Switch User

Dashboard

eRIC Archive

Admin

**IRB**

Submissions

Meetings

Reports

Library

Institutional Profiles

Help Center

IRB

IRB

Create New Study

Report New Information

In-Review

**Active**

New Information Reports

Final IRB

Relying Sites






All Submissions

Archived

Search ?

Filter by ? ID ▾

+ Add Filter ✕ Clear All

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name	Expiration Date
 STUDY00008164	Example	1/8/2025 9:55 AM	Approved	Timothy	Rodriguez	Timothy	Rodriguez	
 STUDY00004559	Roche GN42272	1/8/2025 1:00 AM	Approved	Faria	Amjad	Naomi	Skarsgard	2/7/2025
 STUDY00003566	ImmuKnow in Sarcoid	1/8/2025 1:00 AM	Approved	Farooq	Sheikh	Diamond	Tompkins	2/7/2025
 2013-0058	CDC Public Health Surveillance Project HTC Population Profile	1/8/2025 1:00 AM	Approved	Craig	Kessler	Irene	Alvarez - Mendoza	4/8/2025
 2016-0914	Gut-vaginal microbiome function in natural and treatment-mediated controlled HIV	1/8/2025 1:00 AM	Approved	Daniel	Merenstein	Christopher	Kim	4/8/2025



- This is a study home page. Select **Create Modification/CR** to begin the modification application.

DashboardeRIC ArchiveAdmin**IRB**

SubmissionsMeetingsReportsLibraryInstitutional ProfilesHelp Center

IRB > ExampleAdmin ViewHelp

Approved

STUDY00008164: Example

Entered IRB: 1/8/2025 9:53 AM  
Initial approval: 1/8/2025  
Initial effective: 1/8/2025  
Effective: 1/8/2025  
Last updated: 1/8/2025 9:55 AM

**Principal investigator:** Timothy Rodriguez  
**Submission type:** Initial Study  
**Primary contact:** Timothy Rodriguez  
**PI proxies:**

**IRB office:** MHRI IRB  
**Committee:**  
**IRB coordinator:** Timothy Rodriguez  
**Letter:** [Correspondence\\_for\\_STUDY00008164.pdf\(0.01\)](#) ...  
**Regulatory authority:** 2018 Requirements

Next Steps

View Study

Printer Version

Create Modification/CR

Report New Information

Send Letter

Prepare Letter

Pre-Submission

Pre-Review

IRB Review

Post-Review

Review Complete

Clarification Requested

Clarification Requested

Modifications Required

HistoryFundingContactsDocumentsFollow-on SubmissionsReviewsSnapshotsTraining

Filter by ?

Activity

Enter text to search

Q

+ Add Filter

✕ Clear All

ActivityAuthorActivity Date

MedStar Health

MedStar Health Research Institute

- **Select Modification/Update.**

☰

Modification / Continuing Review

<<

You Are Here: Example > \_IRBSubmission

Creating New: IRB Submission

◀ Go to forms menu Help

Modification / Continuing Review / Study Closure

\* What is the purpose of this submission?

☐ Continuing Review

☐ Modification / Update

☐ Modification and Continuing Review

[Clear](#)

✕ Exit

Save

Continue



- Select **Other Parts of the Study** under Modification Scope.
- The Modification Scope determines what can be updated in this modification.
- If you would like to add additional team members, please also select **Study Team Member Information** under Modification Scope.

**Modification / Continuing Review**

You Are Here: [Example](#) > [\\_IRBSubmission](#)

## Creating New: IRB Submission

[Go to forms menu](#) [Help](#)

### Modification / Continuing Review / Study Closure

**\* What is the purpose of this submission?** [?](#)

☐ Continuing Review

☒ Modification / Update

☐ Modification and Continuing Review

[Clear](#)

**i** To change the PI, choose 'Other parts of the study/site' scope

**Modification scope:**

☐ Study team member information

☒ Other parts of the study

**Note! After you select Continue, you CANNOT change the Modification Scope. If you make a mistake, you will need to discard the current modification and create another modification.**

[✕ Exit](#) [Save](#) [Continue →](#)



- **Complete this page. For item #3, please include a summary list of all changes to the study.**

Validate Compare

Modification / Continuing Review

Modification Summary

Modification Details

Editing: MOD00018436

Go to forms menu Print Help

Modification Information

1. Study enrollment status:

☐ No subjects have been enrolled to date  
☐ Subjects are currently enrolled  
☐ Study is permanently closed to enrollment  
☐ All subjects have completed all study-related interventions  
☐ Collection of private identifiable information is complete

2. Notification of subjects: (check all that apply)


☐ Current subjects will be notified of these changes  
☐ Former subjects will be notified of these changes

Attach files:

If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.

3. \* Summarize the modifications:

Exit Save Continue



While the summary of changes does not need to be a comprehensive statement of change, the summary should include more than just a list of documents that are changed. It is helpful to provide a preview of the types of changes that are included.



- Update sections of the application as needed. Use the left-hand column to navigate.
- If you have questions that are not addressed in this guide, you may refer to the **New Submission Guide** which includes additional detail. You may also contact ORI staff for additional guidance.

ValidateCompare

Basic Study Information

Study Funding Sources

Study Scope

Local Research Locations

Local Site Documents

Additional Information

You Are Here: Example

Editing: IRB00042840

Go to forms menuPrintHelp

Basic Study Information

1. \* Title of study:

Example

2. \* Short title:

Example

3. \* Brief description:

Example

4. \* What kind of study is this?

☒ Multi-site or Collaborative study

ExitSaveContinue







- **When uploading a revised document:**
  - **Do not delete documents**
    - Use the **Update** button
    - This will stack newer versions on top of an older and preserve the document history.
    - This also allow the IRB to easily recognize edits between the new and older version.

### Local Site Documents

#### 1. **Consent forms:** (include an HHS-approved sample consent document, if applicable)

				
Document	Category	Date Modified	Document History	
  MHRI IRB Informed Consent Form Template.docx(0.01)	Consent Form	5/30/2024	History 	

#### 2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

				
Document	Category	Date Modified	Document History	
  Flyer.docx(0.01)	Recruitment Materials	5/30/2024	History 	

#### Other attachments:

+ Add

Document	Category	Date Modified	Document History
There are no items to display			



- On the final page of the modification, click **Finish**.
- This will send you to the study homepage.
- This does not submit the study.

The screenshot shows the 'Final Page' of an IRB submission form. On the left is a sidebar with navigation links: Basic Study Information, Study Funding Sources, Study Scope, Local Research Locations, Local Site Documents, and Additional Information. The main content area has a breadcrumb 'You Are Here: Example' and the title 'Editing: IRB00042840'. Below this is the heading 'Final Page' with an information icon. A message states: 'You have reached the end of the IRB submission form. Read the next steps carefully:'. Two numbered steps follow: '1. Click **Finish** to exit the form.' and '2. Important! To send the submission for review, click **Submit** on the next page.' A large red arrow points from the right towards the word 'Submit' in step 2. At the bottom right, there are three buttons: 'Exit' (with a close icon), 'Save' (with a floppy disk icon), and 'Finish' (in a dark blue box). A red callout box with the text 'Note! Clicking "Finish" does not submit the study.' has an arrow pointing to the 'Finish' button.

Validate Compare

You Are Here: Example

Editing: IRB00042840

Go to forms menu Print Help

### Final Page ⓘ

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, click **Submit** on the next page.

Note! Clicking "Finish" does not submit the study.

Exit Save Finish



- After clicking **Finish**, you will be returned to the modification home page.
- Once on the home page, click **Submit** to submit your modification for review.
- Only the PI or the PI proxies can submit.
  - If you are not the PI or PI Proxy, you will not see the **Submit** option.

IRB > Example > Modification / Update #1 for Study Example

[Admin View](#) [Help](#)

## Pre-Submission

Last updated: 1/8/2025 10:41 AM

# MOD00018435: Modification / Update #1 for Study Example

**Principal investigator:** Timothy Rodriguez  
**Submission type:** Modification / Update  
**Primary contact:** Timothy Rodriguez

**IRB office:** MHRI IRB  
**Committee:**  
**IRB coordinator:** Timothy Rodriguez  
**Regulatory authority:** 2018 Requirements

## Next Steps

Edit Modification/CR

Printer Version

 Submit

 Assign Home IRB

 Manage Ancillary Reviews

 Add Comment

 Add Private Comment

 Discard

 Manage Tags



History

Contacts


Documents

Reviews

Related RNIs

Snapshots

Training

Filter by 

Activity

Enter text to search



+ Add Filter

✕ Clear All



Activity

Author

▼ Activity Date

+

Minor Version Incremented

Rodriguez, Timothy

1/8/2025 10:35 AM



MedStar Health

MedStar Health Research Institute

- After clicking Submit, the status in the orange box should indicate “Pre-Review”.

IRB > Example > Modification / Update #1 for Study Example

[Admin View](#) [Help](#)

Pre-Review

Entered: 1/8/2025 11:01 AM  
Last updated: 1/8/2025 11:01 AM

## MOD00018435: Modification / Update #1 for Study Example

**Principal investigator:** Timothy Rodriguez  
**Submission type:** Modification / Update  
**Primary contact:** Timothy Rodriguez

**IRB office:** MHRI IRB  
**Committee:**  
**IRB coordinator:** Timothy Rodriguez  
**Regulatory authority:** 2018 Requirements

### Next Steps

[View Modification/CR](#)

[Printer Version](#)

☒ [Submit Pre-Review](#)

[Request Pre-Review Clarification](#)

[Assign Coordinator](#)

[Assign Home IRB](#)

[Manage Ancillary Reviews](#)

[Add Comment](#)



History

Contacts

Documents

Reviews

Related RNIs

Snapshots

Training

Filter by



Activity



Enter text to search



+ Add Filter X Clear All



Activity

Author

▼ Activity Date



Submitted

Rodriguez, Timothy

1/8/2025 11:01 AM



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**Congratulations! You have successfully submitted to the MHRI IRB.**

**It's how we **treat people.****



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