



MedStar Health

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

May 13, 2025

# How to Submit a Modification to Add a Team Member

# Who can submit modifications?

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



- When you log into the system, you will be brought to your inbox. Select the **IRB** tab to find your study.

IRB Preview

# Georgetown-MedStar IRB System

Hello, Timothy Rodriguez ▾

Switch User

Dashboard

eRIC Archive

Admin

IRB

Page for Timothy Rodriguez

Create ▾

## Study Expiration Dates

Maximum number of items in a To Do List exceeded. Only the first 100 will be displayed.

Jan 4 2025

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

Jan 6 2025

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

Jan 8 2025

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

Jan

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

My Inbox

Assignments

In Process

## My Inbox

Filter by ?

ID ▾

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

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- 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

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# 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 homepage. Select **Create Modification/CR** to begin the modification application.

DashboardeRIC ArchiveAdmin**IRB**

SubmissionsMeetingsReportsLibraryInstitutional ProfilesHelp Center

IRB > ExampleAdmin ViewHelp

Approved

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

**STUDY00008164: Example**

**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

Activity

Author

Activity Date

MedStar Health

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- **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 **Study Team Member Information** under **Modification Scope**.
- The **Modification Scope** determines what can be updated in this modification.

**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 list the names of team members being added to the study.**

ValidateCompare

Modification / Continuing Review

Modification Summary

Modification Details

Editing: MOD00018435

Go to forms menuPrintHelp

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: ?

Addition of team members: John Doe

ExitSaveContinue

It is helpful to name each of the team members to be added in the summary of modifications.





- Add team members to this page.
- If you cannot find a team member in the system, it means they do not have an account.
- See next slide for instructions on how to create an account.
- All team members must complete institutional requirements (e.g., CITI and COI) prior to approval.

The screenshot shows a web interface for editing an IRB form (IRB00042840). The left sidebar has a 'Local Study Team Members' link highlighted in orange. A red arrow points from this link to the 'Add' button in the first section. The main content area has a breadcrumb 'You Are Here: Example' and a title 'Editing: IRB00042840'. Below this is the 'Local Study Team Members' section with two sub-sections: '1. Identify each additional person involved in the design, conduct, or reporting of the research:' and '2. External team member information:'. Each sub-section has an 'Add' button. A red arrow points from the 'Add' button in the second section to a red text box. At the bottom right, there are 'Exit', 'Save', and 'Finish' buttons. A red arrow points from a red text box to the 'Finish' button.

Local Study Team Members

You Are Here: Example

Editing: IRB00042840

Go to forms menu Print Help

Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:

+ Add

Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
There are no items to display					

2. External team member information:

+ Add

Name	Description
There are no items to display	

Do not add MedStar or GU affiliates to this section. You may use the section to add CITI certificates or COI paper forms.

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

Exit Save Finish



# How to create an account in the system

- For MedStar affiliates:
  - In most cases, the manager or department head of the individual will need to submit a request in Identity IQ (IIQ) system. In some cases, this responsibility may be delegated to administrative staff.
  - When submitting the request, they should select the role titled “PI or Study Coordinator”.
- For Georgetown affiliates:
  - Please contact the Georgetown IRB Office at [irboard@georgetown.edu](mailto:irboard@georgetown.edu).



- 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

Q

+ Add Filter X Clear All

⚙

Activity

Author

▼ Activity Date

+

Minor Version Incremented

Rodriguez, Timothy

1/8/2025 10:35 AM



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- 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.**

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