



MedStar Health

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

May 13, 2025

# How to Submit a Study Closure

# Before submitting the study closure...

Please consider the status of publications/presentations. Sometimes, editors or conference organizers may request additional information requiring new data analysis. In this case, active IRB approval is required as data analysis is a research activity. To avoid additional submissions to the IRB, it is recommended that the IRB application remain open and active until all anticipated publications and presentations have been accepted.



# Who can submit study closures?

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



- Georgetown University

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# Georgetown-MedStar IRB System

Hello, Timothy Rodriguez

Switch User

Dashboard

erIC Archive

Admin

IRB

Create ▾

Enter search terms to filter list

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

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

## Georgetown-MedStar IRB System

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 close.



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

Filter by ?

ID ▾

Enter text to search

Q

+ 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

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

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- **Select Continuing Review.**

**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](#)

**Note! After you select Continue, you CANNOT change the purpose of the submission. If select the incorrect purpose, you will need to discard the current submission and create another submission.**

[Exit](#) [Save](#) [Continue](#) ➔



- **Complete items #1-4.**
  - Use the question mark icon to get more information about each item.
- **Review item #4. If the first four research milestones are selected, then the study closure acknowledgement will appear (item #5).**

Modification /  
Continuing Review

Continuing Review  
/ Study Closure  
Information

## Continuing Review / Study Closure Information

1. \* Specify enrollment totals at this investigator's sites: ?

21

2. \* Specify enrollment totals at this investigator's sites since last approval:

0

3. \* Specify enrollment totals study-wide: ?

54

4. Research milestones: (select all that apply) ?

- ☒ Study is permanently closed to enrollment OR was never open for enrollment
- ☒ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- ☒ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ☒ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ☐ Remaining study activities are limited to data analysis
- ☐ Study remains active only for long-term follow-up of subjects

**i Important!** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

5. \* I acknowledge that this study will be closed: ☒



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- **Complete items #6-8.**
- **Attach the required Progress Summary document in item #8. This template can be found in the ORI website. If applicable, please attach other documents such as multi-center trial reports, DMC reports, SAE reports, IND annual reports, and protocol deviation logs.**

Modification / Continuing Review

Continuing Review / Study Closure Information

6. Do any investigators or research staff have a financial interest related to the research that was not described in a previous application? ?

☐ Yes ☒ No [Clear](#)

7. Check the items that are true since the last IRB approval for all sites involved in the study: (Initial review or last continuing review)

- ☒ NO subjects experienced unexpected harm
- ☒ Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- ☒ NO subjects withdrew from the study
- ☒ NO unanticipated problems involving risks to subjects or others
- ☒ NO complaints about the study
- ☒ NO publications in the literature relevant to risks or potential benefits
- ☒ NO interim findings
- ☒ NO multi-center trial reports
- ☒ NO data safety monitoring reports
- ☒ NO regulatory actions that could affect safety and risk assessments
- ☒ NO other relevant information regarding this study, especially information about risks
- ☒ In the opinion of the PI, the risks and potential benefits are unchanged
- ☒ All modifications to the protocol have been submitted to the IRB
- ☒ All problems that require prompt reporting to the IRB have been submitted

8. Attach supporting documents: (include an explanation of each item left unchecked above) ?

+ Add

Name

 Progress Summary for Continuing Review or Closure Template.docx(0.01)

✕ Exit

💾 Save

Continue →



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

Modification /  
Continuing Review

Continuing Review /  
Study Closure  
Information

Editing: CR00004438

◀ 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.

ⓧ Exit

💾 Save

Finish

Note! Clicking “Finish” does not submit the study closure.



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- After clicking **Finish**, you will be returned to the study closure home page.
- Once on the home page, click **Submit** to submit the study closure.
- 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 > Continuing Review for Study Example Admin View Help

**Pre-Submission**

Last updated: 2/19/2025 10:32 AM

**Next Steps**

Edit Modification/CR

Printer Version

- Submit
- Assign Home IRB
- Manage Ancillary Reviews
- Add Comment
- Add Private Comment
- Discard
- Manage Tags

## CR00004438: Continuing Review for Study Example

**Principal investigator:** Timothy Rodriguez

**Submission type:** Continuing Review

**Primary contact:** Timothy Rodriguez

**IRB office:** MHRI IRB

**Committee:**

**IRB coordinator:** Timothy Rodriguez

**Regulatory authority:** 2018 Requirements

History

Contacts

Documents

Reviews

Snapshots

Training

**Filter by** Activity  Search + Add Filter ✕ Clear All

Activity	Author	Activity Date
Minor Version Incremented	Rodriguez, Timothy	2/19/2025 9:48 AM



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

IRB > Example > Continuing Review for Study Example Admin View ? Help

Pre-Review

Enter: 2/19/2025 10:48 AM  
Last updated: 2/19/2025 10:48 AM

Next Steps

View Modification/CR

Printer Version

☒ Submit Pre-Review

Request Pre-Review Clarification

Assign Coordinator

Assign Home IRB

Manage Ancillary Reviews

Add Comment

Add Private Comment

Withdraw

CR00004438: Continuing Review for Study Example

Principal investigator: Timothy Rodriguez

Submission type: Continuing Review

Primary contact: Timothy Rodriguez

IRB office: MHRI IRB

Committee:

IRB coordinator: Timothy Rodriguez

Regulatory authority: 2018 Requirements

```
graph LR; A([Pre-Submission]) --> B([Pre-Review]); B --> C([IRB Review]); C --> D([Post-Review]); D --> E([Review Complete]); B --> B1([Clarification Requested]); B1 --> B; C --> C1([Clarification Requested]); C1 --> C; D --> D1([Modifications Required]); D1 --> D;
```

History | Contacts | Documents | Reviews | Snapshots | Training

Filter by ? Activity  + Add Filter ✕ Clear All

Activity	Author	Activity Date
Submitted	Rodriguez, Timothy	2/19/2025 10:48 AM
Minor Version Incremented	Rodriguez, Timothy	2/19/2025 9:48 AM



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

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