

GEORGETOWN UNIVERSITY



Georgetown-MedStar IRB System

How to Submit a Continuation in the Georgetown-MedStar IRB System

Knowledge and Compassion
Focused on You

When you log into the system, you will be brought to your inbox.
Select the IRB tab on the top of the screen.

GEORGETOWN UNIVERSITY Georgetown-MedStar IRB System Hello, Principal24 Investigator24

My Inbox IRB

Components

Create New Study Report New Information

Submissions Meetings Reports Library Help Center

My Inbox

Filter by ID Enter text to search for + Add Filter x Clear All

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY00000160_SITE01	Site for External	11/18/2018 10:02 AM	11/18/2018 10:02 AM	Pre-Submission	
STUDY00000139	x x	11/14/2018 2:51 PM	11/14/2018 2:52 PM	Pre-Submission	
RNI00000021	CCO information	11/7/2018 3:41 PM	11/7/2018 3:41 PM	Pre-Submission	
STUDY00000066_SITE01	Site for CCO test external	11/7/2018 3:27 PM	11/7/2018 3:27 PM	Pre-Submission	
STUDY00000055_SITE01	Site for External IRB	10/18/2018 11:22 AM	10/18/2018 11:22 AM	Pre-Submission	

5 items page 1 of 1 25 / page

Once in the IRB Tab, select the **Active** study list.

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 MedStar Health

Georgetown-MedStar
IRB System Training Site

Hello, Principal24 Investigator2

>>
My Inbox
IRB

Submissions
Meetings
Reports
Library
Help Center

IRB

Create New Study

Report New Information

In-Review

Active

Archived

New Information Reports

External IRB Studies

Sites

All Submissions

Filter by ?

ID

Enter text to search for

Q

+ Add Filter

x Clear All

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name	Submission Type
 STUDY00000186	TS - MHRI	12/4/2018 3:59 PM	Non-Committee Review	Principal24	Investigator24	Kate	Cohen	Initial Study
 STUDY00000225	24	11/28/2018 2:47 PM	Pre-Review	Principal24	Investigator24			Initial Study
 STUDY00000149	IBSA	11/15/2018 9:43 AM	Pre-Review	Principal24	Investigator24			Initial Study
 STUDY00000147	PBA in OI	11/15/2018 9:42 AM	Pre-Review	Principal24	Investigator24			Initial Study

Once in the Active study tab, **select the study** you wish to submit a continuation for.

The screenshot shows the Georgetown-MedStar IRB System Training Site interface. The header includes the Georgetown University and MedStar Health logos, the site title 'Georgetown-MedStar IRB System Training Site', and a user greeting 'Hello, Principal24 Investigator2'. Below the header is a navigation bar with tabs for 'My Inbox', 'IRB', 'Submissions', 'Meetings', 'Reports', 'Library', and 'Help Center'. The 'IRB' tab is selected. On the left side, there are two buttons: 'Create New Study' and 'Report New Information'. The main content area displays a table of studies under the 'Active' tab. The table has columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator First Name, Coordinator Last Name, and Expiration Date. Three studies are listed: 'New Study', 'Cool Stuff', and 'Test PI24 Study'. At the bottom, there is a pagination control showing '3 items', 'page 1 of 1', and '25 / page'.

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name	Expiration Date
STUDY00000240	New Study	12/10/2018 3:54 PM	Approved	Principal24	Investigator24	Kate	Cohen	12/9/2019
STUDY00000172	Cool Stuff	12/5/2018 2:44 PM	Approved	Principal24	Investigator24	Kate	Cohen	12/3/2019
STUDY00000022	Test PI24 Study	10/15/2018 3:01 PM	Approved	Principal24	Investigator24			10/14/2019

Once you select the study, you will be brought to the study workspace. On the left of the screen, select **Create Modification/CR.**

The screenshot shows the IRB System Training Site interface for a study workspace. At the top, there is a header with the Georgetown University and MedStar Health logos, the title "Georgetown-MedStar IRB System Training Site", and a user greeting "Hello, Principal24 Investigator24". Below the header is a navigation bar with tabs for "My Inbox", "IRB", "Submissions", "Meetings", "Reports", "Library", and "Help Center". The main content area displays the study details for "STUDY00000240: New Study", which is marked as "Approved". The details include submission dates, principal investigator information, and IRB office/committee information. A flowchart illustrates the review process: Pre-Submission, Pre-Review (with a loop for Clarification Requested), IRB Review (with a loop for Clarification Requested), Post-Review (with a loop for Modifications Required), and Review Complete. On the left side, there is a "Next Steps" panel with buttons for "View Study", "Printer Version", "View Differences", "Create Modification/CR" (highlighted with a red arrow), and "Report New Information". Below this panel are options to "Assign Primary Contact" and "Assign PI Proxy". At the bottom, there is a "History" tab and a table of activity logs.

Approved STUDY00000240: New Study

Entered IRB: 12/5/2018 4:26 PM
Initial approval: 12/10/2018
Initial effective: 12/10/2018
Effective: 12/10/2018
Approval end: 12/9/2019
Last updated: 12/10/2018 3:54 PM

Principal investigator: Principal24 Investigator24
Submission type: Initial Study
Primary contact: Principal24 Investigator24
PI proxies:

IRB office: MHRI IRB
Committee:
IRB coordinator: Kate Cohen
Letter: Correspondence_for_STUDY00000240.pdf(0.01)
Regulatory authority: Pre-2018 Requirements

Next Steps

- View Study
- Printer Version
- View Differences
- Create Modification/CR**
- Report New Information

Assign Primary Contact
Assign PI Proxy

History Funding Contacts Documents Follow-on Submissions Reviews Snapshots Training

Filter by Activity

Activity	Author	Activity Date
Letter Sent	Cohen, Kate	12/10/2018 3:54 PM
Correspondence_for_STUDY00000240.pdf		
IRB Coordinator Assigned	Cohen, Kate	12/10/2018 3:51 PM

Georgetown-MedStar IRB System

You will be prompted to **select the most appropriate submission**. Select the one that applies to your submission. For purposes of this guide, continuing review will be selected.

You Are Here: [New Study](#) > [IRB Submission](#)

[« Back](#)

[Save](#) [Print](#)

[Continue »](#)

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? 

- Continuing Review
- Modification
- Modification and Continuing Review

[Clear](#)

[« Back](#)

[Save](#) [Print](#)

[Continue »](#)

The continuing review page requests study status information. **Complete** the questions on this page.

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MedStar Health

**Georgetown-MedStar
IRB System Training Site**

Edit: IRB Submission - CR00000035

You Are Here: [New Study](#) - [Continuing Review for Study Ne...](#)

[← Back](#)
[Save](#)
[Exit](#)
[Hide/Show Errors](#)
[Print](#)
[Jump To ▾](#)
[Continue >](#)

Continuing Review / Study Closure Information

1. * Specify enrollment totals:

	Subjects Enrolled	Total	Since Last Approval
At this investigator's sites:	?	<input style="width: 40px;" type="text"/>	<input style="width: 40px;" type="text"/>
Study-wide:	?	<input style="width: 40px;" type="text"/>	

2. 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.

3. * 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](#)

4. 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

Once you have completed the continuing review information, you will arrive on the **Final Page**. **Click Finish.**

GEORGETOWN UNIVERSITY

 MedStar Health

Georgetown-MedStar
IRB System **Training Site**

Edit: IRB Submission - CR00000035

You Are Here:  New Study >  Continuing Review for Study Ne...

« Back Save Exit Hide/Show Errors Print Jump To Finish

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.

« Back Save Exit Hide/Show Errors Print Jump To Finish

You should then be taken to the continuation submission workspace. To submit the continuing review, select **Submit** on the left side.

The screenshot displays the Georgetown-MedStar IRB System Training Site interface. At the top, the header includes the Georgetown University and MedStar Health logos, the site title "Georgetown-MedStar IRB System Training Site", and a user greeting "Hello, Principal24 Investigator24". Below the header is a navigation bar with tabs for "Submissions", "Meetings", "Reports", "Library", and "Help Center". The "IRB" tab is currently selected.

The main content area shows a submission workspace for "CR00000035: Continuing Review for Study New Study". The submission details are as follows:

- Principal investigator:** Principal24 Investigator24
- Submission type:** Continuing Review
- Primary contact:** Principal24 Investigator24
- IRB office:** MHRI IRB
- Committee:**
- IRB coordinator:** Kate Cohen
- Regulatory authority:** Pre-2018 Requirements

The "Next Steps" section includes buttons for "Edit Modification/CR" and "Printer Version". A red arrow points to the "Submit" button in the left sidebar. Below the "Submit" button are options for "Manage Ancillary Reviews", "Add Comment", and "Discard".

A process flow diagram illustrates the submission workflow: Pre-Submission (highlighted in orange) leads to Pre-Review, which can lead to Clarification Requested or IRB Review. IRB Review can lead to Clarification Requested or Post-Review. Post-Review can lead to Modifications Required or Review Complete.

At the bottom, there is a "History" tab and a search bar with the text "Filter by Activity" and "No data to display."

Once you click submit, the verification pop up window will appear. **Click OK** to verify the listed statements.

The screenshot displays the Georgetown-MedStar IRB System interface. The main page shows a submission for CR00000035, with a 'Pre-Submission' status. A 'Submit' button is visible in the 'Next Steps' section. A pop-up window titled 'Submit' is overlaid on the page, containing the following text:

By signing below you are verifying that:

- You have obtained the financial interest status ("yes" or "no") of each research staff.
- You have obtained the agreement of each research staff to his/her role in the research.
- You will conduct this Human Research in accordance with requirements in the HRP-103 - Investigator Manual

At the bottom of the pop-up window, there are two buttons: 'OK' and 'Cancel'. A red arrow points to the 'OK' button.

Your continuing review is now submitted. Note that the orange status bar on the left side changes to “Pre-Review.” You can also see the submission action in the Activity list.

The screenshot displays the Georgetown-MedStar IRB System Training Site interface. At the top, the Georgetown University and MedStar Health logos are on the left, and the site title 'Georgetown-MedStar IRB System Training Site' is in the center. A user greeting 'Hello, Principal24 Investigator24' is on the right. Below the header is a navigation menu with 'My Inbox' selected and 'IRB' highlighted. A secondary menu includes 'Submissions', 'Meetings', 'Reports', 'Library', and 'Help Center'. The main content area shows a submission titled 'CR00000035: Continuing Review for Study New Study' with a status bar on the left labeled 'Pre-Review' (indicated by a red arrow). The submission details include: Entered IRB: 12/10/2018 4:25 PM, Last updated: 12/10/2018 4:25 PM, Principal investigator: Principal24 Investigator24, Submission type: Continuing Review, Primary contact: Principal24 Investigator24, IRB office: MHRI IRB, Committee: Kate Cohen, IRB coordinator: Kate Cohen, and Regulatory authority: Pre-2018 Requirements. A 'Next Steps' section contains buttons for 'View Modification/CR' and 'Printer Version', along with links for 'Add Comment', 'Withdraw', and 'Discard'. A process flow diagram shows the stages: Pre-Submission, Pre-Review (highlighted in orange), IRB Review, Post-Review, and Review Complete, with feedback loops for 'Clarification Requested' and 'Modifications Required'. At the bottom, a 'History' tab is active, showing a table with columns for Activity, Author, and Activity Date. The table contains one entry: Submitted by Investigator24, Principal24 on 12/10/2018 4:25 PM (indicated by a red arrow).

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MedStar Health

Georgetown-MedStar IRB System Training Site

Hello, Principal24 Investigator24

» My Inbox **IRB**

Submissions Meetings Reports Library Help Center

Pre-Review CR00000035: Continuing Review for Study New Study

Entered IRB: 12/10/2018 4:25 PM
Last updated: 12/10/2018 4:25 PM

Principal investigator: Principal24 Investigator24
Submission type: Continuing Review
Primary contact: Principal24 Investigator24

IRB office: MHRI IRB
Committee: Kate Cohen
IRB coordinator: Kate Cohen
Regulatory authority: Pre-2018 Requirements

Next Steps

View Modification/CR
Printer Version

Add Comment
Withdraw
Discard

Pre-Submission → **Pre-Review** → IRB Review → Post-Review → Review Complete

Clarification Requested
Clarification Requested
Modifications Required

History Contacts Documents Snapshots Training

Filter by Activity + Add Filter x Clear All

Activity	Author	Activity Date
Submitted	Investigator24, Principal24	12/10/2018 4:25 PM

Congratulations!

You have successfully submitted a study for continuing review in the new Georgetown-MedStar IRB System!

If you have any questions about the steps described, please contact the Office of Research Integrity at MHRI-ORISupport@medstar.net.