

GEORGETOWN UNIVERSITY



# Georgetown-MedStar IRB System

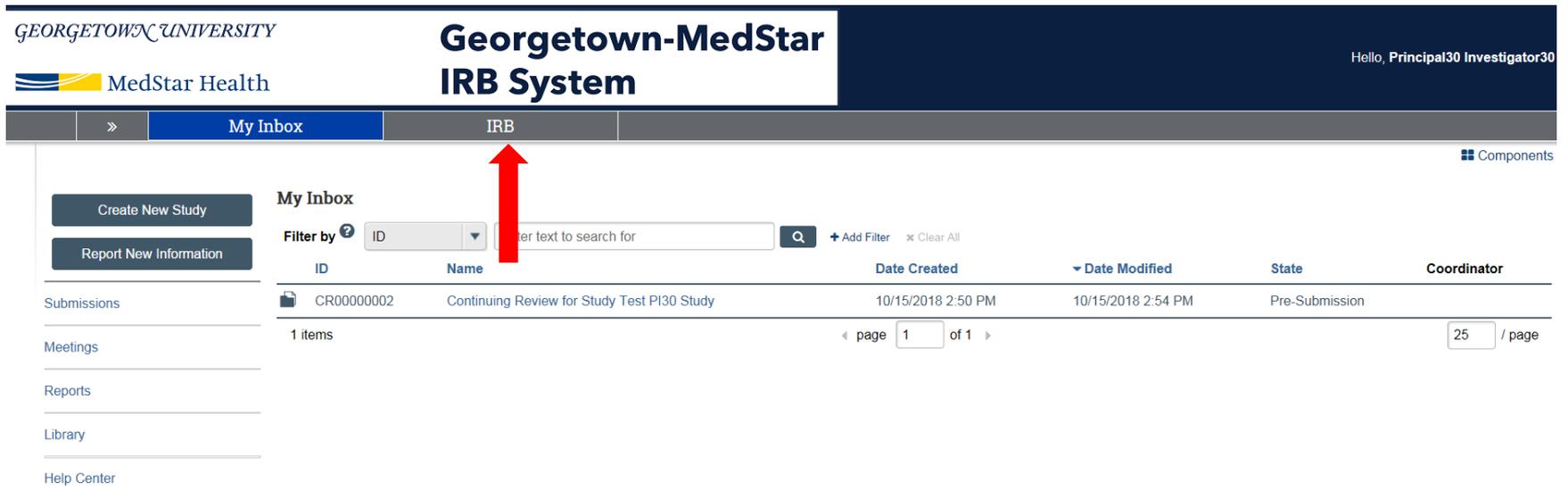
## How to Submit a Modification to Add a Study Team Member in the new Georgetown-MedStar IRB System

November 30, 2018

Knowledge and Compassion  
**Focused on You**

# Georgetown-MedStar IRB System

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



The screenshot shows the top navigation bar of the Georgetown-MedStar IRB System. The 'IRB' tab is highlighted in blue, and a red arrow points to it. The page title is 'Georgetown-MedStar IRB System' and the user is logged in as 'Principal30 Investigator30'. The main content area shows a 'My Inbox' section with a table of items. The table has columns for ID, Name, Date Created, Date Modified, State, and Coordinator. One item is listed: CR0000002, Continuing Review for Study Test PI30 Study, created on 10/15/2018 2:50 PM, modified on 10/15/2018 2:54 PM, in a Pre-Submission state, with Coordinator Principal30 Investigator30. The page also includes a search bar, filter options, and a sidebar with links to Submissions, Meetings, Reports, Library, and Help Center.

GEORGETOWN UNIVERSITY  
MedStar Health

Georgetown-MedStar  
IRB System

Hello, Principal30 Investigator30

» My Inbox IRB Components

Create New Study  
Report New Information

My Inbox  
Filter by ID  Enter text to search for  + Add Filter ✕ Clear All

ID	Name	Date Created	Date Modified	State	Coordinator
CR0000002	Continuing Review for Study Test PI30 Study	10/15/2018 2:50 PM	10/15/2018 2:54 PM	Pre-Submission	Principal30 Investigator30

1 items      < page 1 of 1 >      25 / page

Submissions  
Meetings  
Reports  
Library  
Help Center

# Georgetown-MedStar IRB System

Once you are in the IRB tab, you will want to select the **“Active” tab**, indicated by the red arrow on the image. Once in the active studies tab, you can select the study you are submitting the amendment for by **clicking on the study title**.

GEORGETOWN UNIVERSITY Georgetown-MedStar IRB System Hello, Principal30 Investigator30

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 + Add Filter x Clear All

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name	Submission Type
STUDY00000185	Training	11/19/2018 1:44 PM	Pre-Review	Principal30	Investigator30			Initial Study
STUDY00000138	job performance	11/14/2018 2:42 PM	Pre-Review	Principal30	Investigator30			Initial Study
STUDY00000116	STARA	11/14/2018 1:44 PM	Pre-Review	Principal30	Investigator30			Initial Study
STUDY00000084	yyy	11/13/2018 2:51 PM	Pre-Review	Principal30	Investigator30			Initial Study
MOD00000011	Modification #1 for Study Test PI30 Study	10/15/2018 3:12 PM	Pre-Review	Principal30	Investigator30			Modification
CR00000002	Continuing Review for Study Test PI30 Study	10/15/2018 2:54 PM	Pre-Submission	Principal30	Investigator30			Continuing Review
STUDY00000043	Test AC study 20181015	10/15/2018 2:41 PM	Pre-Review	Principal30	Investigator30			Initial Study

7 items page 1 of 1 25 / page

Once you arrive in the study workspace, you will have the option to **submit a modification** on the left side of the workspace (indicated by a red arrow here).

GEORGETOWN UNIVERSITY Georgetown-MedStar IRB System Hello, Principal30 Investigator30

MedStar Health

» My Inbox IRB Submissions Meetings Reports Library Help Center

Approved

## STUDY00000028: Test PI30 Study

Entered IRB: 10/14/2018 9:29 PM  
 Initial approval: 10/15/2018  
 Initial effective: 10/15/2018  
 Effective: 10/15/2018  
 Approval end: 10/14/2019  
 Last updated: 10/15/2018 3:01 PM

**Principal investigator:** Principal30 Investigator30  
**Submission type:** Initial Study  
**Primary contact:** System Administrator  
**PI proxies:**

**IRB office:** MHRI IRB  
**Committee:**  
**IRB coordinator:**  
**Letter:** Correspondence\_for\_STUDY00000028.pdf(0.01)  
**Regulatory authority:** Pre-2018 Requirements

### Next Steps

- [View Study](#)
- [Printer Version](#)
- [View Differences](#)
- [Create Modification/CR](#)
- [Report New Information](#)



History Funding Contacts Documents Follow-on Submissions Reviews Snapshots Training

Filter by <sup>?</sup> Activity

Activity	Author	Activity Date
<b>i</b> Modification MOD00000011 Opened Modification: MOD00000011	Investigator30, Principal30	10/15/2018 3:01 PM
<b>i</b> Continuing Review CR00000002 Opened Continuing Review: CR00000002	Investigator30, Principal30	10/15/2018 2:50 PM
<b>i</b> Letter Sent	Administrator, System	10/15/2018 1:44 AM

# Georgetown-MedStar IRB System

You will see the modification/CR screen that allows you to select the type of submission you would like to create.

To add a study team member, **select “modification”** then **click continue.**

GEORGETOWN UNIVERSITY Georgetown-MedStar IRB System New: IRB Submission

MedStar Health

You Are Here: [Test PI26 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 »](#)

Once you select modification, you will then select the modification scope. To add a study team member, **select “Study team member information.”** Then **click continue.**

### Modification / Continuing Review / Study Closure

**\* What is the purpose of this submission?** 

- Continuing Review
- Modification
- Modification and Continuing Review

[Clear](#)

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

**Modification scope:**

- Study team member information
- Other parts of the study



# Georgetown-MedStar IRB System

The modification information page will ask you for information about the study. *Note that questions 1 and 2 are not required.*

For the purposes of adding a study team member, please **complete question 3** with the statement of who you are adding to the study.

GEORGETOWN UNIVERSITY  
 MedStar Health

**Georgetown-MedStar  
IRB System**

Edit: IRB Submission - MOD00000033

You Are Here:  Test P126 Study  Modification #2 for Study Test...

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

## 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:

Addition of Study Coordinator, Jane Doe.

You will be directed to the study team member page.  
**Select “Add”** in question 1 to add MedStar associates to your study.

You Are Here:  Test PI26 Study

[« Back](#)

[Save](#)

[Exit](#)

[Hide/Show Errors](#)

[Print](#)

[Jump To ▾](#)

[Continue »](#)

### 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

[« Back](#)

[Save](#)

[Exit](#)

[Hide/Show Errors](#)

[Print](#)

[Jump To ▾](#)

[Continue »](#)

# Georgetown-MedStar IRB System

A pop up window will appear where you can select the individual you are adding to the study. **Click the three dots** next to the study team member field. Once you have selected the study team member, **complete questions 2-4 and click “OK”** when you are finished. Once the pop up window closes and your study team member appears on the screen, **click continue.**

GEORGETOWN UNIVERSITY  
MedStar Health

Georgetown-MedStar  
IRB System

Edit: IRB Submission - IRB00000043

You Are Here: Test PI26 Study

Study Team Members

1. Identify each additional person involved in the design, co...

2. External team member information:

3. \* Study team member: ?

4. \* Role in research: (check all that apply)

5. \* Is the team member involved in the consent process?

6. \* Does the team member have a financial interest related to this research? ?

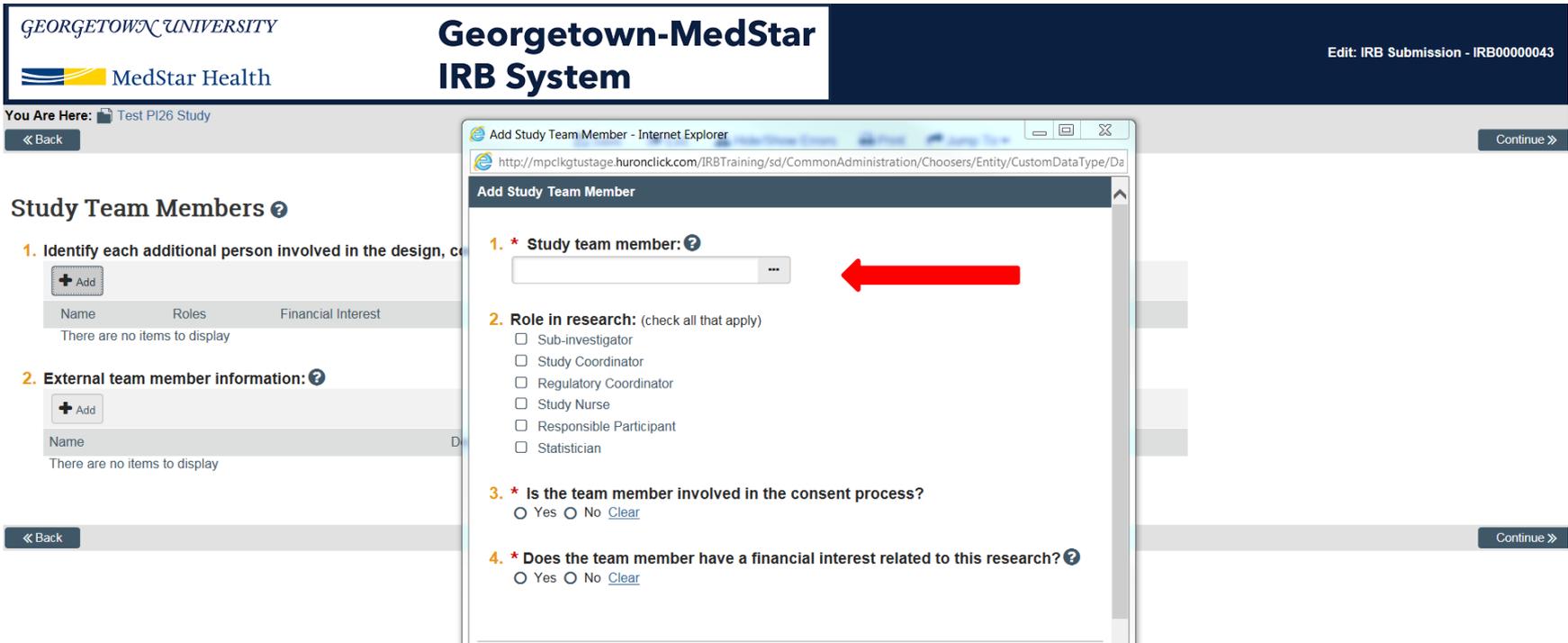
Internet Explorer window: Add Study Team Member

1. \* Study team member: ?

2. Role in research: (check all that apply)

3. \* Is the team member involved in the consent process?

4. \* Does the team member have a financial interest related to this research? ?



The study scope page may not populate with answers in your first submission after the data migration.

**Complete** the study scope information page with accurate information about your protocol. If you answer yes to question 2 or question 3, you will be prompted to complete another page on the drug or device involved in your study.

### Study Scope

1. \* Are there other research locations where the investigator will conduct or oversee the research?   
 Yes  No [Clear](#)
2. \* Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?   
 Yes  No [Clear](#)
3. \* Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?  
 Yes  No [Clear](#)

After completing the study scope page and the drug or device page if applicable, you will arrive at the Local Site Document page. Here you can **upload your consent form, recruitment materials or other documents approved by the IRB.**

**Please note that this is not required at this time, but feel free to complete this if you wish. Please upload any documents in a Word format.**

You Are Here: Test PI26 Study

« Back Save Exit Hide/Show Errors Print Jump To » Continue »

### Local Site Documents ⓘ

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

+ Add

Document	Category	Date Modified	Document History
 HRP-502 - TEMPLATE CONSENT DOCUMENT.docx(0.01)	Consent Form	10/14/2018	History 

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

+ Add

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

**3. Other attachments:**

+ Add

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

You will now see the Additional Information page.  
Please **complete these three questions** for your  
protocol and **click continue**.

You Are Here:  Test PI26 Study

[« Back](#)

 Save

 Exit

 Hide/Show Errors

 Print

 Jump To ▾

[Continue »](#)

### Additional Information

1. \* Is the PI a Georgetown University Student?

Yes  No [Clear](#)

Note – for Georgetown University student submissions, please ensure a Responsible Participant is listed on the Study Team Members page and attach a signed Responsible Participant statement on the Local Sites Document page.

2. \* Is the PI a MedStar fellow or resident?

Yes  No [Clear](#)

3. \* Will the research involve human subjects under the age of 18 years old?

Yes  No [Clear](#)

For GU IRB protocols only: If yes, click here to complete any Georgetown Protection of Minors required activities

[« Back](#)

 Save

 Exit

 Hide/Show Errors

 Print

 Jump To ▾

[Continue »](#)

You should then arrive on the Final Page. **Click Finish.**

You Are Here:  Test PI26 Study

[← 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](#)

Once you finish the submission, you will arrive at your study's modification work space. This is the workspace for the modification you have just created. **You will need to click "Submit" on the left side of your screen to submit the modification to the IRB.**

The screenshot displays the Georgetown-MedStar IRB System interface. At the top, the header includes the Georgetown University and MedStar Health logos, the system name "Georgetown-MedStar IRB System", and a user greeting "Hello, Principal26 Investigator26". Below the header is a navigation bar with tabs for "My Inbox", "IRB", "Submissions", "Meetings", "Reports", "Library", and "Help Center".

The main content area shows a submission titled "MOD00000033: Modification #2 for Study Test PI26 Study". Key details include:  
Principal investigator: Principal26 Investigator26  
Submission type: Modification  
Primary contact: System Administrator  
IRB office: MHRI IRB  
Committee:  
IRB coordinator:  
Regulatory authority: Pre-2018 Requirements

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

On the left side, under "Next Steps", there are buttons for "Edit Modification/CR", "Printer Version", "View Differences", and "Submit" (highlighted with a red arrow). Below these are "Manage Ancillary Reviews", "Add Comment", and "Discard".

At the bottom, there is a "History" section with tabs for "Contacts", "Documents", "Related RNIs", "Snapshots", and "Training". A search bar is present with the text "Filter by Activity" and "Enter text to search for". Below the search bar, it states "No data to display."

# Georgetown-MedStar IRB System

Once you click “submit” you will get a pop up window that asks you as the **PI to verify** the statements written. **Click OK.**

The screenshot displays the Georgetown-MedStar IRB System interface. The top navigation bar includes the Georgetown University and MedStar Health logos, and a user greeting: "Hello, Principal26 Investigator26". The main content area shows a submission for "MOD000000" with a "Pre-Submission" status. A "Next Steps" section contains buttons for "Edit Modification/CR", "Printer Version", "View Differences", "Submit", "Manage Ancillary Reviews", "Add Comment", and "Discard". A "Submit" button is highlighted in orange. A pop-up window titled "Submit" is overlaid on the page, containing the following text:

Execute "Submit" on MOD00000033 - Internet Explorer  
http://mpclkgststage.huronclick.com/IRBTraining/sd/ResourceAdministration/Activity/form?ActivityType=com.web

**Submit**

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

OK Cancel

You should then be taken back to the modification's workspace. The orange study status bar on the left side of your screen should now say "Pre-Review." The Pre-Review bubble on the workflow map will be highlighted orange.

GEORGETOWN UNIVERSITY Georgetown-MedStar IRB System Hello, Principal26 Investigator26

MedStar Health

» My Inbox IRB Submissions Meetings Reports Library Help Center

Pre-Review

## MOD00000033: Modification #2 for Study Test PI26 Study

Entered IRB: 11/29/2018 6:31 PM  
Last updated: 11/29/2018 6:31 PM

**Principal investigator:** Principal26 Investigator26  
**Submission type:** Modification  
**Primary contact:** System Administrator

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

### Next Steps

- View Modification/CR
- Printer Version
- View Differences

- Add Comment
- Withdraw
- Discard



History	Contacts	Documents	Related RNIs	Snapshots	Training
Filter by <span>Activity</span> <input type="text" value="Enter text to search for"/> <span>+ Add Filter</span> <span>✕ Clear All</span>					
Activity	Author	Activity Date			
Submitted	Investigator26, Principal26	11/29/2018 6:31 PM			

## **Congratulations!**

You have successfully submitted a new study in the 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](mailto:MHRI-ORISupport@medstar.net).