

GEORGETOWN UNIVERSITY

 MedStar Health

Georgetown-MedStar IRB System

How to Submit a New Study in the Georgetown-MedStar IRB System

December 5, 2018

Knowledge and Compassion
Focused on You

When you log into the system, you will be brought to your inbox.
Select Create New Study on the left side of the screen.

GEORGETOWN UNIVERSITY Georgetown-MedStar IRB System Hello, Principal30 Investigator30

MedStar Health

My Inbox IRB Components

Create New Study Report New Information

My Inbox

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

ID	Name	Date Created	Date Modified	State	Coordinator
CR00000002	Continuing Review for Study Test PI30 Study	10/15/2018 2:50 PM	10/15/2018 2:54 PM	Pre-Submission	

1 items < page 1 of 1 > 25 / page

Submissions Meetings Reports Library Help Center

The **Basic Information** page is the first page of your new study submission. **Complete the information on this page.**

Basic Information

1. * Title of study:

2. * Short title:

3. * Brief description: 

4. * Principal investigator:

Question 6: Select which IRB you are submitting the study to.

Question 7: If you are asking the MHRI IRB to review your study, select No. If you are asking the MHRI IRB to rely on another IRB, select Yes and see the guide for submitting a study to an external IRB.

4. * Principal investigator:

Principal24 Investigator24

5. * Does the investigator have a financial interest related to this research? 

Yes No [Clear](#)

6. * Which IRB should oversee this study?

- Georgetown IRB
 - MHRI IRB 
 - Qatar IRB
- [Clear](#)

Your IRB selection is a request and will be reviewed by the IRB staff. If you have a question regarding to which IRB you should submit, please contact your institution's IRB Office.

7. * Will an external IRB act as the IRB of record for this study? 

Yes No [Clear](#) 

Important! Once you save or click the continue button, your answer to this question cannot be changed. If you lock in the wrong answer, you will need to create a new study with the correct information.

8. * What kind of study is this?

- Multi-site study (More than one site will conduct the entire study)
 - Collaborative study (each site will conduct a portion of the study)
 - Single-site study
- [Clear](#)

9. * Attach the protocol:

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

Question 8: Select the type of study you are submitting. Even if there are other sites of this study, only select the option that you are asking the MHRI IRB to review.

If you select multi-site study, you are asking the MHRI IRB to review multiple sites for the study. If you are only submitting MedStar sites, select Single Site study

6. * Which IRB should oversee this study?

- Georgetown IRB
 - MHRI IRB
 - Qatar IRB
- [Clear](#)

Your IRB selection is a request and will be reviewed by the IRB staff. If you have a question regarding to which IRB you should submit, please contact your institution's IRB Office.

7. * Will an external IRB act as the IRB of record for this study? 

- Yes No [Clear](#)

Important! Once you save or click the continue button, your answer to this question cannot be changed. If you lock in the wrong answer, you will need to create a new study with the correct information.

8. * What kind of study is this?

- Multi-site study (More than one site will conduct the entire study)
 - Collaborative study (each site will conduct a portion of the study)
 - Single-site study
- [Clear](#)



9. * Attach the protocol:

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

Georgetown-MedStar IRB System

Question 9: Click **Add to attach your protocol. A second pop up window will appear and you can attach your protocol and click **OK**. Then **Click Continue** at the bottom of the page.**

4. * Principal investigator:

Principal24 Investigator24

5. * Does the investigator have a financial interest related to this study?

Yes No [Clear](#)

6. * Which IRB should oversee this study?

- Georgetown IRB
- MHRI IRB
- Qatar IRB

[Clear](#)

Your IRB selection is a request and will be reviewed by the IRB staff. If you

7. * Will an external IRB act as the IRB of record for this study?

Yes No [Clear](#)

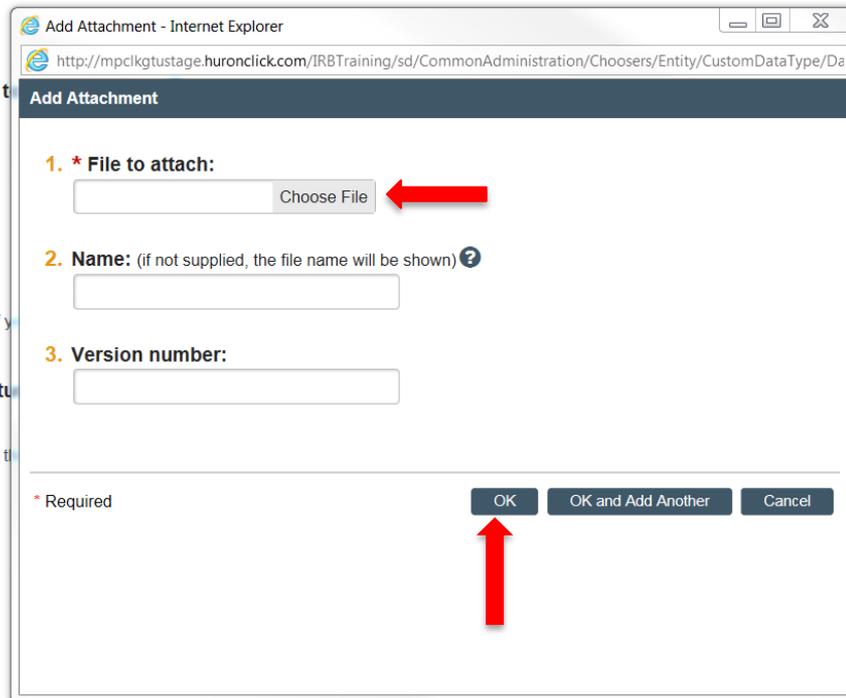
Important! Once you save or click the continue button, your answer to this question will be saved.

8. * What kind of study is this?

- Multi-site study (More than one site will conduct the entire study)
- Collaborative study (each site will conduct a portion of the study)
- Single-site study

[Clear](#)

9. * Attach the protocol:



Document	Category	Date Modified	Document History
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The next page is the Funding Sources page. To add a funding source, **click Add** and a pop up window will appear. To select a funding organization, **click on the three dots**.

The screenshot displays the Georgetown-MedStar IRB System Training Site interface. The main page header includes the Georgetown University and MedStar Health logos, the site title "Georgetown-MedStar IRB System Training Site", and the text "Edit: IRB Submission - STUDY0000240". The breadcrumb trail shows "You Are Here: New Study". The "Funding Sources" section is active, with a red arrow pointing to the "+ Add" button. Below the button is a table with columns "Funding Source" and "Sponsor's Funding ID", containing the text "There are no items to display". A "Continue »" button is visible in the top right. A pop-up window titled "Add Funding Source" is overlaid on the page. It contains a question mark icon, a red arrow pointing to the "1. * Funding organization:" dropdown menu, and three other fields: "2. Sponsor's funding ID: (assigned by external sponsor)", "3. Grants office ID: (assigned internally)", and "4. Attach files: (include any grant applications)". The "Attach files" section includes an "+ Add" button and a table with columns "Document", "Category", "Date Modified", and "Document History", also containing the text "There are no items to display". A "Continue »" button is located at the bottom right of the pop-up window.

A second pop up window will appear. **Select the funding source** for your study from the list, if applicable.

Note: If your funding source is not on the list, close the window and do not enter a funding source. Contact ORI (MHRI-ORIHeldesk@medstar.net) to have your funding source added.

The screenshot shows the 'Funding Sources' section of the IRB submission interface. A pop-up window titled 'Select Organization' is open, displaying a list of organizations. The background page shows the 'Funding Sources' section with a '1. Identify each organization supplying funding for the study' instruction and an 'Add' button. The pop-up window has a search filter set to 'Name' and shows a list of organizations with columns for Name, Category, and Parent Organization.

Name	Category	Parent Organization
<input type="radio"/> MCRC - MWHC		MedStar Washington Hospital Center
<input type="radio"/> 2U	Industry	
<input type="radio"/> AAC&U Bringing Theory to Practice Well-Being Initiative	None	
<input type="radio"/> AANP	Foundation	
<input type="radio"/> Aarhus University	College	Aarhus University
<input type="radio"/> AB Science	Industry	
<input type="radio"/> Abbott Laboratories	Sponsor	
<input type="radio"/> Abbott Laboratories Services Corp	Sponsor	
<input type="radio"/> AbbVie Inc.	Industry	
<input type="radio"/> ABC inc test	Industry	
<input type="radio"/> Ablynx NV	Industry	

Add Study Team members on this page. See next slide for additional details

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Georgetown-MedStar IRB System **Training Site**

Edit: IRB Submission - STUDY00000240

You Are Here:  New 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: 



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

2. External team member information: 



Name	Description
There are no items to display	

[« Back](#) [Save](#) [Exit](#) [Hide/Show Errors](#) [Print](#) [Jump To](#) [Continue »](#)

For Question 1, add internal MedStar team members by **clicking Add**. A pop up window will appear. Click the **three dots** to select a team member from the drop down. Complete additional information in the pop up window and **click OK**.

The screenshot displays the 'Georgetown-MedStar IRB System Training Site' interface. The main page shows the 'Study Team Members' section with a table and two 'Add' buttons. A red arrow points to the first 'Add' button. A pop-up window titled 'Add Study Team Member' is open, showing a form with four questions. A red arrow points to the three dots in the first question's input field.

Study Team Members

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

+ Add

Name	Roles	Financial Interest
There are no items to display		

2. External team member information:

+ Add

Name	Designation
There are no items to display	

Add Study Team Member

1. * Study team member: ?

...

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

- Sub-investigator
- Study Coordinator
- Regulatory Coordinator
- Study Nurse
- Responsible Participant
- Statistician

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

Yes No [Clear](#)

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

Yes No [Clear](#)

* Required

[OK](#) [OK and Add Another](#) [Cancel](#)

Question 2: If you have study team members who are external to MedStar, you will add them in question 2. Click Add. A pop up window will appear and will prompt you to add a file with the list of the external study team members. Please use the template for the external study team member information provided on the MHRI IRB website here.

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. The user is logged in as 'Edit: IRB Submission - STUDY00000240'. Below the header, a navigation bar includes 'You Are Here: New Study', 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'.

The main content area is titled 'Study Team Members'. It contains two sections:

- 1. Identify each additional person involved in the design, conduct, or**
This section has an 'Add' button and a table with columns for Name, Roles, and Financial Interest. One entry is visible: Neil J. Weissman, Sub-investigator, no.
- 2. External team member information: ?**
This section has an 'Add' button and a table with columns for Name and Description. Below the table, it says 'There are no items to display'.

A red arrow points to the 'Add' button in section 2. A 'Submit a Document' pop-up window is overlaid on the page. It has a title bar 'No Title - Internet Explorer' and a URL 'http://mpckgustage.huronclick.com/IRBTraining/sd/ResourceAdministration/Document/FormFor'. The pop-up contains a 'Title' field with a note 'If not provided, the name of the file will be used', a 'File' field with a 'Choose File' button (indicated by a red arrow), and a 'Show Advanced Options' button. At the bottom, there are 'Required', 'OK', 'OK and Add Another', and 'Cancel' buttons.

Complete the information on the study scope page.

Note: For Question 1, only select Yes if the study will be conducted outside of the MedStar health system.

If you select Yes for either Question 2 or Question 3, you will be prompted for additional information on the next page.

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**Georgetown-MedStar
IRB System Training Site**

Edit: IRB Submission - STUDY0000240

You Are Here:  New Study

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

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](#)

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

If you select **Yes** to the **Drug** question on the study scope page, you will see the screen below. Add the information about the drug used in your study, using the **Add button**. Complete the drug information in the pop up window using the same process you used to add a funding source.

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Georgetown-MedStar
IRB System **Training Site**

Edit: IRB Submission - STUDY00000238

You Are Here: External

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

Drugs

1. * List all drugs, biologics, foods, and dietary supplements to be used in the study:



Generic Name	Brand Name	Attachment Name
There are no items to display		

2. * Will the study be conducted under any IND numbers? 

Yes No [Clear](#)

3. Attach files: (such as IND or other information that was not attached for a specific drug) 



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

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



If you select **Yes** to the **Device** question on the study scope page, you will see the screen below. Add the information about the device used in your study, using the **Add** button. Complete the device information in the pop up window using the same process you used to add a funding source.

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Georgetown-MedStar IRB System Training Site

Edit: IRB Submission - STUDY00000238

You Are Here: External

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

Devices ⓘ

1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:



Device	Humanitarian Use Device	Attachment Name
There are no items to display		

2. * Device exemptions applicable to this study: ⓘ

- IDE number
- HDE number
- Claim of abbreviated IDE (nonsignificant risk device)
- Exempt from IDE requirements

[Clear](#)

3. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device) ⓘ

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

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

The Local Site Document is where you will upload any site specific documents the IRB needs to review such as consent forms, recruitment materials, survey instruments, etc. Upload these documents using the **Add** option under the applicable category.

GEORGETOWN UNIVERSITY Georgetown-MedStar IRB System **Training Site** Edit: IRB Submission - STUDY00000240

MedStar Health

You Are Here: New 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)

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

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

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

3. Other attachments:

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

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

On the Additional Information page, **answer the three questions** and then click **continue**.



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Georgetown-MedStar
IRB System Training Site

Edit: IRB Submission - STUDY00000240

You Are Here:  New 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

You have arrived on the final page. **To review any information added on previous pages, use the Jump To function. Otherwise, click Finish.**



The screenshot displays the final page of an IRB submission form. At the top, there is a header with the Georgetown University and MedStar Health logos on the left, the text "Georgetown-MedStar IRB System Training Site" in the center, and "Edit: IRB Submission - STUDY00000240" on the right. Below the header is a navigation bar with buttons for "Back", "Save", "Exit", "Hide/Show Errors", "Print", "Jump To", and "Finish". The "Jump To" button is highlighted with a red arrow pointing upwards. Below the navigation bar, the text "Final Page" is displayed, followed by instructions: "You have reached the end of the IRB submission form. Read the next steps carefully:" and a list of two steps: "1. Click Finish to exit the form." and "2. Important! To send the submission for review, click Submit on the next page." A red arrow points downwards from the "Finish" button in the navigation bar.

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IRB System Training Site

Edit: IRB Submission - STUDY00000240

You Are Here: New 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

You will then arrive at the study workspace page.

Note: The status bar on the left and the workflow map indicate your study is in the pre-submission status.

The screenshot displays the Georgetown-MedStar IRB System Training Site interface. At the top, the 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 bar with 'My Inbox' and 'IRB' selected, and other options like 'Submissions', 'Meetings', 'Reports', 'Library', and 'Help Center'. The main content area shows a study workspace for 'STUDY00000240: New Study'. On the left, a 'Pre-Submission' status bar is highlighted with a red arrow. Below it, 'Next Steps' includes 'Edit Study', 'Printer Version', and 'View Differences'. A 'Submit' button is also visible. The study details include: Principal investigator: Principal24 Investigator24; Submission type: Initial Study; Primary contact: Principal24 Investigator24; PI proxies: (empty); IRB office: MHRI IRB; Committee: (empty); IRB coordinator: (empty). A workflow diagram shows the process from 'Pre-Submission' (highlighted with a red arrow) to 'Pre-Review', 'IRB Review', 'Post-Review', and 'Review Complete'. 'Pre-Review' and 'IRB Review' both have 'Clarification Requested' loops. 'Post-Review' has a 'Modifications Required' loop. At the bottom, there is a 'History' tab and a search bar with filters for 'Activity' and 'Author'.

You have not yet submitted your study! Ensure that you complete the next steps to submit your protocol.

You have not yet submitted your study. To submit, select the submit option on the left.

Note: Only the PI and the PI proxy can submit the study. If you have not yet assigned a PI proxy, you can easily do so by selecting Assign PI Proxy on the left. You can do this before or after submission of this study.

The screenshot shows the 'Georgetown-MedStar IRB System Training Site' interface. At the top, there is a navigation bar with 'My Inbox', 'IRB', 'Submissions', 'Meetings', 'Reports', 'Library', and 'Help Center'. The main content area is titled 'STUDY00000240: New Study'. It includes a 'Pre-Submission' section with a 'Next Steps' list containing 'Edit Study', 'Printer Version', 'View Differences', 'Submit', 'Assign Primary Contact', 'Assign PI Proxy', 'Manage Ancillary Reviews', 'Manage Guest List', and 'Add Related Grant'. A flowchart illustrates the process: Pre-Submission leads to Pre-Review, which can lead to IRB Review or Clarification Requested. IRB Review can lead to Post-Review or Clarification Requested. Post-Review can lead to Review Complete or Modifications Required. Metadata includes: Principal investigator: Principal24 Investigator24, Submission type: Initial Study, Primary contact: Principal24 Investigator24, PI proxies: (empty), IRB office: MHRI IRB, Committee: (empty), and IRB coordinator: (empty). A 'History' tab is active, showing a table with columns for Activity, Author, and Activity Date. The first entry is 'Study Created' by 'Investigator24, Principal24' on '12/5/2018 3:17 PM'. Two red arrows point to the 'Submit' and 'Assign PI Proxy' options in the 'Next Steps' list.

Once you click the submit option, a pop up window will prompt you to **verify the listed statements** as the PI or on behalf of the PI as the PI proxy. **Click OK.**

The screenshot displays the Georgetown-MedStar IRB System interface. The main page shows a 'Pre-Submission' status for 'STUDY0000'. 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 dialog box, there are 'OK' and 'Cancel' buttons. A red arrow points to the 'OK' button. The background interface includes a navigation menu with 'Submissions', 'Meetings', and 'Reports', and a sidebar with 'Next Steps' including 'Edit Study', 'Printer Version', and 'View Differences'. The top right corner of the page says 'Hello, Principal24 Investigator24'.

Once you have submitted the study, note that status bar on the left now says Pre-Review and the Pre-Review bubble on the workflow map is selected.

The screenshot displays the Georgetown-MedStar IRB System Training Site interface. At the top, the 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 bar with tabs for "My Inbox", "IRB", "Submissions", "Meetings", "Reports", "Library", and "Help Center".

The main content area shows the details for "STUDY00000240: New Study". A red arrow points to the "Pre-Review" status bar on the left. The study details include:
Entered IRB: 12/5/2018 4:26 PM
Last updated: 12/5/2018 4:26 PM
Principal investigator: Principal24 Investigator24
Submission type: Initial Study
Primary contact: Principal24 Investigator24
PI proxies:
IRB office: MHRI IRB
Committee:
IRB coordinator:

Under "Next Steps", there are buttons for "View Study", "Printer Version", and "View Differences". Below these are several utility links like "Assign Primary Contact", "Assign PI Proxy", "Manage Guest List", "Add Related Grant", "Add Comment", "Copy Submission", and "Withdraw".

A workflow diagram shows the process flow: Pre-Submission -> Pre-Review (highlighted with a red arrow) -> IRB Review -> Post-Review -> Review Complete. There are also feedback loops for "Clarification Requested" between Pre-Submission, Pre-Review, IRB Review, and Post-Review, and "Modifications Required" between IRB Review and Post-Review.

At the bottom, there is a "History" tab with a search filter set to "Activity". The activity log shows:

Activity	Author	Activity Date
Submitted	Investigator24, Principal24	12/5/2018 4:26 PM
Study Created	Investigator24, Principal24	12/5/2018 3:17 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.