

GEORGETOWN UNIVERSITY



Georgetown-MedStar IRB System

How to Submit a Study in the Georgetown-MedStar IRB System that will be Reviewed by an External IRB

December 5, 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 Create New Study option on the left side 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

You will be directed to the IRB Submission page.
Complete the information on the Basic Information page.

GEORGETOWN UNIVERSITY Georgetown-MedStar IRB System New: IRB Submission

 MedStar Health

You Are Here: IRB Submission

[Back](#) [Save](#) [Print](#) [Continue](#)

Basic Information

1. * Title of study:

2. * Short title:

3. * Brief description:

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.

For Question 6: Select the MHRI IRB For Question 7: Select Yes

Basic Information

1. * Title of study:

External IRB submission in the test system

2. * Short title:

External

3. * Brief description: 

Test submission

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.

Question 8: If you are asking the MHRI IRB to consider only a MedStar site, 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:

[+ Add](#)

Document	Category	Date Modified	Docun
Update IRB of Record form.docx(0.01)	IRB Protocol	12/4/2018	Histor

Georgetown-MedStar IRB System

Question 9 requires you to upload the protocol. When you select **Add**, a pop up window will appear where you can select the file for upload. To upload a file, select **Choose File**. Then 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 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
- 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
- 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:

+ Add

Add Attachment - Internet Explorer
http://mpclkgstusage.huronclick.com/IRBTraining/sd/CommonAdministration/Choose

Add Attachment

- * File to attach:
 Choose File
- Name: (if not supplied, the file name will be shown)
- Version number:

* Required

OK OK and Add Another Cancel

Document Category Date Modified Document History

There are no items to display

Georgetown-MedStar IRB System

The next page of the submission will prompt you to select which external IRB you are asking the MHRI IRB to rely on. For Question 1, click the three dots, which will prompt the appearance of a pop up window.

External IRB

- * External IRB:** ...
- External study ID:**
- Approval letter from external IRB:** [None]
- Initial approval date by external IRB:**
- Last day of approval period:**

Select IRB Institutional Profile

Filter by: Institution

1-1 of 1

Institution	Points of Contact
<input type="radio"/> GREEN FIELDS UNIVERSITY	none

1-1 of 1

Continue >>

Edit: IRB Submission - STUDY00000238

Georgetown-MedStar IRB System

In the pop up window, **select the IRB** you are requesting the MHRI IRB to rely on. Then click **OK**.

Note: The system will have the most commonly used external IRBs listed, but if the one you are using is not listed, you will need to contact ORI (MHRI-ORIHeldesk@medstar.net) to have the institutional profile in the system before you can make your submission.

The screenshot displays the 'Select IRB Institutional Profile' pop-up window. The window title is 'Select IRB Institutional Profile - Internet Explorer'. The URL is 'http://mpclkgustage.huronclick.com/IRBTraining/sd/CommonAdministration/Choosers/Entity/Chooser?targetType='. The window contains a 'Filter by' dropdown set to 'Institution', a search box, and 'Go', 'Clear', and 'Advanced' buttons. Below the filter is a table with the following data:

Institution	Points of Contact
<input checked="" type="radio"/> GREEN FIELDS UNIVERSITY	none

The table shows 'Total Selected: 1' and navigation arrows. Below the table are 'OK' and 'Cancel' buttons. A red arrow points to the 'OK' button. Another red arrow points to the 'External IRB' field in the main form on the left.

The main form on the left is titled 'External IRB' and contains the following steps:

- * External IRB:** A text input field with a dropdown arrow.
- External study ID:** A text input field with a help icon.
- Approval letter from external IRB:** A text input field with a '[None]' button and an 'Upload' button.
- Initial approval date by external IRB:** A date picker field with a help icon.
- Last day of approval period:** A date picker field with a help icon.

Complete the rest of the External IRB page to the best of your ability. Please identify the reason why your study should be reviewed by an external IRB in Question 6.

External IRB

1. * External IRB:

GREEN FIELDS UNIVERSITY

2. External study ID:

3. Approval letter from external IRB:

[None]

4. Initial approval date by external IRB:

5. Last day of approval period:

6. Specify the reason the study should be reviewed by an external IRB:

7. Common Rule regulatory requirements:

Pre-2018 Requirements

2018 Requirements

[Clear](#)

8. Regulatory oversight: (check all that apply)

DOD (Department of Defense)

DOE (Department of Energy)

...

You will be directed to the funding source page. Please add a funding source, if applicable, by clicking the Add button.

You Are Here: External

« Back

Save Exit Hide/Show Errors Print Jump To ▾

Continue »

Funding Sources ⓘ

1. Identify each organization supplying funding for the study:



Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

« Back

Save Exit Hide/Show Errors Print Jump To ▾

Continue »

If you selected **Add**, a pop up window will appear. Select the **three dots** to find a funding source.

The screenshot displays the 'Georgetown-MedStar IRB System Training Site' interface. On the left, the 'Funding Sources' section is visible, with a '+ Add' button. The main content area shows a pop-up window titled 'Add Funding Source' with the following steps:

- * Funding organization:** A dropdown menu with a red arrow pointing to the three dots (more options) icon.
- Sponsor's funding ID:** (assigned by external sponsor) - Input field.
- Grants office ID:** (assigned internally) - Input field.
- Attach files:** (include any grant applications) - Includes an '+ Add' button and a table with columns: Document, Category, Date Modified, Document History. Below the table, it says 'There are no items to display'.

The background shows the 'Edit: IRB Submission - STUDY00000238' header and a 'Continue' button.

Georgetown-MedStar IRB System

A second pop up window will appear. **Select** the funding source from this list and click **OK**. You will then arrive on the original pop up window. Fill in additional information, if applicable, and click **OK**.

The screenshot displays the 'Funding Sources' section of the IRB submission interface. The main window shows the Georgetown University and MedStar Health logos at the top. Below the header, there is a 'You Are Here' breadcrumb and a 'Back' button. The 'Funding Sources' section includes a heading and a numbered instruction: '1. Identify each organization supplying funding for the study'. An 'Add' button is visible, followed by a table with columns for 'Funding Source' and 'Sponsor's Funding ID'. The table currently contains no items.

A 'Select Organization' pop-up window is overlaid on the main interface. It features a search filter by 'Name' and a 'Go' button. Below the filter is a table listing various organizations with their categories and parent organizations. The table includes the following entries:

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	

The pop-up window also includes 'OK' and 'Cancel' buttons at the bottom.

You will arrive on the Study Scope page. Complete the information as applicable to your study.

Note: If you select yes for either question, an additional page will appear where you fill out information about the drug or device.

GEORGETOWN UNIVERSITY

 MedStar Health

**Georgetown-MedStar
IRB System Training Site**

Edit: IRB Submission - STUDY00000238

You Are Here: External

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

Study Scope

1. * 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](#)
2. * 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, 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.

GEORGETOWN UNIVERSITY

 MedStar Health

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](#)

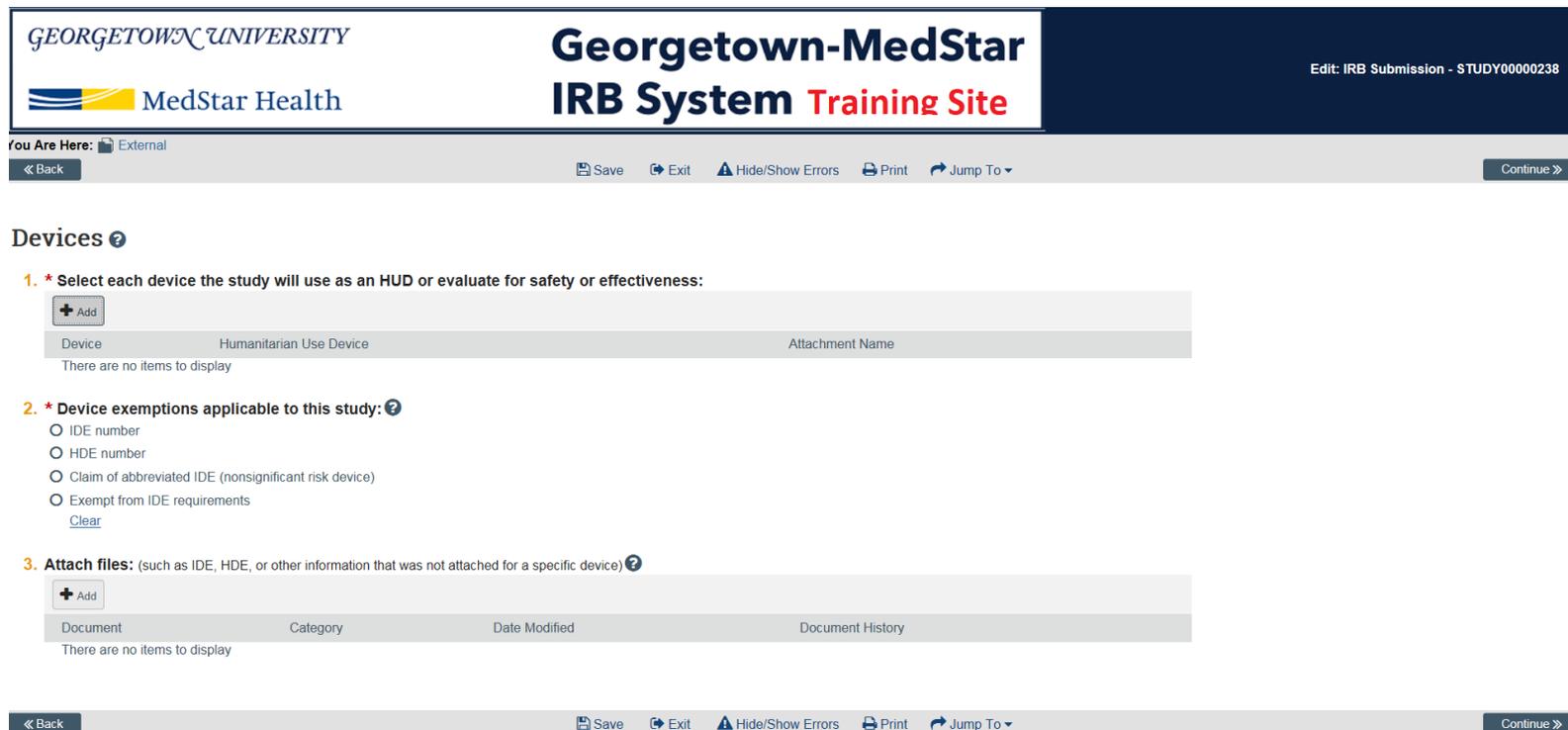
3. Attach files: (such as IND or other information that was not attached for a specific drug) ⓘ



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, 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.



The screenshot shows the 'Georgetown-MedStar IRB System Training Site' interface. At the top, there is a header with the Georgetown University and MedStar Health logos on the left, the site title 'Georgetown-MedStar IRB System Training Site' in the center, and 'Edit: IRB Submission - STUDY00000238' on the right. Below the header is a navigation bar with 'You Are Here: External' and buttons for 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'. The main content area is titled 'Devices' and contains three sections:

- Select each device the study will use as an HUD or evaluate for safety or effectiveness:** This section includes an 'Add' button and a table with columns 'Device' and 'Attachment Name'. The table is currently empty, displaying 'There are no items to display'.
- Device exemptions applicable to this study:** This section includes radio button options for 'IDE number', 'HDE number', 'Claim of abbreviated IDE (nonsignificant risk device)', and 'Exempt from IDE requirements'. There is also a 'Clear' link.
- Attach files:** (such as IDE, HDE, or other information that was not attached for a specific device) This section includes an 'Add' button and a table with columns 'Document', 'Category', 'Date Modified', and 'Document History'. The table is currently empty, displaying 'There are no items to display'.

At the bottom of the screenshot, there is another navigation bar with 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue' buttons.

You should then arrive on the final page. Click Finish.

You Are Here:  External

[« 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.

[« Back](#)

 Save

 Exit

 Hide/Show Errors

 Print

 Jump To ▾

[Finish](#)



You will then arrive at the study workspace. Note that the orange status bar on the left side of your screen will say “External IRB”

GEORGETOWN UNIVERSITY
MedStar Health

Georgetown-MedStar IRB System Training Site

Hello, Principal24 Investigator24 ▾

» My Inbox IRB

Submissions Meetings Reports Library Help Center

External IRB STUDY00000238: External

Initial approval:
Approval end:
Last updated: 12/4/2018 12:08 PM

Lead principal investigator: Principal24 Investigator24
Local site: STUDY00000238_SITE01

External IRB: GREEN FIELDS UNIVERSITY
External IRB approval letter:
Regulatory authority: Pre-2018 Requirements

External IRB → Closed

History Funding Documents

Filter by Activity + Add Filter x Clear All

Activity	Author	Activity Date
Site Created	Investigator24, Principal24	12/4/2018 11:51 AM
Link: Site for External		
Study Created	Investigator24, Principal24	12/4/2018 11:51 AM

Correspond with sIRB
Add Comment

(IRB - Study - External IRB)

You haven't submitted yet! Please ensure that you complete the next steps to submit your protocol.

You haven't submitted yet! You are currently looking at the workspace for the protocol. Click on the link to the local site above the workflow map.

GEORGETOWN UNIVERSITY **Georgetown-MedStar IRB System Training Site** Hello, Principal24 Investigator24

MedStar Health

» My Inbox **IRB**

Submissions Meetings Reports Library Help Center

External IRB

Initial approval:
Approval end:
Last updated: 12/4/2018 12:08 PM

Next Steps

- Edit Study
- Printer Version
- View Differences
- Report New Information

Correspond with sIRB

Add Comment

STUDY00000238: External

Lead principal investigator: Principal24 Investigator24
Local site: STUDY00000238_SITE01

External IRB: GREEN FIELDS UNIVERSITY
External IRB approval letter:
Regulatory authority: Pre-2018 Requirements



History Funding Documents

Filter by Activity + Add Filter x Clear All

Activity	Author	Activity Date
Site Created	Investigator24, Principal24	12/4/2018 11:51 AM
Study Created	Investigator24, Principal24	12/4/2018 11:51 AM

Click Edit Site on the left hand side of the screen.

GEORGETOWN UNIVERSITY
MedStar Health

Georgetown-MedStar IRB System Training Site

Hello, Principal24 Investigator24 ▾

» My Inbox IRB
Submissions Meetings Reports Library Help Center

Pre-Submission
Last updated: 12/4/2018 11:51 AM

Next Steps

- Edit Site
- Printer Version
- View Differences

Assign Primary Contact
Manage Guest List
Add Related Grant
Add Comment
Discard

STUDY00000238_SITE01: Site for External

Principal investigator: IRB Site
Submission type: IRB Site
Primary contact:
PI proxies:

IRB office: MHRI IRB
Committee:
IRB coordinator:
Regulatory authority: Pre-2018 Requirements
Study: STUDY00000238 [🔗](#)
External study ID:

Pre-Submission → Pre-Review → Pending sIRB Review → Post-Review → Review Complete
Clarification Requested (Pre-Review to Pending sIRB Review)
Modifications Required (Post-Review to Pending sIRB Review)

History Funding Contacts Documents Reviews Snapshots Training

Filter by [?] Activity ▾ Enter text to search for 🔍 + Add Filter ✕ Clear All

Activity	Author	Activity Date
Site Created	Investigator24, Principal24	12/4/2018 11:51 AM

You will arrive on the study site submission page. Complete the information requested on this page and click continue. Note that the questions designated with the **red** asterisk are required.

You Are Here: Site for External

<< Back Save Exit Hide/Show

Basic Information

- * Title of site:**
- * Short title:**
- * Brief description:** ⓘ
- * Principal investigator:**
Principal24 Investigator24
- * Does the investigator have a financial interest related to this research?** ⓘ
 Yes No [Clear](#)
- * Which IRB should oversee this study?**
 Georgetown IRB
 MHRI IRB
 Qatar IRB
[Clear](#)

<< Back Save Exit Hide/Show

The next page will be funding source. Select funding source for the study site, if applicable by using the **Add** option.

GEORGETOWN UNIVERSITY
MedStar Health

**Georgetown-MedStar
IRB System Training Site**

Edit: IRB Submission - STUDY00000238_SITE01

You Are Here: Site for External

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

Funding Sources ⓘ

1. Identify each organization supplying funding for the study:

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

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

You will then arrive at the Study Team Members page. **Add the study team members** by clicking the Add option.

GEORGETOWN UNIVERSITY
MedStar Health

Georgetown-MedStar
IRB System **Training Site**

Edit: IRB Submission - STUDY00000238_SITE01

You Are Here: Site for External

« 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:



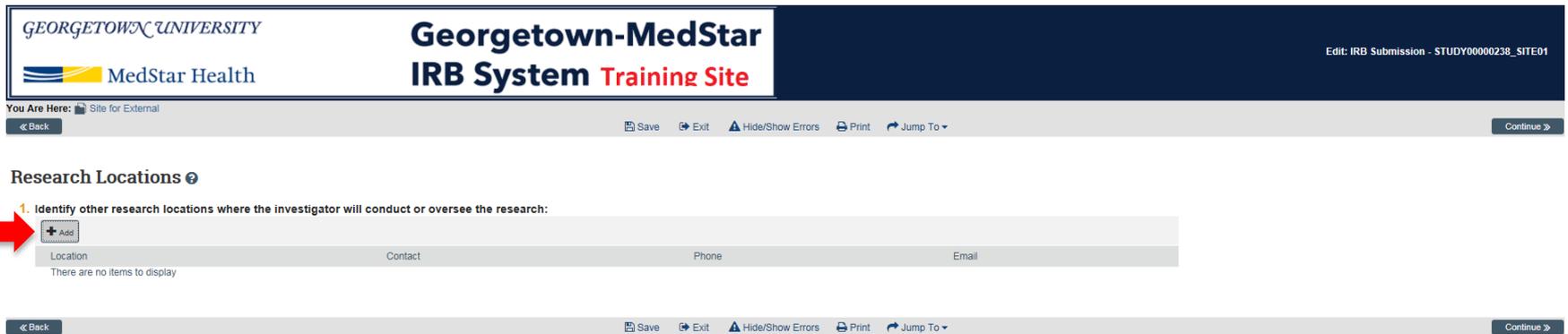
Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
There are no items to display					

2. External team member information:

Name	Description
There are no items to display	

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

For the Research Locations page, add non-MedStar sites you are asking the MHRI IRB to review by using the **Add** option.



The screenshot shows the top navigation bar with the Georgetown University and MedStar Health logos on the left, the title "Georgetown-MedStar IRB System Training Site" in the center, and the text "Edit: IRB Submission - STUDY0000230_SITE01" on the right. Below the navigation bar is a breadcrumb trail "You Are Here: Site for External" and a utility bar with buttons for "Back", "Save", "Exit", "Hide/Show Errors", "Print", "Jump To", and "Continue".

The main content area is titled "Research Locations" and contains a step instruction: "1. Identify other research locations where the investigator will conduct or oversee the research:". Below this instruction is a table with a red arrow pointing to an "Add" button in the first column. The table has four columns: "Location", "Contact", "Phone", and "Email". The "Location" column contains the text "There are no items to display".

Location	Contact	Phone	Email
There are no items to display			

The Local Site Documents page is where you will upload MedStar specific documents for the study, like the consent form or recruitment materials.

GEORGETOWN UNIVERSITY **Georgetown-MedStar IRB System Training Site** Edit: IRB Submission - STUDY00000238_SITE01

MedStar Health

You Are Here: Site for External

« 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

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

You will then arrive on the final page. Click **Finish**.



The screenshot shows the final page of the 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 - STUDY00000238_SITE01" on the right. Below the header is a navigation bar with a "Back" button on the left and "Save", "Exit", "Hide/Show Errors", "Print", and "Jump To" buttons in the center, and a "Finish" button on the right. The main content area contains the heading "Final Page" followed by instructions: "You have reached the end of the IRB submission form. Read the next steps carefully:" and a numbered list: "1. Click **Finish** to exit the form." and "2. **Important!** To send the submission for review, click **Submit** on the next page." At the bottom, there is another navigation bar identical to the one above, with a "Finish" button on the right.



You will then be directed to the study local site workspace. You will now have the option to submit the study.

GEORGETOWN UNIVERSITY Georgetown-MedStar IRB System Training Site Hello, Principal24 Investigator24

My inbox IRB Submissions Meetings Reports Library Help Center

Pre-Submission

STUDY00000238_SITE01: Site for External

Last updated: 12/4/2018 1:06 PM

Principal investigator: Principal24 Investigator24
Submission type: IRB Site
Primary contact: Principal24 Investigator24
PI proxies:

IRB office: MHRI IRB
Committee:
IRB coordinator:
Regulatory authority: Pre-2018 Requirements
Study: STUDY00000238
External study ID:

Next Steps

- Edit Site
- Print or Version
- View Differences
- Submit
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Correspond with sIRB
- Add Comment
- Discard

History Funding Contacts Documents Reviews Snapshots Training

Filter by Activity + Add Filter X Clear All

Activity	Author	Activity Date
Site Created	Investigator24, Principal24	12/4/2018 11:51 AM

Either before or after you submit, you will also have the option to assign a PI proxy for this study. Reference the Assigning a PI Proxy guide for detailed instructions.

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 bar with 'My Inbox' and 'IRB' tabs, and a secondary bar with 'Submissions', 'Meetings', 'Reports', 'Library', and 'Help Center'.

The main content area shows a study page for 'STUDY00000238_SITE01: Site for External'. On the left, there is a 'Pre-Submission' section with a 'Last updated: 12/4/2018 1:06 PM' timestamp and a 'Next Steps' sidebar containing buttons for 'Edit Site', 'Printer Version', and 'View Differences', along with a list of actions like 'Submit', 'Assign Primary Contact', 'Assign PI Proxy', 'Manage Ancillary Reviews', 'Manage Guest List', 'Add Related Grant', 'Correspond with sIRB', 'Add Comment', and 'Discard'.

The study details include: Principal investigator: Principal24 Investigator24; Submission type: IRB Site; Primary contact: Principal24 Investigator24; PI proxies: (none listed); IRB office: MHRI IRB; Committee: (none listed); IRB coordinator: (none listed); Regulatory authority: Pre-2018 Requirements; Study: STUDY00000238; External study ID: (link).

A workflow diagram shows the process: Pre-Submission leads to Pre-Review, which can lead to Pending sIRB Review. From Pending sIRB Review, it can go to Post-Review or back to Pre-Review. Post-Review can lead to Review Complete or back to Pending sIRB Review. There are also paths for 'Clarification Requested' (from Pre-Review to Pending sIRB Review) and 'Modifications Required' (from Post-Review to Pending sIRB Review).

At the bottom, there is a 'History' section with tabs for 'Funding', 'Contacts', 'Documents', 'Reviews', 'Snapshots', and 'Training'. A search bar is present with 'Filter by' set to 'Activity' and a search input field. Below the search bar is a table with columns 'Activity', 'Author', and 'Activity Date'. The table contains one entry: 'Site Created' by 'Investigator24, Principal24' on '12/4/2018 11:51 AM'.

Once you click submit, you will see a pop up window that will ask for your verification of the listed statements. Click **OK**.

The screenshot displays the Georgetown-MedStar IRB System Training Site interface. The top navigation bar includes the university and MedStar Health logos, the site title "Georgetown-MedStar IRB System Training Site", and a user greeting "Hello, Principal24 Investigator24". The main content area shows a "Pre-Submission" section for "STUDY00000238_SITE01: SI". A workflow diagram indicates the current step is "Pre-Submission", with subsequent steps for "Pre-Review", "Clarification Requested", and "Pending sIRB Review". A "Submit" button is visible in the "Next Steps" section. A modal dialog box titled "Submit" is overlaid on the screen, containing the following text:

Execute "Submit" on STUDY00000238_SITE01 - Internet Explorer
http://mpclkgstustage.huronclick.com/IRBTraining/sd/ResourceAdministration/Activity

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

The background interface also shows a "History" tab with a table of activities:

Activity	Activity Date
Site Created	12/4/2018 11:51 AM

Your study has now been submitted. Note that the orange study status box on the left side of your screen says Pre-Review.

Pre-Review

Entered IRB: 12/4/2018 1:24 PM
Last updated: 12/4/2018 1:24 PM

Next Steps

- View Site
- Printer Version
- View Differences
- Assign Primary Contact
- Assign PI Proxy
- Manage Guest List
- Add Related Grant
- Correspond with sIRB
- Add Comment
- Withdraw
- Discard

STUDY00000238_SITE01: Site for External

Principal investigator: Principa24 Investigator24
Submission type: IRB Site
Primary contact: Principa24 Investigator24
PI proxies:

IRB office: MHRI IRB
Committee:
IRB coordinator:
Regulatory authority: Pre-2018 Requirements
Study: STUDY00000238
External study ID:

```

    graph LR
      A[Pre-Submission] --> B[Pre-Review]
      B --> C[Pending sIRB Review]
      C --> D[Post-Review]
      D --> E[Review Complete]
      C --> F[Modifications Required]
      F --> C
      B --> G[Clarification Requested]
      G --> B
  
```

Activity	Author	Activity Date
Submitted	Investigator24, Principa24	12/4/2018 1:24 PM
Site Created	Investigator24, Principa24	12/4/2018 11:51 AM

Congratulations!

You have successfully submitted a study for reliance on an External IRB 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-ORHelpDesk@medstar.net.