


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

December 5, 2018

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

 MedStar Health

**Georgetown-MedStar
IRB System**

Hello, Principal30 Investigator30

»

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IRB

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Filter by ID Enter text to search for + Add Filter 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

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:

 Add

Document

Category

Date Modified

Document History

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:

+ Add

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
☐ MHRIRB
☐ 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:




Add Attachment - Internet Explorer

http://mpclkgstustage.huronclick.com/IRBTraining/sd/CommonAdministration/Choosers/Entity/CustomDataType/De

Add Attachment

1. * File to attach:

[Choose File](#)

2. Name: (if not supplied, the file name will be shown) 

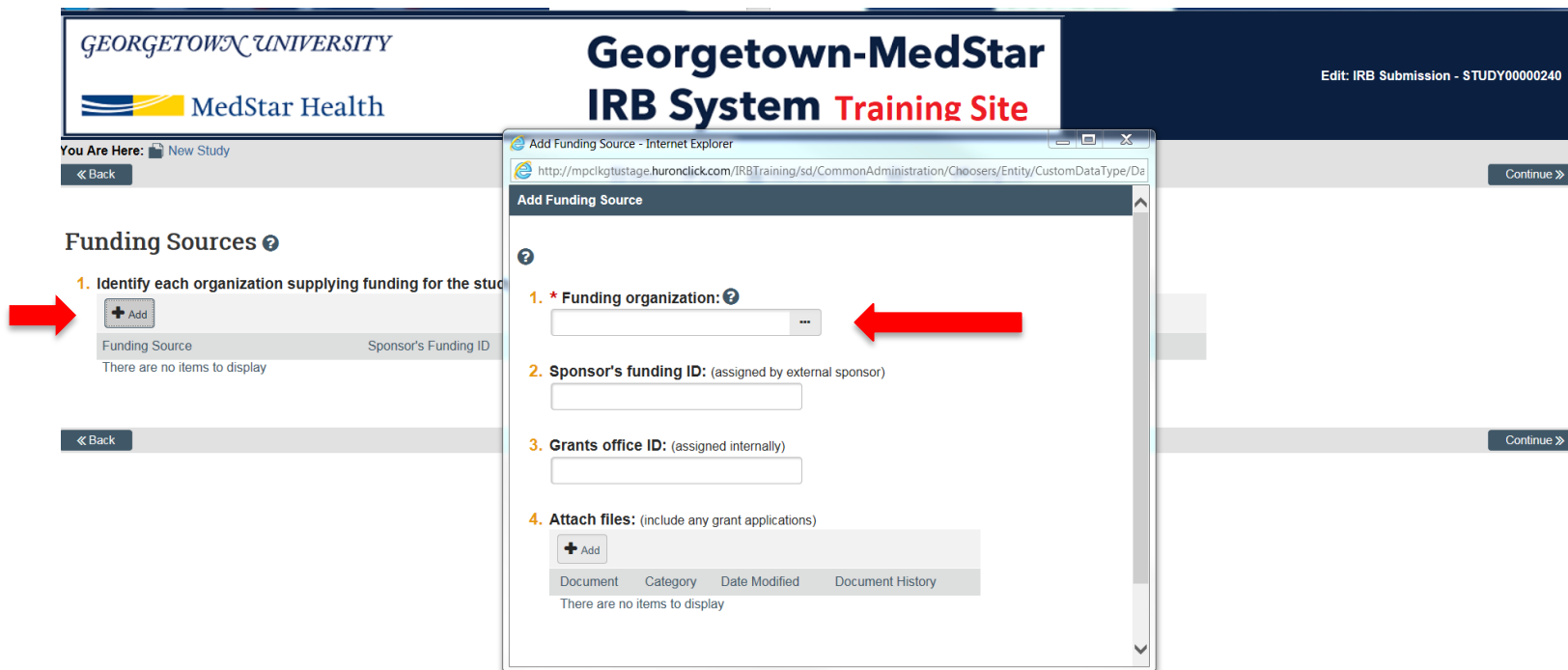
3. Version number:

* Required

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



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 header includes the Georgetown University and MedStar Health logos, the site title "Georgetown-MedStar IRB System Training Site", and a user identifier "Edit: IRB Submission - STUDY00000240".

The "Funding Sources" section is active, showing a list of funding sources with columns for "Funding Source" and "Sponsor's Funding ID". A red arrow points to the "+ Add" button in the top left of this section.

A pop-up window titled "Add Funding Source" is open, showing a form with the following steps:

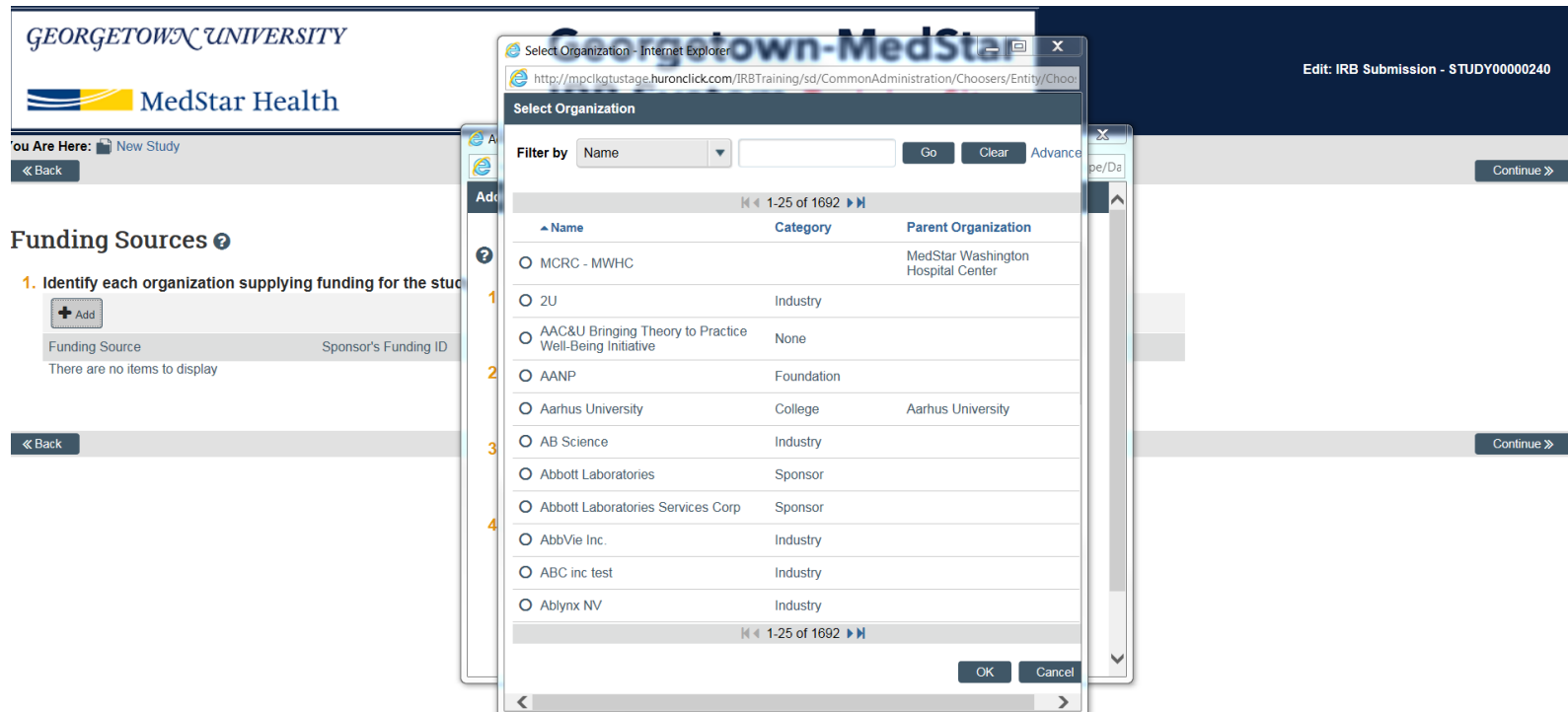
- 1. * Funding organization:** A dropdown menu with a three-dot icon. A red arrow points to this icon.
- 2. Sponsor's funding ID:** (assigned by external sponsor) - A text input field.
- 3. Grants office ID:** (assigned internally) - A text input field.
- 4. Attach files:** (include any grant applications) - A section with an "+ Add" button and a table with columns: Document, Category, Date Modified, and Document History. Below the table, it states "There are no items to display".

The pop-up window also includes a "Continue" button in the bottom right corner.

Georgetown-MedStar IRB System

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 displays the Georgetown-MedStar IRB System interface. The main window shows the 'Funding Sources' section with a 'New Study' button and a 'Back' button. A 'Funding Sources' table is visible, but it is empty, displaying 'There are no items to display'. A 'Select Organization' pop-up window is overlaid on the main window, showing a list of organizations to select from. The pop-up window has a 'Filter by' dropdown set to 'Name' and a 'Go' button. The list of organizations is as follows:

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 a '1-25 of 1692' pagination indicator and 'OK' and 'Cancel' buttons at the bottom.

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

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IRB System Training Site**

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Study Team Members [?](#)

- 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					
- External team member information: [?](#)

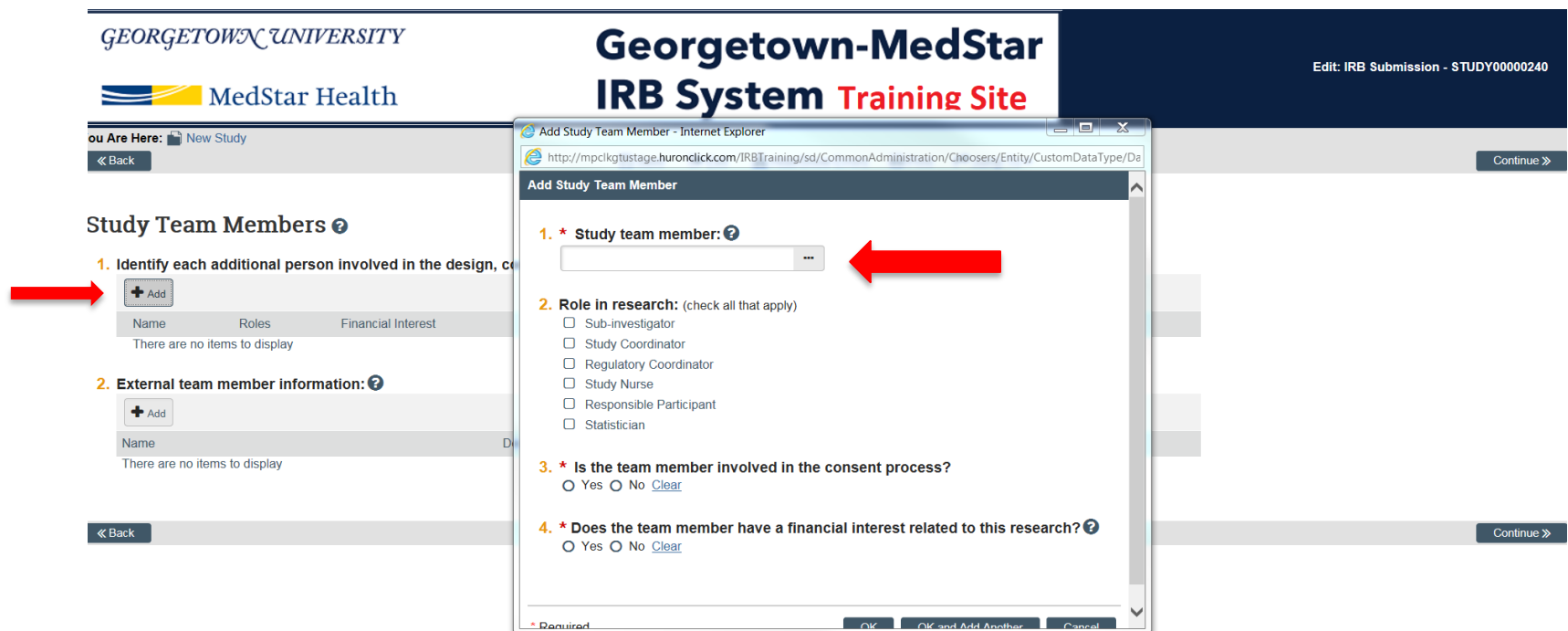
+

Add

Name	Description
There are no items to display	

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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 for adding members. A red arrow points to the '+ Add' button. A pop-up window titled 'Add Study Team Member' is open, showing a form with the following steps:

- * Study team member:** A dropdown menu with a red arrow pointing to the three dots icon.
- Role in research:** (check all that apply)
 - ☐ Sub-investigator
 - ☐ Study Coordinator
 - ☐ Regulatory Coordinator
 - ☐ Study Nurse
 - ☐ Responsible Participant
 - ☐ Statistician
- * Is the team member involved in the consent process?**
 - ☐ Yes ☐ No [Clear](#)
- * Does the team member have a financial interest related to this research?**
 - ☐ Yes ☐ No [Clear](#)

The pop-up window has buttons for 'OK', 'OK and Add Another', and 'Cancel' at the bottom.

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.

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Study Team Members ?

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

+ Add

Name	Roles	Financial Inter
<div style="display: flex; align-items: center;">  <div>Neil J. Weissman</div> </div>	Sub-investigator	no

2. External team member information: ?

+ Add

Name	Description
There are no items to display	

No Title - Internet Explorer

http://mpckgtustage.huronclick.com/IRBTraining/sd/ResourceAdministration/Document/FormFor

Submit a Document Help

Title: If not provided, the name of the file will be used

* File: Choose File

Show Advanced Options

* Required

OK
OK and Add Another
Cancel

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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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IRB System Training Site


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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](#)

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**

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Drugs

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

+

Add

Generic Name	Brand Name	Attachment Name
There are no items to display		
- Will the study be conducted under any IND numbers?

☐ Yes
 ☐ No
 [Clear](#)
- Attach files: (such as IND or other information that was not attached for a specific drug)

+


Add

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

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[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

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Continue »

Devices ?

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

+ Add

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) ?

+ Add

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

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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.

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Local Site Documents ?

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

 Add

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) ?

 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			

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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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

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

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Edit: IRB Submission - STUDY00000240

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[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.

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[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.



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Georgetown-MedStar IRB System Training Site

Hello, Principal24 Investigator24 ▾

» My Inbox IRB Submissions Meetings Reports Library Help Center

Pre-Submission STUDY00000240: New Study

Last updated: 12/5/2018 4:19 PM

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

IRB office: MHRI IRB
Committee:
IRB coordinator:

Next Steps

Edit Study
 Printer Version
 View Differences

Submit
 Assign Primary Contact
 Assign PI Proxy
 Manage Ancillary Reviews
 Manage Guest List

Workflow Map:

```

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 Funding Contacts Documents Reviews Snapshots Training

Filter by **Activity**

Activty Author ▼ Activity Date

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.

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IRB System Training Site**

Hello, Principal24 Investigator24 ▾

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Pre-Submission

Last updated: 12/5/2018 4:19 PM

Next Steps

Edit Study

Printer Version

View Differences

Submit

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Related Grant

STUDY00000240: New Study

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

IRB office: MHRI IRB
Committee:
IRB coordinator:

Pre-Submission

Pre-Review

IRB Review

Post-Review

Review Complete

Clarification Requested

Clarification Requested

Modifications Required

History Funding Contacts Documents Reviews Snapshots Training

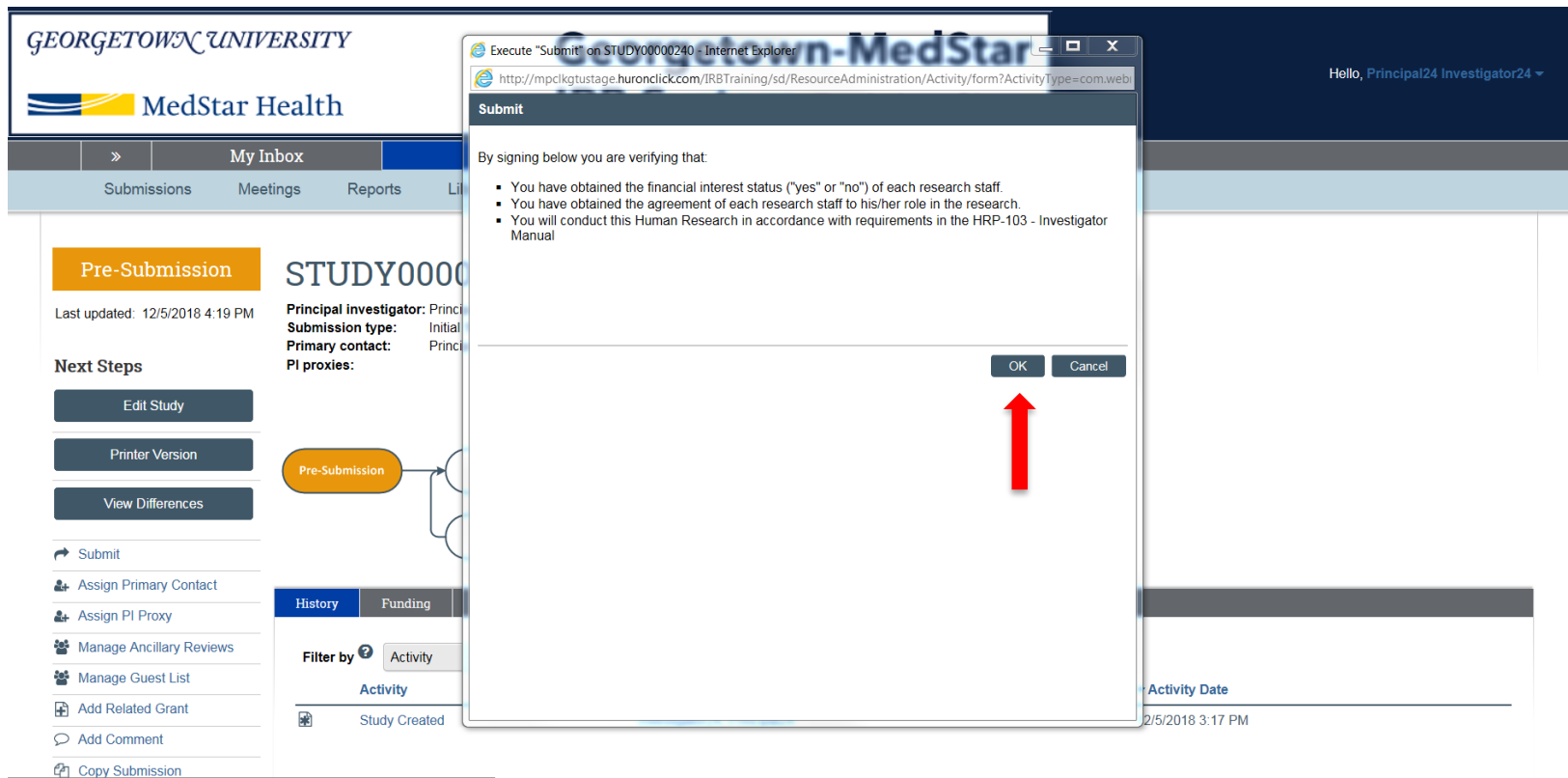
Filter by **Activity** Enter text to search for **Q** + Add Filter x Clear All

Activity **Author** **Activity Date**

Study Created Investigator24, Principal24 12/5/2018 3:17 PM

Georgetown-MedStar IRB System

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 window shows the 'Pre-Submission' status for 'STUDY0000'. A pop-up window titled 'Submit' is overlaid, prompting the user to verify the following statements:

- 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

The pop-up window includes 'OK' and 'Cancel' buttons. A red arrow points to the 'OK' button. The background interface shows a sidebar with 'Next Steps' (Edit Study, Printer Version, View Differences, Submit, Assign Primary Contact, Assign PI Proxy, Manage Ancillary Reviews, Manage Guest List, Add Related Grant, Add Comment, Copy Submission) and a main content area with 'History' and 'Funding' tabs. The 'History' tab is active, showing a table with columns 'Activity' and 'Activity Date'.

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.

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Hello, Principal24 Investigator24

» My Inbox **IRB**

Submissions Meetings Reports Library Help Center

Pre-Review

Entered IRB: 12/5/2018 4:26 PM
Last updated: 12/5/2018 4:26 PM

Next Steps

View Study

Printer Version

View Differences

Assign Primary Contact

Assign PI Proxy

Manage Guest List

Add Related Grant

Add Comment

Copy Submission

Withdraw

STUDY00000240: New Study

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

IRB office: MHRI IRB
Committee:
IRB coordinator:

Pre-Submission

Pre-Review

Clarification Requested

IRB Review

Clarification Requested

Post-Review

Modifications Required

Review Complete

History Funding Contacts Documents Reviews Snapshots Training

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

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-ORISHelpDesk@medstar.net.