



MedStar Health

It's how we **treat people.**

September 11, 2024

How to submit a new study in the Georgetown-MedStar IRB system

- When you log into the system, you will be brought to your inbox. Select **Create** on the left side of the screen to begin creating your submission.

Page for Timothy Rodriguez

Dashboard eRIC Archive Admin IRB

Georgetown University
MedStar Health

Georgetown-MedStar IRB System

Hello, Timothy Rodriguez

Switch User

IRB Preview

Page for Timothy Rodriguez

Create

Study Expiration Dates

Enter search terms to filter list

Maximum number of items in a To Do List exceeded. Only the first 100 will be displayed.

| Month | Date | Study ID | Name | CR | Coordinator | Days Ago |
|-------|---------|----------------|----------------------|----------|----------------|------------|
| May | 11 2024 | 2016-0914: | Gut...controlled HIV | CR: none | Kim | 5 days ago |
| May | 13 2024 | STUDY00006441: | ...ians in Qatar | CR: none | Chebbi Ghannay | 3 days ago |
| May | 14 2024 | STUDY00004893: | ...ome AXS-07-304 | CR: none | Kim | 2 days ago |
| May | 14 2024 | Pro00000418: | T...tal bottleneck | CR: none | Kim | 2 days ago |

page 1

My Inbox Assignments In Process

My Inbox

Filter by ID Enter text to search

+ Add Filter X Clear All

| ID | Name | Date Created | Date Modified | State | Coordinator |
|---------------|---|--------------------|--------------------|----------------|-------------------|
| STUDY00007010 | Testing | 5/9/2024 2:19 PM | 5/9/2024 2:19 PM | Pre-Submission | |
| STUDY00007000 | Test MSS_202309121611451849 | 9/12/2023 6:42 AM | 9/12/2023 6:46 AM | Pre-Review | |
| STUDY00006943 | Robotic Platform Case Series | 8/18/2023 2:55 PM | 8/22/2023 7:59 PM | Pre-Review | |
| STUDY00006958 | Glycemic AI/ML - Shara + Gao | 8/22/2023 12:09 PM | 8/22/2023 3:56 PM | Pre-Review | Timothy Rodriguez |
| STUDY00006904 | Medicaid Doula Program and Racial Equity | 8/4/2023 2:18 PM | 8/21/2023 3:58 PM | Pre-Review | Timothy Rodriguez |
| STUDY00006946 | Aesthetic cholecystectomies | 8/19/2023 11:56 AM | 8/21/2023 2:22 PM | Pre-Review | Timothy Rodriguez |
| MOD00015292 | Modification / Update #1 for Study AADB - MedCognetics, Inc - Pilot | 8/21/2023 10:15 AM | 8/21/2023 10:18 AM | Pre-Review | Timothy Rodriguez |
| MOD00015291 | Modification / Update #1 for Study AADB Ang LI Pilot | 8/21/2023 10:14 AM | 8/21/2023 10:14 AM | Pre-Review | Timothy Rodriguez |

- The Basic Study Information page is the first page of your new study submission. Complete the items in this page.

The screenshot shows a web interface for creating a new IRB submission. The page title is 'Creating New: IRB Submission' and the breadcrumb is 'You Are Here: > IRBSubmission'. The main heading is 'Basic Study Information'. There are five numbered fields:

- 1. * Title of study:** A large text input field. A red callout box points to it with the text: 'The short title identifies the study throughout the IRB system. Use something brief but descriptive to identify the study.'
- 2. * Short title: ?** A smaller text input field. A red callout box points to it with the text: 'The short title identifies the study throughout the IRB system. Use something brief but descriptive to identify the study.'
- 3. * Brief description: ?** A large text input field. A red callout box points to it with the text: 'In the Brief description, please give a summary of the study and clearly mention what is the research activity. Is it a chart review? Is it a survey? Is it an interventional drug study?'
- 4. * What kind of study is this? ?** A radio button selection with two options: 'Multi-site or Collaborative study' and 'Single-site study'. A 'Clear' link is below. A red callout box points to the 'Single-site study' option with the text: 'If research activity is occurring only at MedStar locations, then it is a single-site study.'
- 5. * Will an external IRB act as the IRB of record for this study? ?** Radio button selection with 'Yes' and 'No' options, and a 'Clear' link.

At the bottom right, there are three buttons: 'Exit' (with a close icon), 'Save' (with a save icon), and 'Continue' (with a right arrow icon).

- **The Basic Study Information page is the first page of your new study submission. Complete the items in this page.**

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Local Site Documents

Additional Information

Multi-site or Collaborative study
 Single-site study
[Clear](#)

5. * Will an external IRB act as the IRB of record for this study? [?](#)
 Yes No [Clear](#)

6. * Will your IRB act as the single IRB of record for other participating sites? [?](#)

7. * Local principal investigator: [?](#)
 ...

8. * Does the local principal investigator have a financial interest related to this research? [?](#)
 Yes No [Clear](#)

9. * Which IRB should oversee this study? [?](#)
 Georgetown IRB
 MHRI IRB
 Qatar IRB
[Clear](#)

10. * Attach the protocol: [?](#)
[+ Add](#)

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

[Exit](#) [Save](#) [Continue](#)

Select Yes if there are GU affiliates from the GU main campus on the study team. For other external institutions, MHRI does not typically agree to serve as the sIRB.

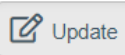


If research activity is occurring at a GU facility (e.g., MGUH) or the PI is primarily affiliated with GU, the overseeing IRB should be GU.

When uploading a document, click "Add".

Attach only protocol related documents here. Other documents can be attached in later sections.

- **When uploading a revised document (as a response to clarification or for future modifications):**
 - **Do not delete documents**
 - Use the **Update** button
 - This will stack newer versions on top of an older and preserve the document history.
 - This also allow the IRB to easily recognize edits between the new and older version.

9. * Attach the protocol: ?

| + Add | | | | |
|--|---|---------------|------------------|---|
| Document | Category | Date Modified | Document History | |
|  Update |  MHRI IRB Protocol Template.docx(0.01) | IRB Protocol | 5/30/2024 | History  |



- Add funding information to this page.

Study Funding Sources

1. Identify each organization supplying funding for the study:



+ Add

Funding Source

Sponsor's Funding ID

Grants Office ID

Attachments

There are no items to display



- After clicking “Add”, a new window will slide out to add the funding source.

Add Funding Source

1. * Funding organization: ...

2. Sponsor's funding ID: (assigned by external sponsor)

3. Grants office ID: (assigned internally)

4. Attach files: (include any grant applications)

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


* Required

If you cannot find your funding source, search alternate variations of the name, e.g. NIH, National Institute of Health, National Institutes of Health.
If you still cannot find your funding source, please contact the ORI staff.

If your study does not have funding, select No Funding.

- Add all team members to this page.
- If you cannot find a team member in the system, it means they do not have an account.
- All team members must complete institutional requirements (e.g., CITI and COI) prior to approval.
- See next slide for instructions on how to create an account.


Local 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

Do not add MedStar or GU affiliates to this section. You may use the section to add CITI certificates or COI paper forms.

For most cases, MHRI IRB will NOT serve as the IRB of Record.



How to create an account in the system

- For MedStar affiliates:
 - Your manager or department head will need to submit a request in Identity IQ (IIQ). When submitting the request, they will select the role titled “PI or Study Coordinator”.
- For Georgetown affiliates:
 - Please contact the Georgetown IRB Office at irboard@georgetown.edu.



- This page is intended to identify FDA regulated research.
- Please note secondary use of data (i.e. chart or records review) may not be considered FDA regulated research.


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](#)


Selecting Yes will open additional
pages in the IRB application.

- Add all MedStar locations where research activity will be physically conducted.
- Do not add locations external to MedStar.

Local Research Locations

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

 + Add

Location

Contact

Phone

Email

There are no items to display



- The Drugs page becomes available when you select Yes to the drug question in the Study Scope page.

Drugs


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

Attach a drug brochure or pamphlet when adding drug information.

| Generic Name | Brand Name | Drug Type | 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) 


Attach all other documentation related to the study drug. This will help with the IRB review.

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




- The Devices page becomes available when you select Yes to the device question in the Study Scope page.

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 | | |

When adding the device, upload documentation to indicate FDA cleared or approved indications when available.

2. * Device exemptions applicable to this study: 

- IDE number
 - HDE number
 - Claim of abbreviated IDE (nonsignificant risk device)
 - Exempt from IDE requirements
- [Clear](#)

If requesting for an abbreviated IDE, please provide justification that the device is nonsignificant risk. The IRB will determine if it meets criteria.

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 | | | |


Attach all other documentation related to the study device. This will help with the IRB review.




- **Add all other study documents as appropriate to each section in this page.**

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 | | | |






- **When uploading a revised document (as a response to clarification or for future modifications):**
 - **Do not delete documents**
 - Use the **Update** button
 - This will stack newer versions on top of an older and preserve the document history.
 - This also allow the IRB to easily recognize edits between the new and older version.

Local Site Documents

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

| <input type="button" value="+ Add"/> | | | | |
|---|--------------|---------------|------------------|---|
| Document | Category | Date Modified | Document History | |
|  Update  MHRI IRB Informed Consent Form Template.docx(0.01) | Consent Form | 5/30/2024 | History |  |

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

| <input type="button" value="+ Add"/> | | | | |
|---|-----------------------|---------------|------------------|---|
| Document | Category | Date Modified | Document History | |
|  Update  Flyer.docx(0.01) | Recruitment Materials | 5/30/2024 | History |  |

Other attachments:

| <input type="button" value="+ Add"/> | | | | |
|--------------------------------------|----------|---------------|------------------|--|
| Document | Category | Date Modified | Document History | |
| There are no items to display | | | | |



- **Complete this page.**

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](#)

Per MedStar GME policy, trainees cannot serve as the PI on research studies. Assign an appropriate PI and select No to this item.

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

- Click **Finish** to send you to the study homepage.
- This **does not** submit the study.

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.



Note! Clicking “Finish” does not submit the study.

 Exit

 Save

Finish



- Click **Submit** to submit your study for review.
- Only the PI or the PI proxies can Submit. If you would like to be listed as a PI proxy, please contact the PI to assign you. The ORI staff may also assign you as PI proxy with an email request from the PI.

Pre-Submission

Last updated: 5/30/2024 2:06 PM

Next Steps

[Edit Study](#)

[Printer Version](#)

- [Submit](#)
- [Assign Home IRB](#)
- [Assign PI Proxy](#)
- [Manage Ancillary Reviews](#)
- [Manage Guest List](#)
- [Add Related Grant](#)
- [Add Comment](#)
- [Discard](#)
- [Manage Tags](#)

STUDY00007011: Example

Principal investigator: Timothy Rodriguez

Submission type: Initial Study

Primary contact: Timothy Rodriguez

PI proxies:

IRB office: MHRI IRB

Committee:

IRB coordinator:

| History | Funding | Contacts | Documents | Reviews | Snapshots | Training |
|---|--------------------|--------------------|-----------|---------|-----------|----------|
| <p>Filter by Activity <input type="text" value="Enter text to search"/> + Add Filter × Clear All</p> | | | | | | |
| Activity | Author | Activity Date | | | | |
| Study Created | Rodriguez, Timothy | 5/30/2024 11:39 AM | | | | |

- After clicking Submit, the status in the orange box should indicate “Pre-Review”.

Pre-Review

STUDY00007011: Example

Principal investigator: Timothy Rodriguez
Submission type: Initial Study
Primary contact: Timothy Rodriguez
PI proxies:

IRB office: MHRI IRB
Committee:
IRB coordinator:

Next Steps

View Study

Printer Version

Assign Coordinator

Assign Home IRB

Assign PI Proxy

Assign IRB

Manage Ancillary Reviews

Manage Guest List

Add Related Grant

Add Comment

Withdraw

Discard

Manage Tags



| History | Funding | Contacts | Documents | Reviews | Snapshots | Training |
|--|--------------------|--------------------|-----------|---------|-----------|----------|
| Filter by Activity <input type="text" value="Enter text to search"/> + Add Filter ✕ Clear All | | | | | | |
| Activity | Author | Activity Date | | | | |
| Submitted | Rodriguez, Timothy | 5/30/2024 2:38 PM | | | | |
| Study Created | Rodriguez, Timothy | 5/30/2024 11:39 AM | | | | |

Congratulations! You have successfully submitted to the MHRI IRB.

It's how we **treat people.**



MedStar Health