MedStar Health

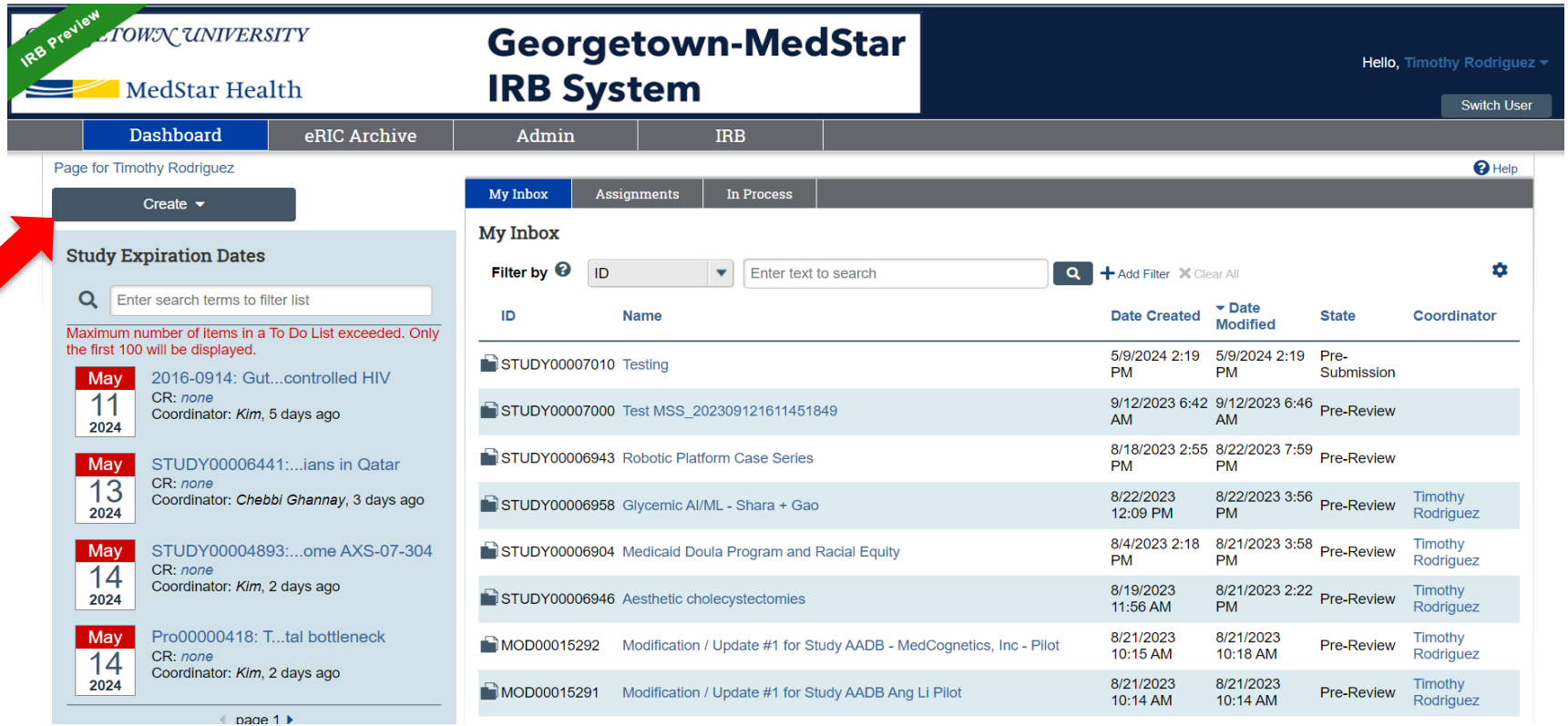
It's how we treat people.

September 11, 2024

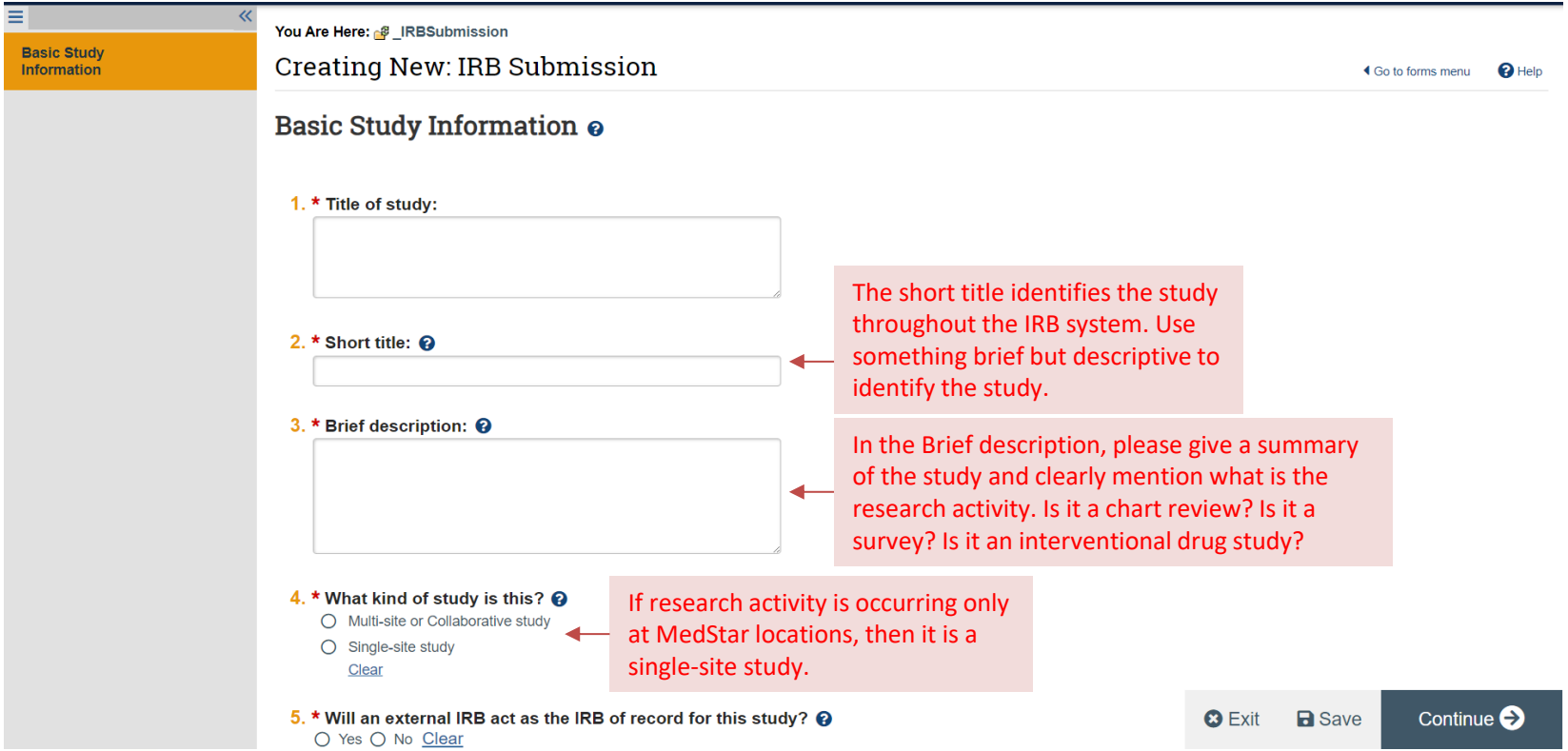
How to submit a new study in the Georgetown-MedStar IRB system

MedStar Health Research Institute

- **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.**



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



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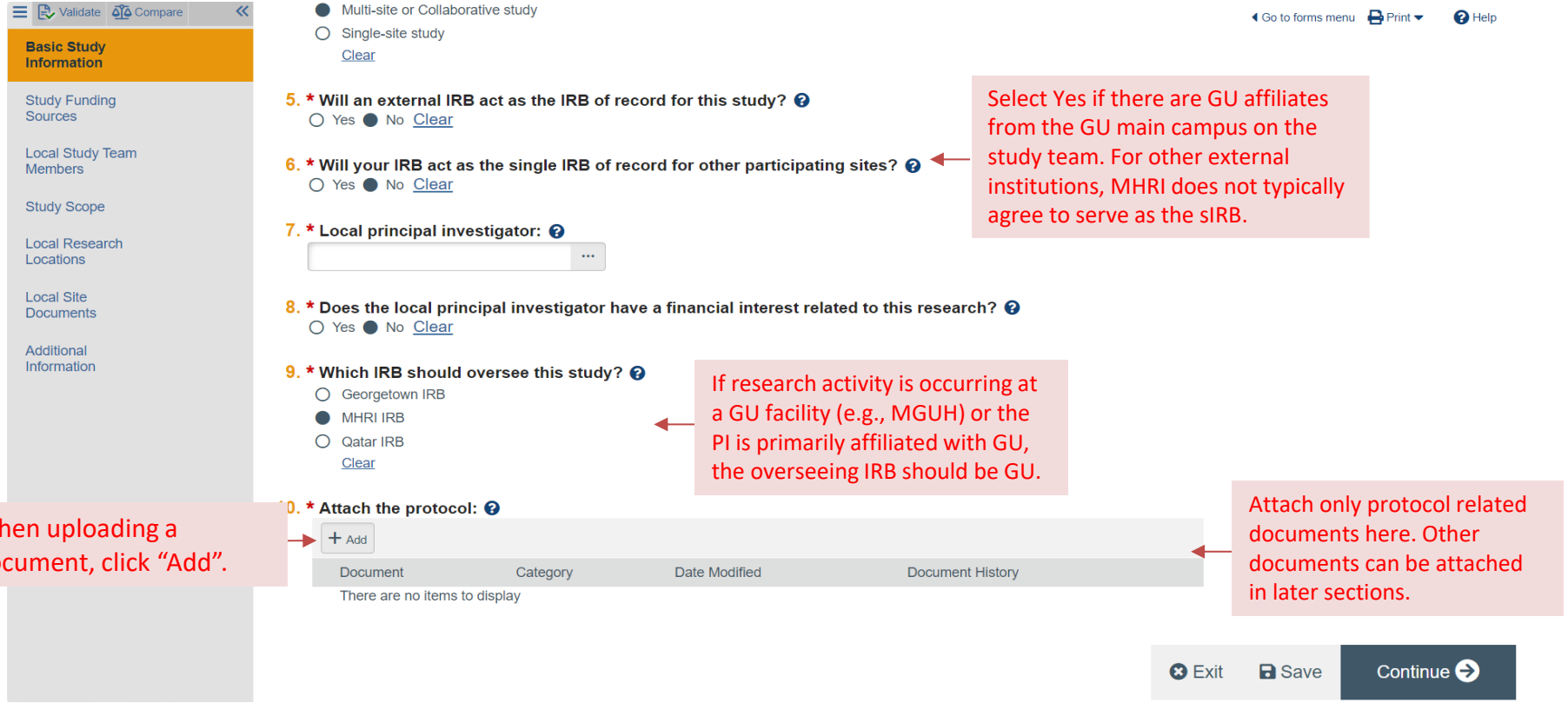
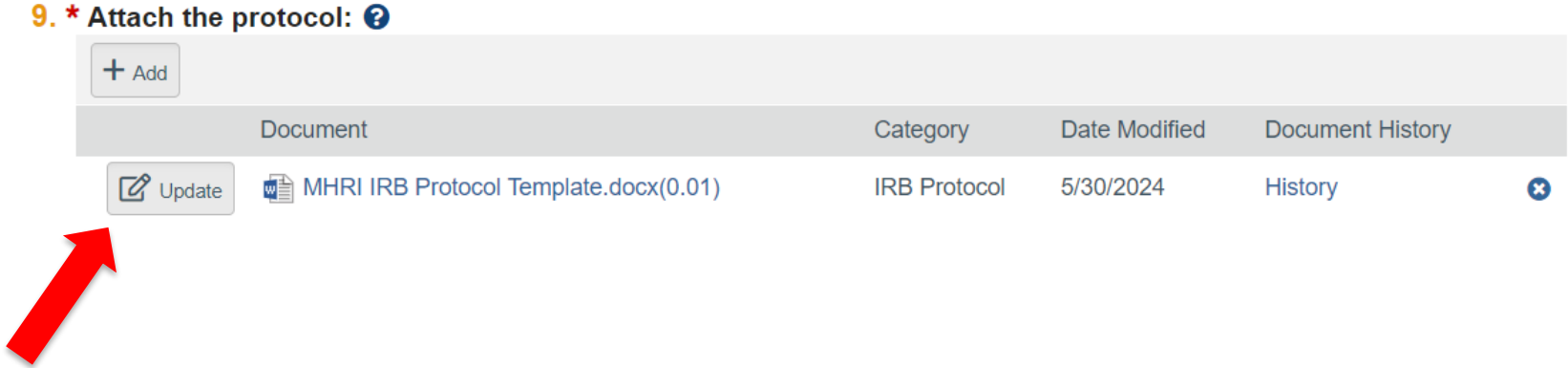
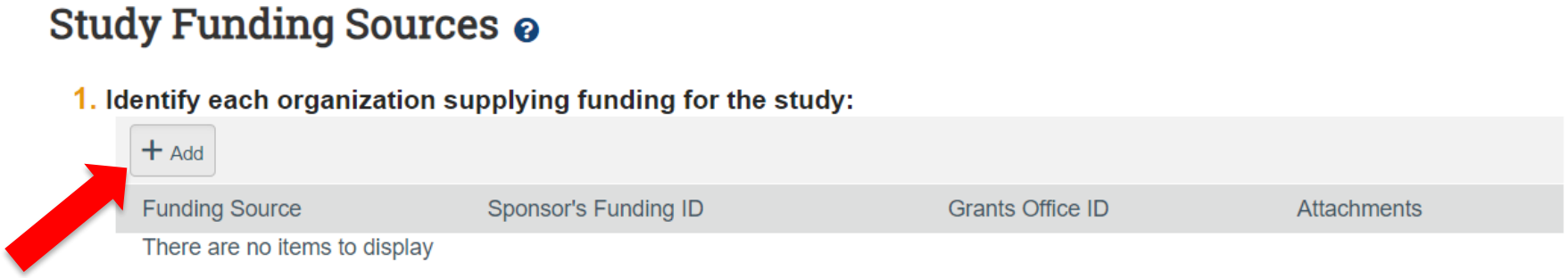


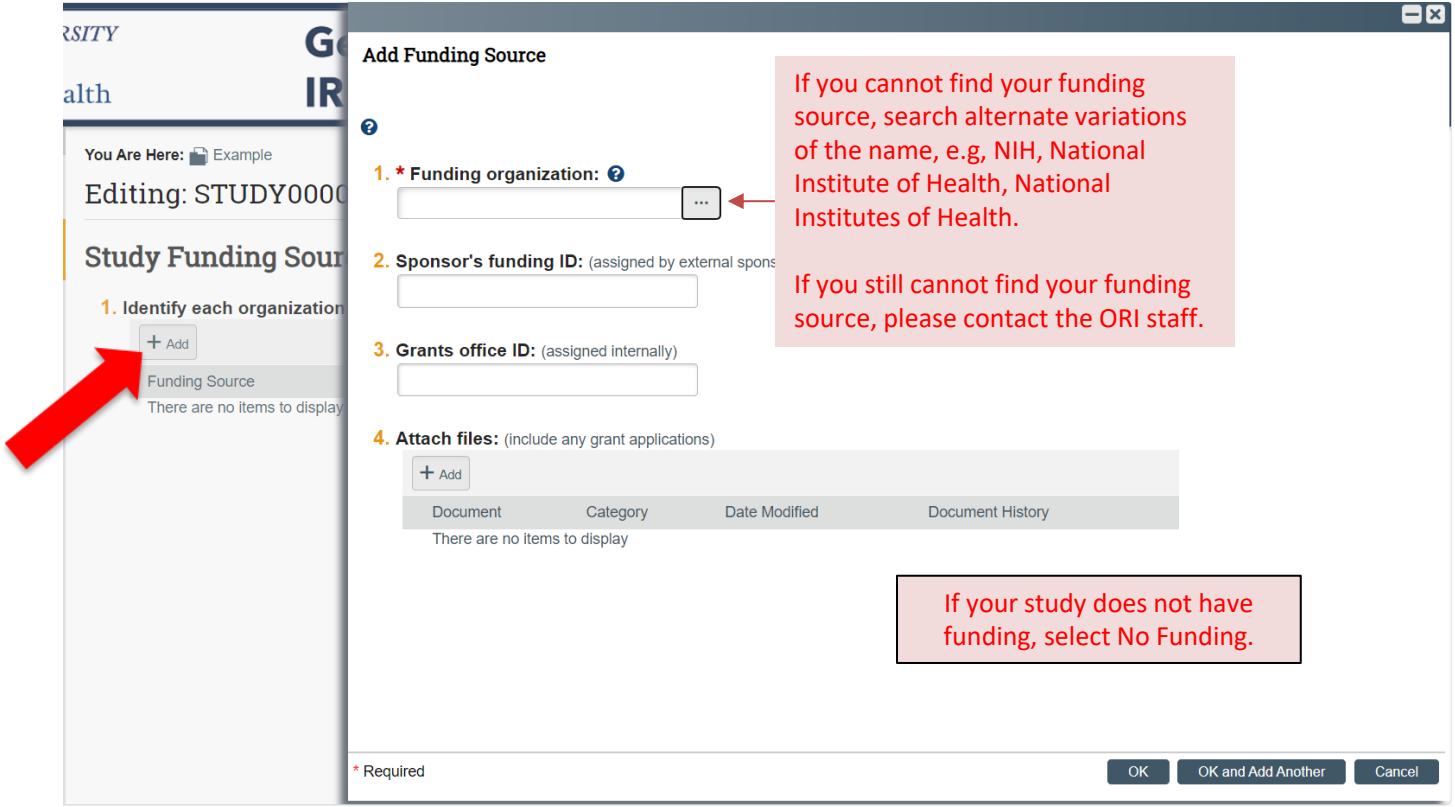
- **When uploading a revised document (as a response to clarification or for future modifications):**
  - **Do not delete documents**
    - **Use the Update button**
    - **This will stack newer versions on top of an older and preserve the document history.**
    - **This also allow the IRB to easily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



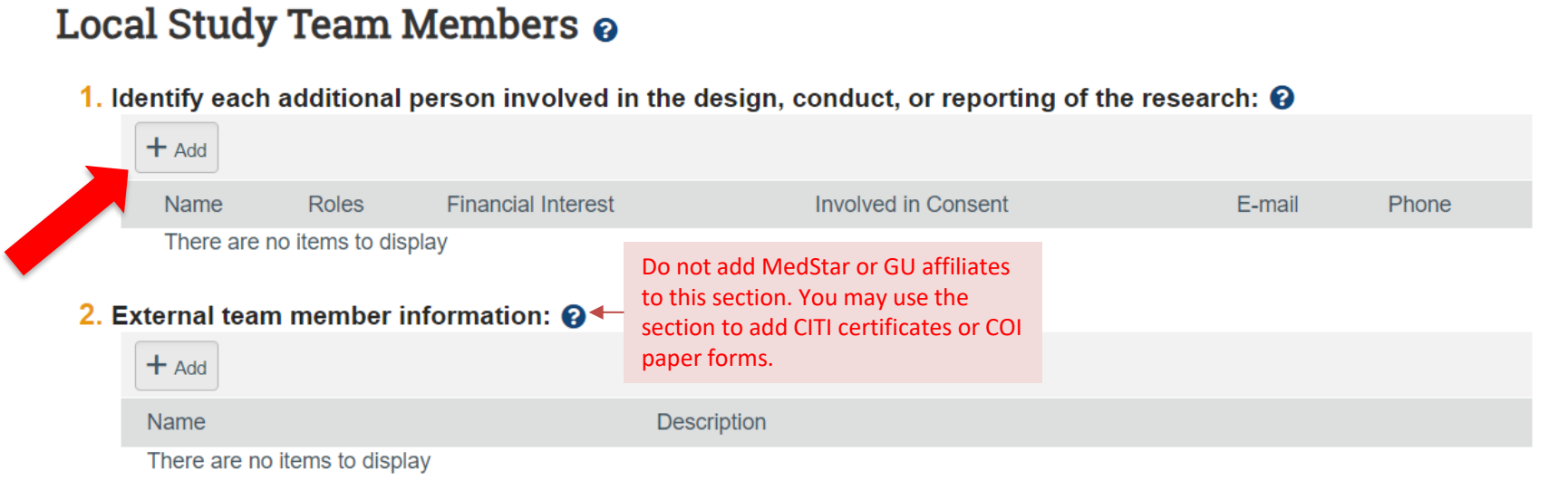
- **Add funding information to this page.**



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



- **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.**



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

MedStar Health

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.**

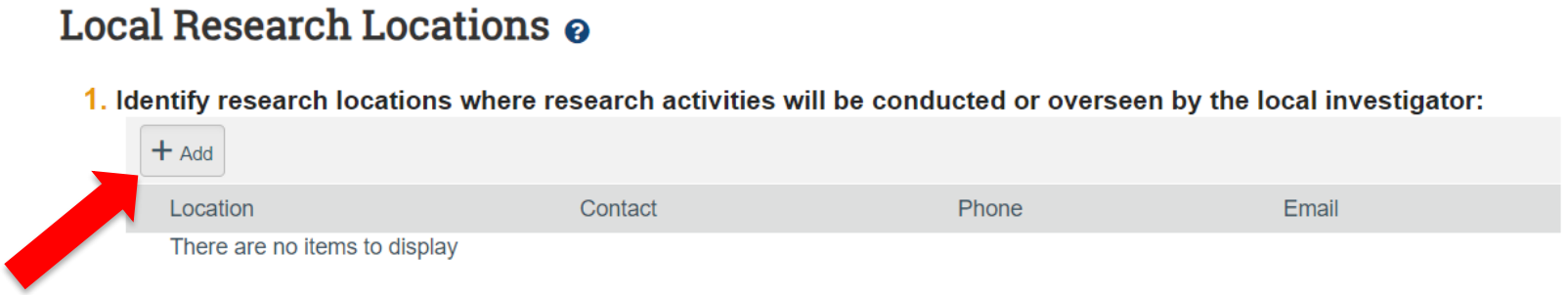
Study Scope

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

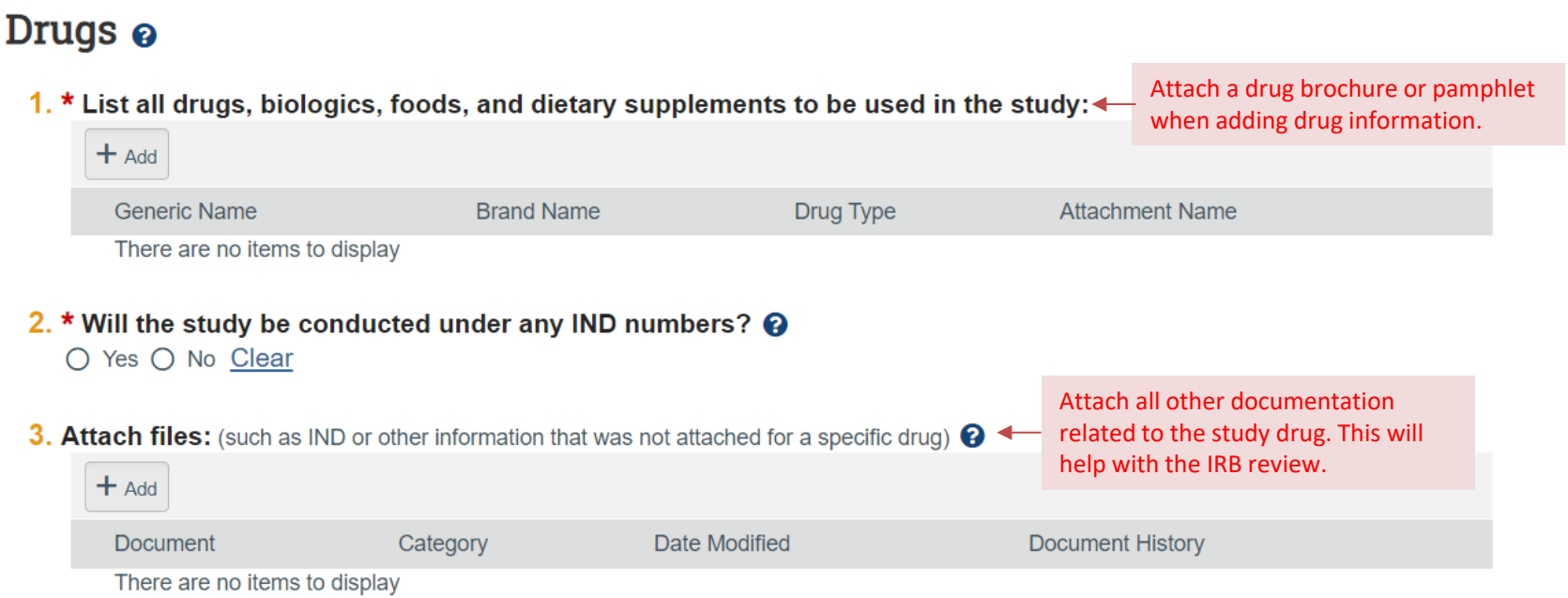
2. * **Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**
   ○ Yes ○ No Clear

Selecting Yes will open additional pages in the IRB application.

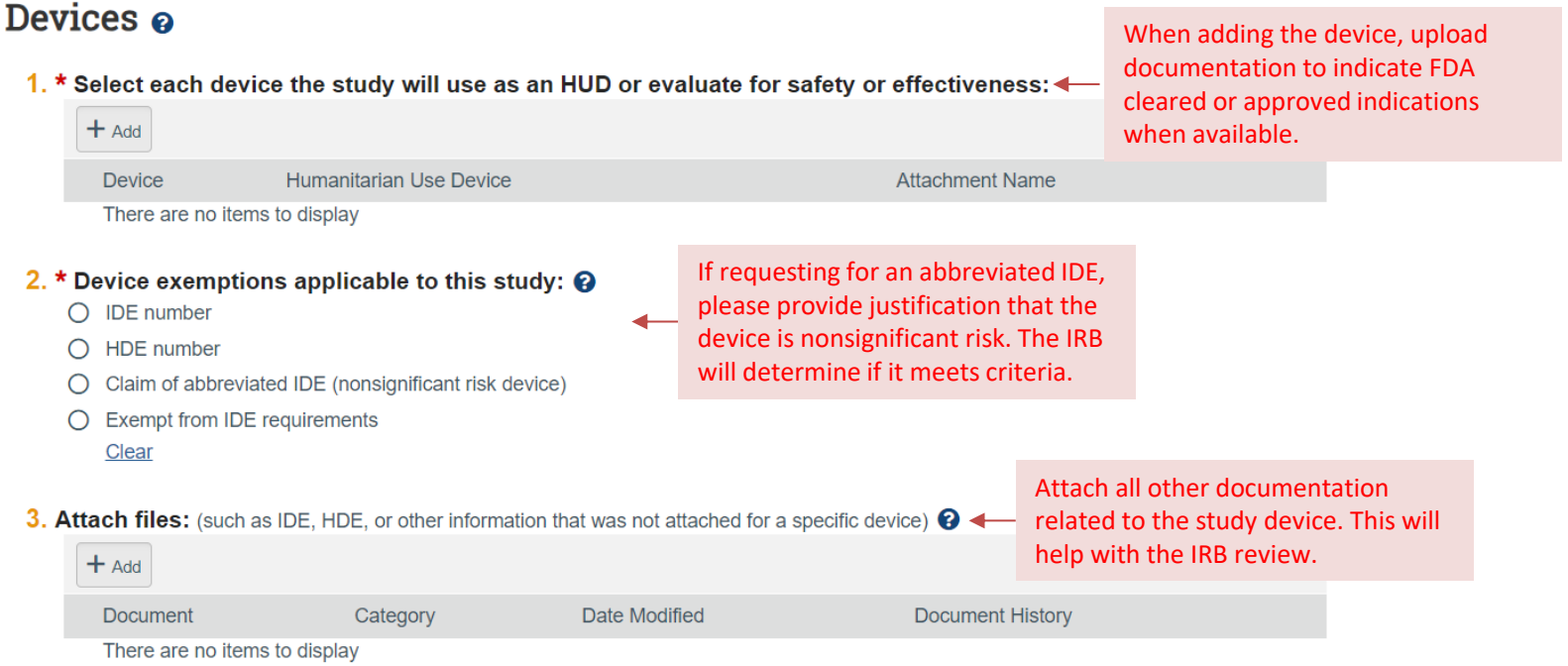
- **Add all MedStar locations where research activity will be physically conducted.**
- **Do not add locations external to MedStar.**



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



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



- **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)

+ 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

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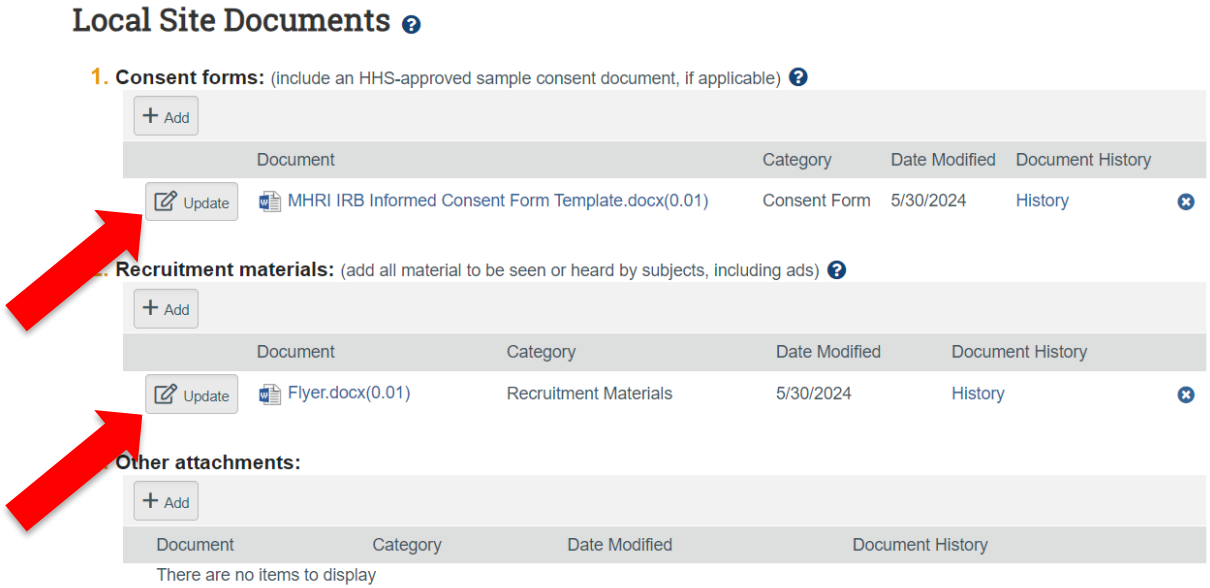


- **Complete this page.**

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.

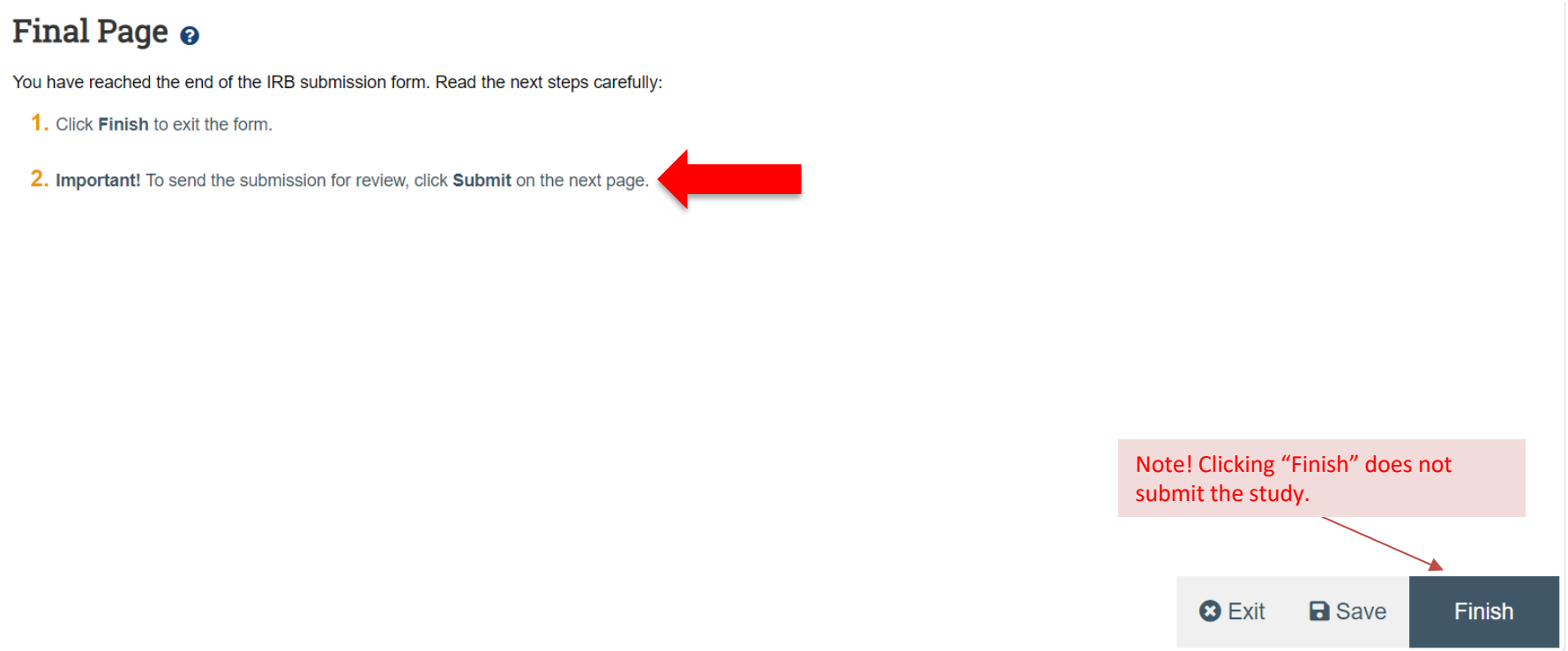
2. * **Is the PI a MedStar fellow or resident?**
   ○ Yes ○ No Clear

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

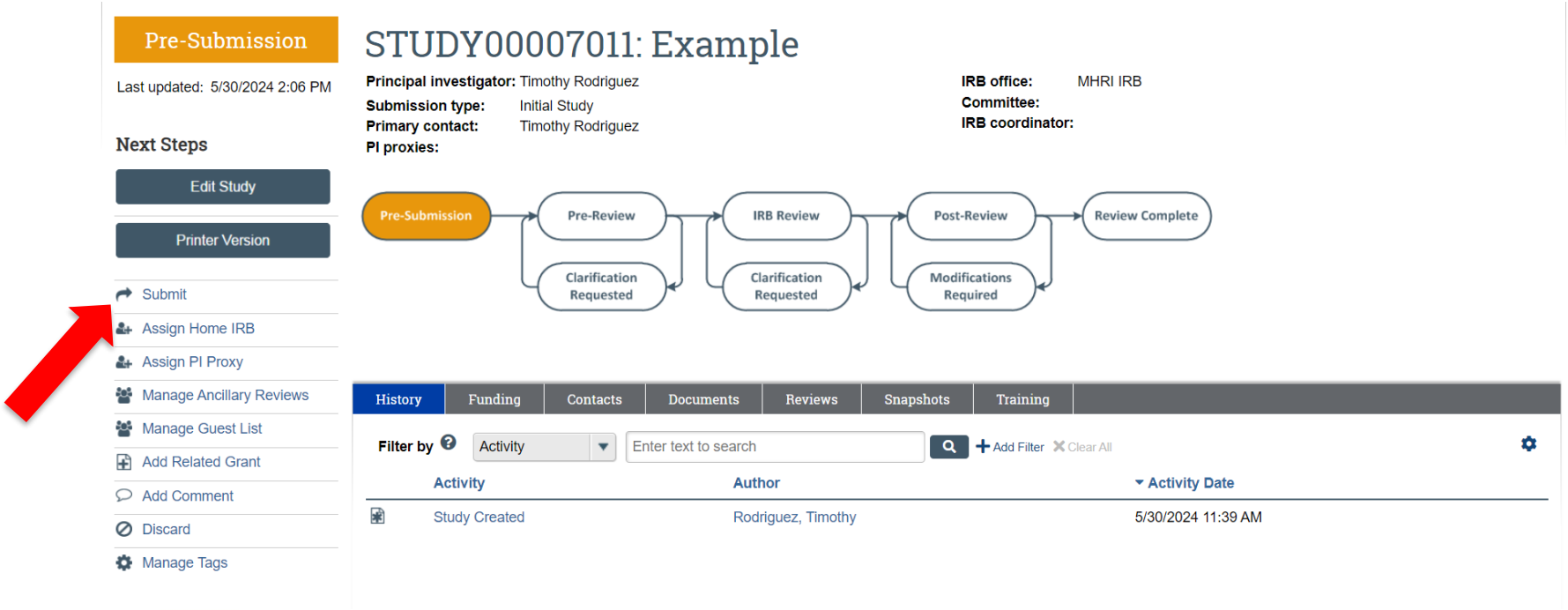
3. * **Will the research involve human subjects under the age of 18 years old?**
   ○ Yes ○ No Clear

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

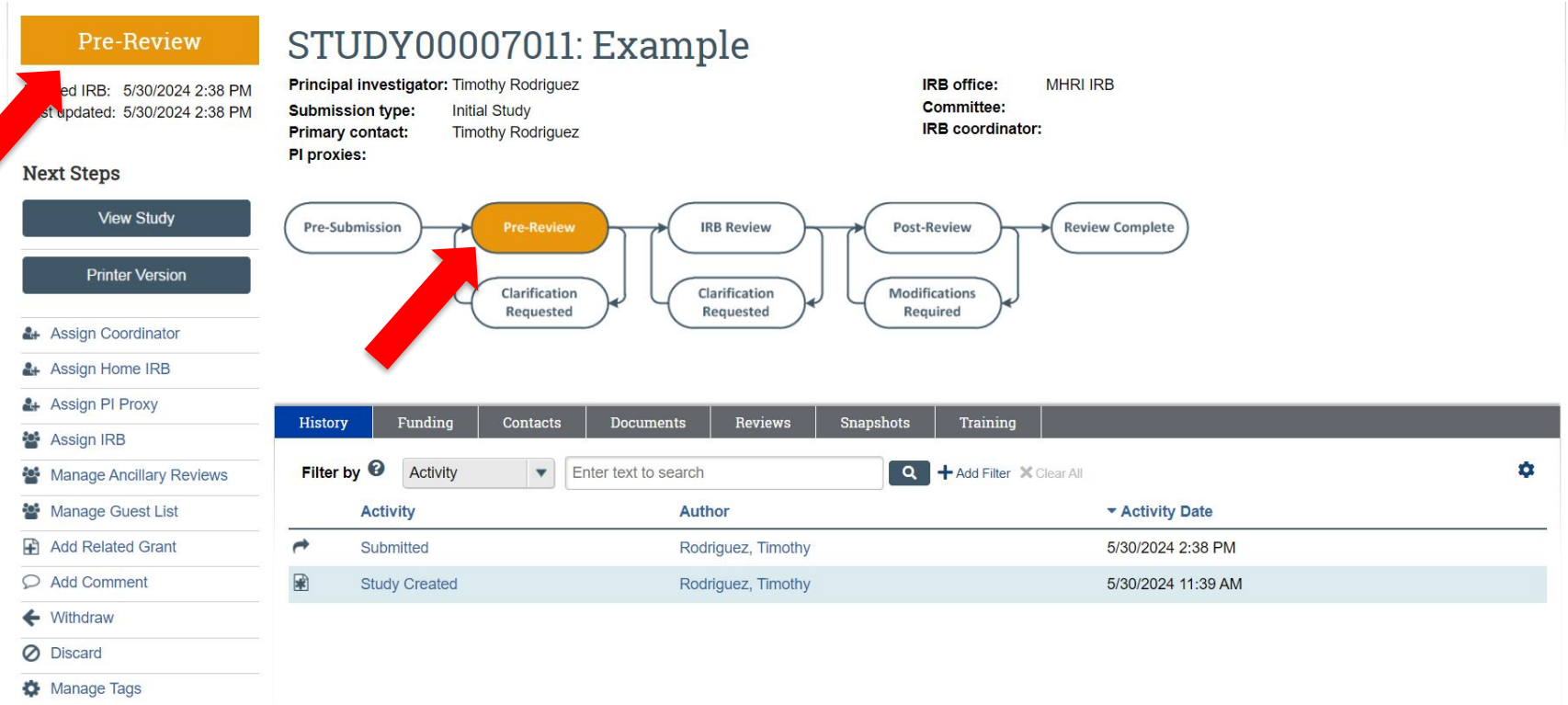
- **Click Finish to send you to the study homepage.**
- **This does not submit the study.**



- **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.**



- **After clicking Submit, the status in the orange box should indicate "Pre-Review".**



Congratulations! You have successfully submitted to the MHRI IRB.

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