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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

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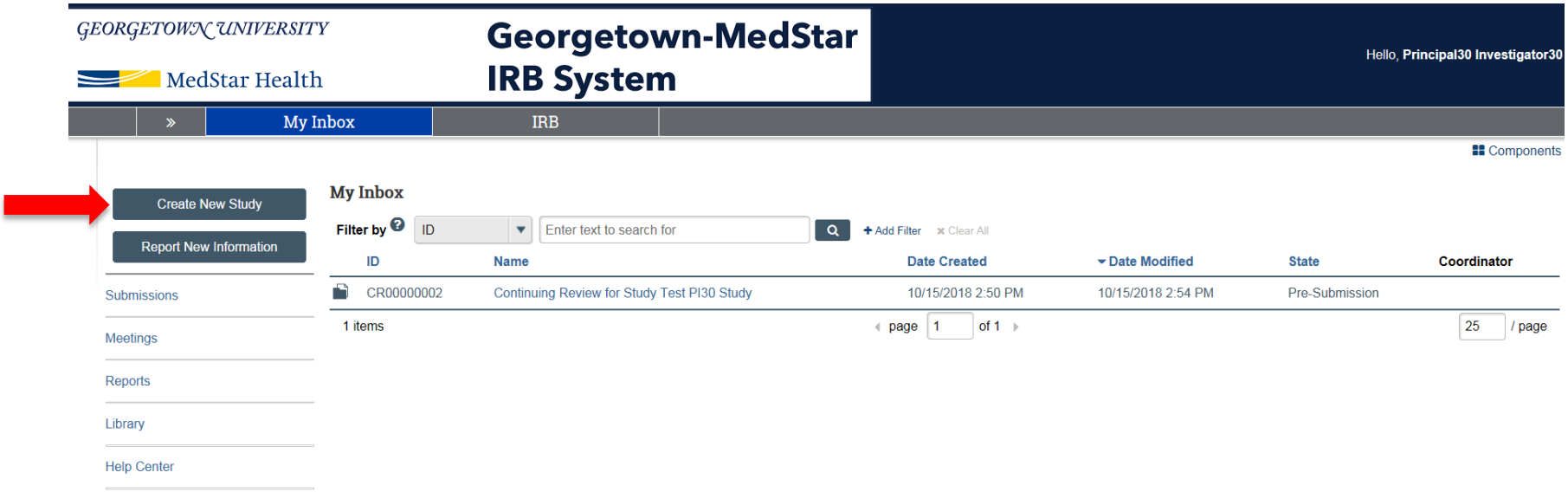
When you log into the system, you will be brought to your inbox.
Select Create New Study on the left side of the screen.



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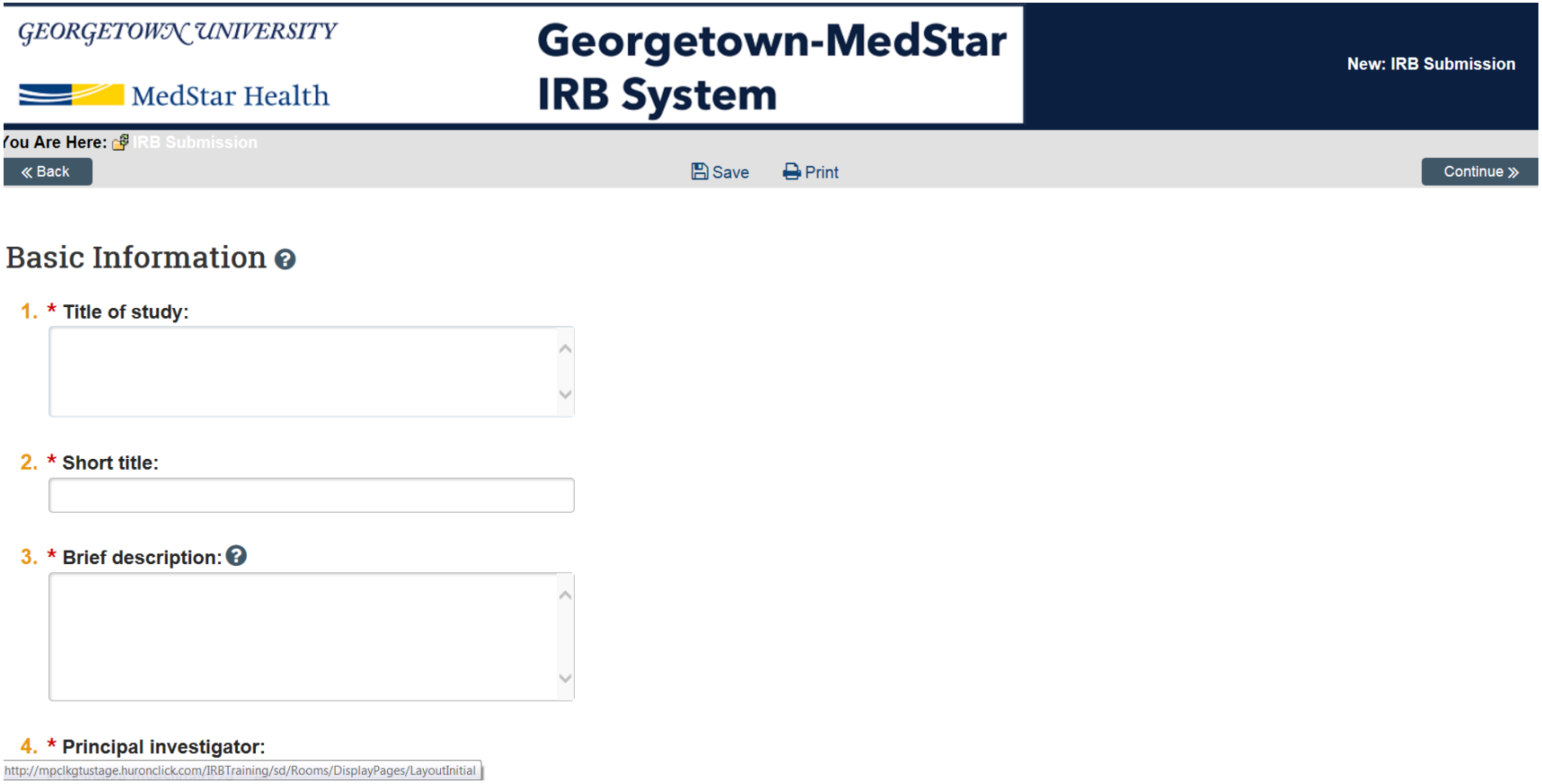
The Basic Information page is the first page of your new study submission. Complete the information on this page.



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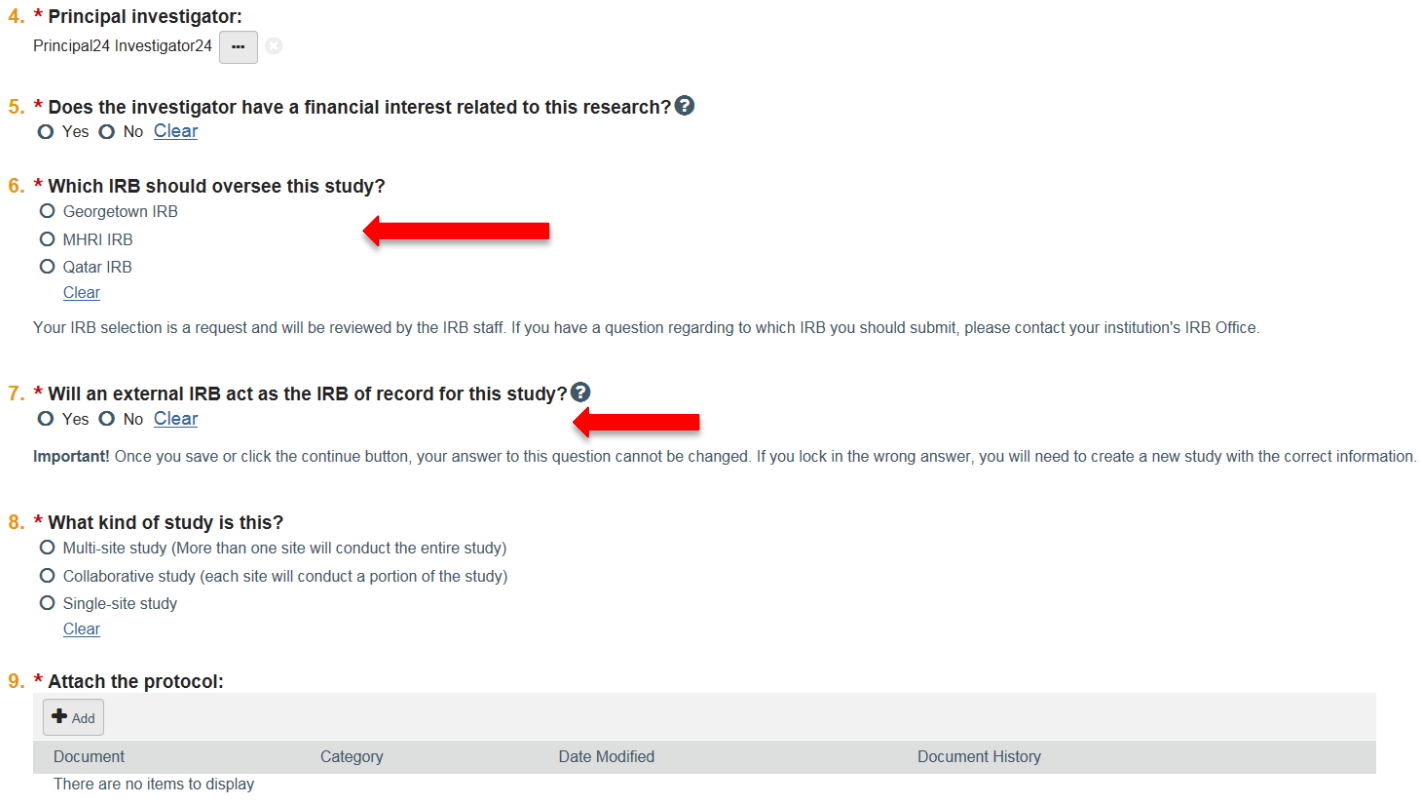
Question 6: Select which IRB you are submitting the study to.

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.



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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?**
   - O Georgetown IRB
   - O MHRI IRB
   - O 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?**
   O Yes O 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?**
   - O Multi-site study (More than one site will conduct the entire study)
   - O Collaborative study (each site will conduct a portion of the study)
   - O Single-site study

   Clear

9. * **Attach the protocol:**

   + Add

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

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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 t**
   O Yes O No Clear

6. * **Which IRB should oversee this study?**
   - O Georgetown IRB
   - O MHRI IRB
   - O Qatar IRB

   Clear

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

7. * **Will an external IRB act as the IRB of record for this stu**
   O Yes O No Clear

   Important! Once you save or click the continue button, your answer to t information.

8. * **What kind of study is this?**
   - O Multi-site study (More than one site will conduct the entire study)
   - O Collaborative study (each site will conduct a portion of the study)
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   Clear

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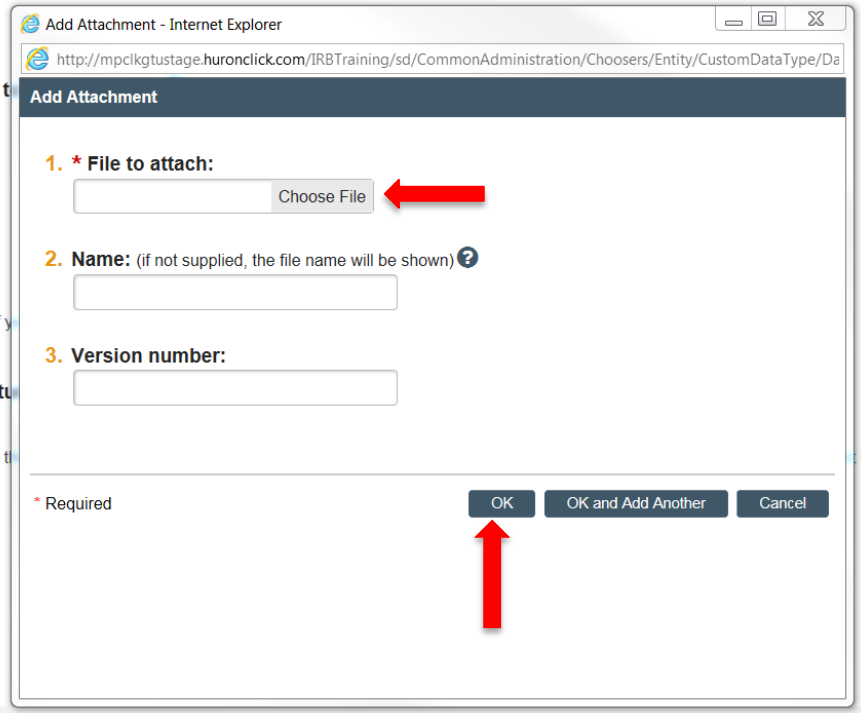

Add

Document	Category	Date Modified	Document History

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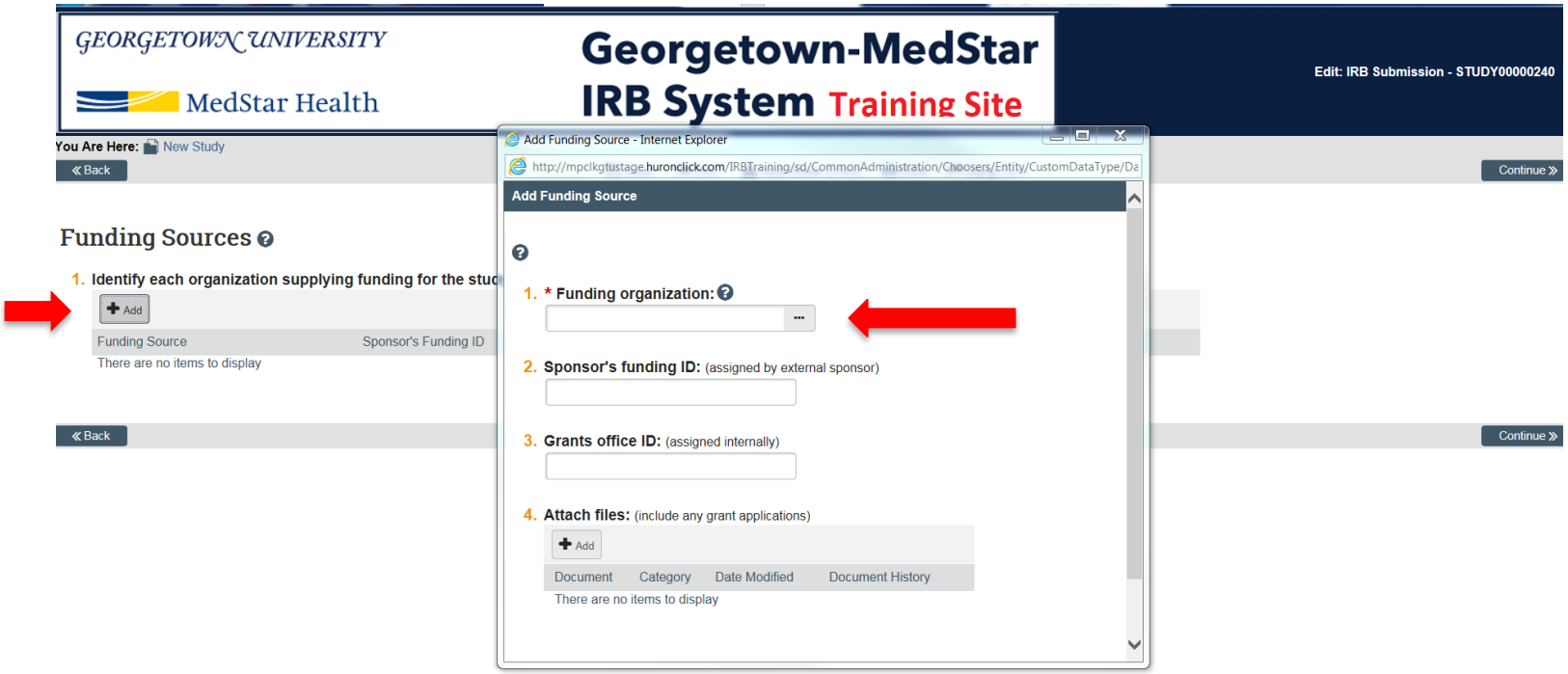
The next page is the Funding Sources page. To add a funding source, click Add and a pop up window will appear. To select a funding organization, click on the three dots.



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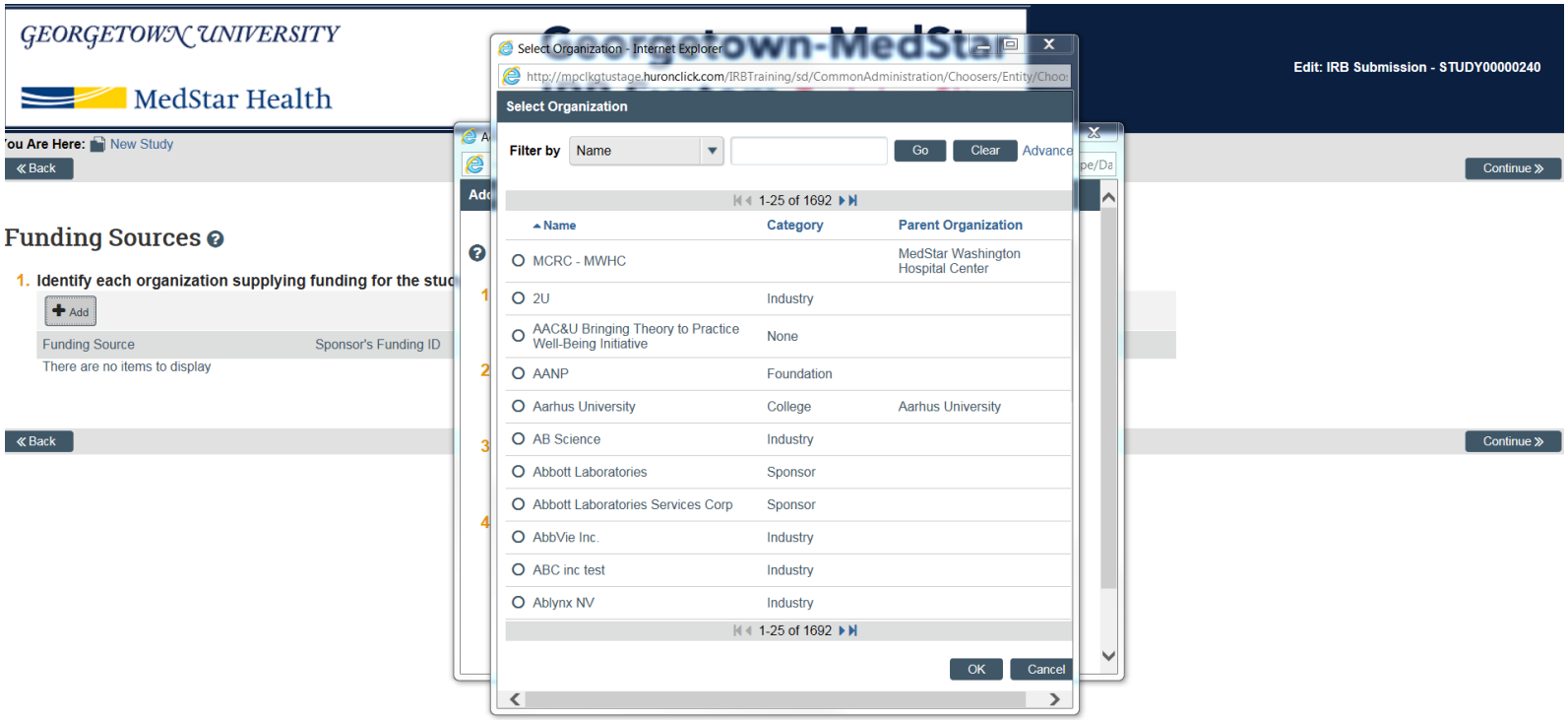
A second pop up window will appear. Select the funding source for your study from the list, if applicable.

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



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

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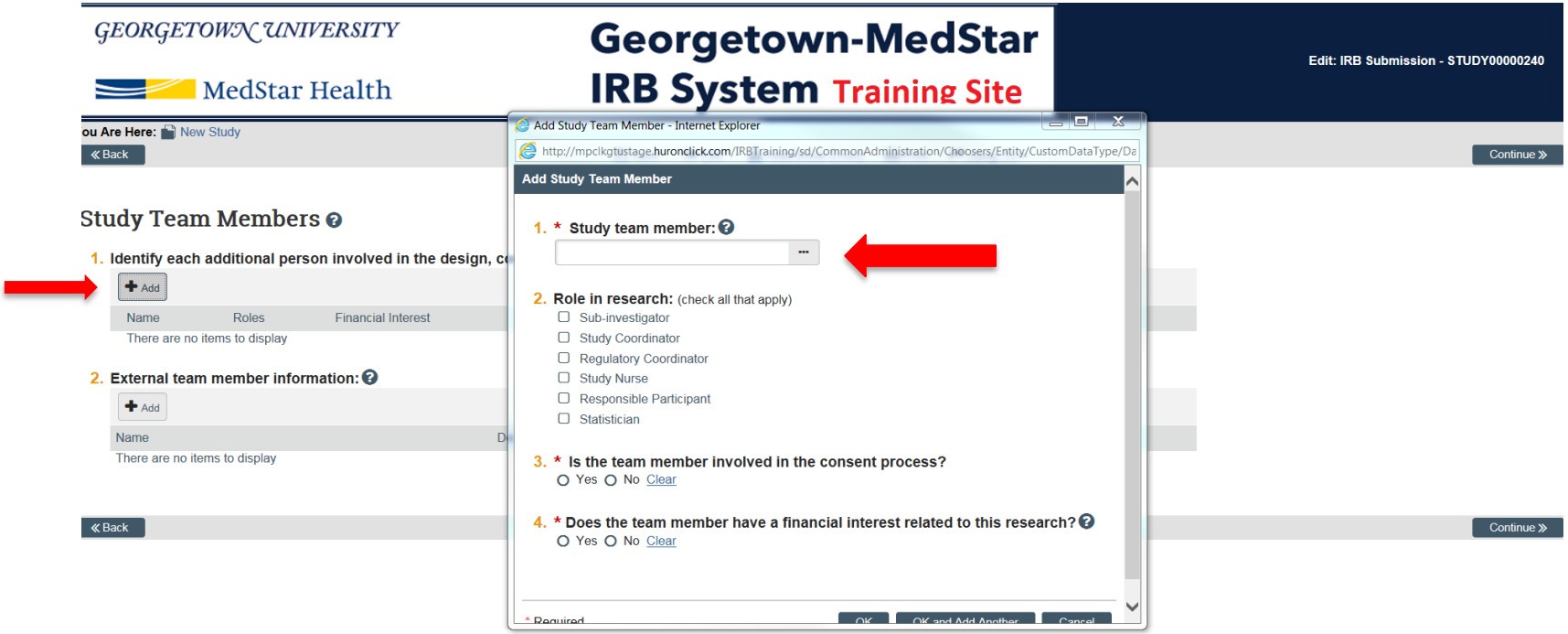
For Question 1, add internal MedStar team members by clicking Add. A pop up window will appear. Click the three dots to select a team member from the drop down. Complete additional information in the pop up window and click OK.



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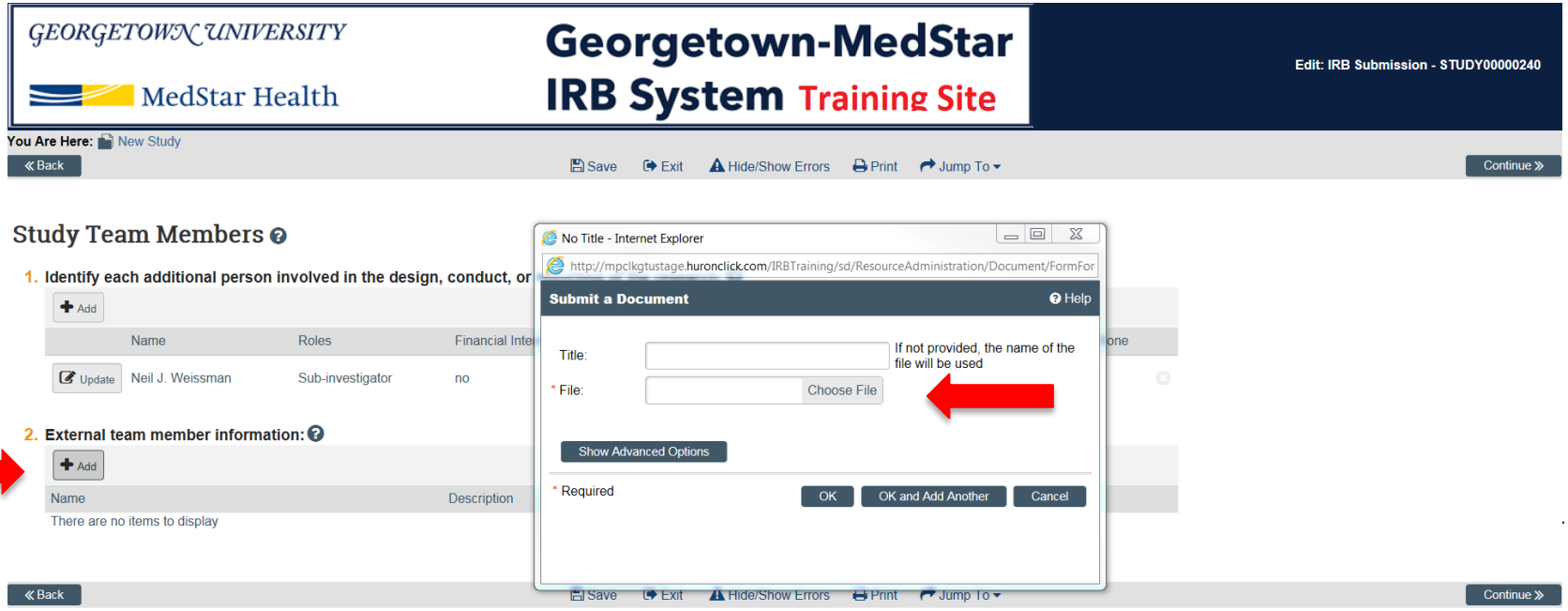
Question 2: If you have study team members who are external to MedStar, you will add them in question 2. Click Add. A pop up window will appear and will prompt you to add a file with the list of the external study team members. Please use the template for the external study team member information provided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



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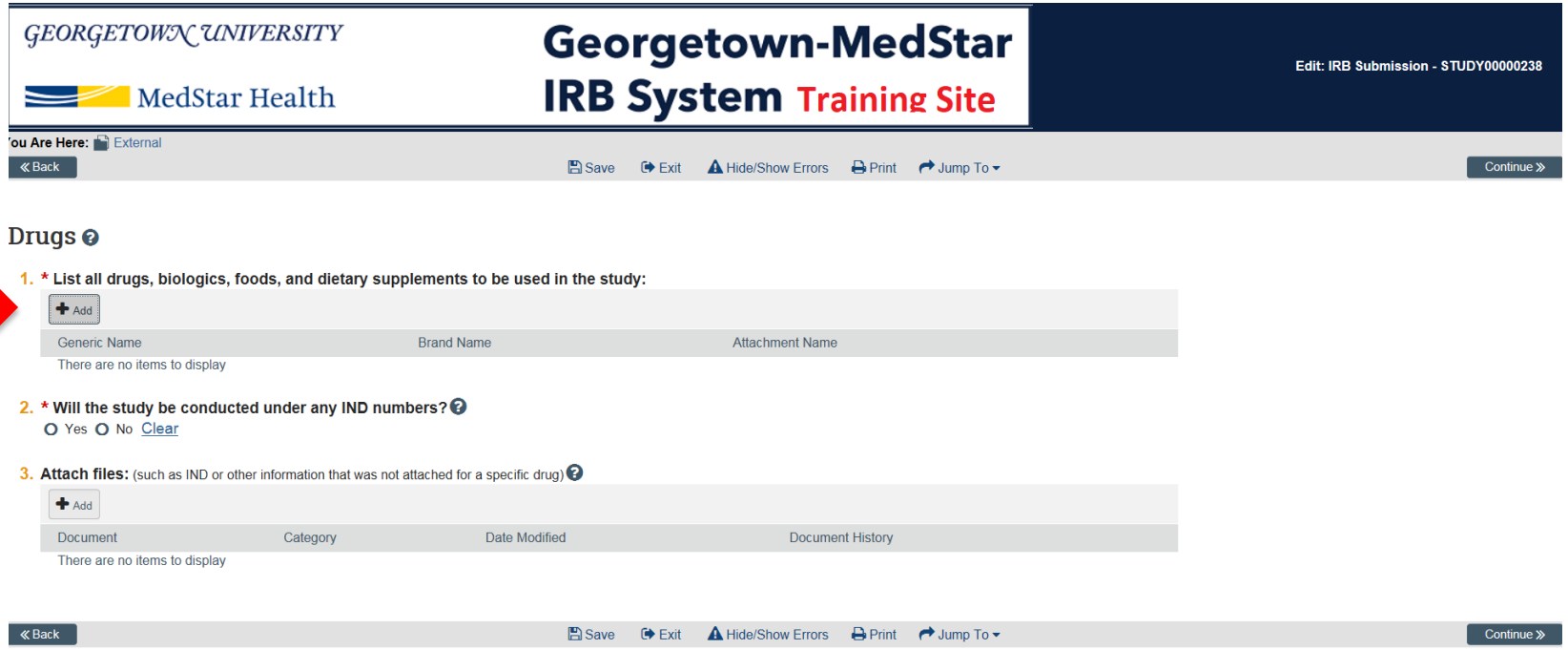
If you select Yes to the Drug question on the study scope page, you will see the screen below. Add the information about the drug used in your study, using the Add button. Complete the drug information in the pop up window using the same process you used to add a funding source.



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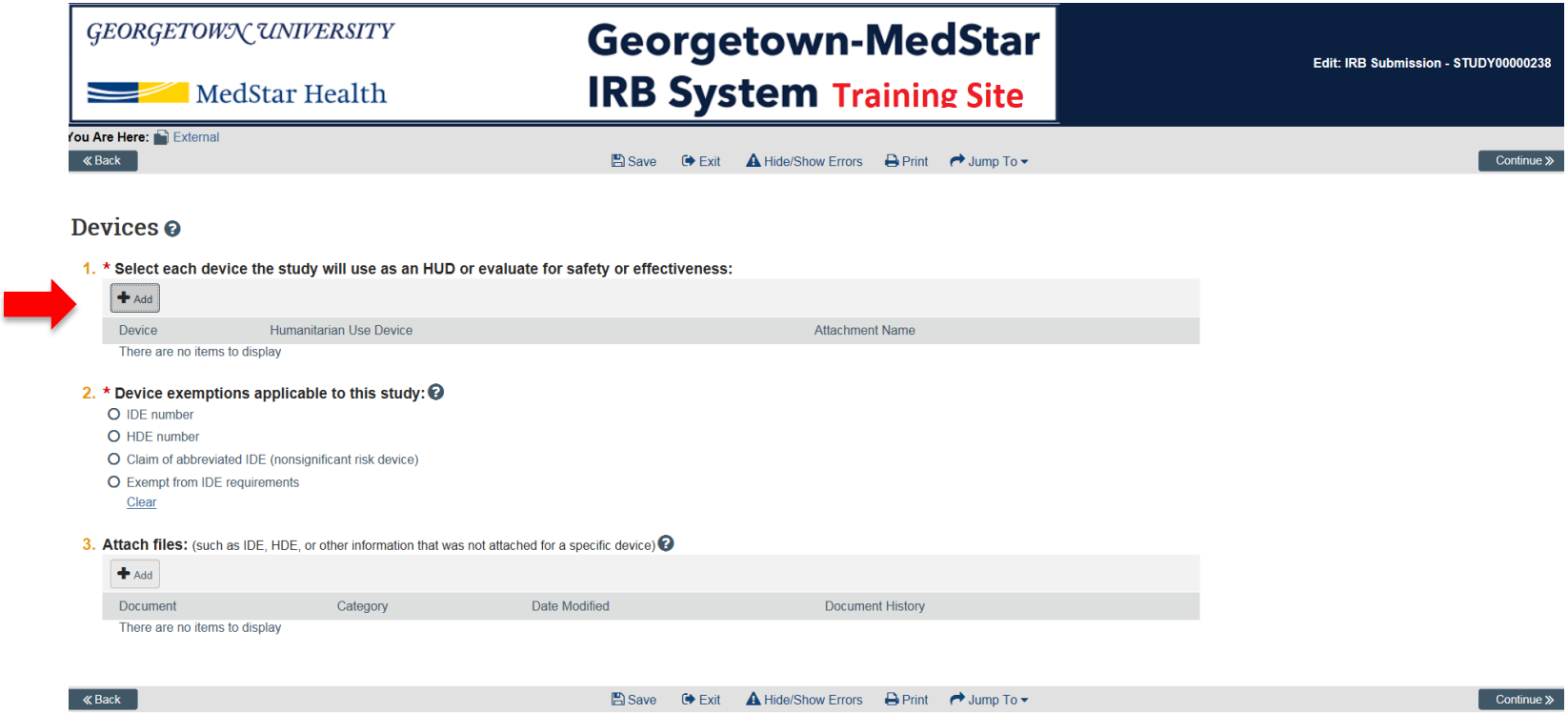
If you select Yes to the Device question on the study scope page, you will see the screen below. Add the information about the device used in your study, using the Add button. Complete the device information in the pop up window using the same process you used to add a funding source.



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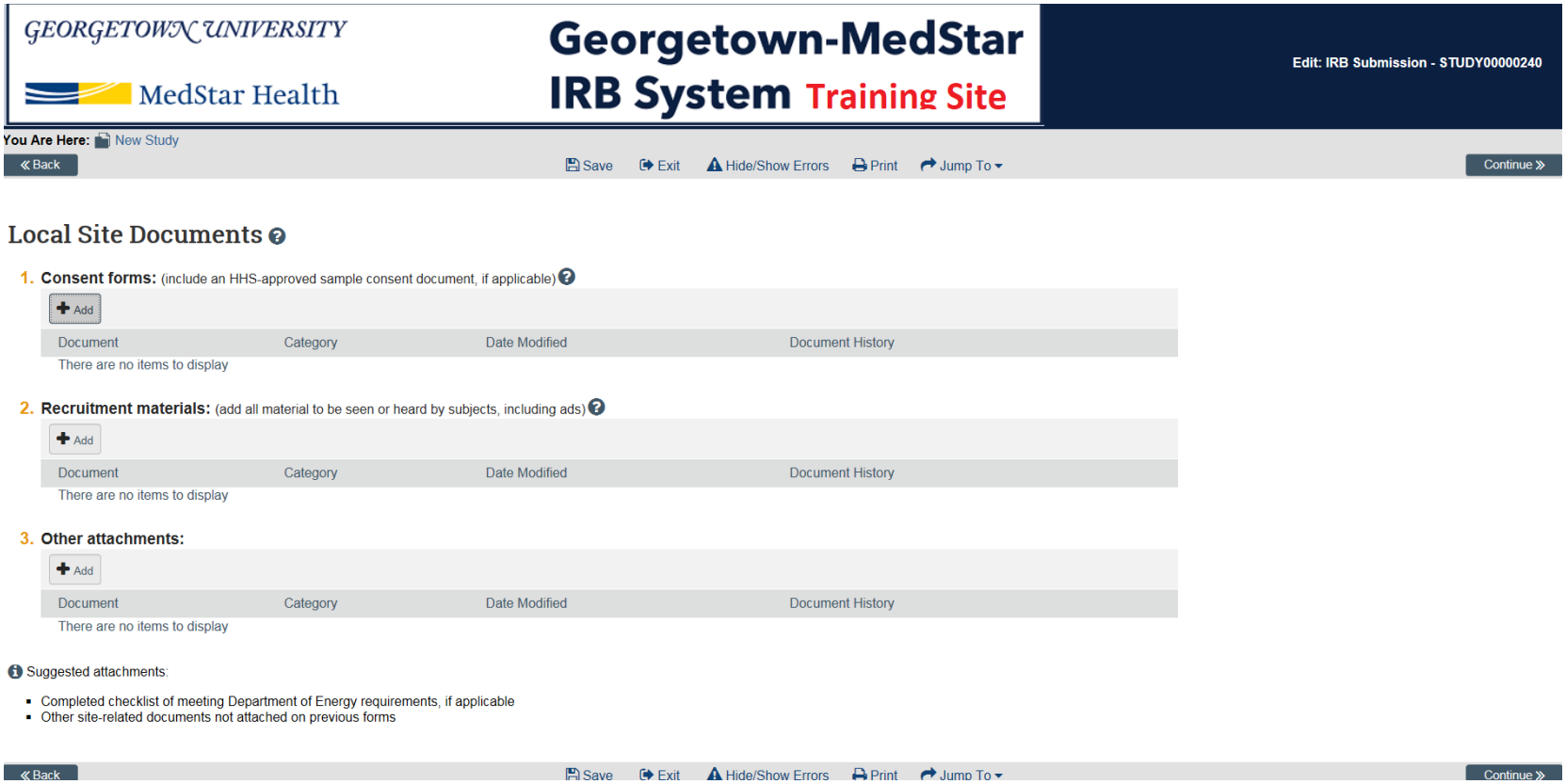
The Local Site Document is where you will upload any site specific documents the IRB needs to review such as consent forms, recruitment materials, survey instruments, etc. Upload these documents using the Add option under the applicable category.



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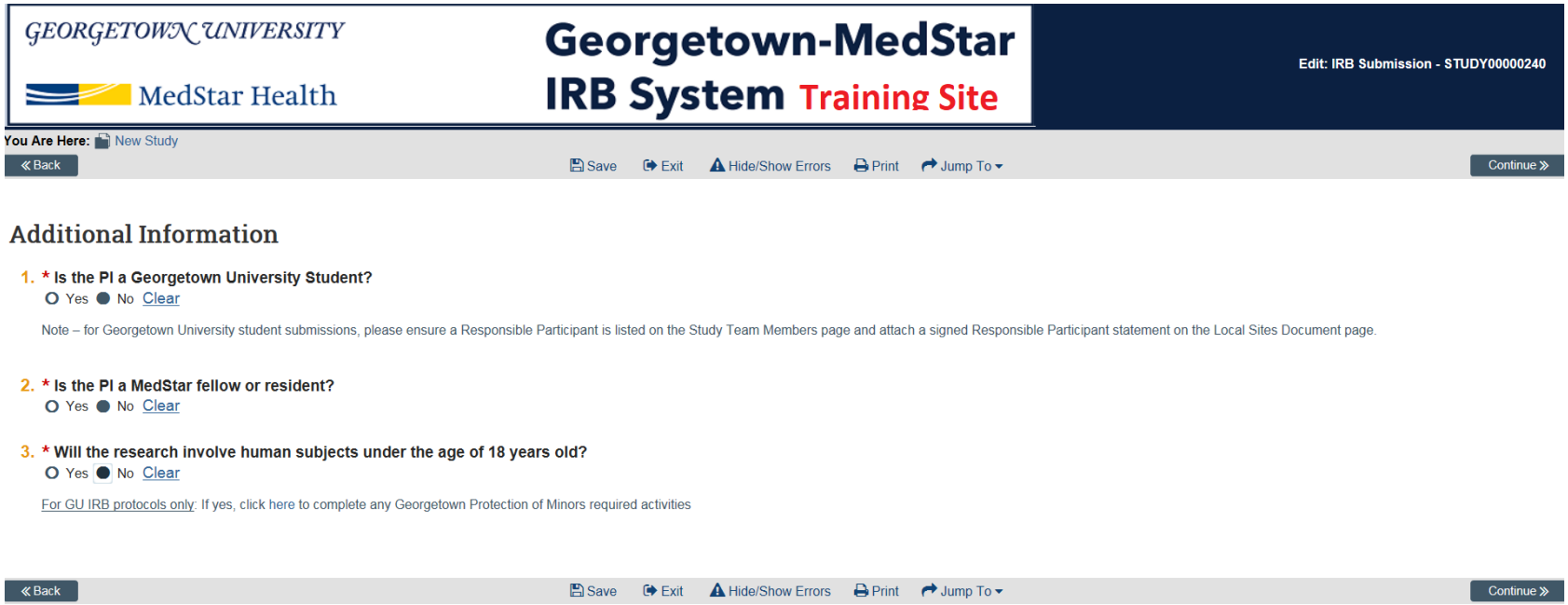
On the Additional Information page, answer the three questions and then click continue.



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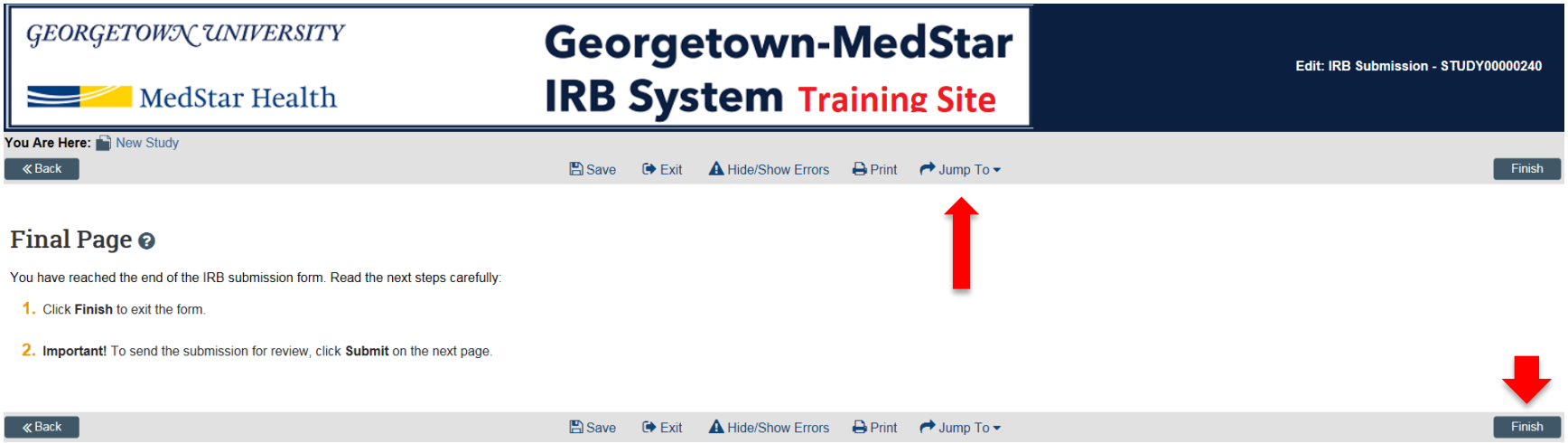
You have arrived on the final page. To review any information added on previous pages, use the Jump To function. Otherwise, click Finish.



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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.

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

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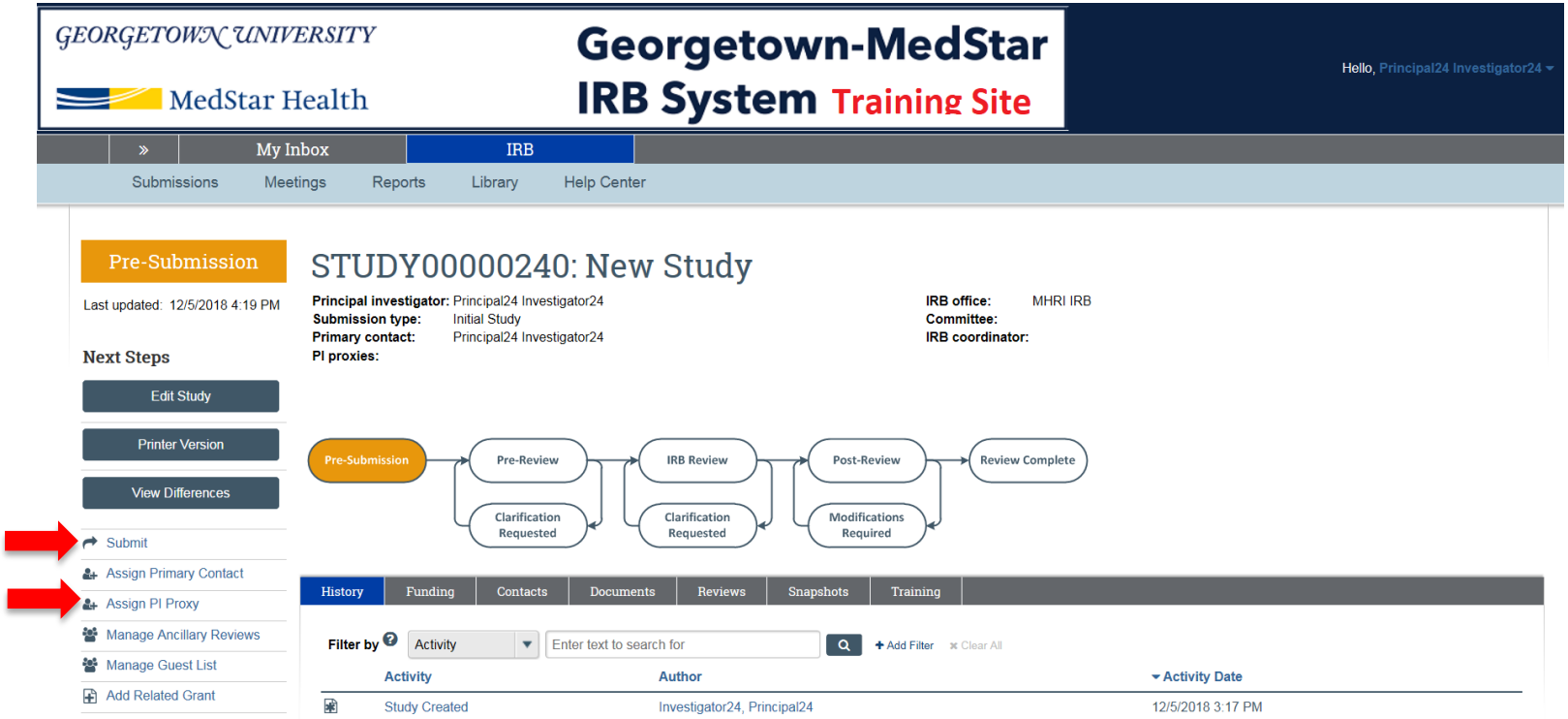
You have not yet submitted your study. To submit, select the submit option on the left.

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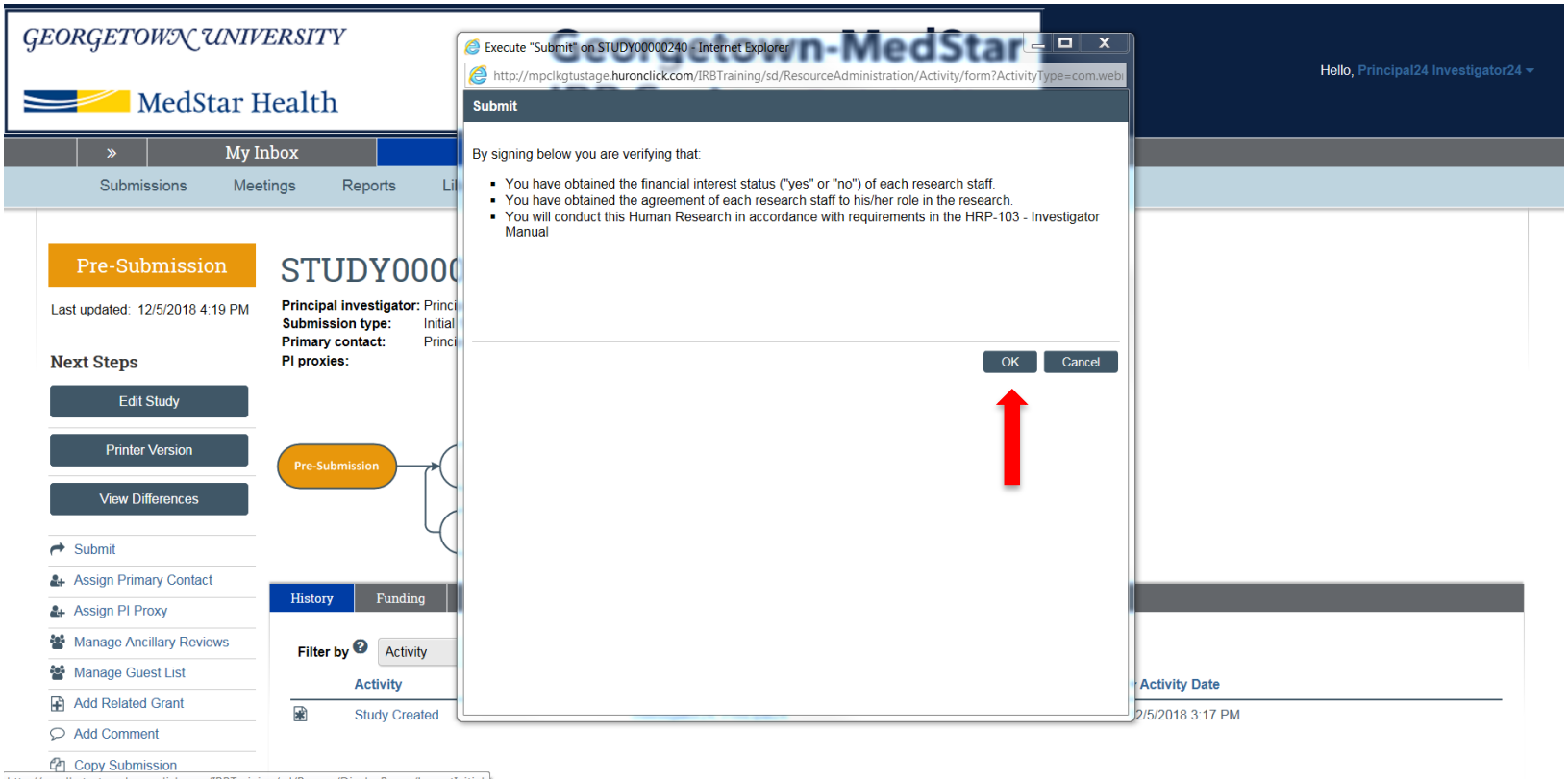
Once you click the submit option, a pop up window will prompt you to verify the listed statements as the PI or on behalf of the PI as the PI proxy. Click OK.



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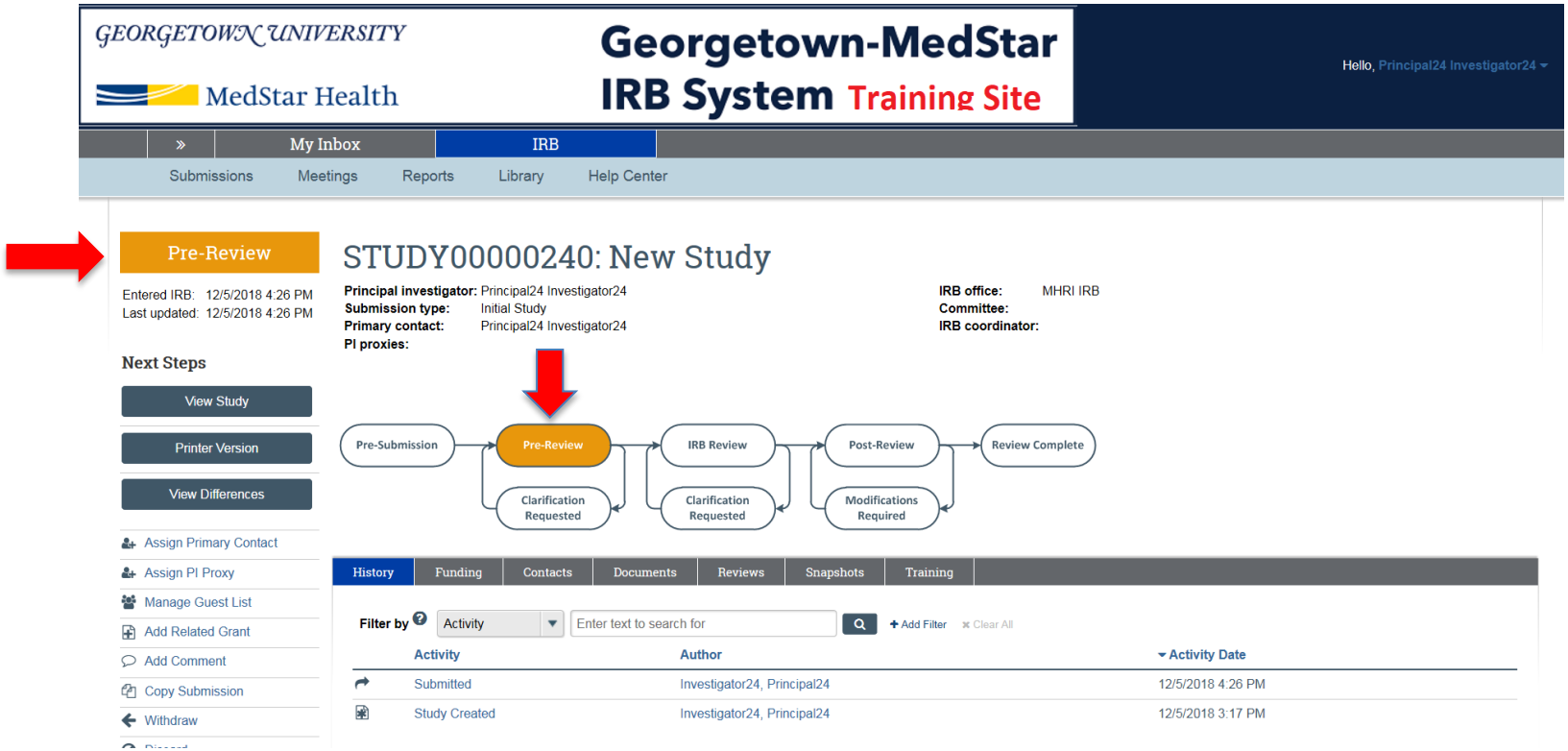
Once you have submitted the study, note that status bar on the left now says Pre-Review and the Pre-Review bubble on the workflow map is selected.



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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-ORIHelpDesk@medstar.net.