

## Clarification Requested and/or Modifications Required



At several points during the review process, the IRB may request clarifications or require modifications from the research team prior to making a determination.

### WORK INSTRUCTIONS

1. When your study requires revision or additional information, you will be notified via PACS e-mail. The message will provide you with a study link. Click on the study link, it will direct you to the workspace.

label:pacs

STUDY00000894 clarification was requested

pacsirb@binghamton.edu  
10:35 AM (0 minutes ago)

Template: IRB\_T\_Several States\_ClarificationRequested

**Notification of Requested Clarifications**

To: [Ayun Elizabeth Shn](#)

Link: [STUDY00000894](#) ← 1.

From: [Ayun Elizabeth Shn](#)

Title: TEST

Description: Clarifications have been requested on this submission. This requires a response from you. For additional details, click on the link above to review and provide clarification.

Confidentiality Notice  
The information contained in and/or attached to this email message may be confidential. If you are not the intended or authorized recipient, you are hereby notified that any unauthorized distribution, dissemination, or copying of this transmission is prohibited. If you have received this transmission in error, please contact the sender immediately and destroy all copies.

Click here to Reply or Forward

Using 0.97 GB

Engage Policies

Last account activity: 2 minutes ago

- Click on **Clarification Requested** (or **Modifications Requested**) to direct you to the detail page of the request.

Home Courses Agreements COI Facilities Grants IACUC **IRB** Safety Jiyun Elizabeth Shin | My Inbox |

IRB > TEST

**Clarification Requested (Pre-Review)** **STUDY0000894: TEST**

**Principal investigator:** Jiyun Elizabeth Shin **IRB office:** Binghamton University IRB Office  
**Submission type:** Initial Study  
**Primary contact:** Jiyun Elizabeth Shin  
**IRB coordinator:**

Entered IRB: 6/12/2017 10:23 AM  
 Initial approval:  
 Effective:  
 Approval end:  
 Modified: 6/12/2017 10:35 AM

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete  
 Clarification Requested → Clarification Requested → Modifications Required

**My Current Actions**

Edit Study  
 Printer Version  
 View Differences  
 Submit Response

**History** Funding Project Contacts Documents Reviews Snapshots

Filter by Activity Go Clear Advanced

Activity	Author	Activity Date
Clarification Requested	Shin, Jiyun Elizabeth	6/12/2017 10:35 AM

Please submit an informed consent.

- Upon viewing the request, click on **Return to Workspace**.

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IRB > TEST

**<< Return to Workspace** < Prev 1 / 4 Next >

**Activity Details (Clarification Requested)** Pre-reviewer sends the submission back to the study team for clarifications.

**Author:** Jiyun Elizabeth Shin (020 Binghamton University)  
**Logged For (IRB Submission):** TEST  
**Activity Date:** 6/12/2017 10:35 AM

**Form:**  
 Please make the following changes or provide the requested information:  
 Please submit an informed consent.

**Supporting documents:**  
 Name  
 There are no items to display

- You can also view the request directly by logging into PACS Portal. After logging into PACS Portal, click the **IRB** tab to find the study that requires your response.

Jiyun Elizabeth Shin | My Inbox | Projects | Logoff

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IRB

4.

Create New Study  
Report New Information

Submissions  
Meetings  
Reports  
Library  
Help Center

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator	Submission Type
STUDY00000894	TEST	6/12/2017 10:35 AM	Clarification Requested (Pre-Review)	Jiyun Elizabeth	Shin		Initial Study
MOD00000892	Modification #5 for Study STUDY00000883	6/9/2017 1:11 PM	Pre-Submission	Jiyun Elizabeth	Shin		Modification
CR00000267	Continuing Review for Study STUDY00000883	6/9/2017 1:10 PM	Pre-Submission	Jiyun Elizabeth	Shin		Continuing Review

- Follow the instructions #2 and #3 above to view the request and to return to workspace.
- If you need to upload a revised or requested document, click **Edit Study** under **Current Actions**.

Jiyun Elizabeth Shin | My Inbox | Projects | Logoff

Home Courses Agreements COI Facilities Grants IACUC **IRB** Safety

IRB > TEST

Components

**STUDY00000894: TEST**

Principal investigator: Jiyun Elizabeth Shin  
Submission type: Initial Study  
Primary contact: Jiyun Elizabeth Shin  
IRB coordinator:

IRB office: Binghamton University IRB Office

Entered IRB: 6/12/2017 10:23 AM  
Initial approval:  
Effective:  
Approval end:  
Modified: 6/12/2017 10:35 AM

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested (highlighted in blue)

6.

**My Current Actions**

**Edit Study** (circled in red)

Printer Version  
View Differences  
Submit Response

History Funding Project Contacts Documents Reviews Snapshots

Filter by Activity

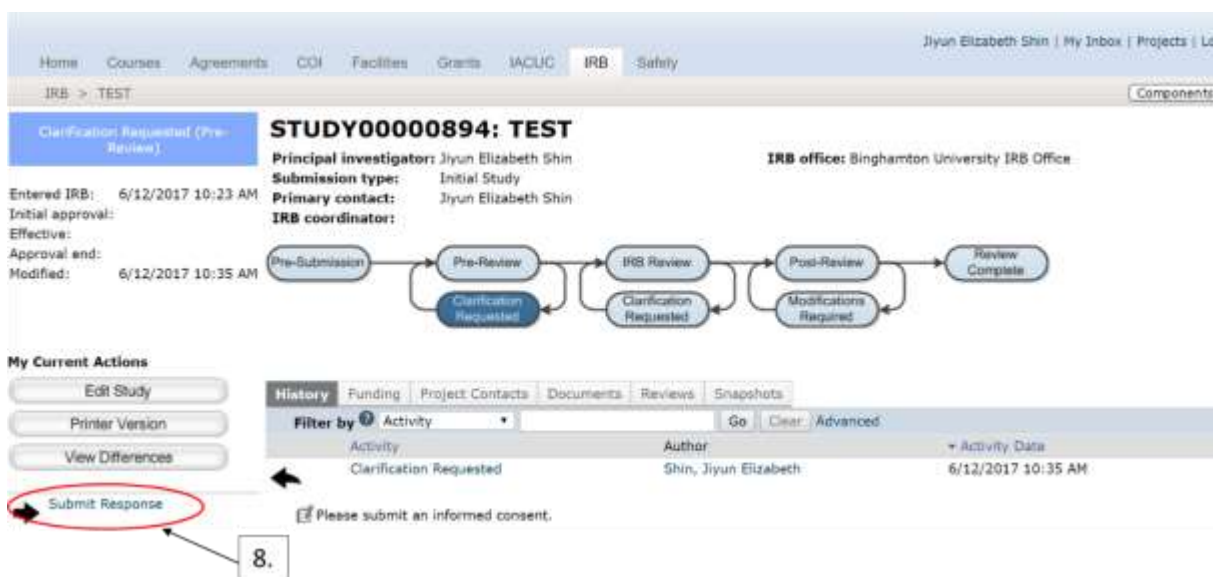
Activity	Author	Activity Date
Clarification Requested	Shin, Jiyun Elizabeth	6/12/2017 10:35 AM

Please submit an informed consent.

7. You can navigate through your previously submitted study by clicking **Continue** in the right hand top or bottom of the page. You can upload the requested document either by clicking **Add** or **Update**. Please note that if you click **Update**, the new document will replace the existing document that you previously have uploaded. Click **Save** to save the changes you made and click **Continue** to navigate through the pages or click **Exit** to exit the page.

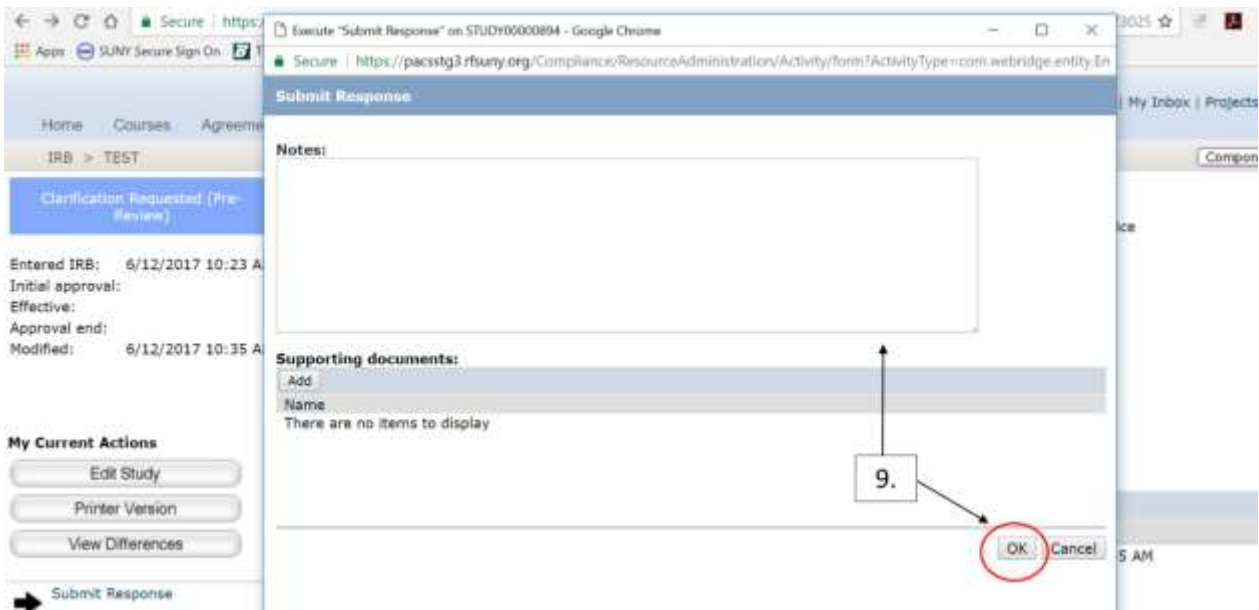


8. Once you exit, you will be directed back to the workspace where you can click on **Submit Response** and provide the requested information/document.

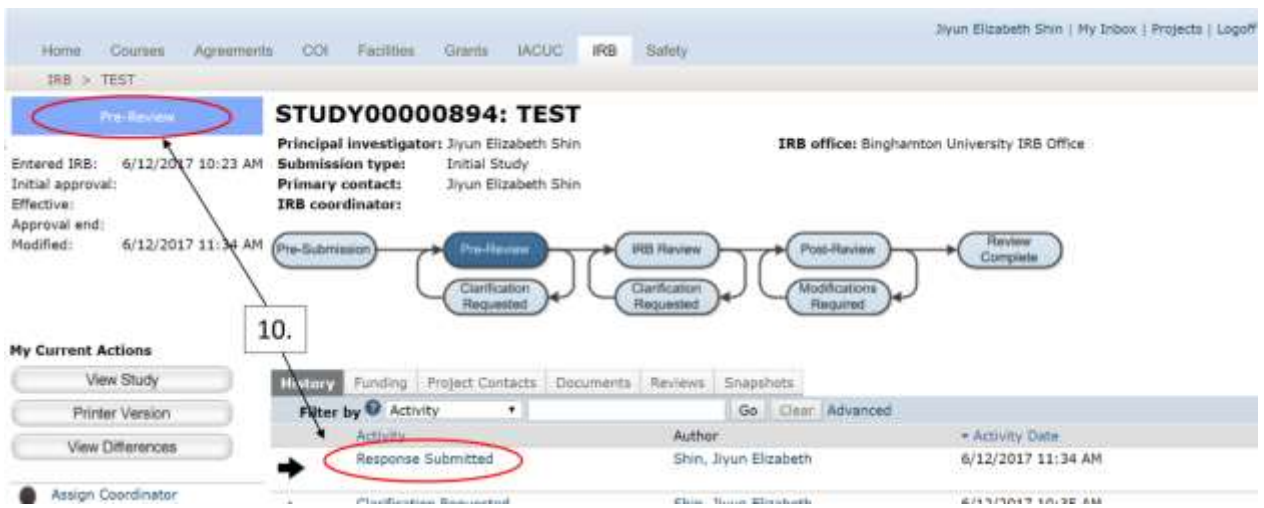


9. After you've provided the information in the **Submit Response** area, click **OK**.

\*Please do not upload the requested document here. Please follow the instructions above (#7) to upload the requested document.



10. If the submission is successful, the study will transition from the **Clarification Requested** (or **Modification Required**) state to the **Pre-Review** (or **Post-Review**) state, and **Response Submitted** will appear under activity history.





Note. Anyone listed on the study can execute the **Submit Response** activity for Reportable New Information (RNI) submissions