

Continuing Review and Modification



WORK INSTRUCTIONS:

1. Log into PACS Portal. Click on the **IRB** tab and then click on the **Active** tab. Click the study in the Approved or Lapsed state that you would like to submit a continuing review or modification.
 - Users can navigate directly to the submission by clicking on the link provided in the Continuing Review Reminder email notification (sent to the PI and Primary Contact 90, 60, 30, and 15 days prior to study expiration) and logging into the system.

Jiyun Elizabeth Shin | My Inbox | Projects | Logoff

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

IRB

IRB

Create New Study
Report New Information

Submissions
Meetings

In-Review **Active** Archived New Information Reports All Submissions

Filter by ID Go Clear Advanced

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator	Expiration Date
STUDY00000893	TEST	6/9/2017 10:49 AM	Approved	Jiyun Elizabeth	Shin	Shin	6/8/2018

2. Within the left hand selection under **My Current Actions**, select the **Create Modification/CR** button.
 - If you are closing a protocol select the **Continuing Review** button. Information for closing a submission can be found within that same option.

The screenshot shows the IRB system interface for a study titled "STUDY0000883: test". The top navigation bar includes links for Home, Courses, Agreements, COI, Facilities, Grants, IACUC, IRB, and Safety. The user is identified as Jiyun Elizabeth Shin. The study details include: Entered IRB: 5/22/2017 11:22 AM, Initial approval: 6/8/2017, Effective: 6/8/2017, Approval end: 6/8/2018, Modified: 6/9/2017 10:33 AM. The principal investigator is Jiyun Elizabeth Shin, the primary contact is Jiyun Elizabeth Shin, and the IRB coordinator is Abigail McConnell. The IRB office is Binghamton University IRB Office, and the letter is IRB Approval letter.pdf(0.01). A workflow diagram shows the process from Pre-Submission to Pre-Review, IRB Review, Post-Review, and Review Complete, with loops for Clarification Requested and Modifications Required. On the left, the "My Current Actions" menu is highlighted, with the "Create Modification / CR" button circled in red. A box with the number "2." has arrows pointing to the "My Current Actions" header and the "Create Modification / CR" button. Below the menu, there is a "History" section with a table of activities.

Activity	Author	Activity Date
Continuing Review CR00000266 closed (Discarded)	Shin, Jiyun Elizabeth	6/9/2017 10:33 AM

3. There are 3 selections to choose from (*Continuing Review, Modification, Modification and Continuing Review*). Click the button pertaining to the type of submission you wish to execute. Click **Continue** in the right hand top or bottom of the page to proceed.

The screenshot shows the "Modification / Continuing Review / Study Closure" form. The title is "Modification / Continuing Review / Study Closure". The question is "What is the purpose of this submission?". There are three radio button options: "Continuing Review", "Modification", and "Modification and Continuing Review". The "Continuing Review" option is selected and circled in red. A box with the number "3." has arrows pointing to the three radio button options and the "Continue >>" buttons at the top and bottom right of the form. The "Continue >>" buttons are also circled in red. The form includes a "Clear" button and a "Save" button.

- If you select *Modification* or *Modification and Continuing Review*, you will be prompted to select what you wish to modify within the study. Select one or both depending on your modification and click **Continue** in the right hand top or bottom of the page.

Click
a human solution

New: IRB Submission

You Are Here: test > _IRBSubmission

<< Back Save | Print... Continue >>

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

Continuing Review

Modification

Modification and Continuing Review

Clear

4.

Modification scope:

Study team member information

Other parts of the study

Active Modification for This Study Modification Type

<< Back Save | Print... Continue >>

- The system will inform you on this page if another continuing review or modification is already open and in progress. To see your previous submissions, click the **Back** button in the left hand top or bottom of the page. If you wish to continue with your current submission, click **Continue** in the right hand top or bottom of the page.

Click
a human solution

New: IRB Submission

You Are Here: test > _IRBSubmission

<< Back Save | Print... Continue >>

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

There is already a Continuing Review under review, MODCR00000391

Modification

Clear

5.

<< Back Save | Print... Continue >>

Note: Skip instruction #6 if you do not need to see your previous submissions.

6. If you submitted in error: follow the instruction from #5 above to go back to your previous submissions, select the submission you wish to discard, and select **Discard** from the left hand menu. It will prompt you to confirm or cancel your request. Once you select "OK" your submission will be discarded.

*Before you discard, please contact our office hsrrc@binghamton.edu or 607-777-7818.

Discard

Discard submission?

Caution: This activity will permanently remove the submission.

6.

OK

Cancel

7. Prior to submission to the IRB, all required fields will need to be completed. Required fields are marked with an asterisks (*).
- Click the **Hide/Show Errors** link in the header of the SmartForm page to display any unanswered questions throughout the SmartForm at the bottom of the page.
 - Use the **Jump To** link to navigate directly to SmartForm pages that are missing information.
 - Submissions with any incomplete information will be redirected to the research team for updates.

Edit: IRB Submission - NODCR0000391

You Are Here: test > Modification and Continuing Re...

<< Back Save | Edit | **Hide/Show Errors** | Print... | **Jump To:** Continuing Review / Study Closure Information >

Continuing Review / Study Closure Information

1. * Specify enrollment totals:

Subjects Enrolled	Total	Since Last Approval
At this investigator's sites:	<input type="text"/>	<input type="text"/>
Study-wide:	<input type="text"/>	

2. Research milestones: (select all that apply)

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

3. * Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?

Yes No Clear

4. Check the items that are true since the last IRB approval (initial review or last continuation review) for all sites involved in the study:

8. When all of the required fields have been completed, click **Finish** in the right hand top or corner of the last SmartForm page to be redirected to the study workspace.

Edit: IRB Submission - CR00000267

You Are Here: test > Continuing Review for Study ST...

<< Back Save | Edit | Hide/Show Errors | Print... | Jump To

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, the principal investigator must click **Submit** on the next page.

<< Back Save | Edit | Hide/Show Errors | Print... | Jump To

9. You will now be directed back to the workspace. You must select **Submit** from the left hand menu for your submission to move forward.
- If, at this point, you feel you have submitted in error you have the option to click **Discard**. Once you follow the prompt, your study will be withdrawn.
 - Once you click **Submit**, you will be prompted regarding your submission and if all is in order you will be directed to the verification box where you'll answer accordingly.

Pre-Submission **MODCR00000391: Modification and Continuing Review #4 for Study STUDY00000883**

Entered IRB: [blank]
Approval: [blank]
Effective: [blank]
Modified: 6/9/2017 11:04 AM

Principal investigator: Jiyun Elizabeth Shin
Submission type: Modification and Continuing Review
Primary contact: Jiyun Elizabeth Shin
IRB coordinator: [blank]

IRB office: Binghamton University IRB Office

Flowchart: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete. Loops: Pre-Review ↔ Clarification Requested, IRB Review ↔ Clarification Requested, Post-Review ↔ Modifications Required.

My Current Actions

Edit Modification / CR | History | Project Contacts | Documents | Reviews | Related RNIs | Snapshots

Printer Version | Filter by Activity | Go | Clear | Advanced

View Differences | No data to display.

Submit (circled in red) ← 9.
Discard (circled in red) ← 9.

10. If the submission is successful, the page will refresh and the study will transition from the **Pre-Submission** state to the **Pre-Review** state.

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

Jiyun Elizabeth Shin | My Inbox | Projects | Logout

IRB > test > Modification and Continuing Review #4 for Study STUDY00000883

Pre-Review **MODCR00000391: Modification and Continuing Review #4 for Study STUDY00000883**

Entered IRB: 6/9/2017 11:05 AM
Approval: [blank]
Effective: [blank]
Modified: 6/9/2017 11:05 AM

Principal investigator: Jiyun Elizabeth Shin
Submission type: Modification and Continuing Review
Primary contact: Jiyun Elizabeth Shin
IRB coordinator: [blank]

IRB office: Binghamton University IRB Office

Flowchart: Pre-Submission → **Pre-Review** → IRB Review → Post-Review → Review Complete. Loops: Pre-Review ↔ Clarification Requested, IRB Review ↔ Clarification Requested, Post-Review ↔ Modifications Required.

My Current Actions

View Modification / CR | History | Project Contacts | Documents | Reviews | Related RNIs | Snapshots

Printer Version | Filter by Activity | Go | Clear | Advanced

View Differences | Activity | Author | Activity Date

10.