Continuing Review Submissions (For studies imported from IRBNet)

You should see all of your imported studies on your IRB page. If you do not see one of your studies, please send an email with the IRBNet ID# to OVPR_myresearchIRB@stonybrook.edu for assistance.

*These are the procedures for your FIRST continuing review submission in myResearch if your study was previously approved in IRBNet. For future continuing reviews, the application data will already be present and you will not need to add information/upload documents again unless they have been revised.

1) Select the study you would like to renew in the My Inbox list. You can filter studies in the Active column or All Submissions column. Note: You can search for studies previously approved in IRBNet by the IRBNet ID.
2) Select Create a Modification/CR
3) Select Modification and Continuing Review

**Important Note:** If you select any option other than Continuing Review and Modification and then select Continue, the system will not allow you to update this selection. You will need to select Discard (on the left navigation area of the main workspace) and start again. Any discarded will appear in the Archived section of your IRB page (under Submissions).

4) You will be asked to select the scope of the modification. Select BOTH options. This will allow you to review the automatically imported information in your application and add documents for review. (See the Continuing Review checklist in the For Investigators library in myResearch or navigate to https://research.stonybrook.edu/myResearch-IRB#checklists-(irb) for the Continuing Review Submission checklist.)
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5) Complete the Continuing Review/Study Closure Information page.

Note that “Since Last Approval” refers to the number of subjects enrolled in your study since the last IRB approval. This may be since the start of the study (if it is the first renewal). If this is not the first renewal, you will enter the number of subjects enrolled since reported at the time of the last renewal.

Also, note that selecting the first four research milestones will result in a request to confirm that the study should be closed.

Select Continue once the page is complete.

<table>
<thead>
<tr>
<th>Specifying enrollment totals:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects Enrolled</td>
</tr>
<tr>
<td>At this site:</td>
</tr>
<tr>
<td>At all sites everywhere that are conducting this protocol:</td>
</tr>
<tr>
<td>Total Number of Subjects</td>
</tr>
</tbody>
</table>

2. Research milestones: (Select all that apply. If enrollment of subjects is ongoing, skip this section.)
- 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. Check the items that are true since the last IRB approval for all sites involved in the study: (Initial review or last continuing review)
- No subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- No subjects withdraw from the study
- No unanticipated problems involving risks to subjects or others
- No complaints about the study
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6) Complete the Modification Information page. If you are making any modifications to the study, summarize each modification and provide a clear rationale for each modification in the text box.

**Modification Information**

1. **Study enrollment status:**
   - [ ] No subjects have been enrolled to date
   - [ ] Subjects are currently enrolled
   - [ ] Study is permanently closed to enrollment
   - [ ] All subjects have completed all study-related interventions
   - [ ] Collection of private identifiable information is complete

2. **Notification of subjects:**
   - [ ] Current subjects will be notified of these changes
   - [ ] Former subjects will be notified of these changes

   ![Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.]

3. **Summarize the modifications:**

7) Once the page is complete, select **Continue** to review each page of the application for accuracy and upload documents as needed. (See the Continuing Review checklist in the For Investigators library in myResearch or navigate to https://research.stonybrook.edu/myResearch-IRB#checklists-(irb) for the Continuing Review Submission checklist.)

On the **Study Team Members** page, confirm that all individuals listed have up-to-date training. If you hover over the color-coded boxes under the IRB Training column you will see when the training will expire. **Note: If you do not see any boxes for human subjects training, contact that study team member to ensure that the appropriate level of human subjects training is completed and their CITI account is linked to their NetID. All study personnel must have up-to-date training prior to IRB approval.**

Be sure to click **Save** on the top/bottom of the page once you complete each page to ensure that you do not lose your work.
8) Once you believe the application is ready to submit, select at the top/bottom of the page to see a list of required sections that have not been completed. This will check for completeness, not verify accuracy of responses.

9) You will reach a Final Page. Be sure to read this page carefully to ensure that you have requested required ancillary reviews prior to submitting your application. **NOTE: Department Chair approval via ancillary review must be obtained before submission. Any continuing review submissions missing documentation of this review will result in a Clarification or submission withdrawal.**

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click Finish to exit the form.
2. On the main page, Click on "Manage Ancillary Reviews", click on "Add" and select your department chair/dep't review con

   - Review type: 'Department Chair (scientific merit, resources)'
   - Is a response required?: YES

   **Note: Do not submit this IRB submission without the PI's Department Chair's documented approval. The PI and study staff the Principal investigator must return to the submission and submit it to the IRB.**

   Select these additional individuals, as applicable, if your research activity involves the facilities, patients, and or/services clinics located at Riverhead, Southold, Plainview, or Medford:

   **Note: You must not commence with your study until all these applicable approvals are documented in myResearch:**

   - Select Rhona Vainer (Chernoff) and Regina Rigore and John Shen
     - Review type: Hospital Budget
     - Is a response required? YES (only one of these individuals must approve the submission before you commence
   - Select the Chief Medical Officer, if your study involves an investigational device, or an FDA-approved device being s
     - Review Type: Other
     - Is a response required? YES
   - Select Eric Spitzer if your study involves Pathology/Laboratory Services
     - Review Type: Pathology
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10) Click Finish to exit the page and select Manage Ancillary Reviews to request all necessary reviews. Refer to the instructions on the Final Page to confirm how to answer the questions on the Manage Ancillary Reviews page.

11) The PI and study team will receive an email notification when the Department Chair/Designated Signatory has submitted a review and accepted/approved the submission. This notification will also appear in the History section (see previous image).

* If an ORC staff member uploads documents related to this study (e.g. previous renewal application, Registration form, etc) you will see these documents in your History section.

12) Once Department Chair/Designated Signatory approval is confirmed, the Principal Investigator can click Submit (see previous image) and agree to the Principal Investigator certification by clicking OK.