Version: February 2026

Submitting a Continuing Review

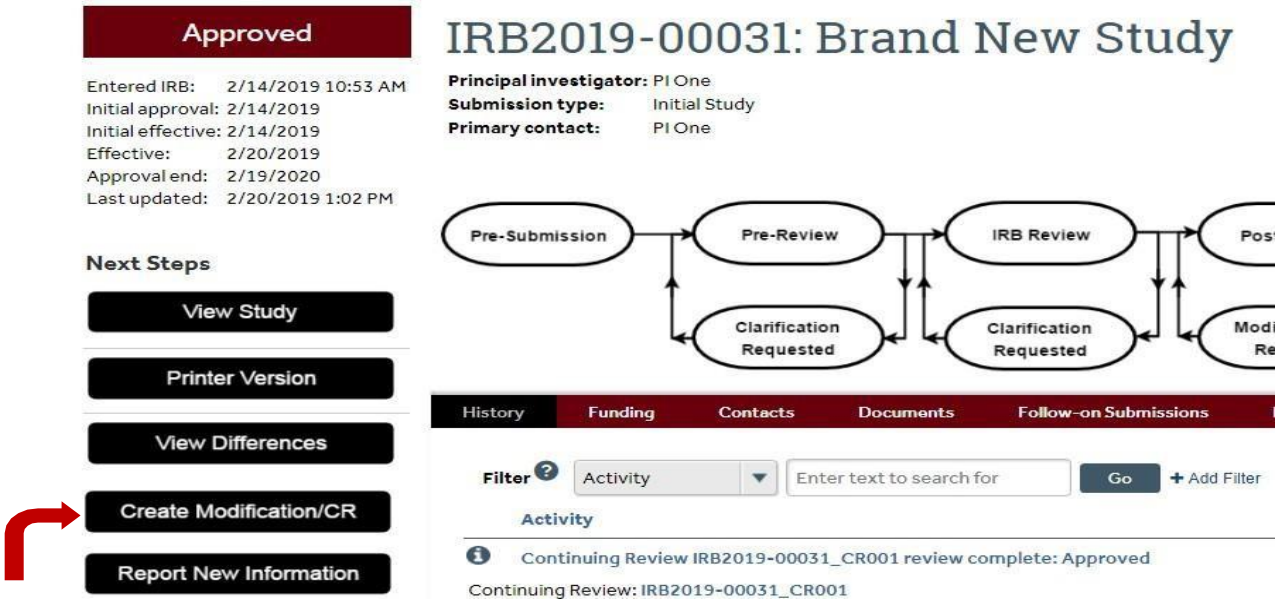
Important: If the first four research milestones listed below are complete, do not use these instructions. Further IRB oversight is not required for your study. Use the Instructions for Closing a Study available here: https://www.stonybrook.edu/commcms/research-compliance/Human-Subjects/submission

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.

NOTE: Click "save" once you complete each page to ensure that the work on that page is saved. myResearch does not autosave.

In order to complete a continuing review, click on the study in your inbox that requires continuing review. In the "Next Steps" section of the study on the left-hand side of the screen select "Create Modification/CR".



Once you have selected "Create Modification/CR" a new page will open. Select "Modification and Continuing Review" on this page.

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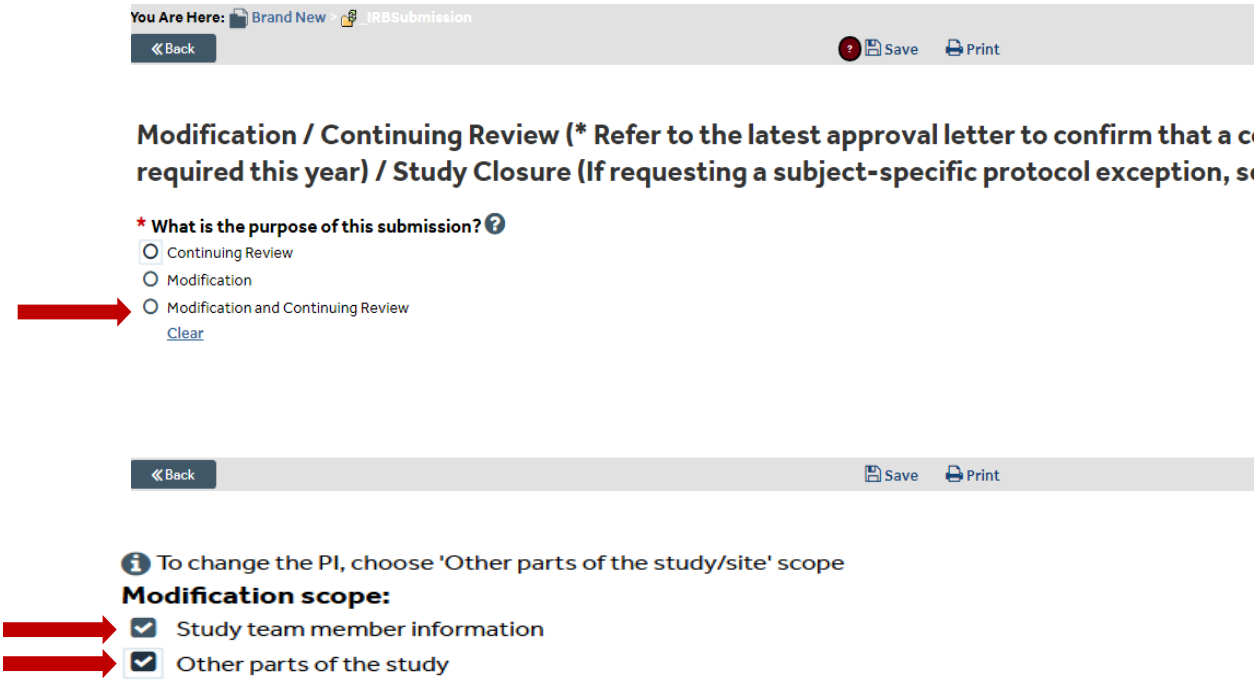
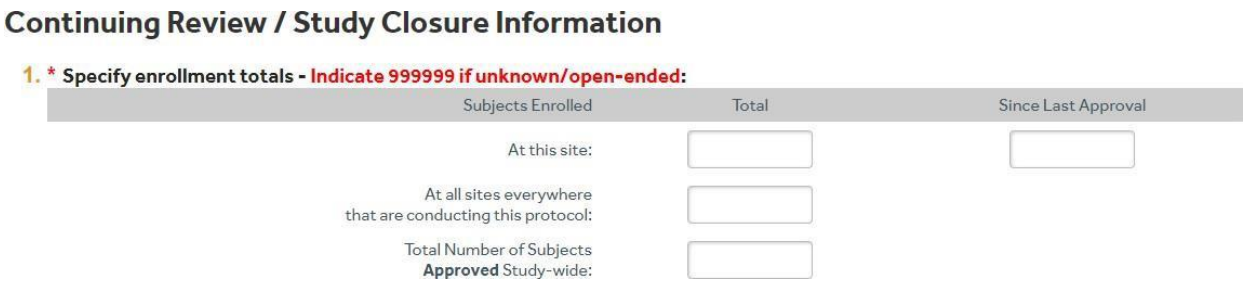


Complete the "Continuing Review" page.



The box on the right-hand side of the screen titled **Since Last Approva**l refers to the number of subjects enrolled in your study since the last IRB approval. If this is not the first renewal, you will enter the number of subjects enrolled since reported at the time of the last renewal.

Total **at this site**: Number of subjects enrolled by the Stony Brook University investigators.

Total **at all sites everywhere that are conducting this protocol**: For a single-site study, this is the same as the total "at this site." Multi-site studies must include the total enrolled from all sites at the time of renewal.

Total number of subjects **approved** study-wide: This is the number of subjects that you are approved to enroll in this study, not the number enrolled so far. Refer to the approved protocol for this number.

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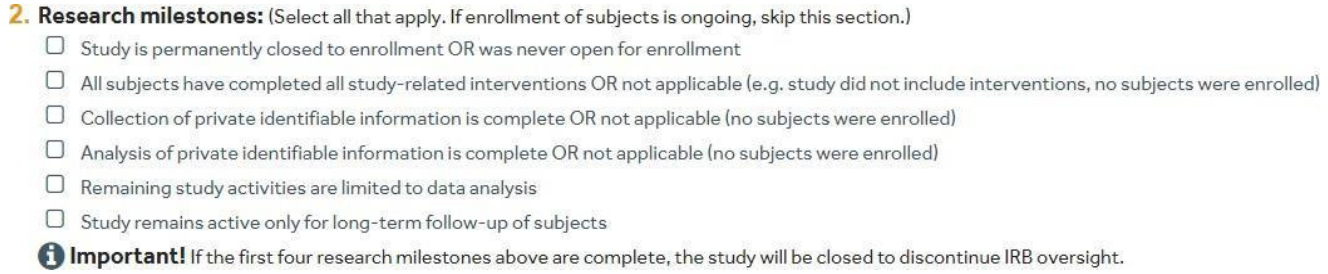
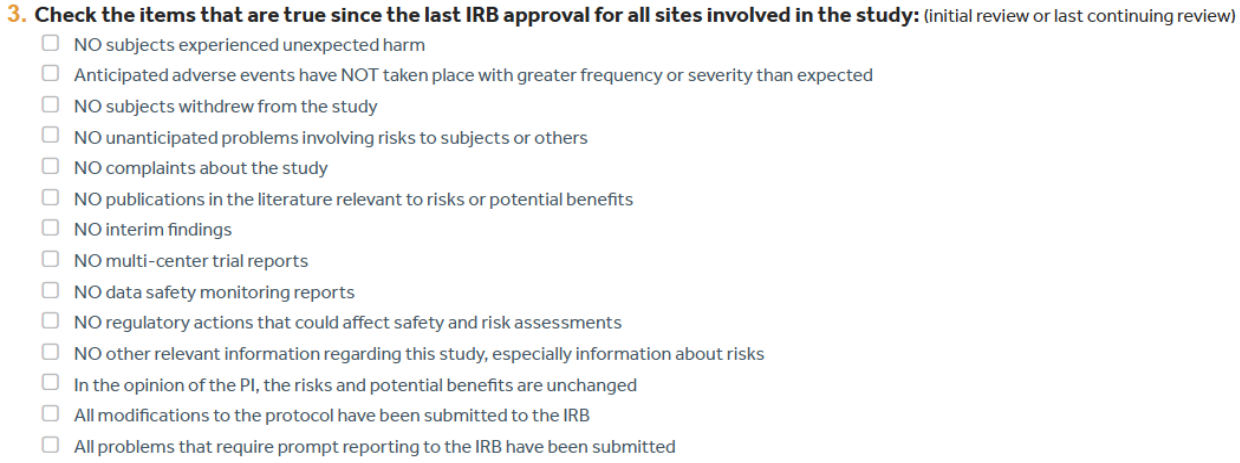
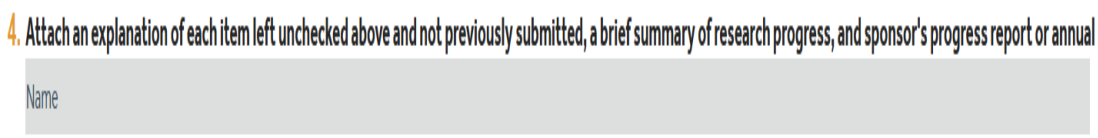

2. **Research milestones:** (Select all that apply. If enrollment of subjects is ongoing, skip this section.)
- ☐ Study is permanently closed to enrollment OR was never open for enrollment
- ☐ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, 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.

For question #2, check all boxes that apply since the last approval period.


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 withdrew from the study
- ☐ NO unanticipated problems involving risks to subjects or others
- ☐ NO complaints about the study
- ☐ NO publications in the literature relevant to risks or potential benefits
- ☐ NO interim findings
- ☐ NO multi-center trial reports
- ☐ NO data safety monitoring reports
- ☐ NO regulatory actions that could affect safety and risk assessments
- ☐ NO other relevant information regarding this study, especially information about risks
- ☐ In the opinion of the PI, the risks and potential benefits are unchanged
- ☐ All modifications to the protocol have been submitted to the IRB
- ☐ All problems that require prompt reporting to the IRB have been submitted

For question #3, check all the boxes that apply since the last approval period.


4. Attach an explanation of each item left unchecked above and not previously submitted, a brief summary of research progress, and sponsor's progress report or annual report, if available.

Name

If there is a box that cannot be checked, upload documentation explaining that item into question #4.


5. Attach the redacted version of the signed consent form and completed inclusion/exclusion checklist for the last subject enrolled (subject name and signature removed):

Add

Name

There are no items to display

If there was enrollment during the recent approval period, upload the redacted consent form and inclusion/exclusion checklist in question #5. If parental permission and child assent are part of the study, upload one of each. Redact the subject/parent/LAR name, initials, and signature for each form on all pages if applicable.

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If there are modifications to the study (i.e., change in procedures, change in study personnel, etc.) summarize each modification and provide a rationale for each modification in the "Summarize the modifications" 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:** (check all that apply; N/A if requesting a subject-specific protocol exception)
   - ☐ Current subjects will be notified of these changes
   - ☐ Former subjects will be notified of these changes

ℹ 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:** ?

Ensure that all modifications are made in the rest of the myResearch application by updating and replacing revised documents, uploading new study documents, and reviewing the study team list.

- Provide the updated version of the protocol (if applicable) using track changes. Make sure to update the version and date on the first page of the protocol.
- Confirm that the study team member list is current and that all CITI training is up to date.
- Provide the current consent/parental permission/assent forms with track changes (if changes are being made to the forms) as well as a clean version for stamping purposes.
- Provide the current recruitment materials.

When the application is ready to submit, select ⚠ Hide/Show Errors. This will show a list of required sections that need to be completed.

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Final Page

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

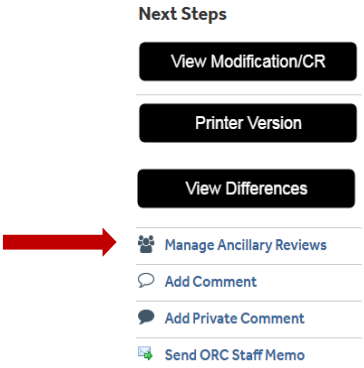
1. Click **Finish** to exit the form.
2. On the main page, Click on "Manage Ancillary Reviews", click on "Add" and **select your department chair/dep't review committee chair**
   - Review type: 'Department Chair (scientific merit, resources)'
   - Is a response required?: YES

Note: Do not submit this IRB submission without the PI's Department Chair's documented approval. The PI and study staff will receive an email notification when the Chair approves the submission. Once Chair approval is obtained, 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 of any of University Hospital's inpatient or outpatient locations (with the exception of the outpatient 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:

On the "Final Page", click "Save" and then "Finish" to exit the form. On the left-hand side of the main page click "Manage Ancillary Reviews". Click "Add" and select the Department Chair for approval.



The Department Chair must submit their review before the study PI can click "submit".

Once the PI clicks "submit" the study will move from "Pre-Submission" to "Pre-Review".