

Continuing Review/Status Report Submissions in **my**RESEARCH IRB

** Do not use this manual for studies with an **external** IRB as the IRB of record. Refer to the **Create an External IRB Submission** manual available here:
<https://www.stonybrook.edu/commcms/research-compliance/Human-Subjects/submission>

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Is IRB re-approval required?

If the first four research milestones listed below are complete, do not use this manual. Further IRB oversight is not required for your study. Use the Close a Study manual available here to formally close your study: <https://www.stonybrook.edu/commcms/research-compliance/Human-Subjects/submission>

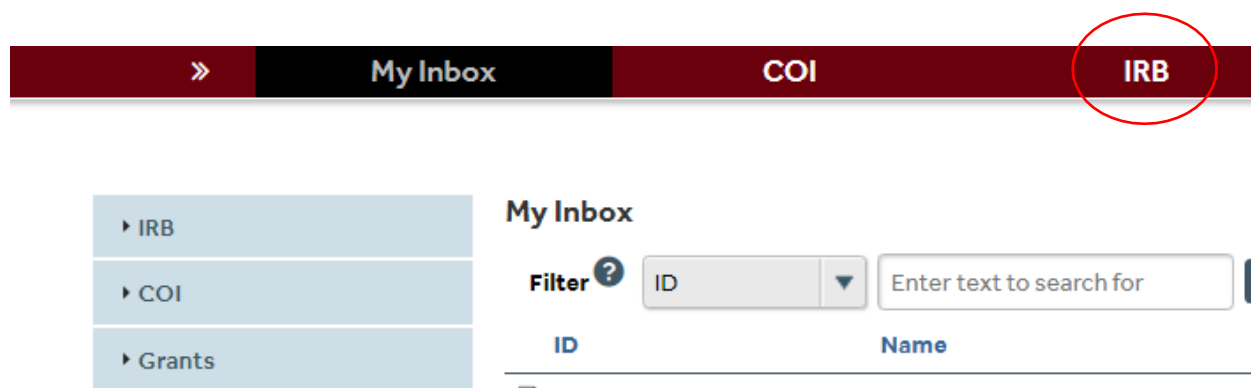
Research milestones: (Select all that apply. If enrollment of subjects is ongoing, skip this section.)

- 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

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

Instructions for studies that have not been previously approved/renewed in myResearch IRB:

1) Click on the **IRB** tab to search for your study.



2) Search using the **All Submissions** tab. You can filter by ID as well as the study name listed in IRBNet or the PI first/last name. **Note:** To properly search by study ID, use only the

numbers before the hyphen in the IRBNet ID.

The screenshot shows the IRBNet interface with a dark red navigation bar at the top. The tabs are: In-Review, Active, Archived, New Information Reports, External IRB Studies, Sites, and All Submissions. The 'All Submissions' tab is highlighted and circled in red. Below the navigation bar is a search filter section. The word 'Filter' is circled in red, followed by a dropdown menu currently set to 'ID'. To the right of the dropdown is a search input field containing the text 'Enter text to search for'. Further right are buttons for 'Go', '+ Add Filter', and 'x Clear All'. Below the search section is a table header with columns: ID, Name, Date Modified, State, PI First Name, and PI Last Name. The first row of the table shows a date '7/31/2010' under the 'Date Modified' column.

** If you are an approved study team member but you do not see one of your studies, please review the following points to obtain access to the study shell in myResearch:

- A. All studies should be available to the PI. If you are the approved PI in IRBNet but you do not see one of your studies, send an email with the IRBNet ID number to OVPR_myresearchIRB@stonybrook.edu for assistance.
- B. If you are not the PI and you do not see one of your studies, first contact the PI to confirm that the study is not already available in myResearch.
 - i. If you do not have access but the study is available to the PI, it means that your name was not included in the imported data. You must ask the PI to assign you as the Primary Contact if you must have access prior to re-approval processing. This requires simply accessing the study and clicking “Assign Primary Contact” in the left navigation area to select your name. This will give you immediate access to the study in myResearch and you will receive all notifications related to this study. **Note:** The primary contact can be changed as often as necessary by any study team member.
 - ii. If the PI also does not have access to the study, send an email with the IRBNet ID number to OVPR_myresearchIRB@stonybrook.edu for assistance.

3) Select the study title. This will route you to the study's shell/parent study page with several actions available to you on the left side of the screen. Select **Create Modification/CR**.

Approved

Entered IRB: 2/14/2019 10:53 AM
 Initial approval: 2/14/2019
 Initial effective: 2/14/2019
 Effective: 2/20/2019
 Approval end: 2/19/2020
 Last updated: 2/20/2019 1:02 PM

Principal investigator: PI One
Submission type: Initial Study
Primary contact: PI One

IRB2019-00031: Brand New Study

Next Steps

- View Study
- Printer Version
- View Differences
- Create Modification/CR**
- Report New Information

History Funding Contacts Documents Follow-on Submissions

Filter [?] Activity Go + Add Filter

Activity

i Continuing Review IRB2019-00031_CR001 review complete: Approved
 Continuing Review: IRB2019-00031_CR001

4) 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.

You Are Here: Brand New > IRBSubmission

« Back Save Print

Modification / Continuing Review (* Refer to the latest approval letter to confirm that a c required this year) / Study Closure (If requesting a subject-specific protocol exception, s

*** What is the purpose of this submission? [?]**

Continuing Review

Modification

Modification and Continuing Review

[Clear](#)

« Back Save Print

5) 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 Submission/Status Report Requirements Checklist.)

You Are Here: Brand New > IRBSubmission

<< Back ? Save Print

Modification / Continuing Review (* Refer to the latest approval letter to confirm if required this year) / Study Closure (If requesting a subject-specific protocol exception)

* What is the purpose of this submission? ?

Continuing Review
 Modification
 Modification and Continuing Review
[Clear](#)

i To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Study team member information
 Other parts of the study

<< Back Save Print

6) Complete the **Continuing Review/Study Closure Information** page.

Continuing Review / Study Closure Information

1. * Specify enrollment totals - Indicate 999999 if unknown/open-ended:

Subjects Enrolled	Total	Since Last Approval
At this site:	<input type="text"/>	<input type="text"/>
At all sites everywhere that are conducting this protocol:	<input type="text"/>	
Total Number of Subjects Approved Study-wide:	<input type="text"/>	

“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/status report). If this is not the first renewal/status report, you will enter the number of subjects enrolled since reported at the time of the last renewal/status report.

Total at this site: Number of subjects enrolled by SBU investigators (by written consent or otherwise)

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.”

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

approved protocol. If you are approved for open-ended enrollment, indicate 999999.

For question 2, check all that apply to this study. If enrollment of subjects will continue in the future, do not select any boxes. If the study involves collection of data only (e.g. chart reviews) and reviews will continue in the future, do not select any boxes.

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

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

For question 3, check the box next to each item to confirm that is true as of the last IRB approval. For example, if no subject experience unexpected harm and no anticipated adverse events took place with greater frequency or severity than expected, these boxes should be checked. If there are any boxes that you cannot check, you must provide appropriate documentation for review. For example, if you do not check that there are no data safety monitoring reports as of the last IRB approval, you are indicating that there *is* such a report and it must be uploaded for question 4.

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

Only upload documents as applicable to your study. **No documents are required for question 5 unless there was enrollment in the most recent approval period and the study was approved with written consent.** A redacted inclusion/exclusion criteria checklist is not required if no such

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):



Name

There are no items to display

document was previously approved. If the study involves written parent permission and written assent, upload the redacted versions of both forms for the last subject enrolled in the most recent approval period. Note: Only subject identifiers (e.g. name, initials, signature) should be redacted.

Select **Continue** once the page is complete.

7) Complete the **Modification Information** page. Confirm that the selections for study enrollment status are consistent with those indicated on the previous page. If you are making any modifications to the study (e.g. previously uploaded documents, procedures, study team), **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: (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: **?**




8) 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://www.stonybrook.edu/commcms/research-compliance/Human-Subjects/submission>) for the Continuing Review/Status Report Submission checklist.)

Reminders related to the various pages:

-   Click on these question mark icons throughout the SmartForm for additional guidance in select sections of the SmartForm.
- Each response must be reviewed carefully for accuracy. There are many fields (e.g. Brief Lay Description) that could not be populated with imported data. It is the PI's responsibility to ensure that all requested information and documents are revised/added as necessary.
- **Attach the protocol:** This refers to the most recently approved protocol document. Do not complete the new protocol template provided in this section as that document is for new studies submitted in myResearch only. If there are any proposed changes since last approved, use Track Changes to identify the updates and be sure to return to the Summarize the Modifications section of the SmartForm to add the summary of changes with appropriate rationale(s).
- **Funding Sources:** You are required to list external funding sources only. The funding sources available in myResearch IRB are linked to the list of sources that have been previously routed through the Grants module. If you would like to request the addition of a particular funding source, you must submit the request at the following webpage: https://www.stonybrook.edu/commcms/osp-ogm/plan_propose/myResearch_Grants/mrg_request. All required fields must be completed before it can be reviewed. If you do not see the funding source available by the end of the next business day, you can contact OVPR IT directly at ovpr-it@stonybrook.edu to check the status.
- On the **Study Team Members** page, confirm that all individuals listed have current CITI human subjects 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 human subjects training boxes for an individual with current 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. Contact the SBU CITI specialist at Maryellen.Herz@stonybrook.edu if assistance is required to complete the NetID/CITI account linking process. **** All research study personnel must have up-to-date training prior to IRB approval.***
- **Consent Forms:** As in the case of the protocol, you are not creating your consent/assent/permission forms using the templates. Upload your most recently approved Word doc version(s) to be re-approved. This should be a clean version (all previously approved tracked changes, highlighting, or comments removed, no watermarks, etc) unless there are new proposed changes. Proposed changes should be indicated using the **Tracked Changes** feature in Word. Again, be sure to return to the Summarize the Modifications section of the SmartForm to add the summary of changes with an appropriate rationale(s). Note: Even if previously approved for a consent waiver (waiver of informed

consent or waiver of documentation), the Supplemental Form G must be completed and uploaded in the Consent Forms section. The template is available in that section.

- **Recruitment Materials:** Be sure to upload all documents that you intend to continue using even if you previously uploaded these documents in IRBNet (e.g. questionnaires, assessments, announcements, flyers, advertisements, recruitment emails, screening materials).
- **Other Attachments:** Upload any remaining documentation that may be necessary for this study (e.g. documentation of lead site/collaborating site ongoing IRB approvals, Application to Conduct Research Activities at Stony Brook University Hospital if the study involves SBU hospital patients/resources/facilities).
- Confirm that only clean or tracked versions of documents are uploaded. **Do not upload any stamped versions of documents (e.g. stamped flyers) as they cannot be re-stamped in the system.**
- 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.

9) 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 only. It will not verify accuracy of responses, which is the investigator's responsibility.

10) You will reach a **Final Page** after the Local Site Documents 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 requested and obtained prior to submission. Any continuing review submissions missing documentation of this review will result in submission withdrawal.**



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 co**
 - 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 serv 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 Vainder (Chernoff) and Regina Rigoroso and John Shen

- 11) Click **Finish** to exit the page and then select **Manage Ancillary Reviews** to request all necessary reviews. Refer to the instructions on the Final Page to determine which ancillary reviews are required and how to answer the questions on the Manage Ancillary Reviews page.

The screenshot displays the IRB2019-00013_MODCR001: Modification #1 for Study Brand New page. The page is titled "Pre-Submission" and shows the last updated time as 2/28/2019 12:34 PM. The submission type is "Modification and Continuing Review" and the primary contact is "PI One". The principal investigator is "PI One".

The "Next Steps" sidebar includes the following options:

- Edit Modification/CR
- Printer Version
- View Differences
- Submit
- Manage Ancillary Reviews
- Add Comment
- Discard

The flowchart illustrates the review process:

```

graph LR
    A([Pre-Submission]) --> B([Pre-Review])
    A --> C([Clarification Requested])
    B --> D([IRB Review])
    C --> E([Clarification Requested])
    D --> F([Post-Submission])
    E --> G([Clarification Requested])
    F --> H([Modif Rec])
  
```

The navigation bar includes the following tabs:

- History
- Contacts
- Documents
- Related RNIs
- Snapshots

The "Filter" section includes a dropdown menu set to "Activity", a search input field, a "Go" button, and an "Add Filter" button.

- 12) The PI and Primary Contact (if the investigator assigns one) 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 red banner in previous image). You can click on the notification link in the **History** section or click on the **Reviews** section that will also appear on the red banner to view the outcome of the review.

- 13) 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**.

Instructions for studies that have been previously approved/renewed in myResearch IRB:

1) Click on the **IRB** tab

The screenshot shows the top navigation bar with four tabs: a chevron icon, 'My Inbox', 'COI', and 'IRB'. The 'IRB' tab is circled in red. Below the navigation bar is a sidebar with three items: 'IRB', 'COI', and 'Grants'. To the right of the sidebar is the 'My Inbox' section, which includes a 'Filter' dropdown menu with 'ID' selected, a search input field with the placeholder text 'Enter text to search for', and a table header with columns 'ID' and 'Name'.

2) Search for the study's shell/parent study page using the **All Submissions** tab. You can use a variety of filters including the study ID option. This will generate a list of all submissions associated with the study based on the filter(s) used. Choose the ID with no underscore (e.g. IRB2019-1234 rather than IRB2019-1234_MOD001).

The screenshot shows the 'All Submissions' tab selected in the top navigation bar, which is circled in red. Below the navigation bar is a search and filter section. The 'Filter' dropdown menu is circled in red, showing 'ID' selected. To the right of the dropdown is a search input field with the placeholder text 'Enter text to search for', a 'Go' button, and links for '+ Add Filter' and 'x Clear All'. Below the search section is a table header with columns: 'ID', 'Name', 'Date Modified', 'State', 'PI First Name', and 'PI Last Name'. The date '7/21/2010' is visible at the bottom of the page.

- 3) Select the study title. This will route you to the study's shell/parent study page with several actions available to you on the left side of the screen. Select **Create Modification/CR**.

Approved

Entered IRB: 2/14/2019 10:53 AM
Initial approval: 2/14/2019
Initial effective: 2/14/2019
Effective: 2/20/2019
Approval end: 2/19/2020
Last updated: 2/20/2019 1:02 PM

Next Steps

- View Study
- Printer Version
- View Differences
- Create Modification/CR**
- Report New Information

IRB2019-00031: Brand New Study

Principal investigator: PI One
Submission type: Initial Study
Primary contact: PI One

History
Funding
Contacts
Documents
Follow-on Submissions

Filter ? Activity ▼ Go + Add Filter

Activity

i Continuing Review IRB2019-00031_CR001 review complete: Approved
Continuing Review: IRB2019-00031_CR001

- 4) 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.

You Are Here: [Brand New](#) > [IRBSubmission](#)

[← Back](#)

? [Save](#) [Print](#)

Modification / Continuing Review (* Refer to the latest approval letter to confirm that a c required this year) / Study Closure (If requesting a subject-specific protocol exception, s

*** What is the purpose of this submission?** ?

Continuing Review

Modification

Modification and Continuing Review

[Clear](#)

[← Back](#)

[Save](#) [Print](#)

5) You will be asked to select the scope of the modification. Select **BOTH** options. **This will allow you to review the most recently approved versions of SmartForm pages/study documents and make revisions as needed.**

You Are Here: [Brand New](#) > [IRBSubmission](#)

[« Back](#) [Save](#) [Print](#)

Modification / Continuing Review (* Refer to the latest approval letter to confirm if required this year) / Study Closure (If requesting a subject-specific protocol exception)

*** What is the purpose of this submission?** [?](#)

Continuing Review
 Modification
 Modification and Continuing Review

[Clear](#)

[i](#) To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Study team member information
 Other parts of the study

[« Back](#) [Save](#) [Print](#)

6) Complete the **Continuing Review/Study Closure Information** page.

Continuing Review / Study Closure Information

1. * Specify enrollment totals - Indicate 999999 if unknown/open-ended:

Subjects Enrolled	Total	Since Last Approval
At this site:	<input type="text"/>	<input type="text"/>
At all sites everywhere that are conducting this protocol:	<input type="text"/>	
Total Number of Subjects Approved Study-wide:	<input type="text"/>	

“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/status report). If this is not the first renewal/status report, you will enter the number of subjects enrolled since reported at the time of the last renewal/status report.

Total at this site: Number of subjects enrolled by SBU investigators (by written consent or otherwise)

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.”

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

approved protocol. If you are approved for open-ended enrollment, indicate 999999.

For question 2, check all that apply to this study. If enrollment of subjects will continue in the future, do not select any boxes. If the study involves collection of data only (e.g. chart reviews) and reviews will continue in the future, do not select any boxes.

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

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

For question 3, check the box next to each item to confirm that is true as of the last IRB approval. For example, if no subject experience unexpected harm and no anticipated adverse events took place with greater frequency or severity than expected, these boxes should be checked. If there are any boxes that you cannot check, you must provide appropriate documentation for review. For example, if you do not check that there are no data safety monitoring reports as of the last IRB approval, you are indicating that there *is* such a report and it must be uploaded for question 4.

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

Only upload documents as applicable to your study. **No documents are required for question 5**

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):



Name

There are no items to display

unless there was enrollment in the most recent approval period and the study was approved with written consent. A redacted inclusion/exclusion criteria checklist is not required if no such document was previously approved. If the study involves written parent permission and written assent, upload the redacted versions of both forms for the last subject enrolled in the most recent approval period. Note: Only subject identifiers (e.g. name, initials, signature) should be redacted.

Select **Continue** once the page is complete.

7) Complete the **Modification Information** page. Confirm that the selections for study enrollment status are consistent with those indicated on the previous page. If you are making any modifications to the study (e.g. previously uploaded documents, procedures, study team), **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: (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

 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.

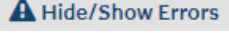
3. * Summarize the modifications: 

8) Once the page is complete, select **Continue** to review each page of the application and the uploaded documents to ensure that all information is current.


Reminders related to the various pages:


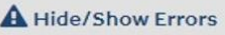
-   Click on these question mark icons throughout the SmartForm for additional guidance in select sections of the SmartForm.

- To help facilitate a more efficient review, please review all sections of the SmartForm/uploaded documents prior to submission for re-approval. This should be done even in the case where the investigator does not initially anticipate that changes are needed.
- **Funding Sources:** You are required to list external funding sources only. The funding sources available in myResearch IRB are linked to the list of sources that have been previously routed through the Grants module. If you would like to request the addition of a particular funding source, you must submit the request at the following webpage: https://www.stonybrook.edu/commcms/osp-ogm/plan_propose/myResearch_Grants/mrg_request. All required fields must be completed before it can be reviewed. If you do not see the funding source available by the end of the next business day, you can contact OVPR IT directly at ovpr-it@stonybrook.edu to check the status.
- On the **Study Team Members** page, confirm that all individuals listed have current CITI human subjects 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 human subjects training boxes for an individual with current 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. Contact the SBU CITI specialist at Maryellen.Herz@stonybrook.edu if assistance is required to complete the NetID/CITI account linking process. **** All research study personnel must have up-to-date training prior to IRB approval.***
- **Other Attachments:** Upload any remaining documentation that may be necessary for this study (e.g. documentation of lead site/collaborating site ongoing IRB approvals, Application to Conduct Research Activities at Stony Brook University Hospital if the study involves SBU hospital patients/resources/facilities).
- If there are any proposed changes to the SmartForm/uploaded documents, be sure to identify each change along with the rationale(s) in the **Summarize the Modifications** section of the SmartForm and track changes in documents. Note: Only the **Track Changes** feature in Word may be used to identify changes to Word docs that need to be stamped (e.g. consent forms, recruitment materials).
- Confirm that only clean or tracked versions of documents are uploaded. **Do not upload any stamped versions of documents (e.g. stamped flyers) as they cannot be re-stamped in the system.**
- 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.

9) Once you believe the application is ready for submission, 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 only. It will not verify accuracy of responses, which is the investigator's responsibility.

10) You will reach a **Final Page** after the Local Site Documents page. Be sure to read this page carefully to ensure that you have requested required ancillary reviews **prior** to submitting your application. Given that this study was previously approved in myResearch IRB, the PI has presumably already ensured that the study was shared with any required ancillary reviewers and their approvals were received prior to study commencement. **NOTE: Department Chair approval via ancillary review must be requested and obtained prior to submission. Any continuing review submissions missing documentation of this review will result in submission withdrawal.**

You Are Here:  Brand New

  Save  

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 coordinator**
 - 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, including 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/serve 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 Vainder (Chernoff) and Regina Riaoroso and John Shen

11) Click **Finish** to exit the page and then select **Manage Ancillary Reviews** to request all necessary reviews. Refer to the instructions on the Final Page to determine which ancillary reviews are required and how to answer the questions on the Manage Ancillary Reviews page.

The screenshot displays the IRB2019-00013_MODCR001: Modification #1 for Study Brand New page. The page is titled 'Pre-Submission' and shows the submission details: Principal investigator: PI One, Submission type: Modification and Continuing Review, and Primary contact: PI One. The submission was last updated on 2/28/2019 at 12:34 PM. The page includes a 'Next Steps' section with buttons for 'Edit Modification/CR', 'Printer Version', and 'View Differences'. A 'Submit' button is also present, along with 'Add Comment' and 'Discard' options. A flowchart illustrates the review process: Pre-Submission leads to Pre-Review, which can lead to IRB Review or Clarification Requested. IRB Review can lead to Post-Review or Clarification Requested. Clarification Requested can lead to Pre-Review or IRB Review. The page also features a 'History' section with tabs for 'Contacts', 'Documents', 'Related RNIs', and 'Snapshots'. A search bar is located at the bottom of the page.

12) The PI and Primary Contact (if the investigator assigns one) 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 red banner in previous image). You can click on the notification link in the History or click on the Reviews section that will also appear on the red banner to view the outcome of the review.

13) 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**.