System to Track and Approve Research

"STAR"

Principal Investigator/Proxy User Guide

Research Administration
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NYC HEALTH+ HOSPITALS

Contents

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I) BACKGROUND INFORMATION

What is the HHC System to Track and Approve Research ("STAR")?

STAR is HHC's new Internet-based research application system that automates the research protocol application, renewal, and approval processes. Principal Investigators (PIs) conducting research at an HHC facility must apply for HHC approval through STAR. STAR replaces ReASOn and the paper 641 form.

Do PIs still need to complete and submit an IRB application?

Yes. HHC approval and IRB approval are different. To receive HHC approval through STAR, an IRB determination is required. The HHC approval review process in not an IRB review.

STAR Users

STAR is used by Principal Investigators who wish to conduct research at one or more HHC facilities as well as facility and Central Office reviewers. The key players are PIs, the Facility Research Coordinator (FRC), Facility Research Review Committee, Facility Executives, and Research Administration at Central Office. Each role is defined below:

- **Principal Investigator**

  PIs are the primary users and are ultimately responsible for ensuring their research project is granted HHC approval as well other approvals required for implementation. PIs can also use STAR to apply for continued renewal, modifications and to formally close a project.

- **PI Proxy**

  A PI can delegate any person on his/her research team to manage STAR. The proxy will act on behalf of the PI and will have the same access rights as the PI. For example, the proxy can edit, submit, modify, respond to reviewers or apply for continued approvals etc. A Proxy can be permanent or temporary (the Proxy can act on behalf of the PI for individual studies). Directions to set up PI proxies are in the next section. **Please note that a primary contact will be copied on notifications but will not have the same access rights as a PI or their proxy.**

- **Facility Research Coordinator ("FRC")**

  The FRC oversees the application through the review process. The FRC is the link between the PIs and reviewers.

- **Facility Research Review Committee ("FRRC")**

  After the FRC ensures the submission is complete, the submission moves to FRRC review. Committee reviewers at the impacted facility conduct their review prior to Executive and Central Office review. At a minimum, the FRRC Chair and Finance (and Pharmacy if it is a drug or device trial) must review and approve of the submission. In some cases, ad-hoc FRRC members can be added. Examples of such reviewers include the PI's Director of Service, subject-matter experts or IT representatives. Committee Reviewers can elect a designee to complete reviews on their behalf. See Reviewer Delegates below.

- **Facility Executives**

  After successful review by the FRRC, the submission is routed to the Executive Committee. The facility executives are the Medical Board President and/or the Medical Director and Executive Director.

- **Reviewer Delegates**

  Committee and Executive Reviewers can elect a delegate to conduct their review, permanently or temporarily (i.e. Reviewer goes on vacation or is the PI on the project). Delegate Reviewers will have full rights and privileges to act on the Reviewer's behalf. Committee and Executive Reviewers who permanently elect a Delegate must formally present a letter to the FRC that states this. The letter will be uploaded to the Delegate Reviewer's research account profile.

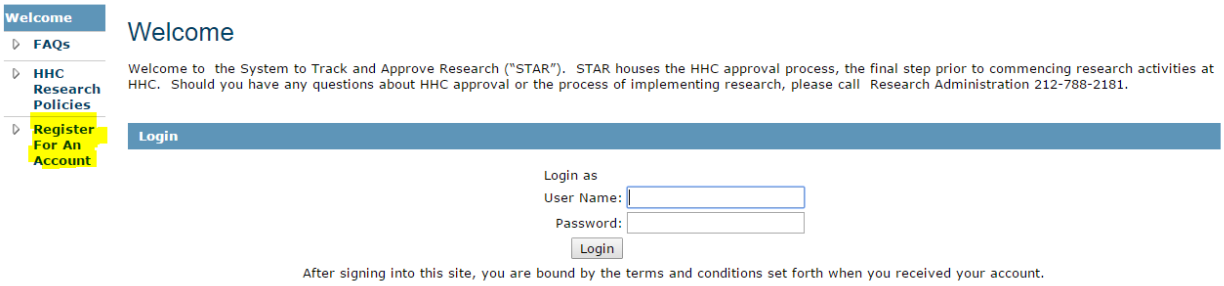
- **Central Office**

  Following Executive review, the submission is reviewed by Research Administration at Central Office. Immediately following Central Office approval, the PI (and other main contacts listed on the submission) will receive an email notification indicating that HHC approval has been granted and research activities can start.

II) ACCESSING STAR

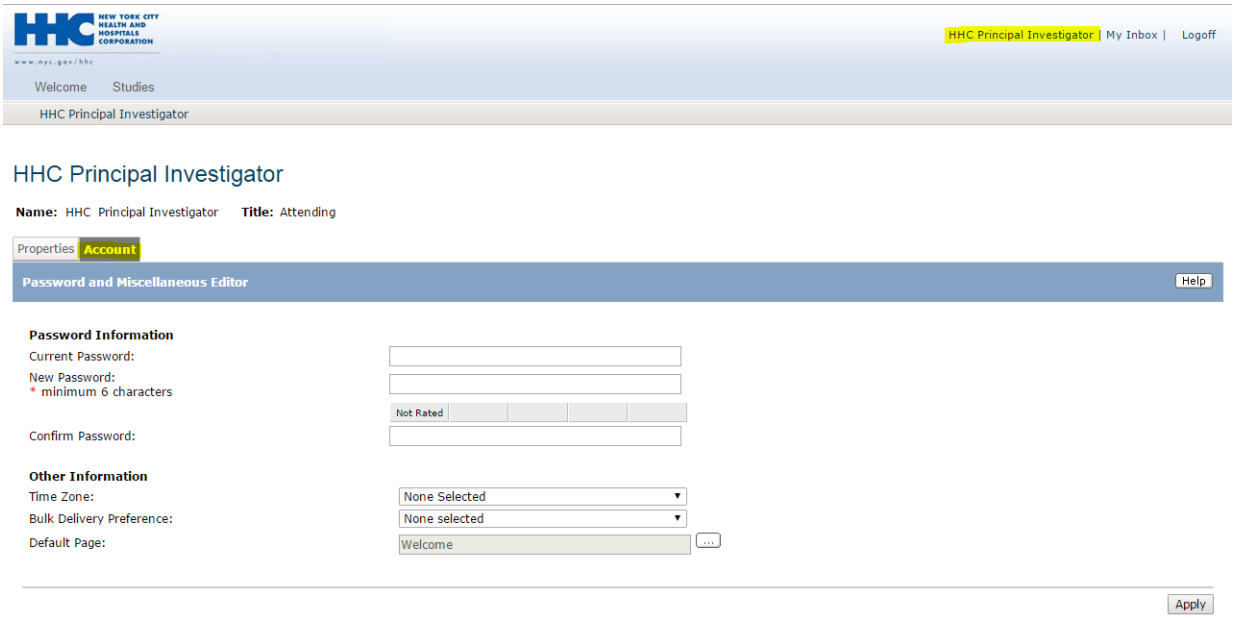
Creating an Account

1. To register, go to http://star.nychhc.org/
   STAR is accessible anywhere the internet is available; it is compatible with all internet browsers such as Chrome, Internet Explorer or Firefox.
2. Click on **Click Here Register for a New Account**. An automated email will be sent with your username and temporary password. Your username is the email address entered during registration.



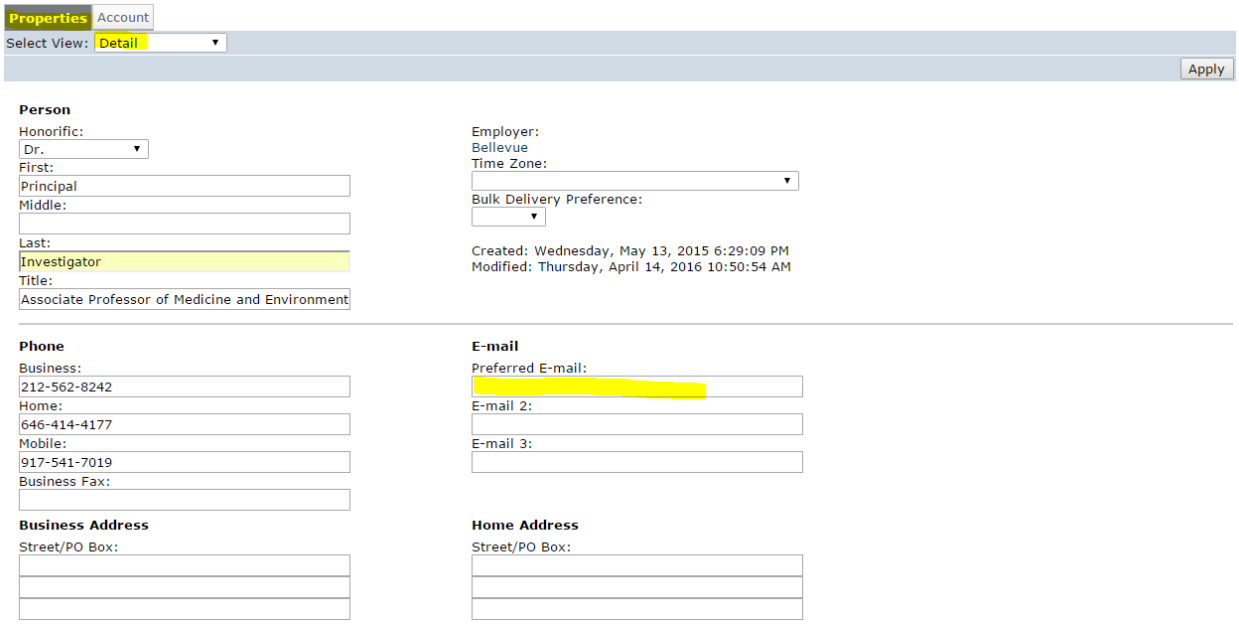
Changing Your Password

1. After logging on, click on your name at the top right.
2. Under the **Account** tab, change your password.



Updating Your Email Address

1. After clicking on your name at the top right corner, click on the **Properties** tab, and then select **Detail** from the dropdown menu.
2. Update your email address in the designated field.

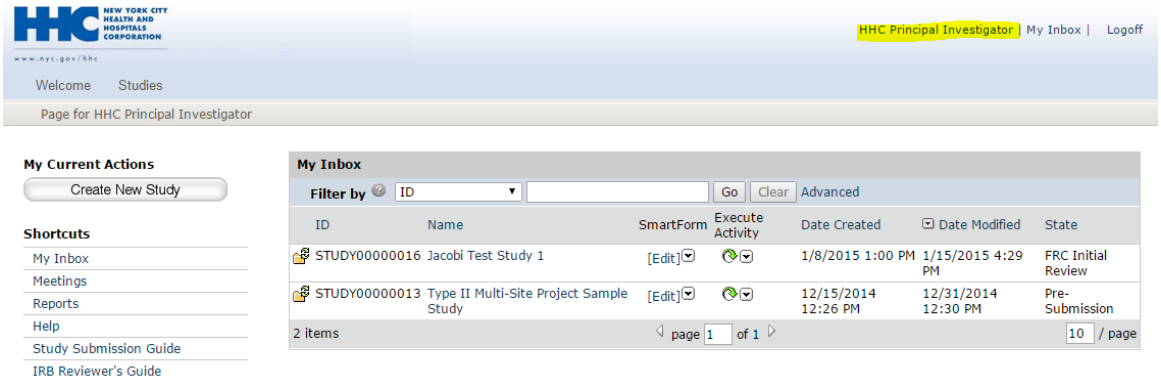


PI Proxies

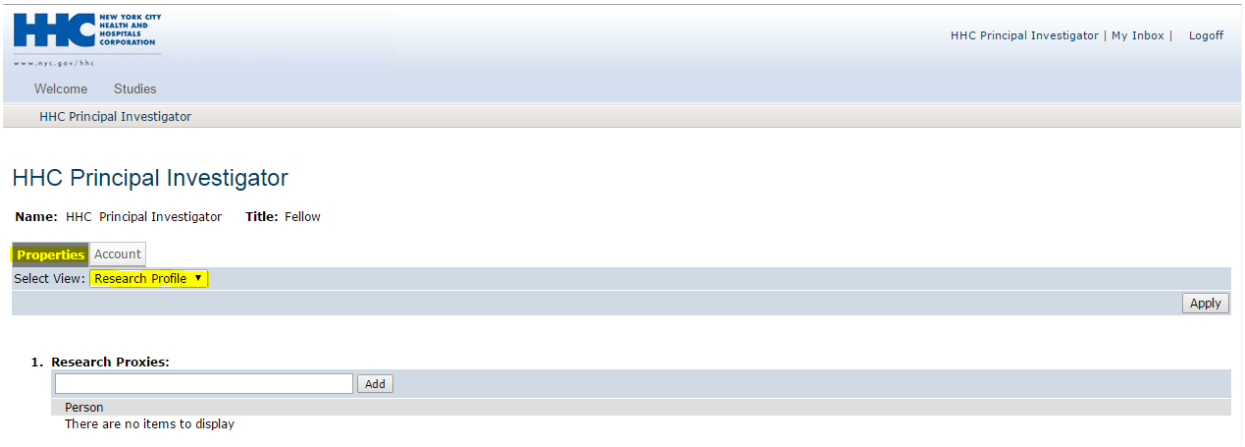
A PI can grant proxy access to a member of their research team. A proxy has the same rights as a PI and may complete actions such as submitting applications, modifying or applying for continued renewal. Proxies can be assigned in two ways:

Permanent proxy: a PI can permanently delegate a research team member(s) to act as their proxy for all studies under their name:

1. The PI and proxy must be registered in the system.
2. PI must sign onto STAR.
3. Click on PI's Name at the top right corner.

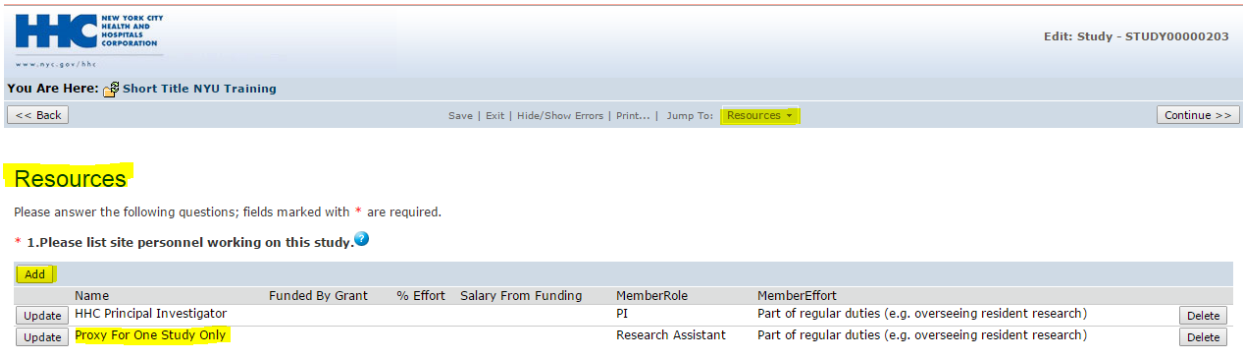


4. Under the **Properties** tab, select **Research Profile** from the **Select View** dropdown.
5. Add the team member(s) who will serve as PI proxies. Once added, these team members can perform all PI activities on behalf of the PI for all current and new studies.

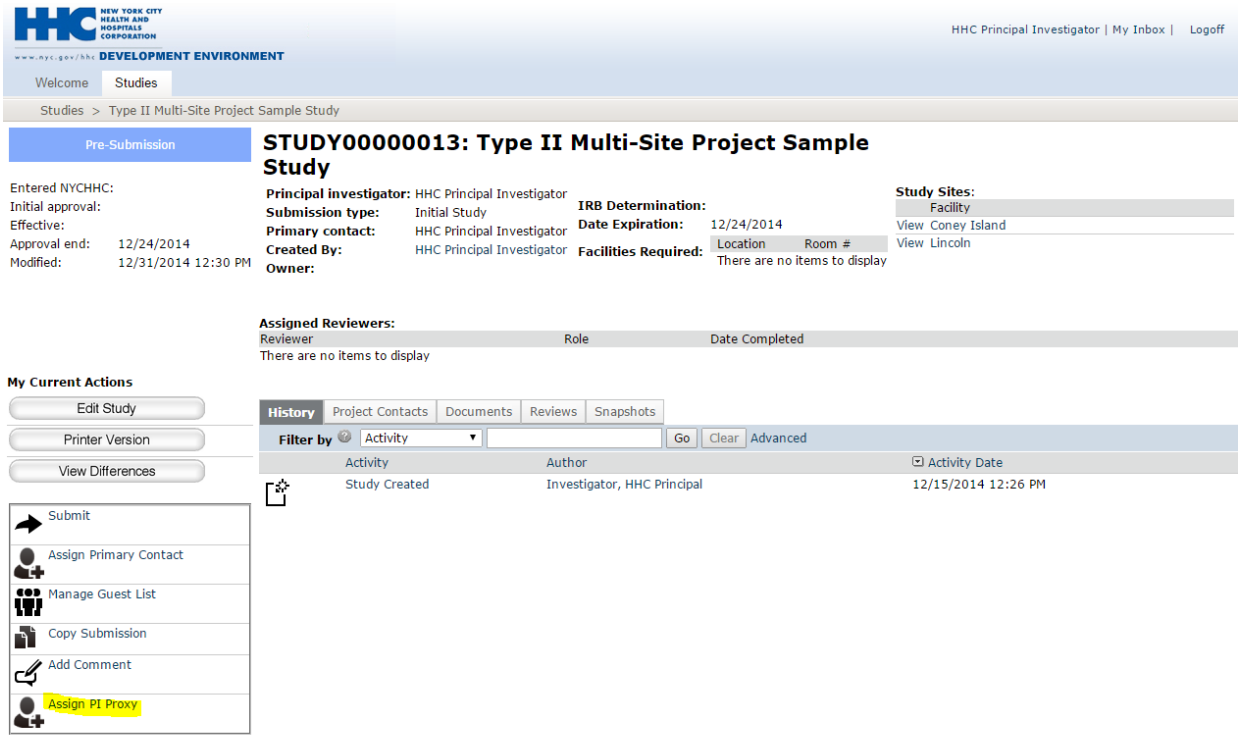


Assigned proxy for one study: a PI can identify a proxy for one study only:

1. The PI and proxy must be registered in the system.
2. After the PI signs on, go to the **Studies** tab at the top left. Locate the study, click on its title.
3. Select **Edit Study** to the left.
4. PI must list the proxy under the **Personnel** section under the **Resources** page of the application.



5. Exit the application.
6. On the left hand side, click on **Assign PI Proxy**.
7. Select proxy's name from the list of personnel.



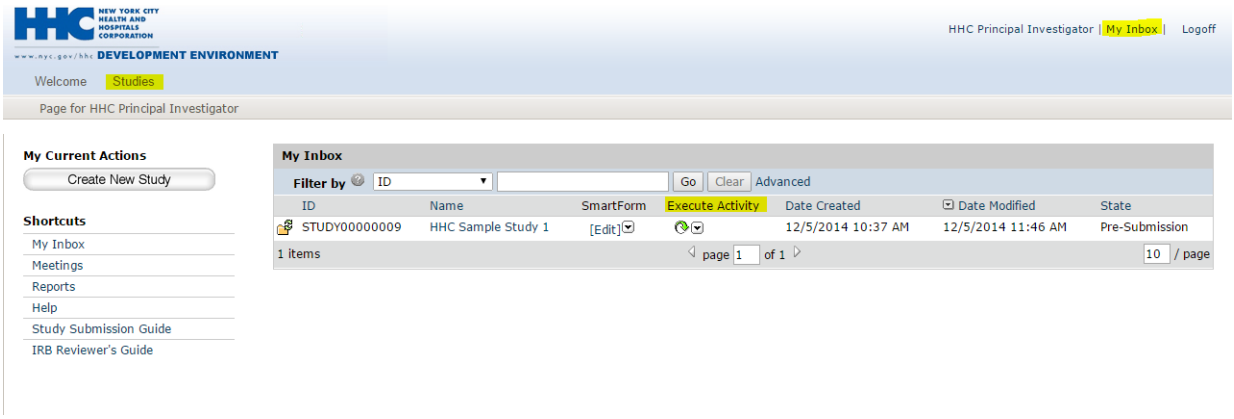
III) MY INBOX (HOMEPAGE)

My Inbox is your homepage. My Inbox will only list studies that require the user to take action ("execute activity") such as submitting a study for review or responding to a clarification request.

You can always return to the **My Inbox** page by clicking on the HHC icon at the top left or by using the **My Inbox** link.

Locating Studies

To locate studies that do not require you to execute an activity, click on **Studies**. The studies are organized by their state (in-review, active, withdrawn, suspended).



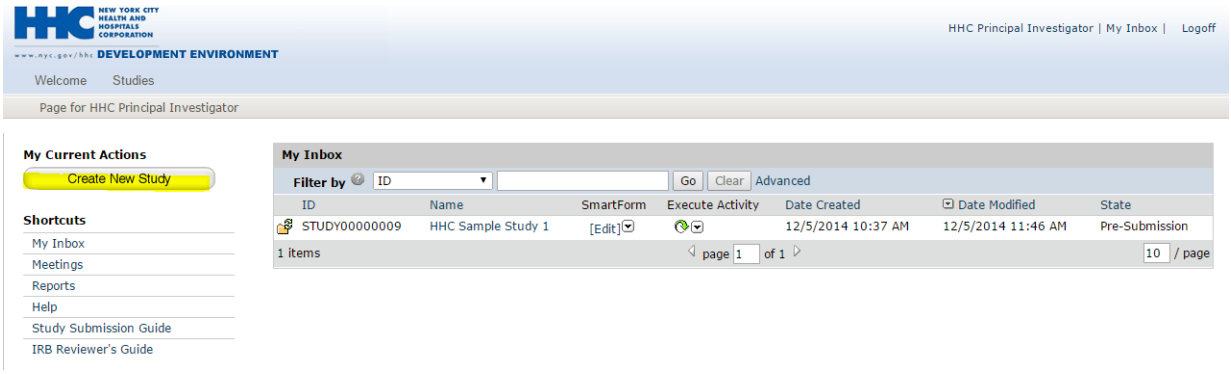
Tip: Use a % sign to search for terms or words that do not appear first. For example, if you need to search for study ID 0000000009, you would enter %9.

IV) CREATING A SINGLE SITE STUDY

You can prepare a new study for HHC approval by entering information into a series of online forms. The number of forms included may change based on the answers provided. The forms tell you where to attach files to provide supporting information.

The simplest approach is to follow the forms in order, answering the questions and clicking **Continue** to save your information and move to the next form. When you reach the end of the series of forms, click the **Finish** button.

1. From My Inbox, click **Create a New Study**.



Basic Information

Fill in the applicable boxes:

1. **Short Title:** Select a short title for your study. STAR will display the short title throughout the system.
2. **Complete Title of Study:** Enter the complete title of the study as it appears on your IRB approval letter.
3. **Site Principal Investigator:** This refers to the PI who will oversee the project at the site. The site PI:
    - Is responsible for the project at their facility and must meet the qualifications of being a PI at HHC (consult HHC Operating Procedures No.: 180-9 for the qualifications).
    - Might differ from the PI of record listed on the IRB documentation. However, the site PI must have been cleared by the IRB as study personnel.
4. **Resident Study:** If this project is part of a student/resident/fellow's required scholarly work, indicate "yes."

5. **Is your project externally funded:**
    - **Yes-** Project receives external money/support through an award or grant where the HHC facility is the prime recipient or subcontractor. See next section.
    - **No-** Project is internally supported by an HHC department or office ("unfunded" project). If you have received a special grant or award from HHC, do not select this option. Go to page 12.

1. **Funder/Sponsor:** Select the entity that directly provides money/support to HHC. Enter the amount awarded to the HHC facility and the award period.

> **Important!** Only enter amounts directly paid to the impacted HHC facility**. If the HHC facility has been subcontracted through an affiliate or another institution, check the subcontract option.** Please attach a copy of the subaward agreement in the Supporting Documents section.
>
> If HHC is subcontracted but there is no money paid to the HHC facility, enter the award amount as "0."

2. **Research Contract Negotiated by Research Administration at Central Office:** All studies that receive money/support from an external institution should have an agreement in place. The contract should either be between HHC and the funder/sponsor (HHC is the prime recipient) or between HHC and the prime recipient (HHC is the subcontractor).
    - **Yes-** Research Administration at Central Office drafted, negotiated and oversaw the entire execution process on behalf of HHC. All contracts executed by Research Administration are signed by the Corporate Chief Medical Officer or his designee.
    - **No-** Identify who drafted, negotiated and oversaw the contracting process between HHC and the funder/sponsor or the prime recipient.
3. **Where Will Study Activities Occur:** Enter only one facility. If this is a multi-site study, please see **Section V**.
4. **Recruitment Only:** Select yes if the study fits the following criteria:
    - Subjects will be recruited or introduced to the study at the Facility for the purpose of meeting the enrollment target.
    - Consenting and other research-related activities will not occur at this facility.
5. **IRB Used:** Select the IRB providing oversight.
6. **IRB Project Number:** Enter the unique ID number given to the project by the IRB.
7. **IRB Determination:** Refer to your IRB approval letter**.** Select Full Board, Expedited or Exempt.

> **Important!** If the IRB determination letter is unavailable, select the best option. This field can be updated at the FRC level if necessary.

8. **IRB Expiration Date:** Enter the expiration date found on the IRB determination letter. This field populates only for Full Board or Expedited studies. This can be updated at the FRC level if unavailable.

Internal Support

1. **HHC Department Funding Project:** Select the department that is supporting the research.

> **Important!** If the project is formally funded by an HHC grant (e.g. CTSI grant), please return to the **Basic Information** page and select "yes" to question #5.

2. **Research Contract Negotiated by Research Administration at Central Office:** If applicable, indicate if Research Administration handled the negotiation process.
3. **Where Will Study Activities Occur:** Enter only one facility. If this is a multi-site study, please see **Section V**.
4. **Recruitment Only:** Select yes if the study fits the following criteria:
    - Subjects will be recruited/introduced to the study at the Facility for the purpose of meeting the enrollment target.
    - Consenting and other research-related activities will not occur at this facility
5. **IRB Used:** Select the IRB providing oversight.
6. **IRB Project Number:** Enter the unique ID number given by the IRB to the project.
7. **IRB Determination:** Refer to your IRB determination letter. Select Full Board, Expedited or Exempt.

> **Important!** If the IRB determination letter is unavailable, select the best option. This field can be updated at the FRC level if necessary.

8. **Date of IRB Expiration:** Enter the expiration date found on the IRB determination letter. This field populates only for Full Board or Expedited studies.

Subject Population

This section asks for more details regarding the subject population being studied.

1. **Who Are Your Subjects:** Indicate all types of subjects recruited during the course of the project.
    - **Enrollment Target:** Indicate the enrollment target for the site.

> **Important!** The enrollment target should be specific to the impacted facility. For example, if Metropolitan Hospital teams with the University of Michigan and Metropolitan needs to recruit 30 out of 100 patients, enter 30 to this question.

2. **Vulnerable Populations:** Indicate if your research involves any of the listed populations.

Subject Interaction

This section pertains to the type of study to be conducted and if there is direct subject contact.

1. **Will there be Direct Subject Interaction:**
    - **Yes**- Interaction includes communication or interpersonal contact between investigator/research team and subject.
        2. **If Yes: Please choose the direct subject interaction method that best describes your approach:** Studies sometimes use several approaches to collect data, please select the primary method.

    - **No**- Absolutely no interaction between investigator/research team and subject.
        2. **If No: Please choose the no direct subject interaction method that best describes your approach:** Select the method used to gather data.

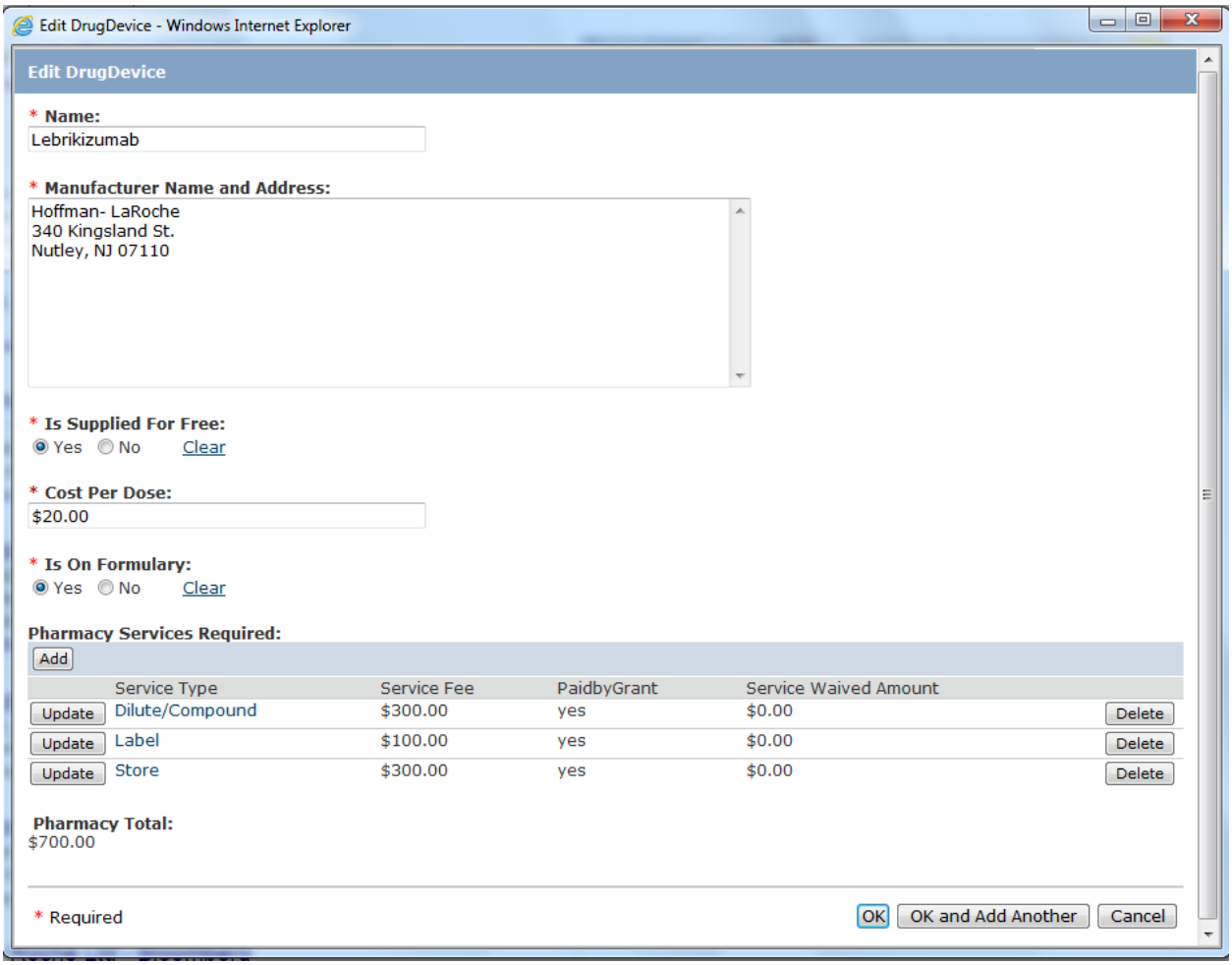
Drug and Device Trials

If you indicated that this was a drug or device trial in the Subject Interaction section, STAR will ask you to complete the drug information.

1. Click on **Add** to start listing investigational drug or device.

2. A pop up screen will appear. Please complete the table and indicate if pharmacy services are required.

3. If some of the information is unavailable, the Pharmacy reviewer has the ability to correct and update the application with the relevant information.


Edit DrugDevice - Windows Internet Explorer
Edit DrugDevice
* Name:
Lebrikizumab
* Manufacturer Name and Address:
Hoffman- LaRoche
340 Kingsland St.
Nutley, NJ 07110
* Is Supplied For Free:
Yes No Clear
* Cost Per Dose:
$20.00
* Is On Formulary:
Yes No Clear
Pharmacy Services Required:
Add
Service Type Service Fee PaidbyGrant Service Waived Amount
Update Dilute/Compound $300.00 yes $0.00 Delete
Update Label $100.00 yes $0.00 Delete
Update Store $300.00 yes $0.00 Delete
Pharmacy Total:
$700.00
* Required
OK
OK and Add Another
Cancel

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Resources

Personnel

Click **Add** to list the PI and personnel working at the site. Per the NYC Health + Hospitals Time and Effort policy, grant effort (%) is required for externally funded studies. Your facility, however, may require that all studies, externally funded or not, include % effort for all study team members. Please consult your FRC for more information.

1. **Study Team Member:** Start with the PI. Use the search function to find the team member; they must be registered in the system.
2. **Member Role:** Select the role that best describes the role of the study team member.
3. **Member Effort:** Select the effort that best describes the effort of the study team member.
4. **Salary Fees**: If this study team member is compensated by a grant, indicate so here.
5. **Grant Effort (%):** If the study team member spends a portion of their time working for the grant and is compensated, enter the percent effort here.
6. **Salary from Grant:** If this information is available, include that here.

OTPS (Other than Personnel Services) Utilization

If the study has a budget and OTPS items are listed, please include them here.

1. Click **Add** to list and describe OTPS items.
2. **Identify**: Select the OTPS item needed. Use the Other options if necessary.
3. **Associated Fee:** Include the total fees associated with this service. If the fee is unknown, leave this section blank. The Finance reviewer can change/update/complete this section.
4. **Description:** Include a brief description of the services requested.
5. **Paid by Grant:** If the study is funded by a grant or an award, indicate if this service is covered.
6. **Waived Amount:** If the associated fee is waived, indicate how much. Finance will double check this amount if it is unavailable.

> **Important!** If the **Associated Fee** is unavailable, Finance can update that section during Committee review if necessary.

Research-related Tests and Procedures

Research- related Procedures and Tests: Enter tests and procedures performed for research purposes only.

> **Tip:** Filter and search for tests and procedures using either the CPT code ("ID") or by the name of the test or procedure ("Description').

Additional Space Needed

If additional space is required to conduct any part of the study at the impacted facility, enter that here. Do not enter space regularly occupied by the study team.

b. Space Needed: Indicate if additional space is needed to conduct any part of the research.

> **Important!** There is no standardized formula across the corporation to calculate the total cost of space per facility. If the total cost of space is unavailable, Finance will enter the correct amount during Committee review.

Medical Records

Please indicate if the study will require medical records and if so, what time of records are required. If the cost of medical records is unknown, please enter "0s." Finance will correct this amount if necessary.

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Medical Records

Please answer the following questions; fields marked with * are required.

* **1.Record type(s):**

- (•) Inpatient
- ( ) Outpatient
- ( ) Both
- ( ) Not Applicable

Clear

	Number	Cost	Waived?
2a.Number of medical records that need to be pulled	0	$0.00	☑
2b.How many charts need to be pulled offsite at a storage/other facility?	0	$0.00	☑
2c.Number of electronic medical records:	13000	$0.00	☑

3.Total Cost:

$0.00

Supporting Documents

Every STAR application is required to attach the minimum for HHC approval:

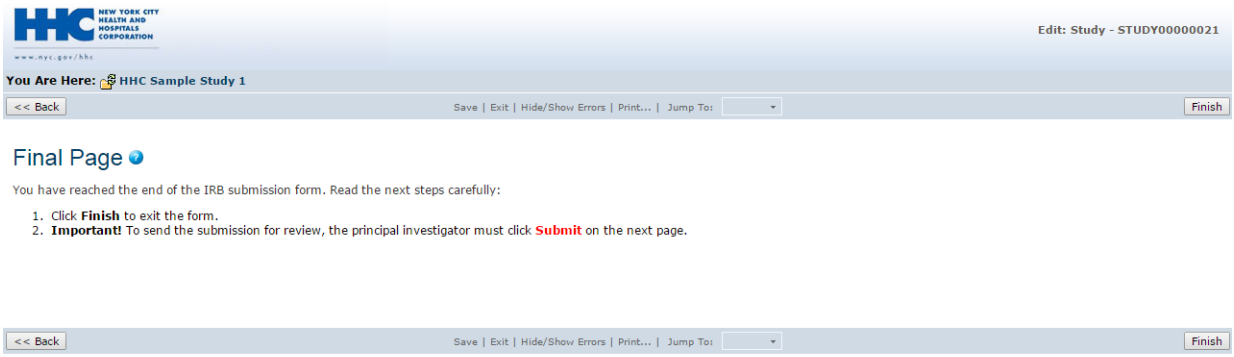
- IRB determination letter (must be full board, expedited or exempt)
- Protocol
- Informed consent form (assent or waiver)
- HIPAA research authorization form (or waiver) if separate from the informed consent form
- Budget if applicable
- Contract/agreement if applicable

> **Important!** Some facilities require additional documents. Contact your FRC for a complete list of site-specific required documents.

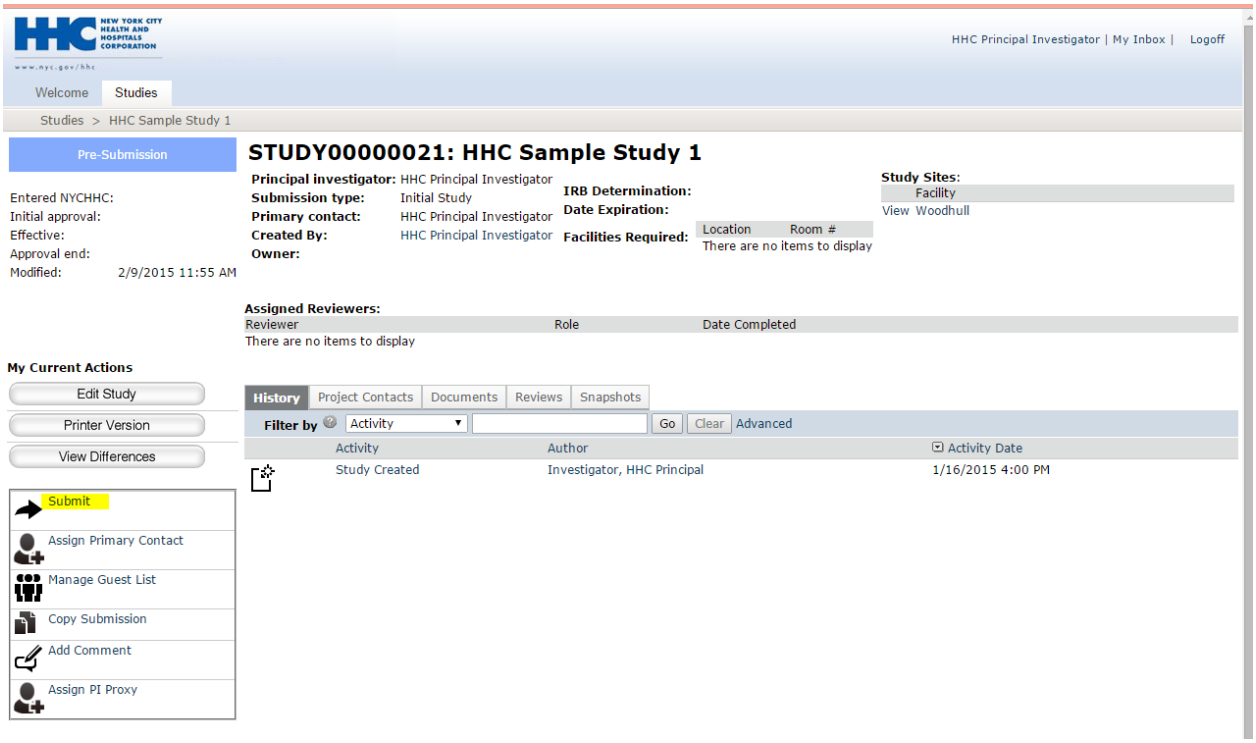
Submitting Your Application

After supporting documents are attached and the PI ensures the application is complete, the PI should submit the application in two steps.

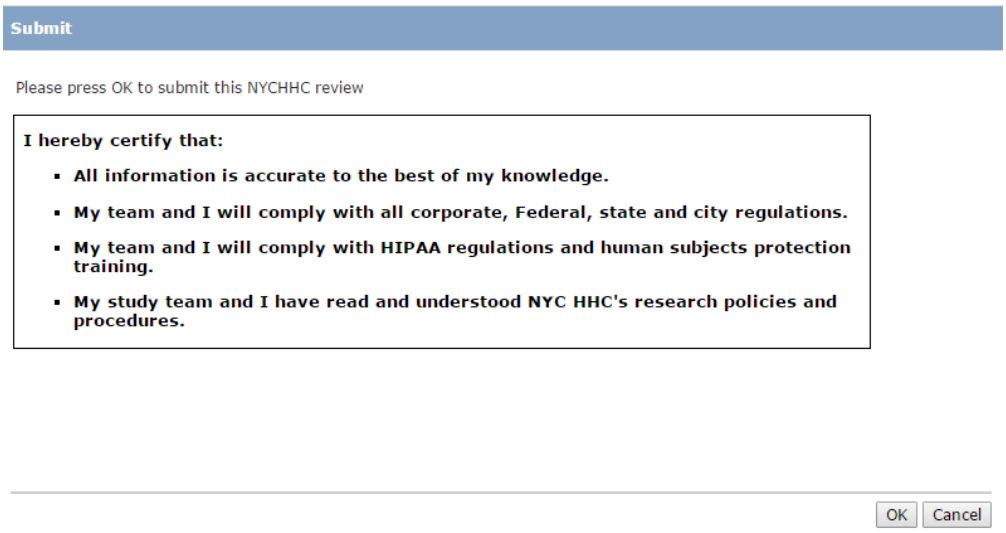
1. Select **Finish** on the Final Page



2. Select **Submit** on the Study History Page



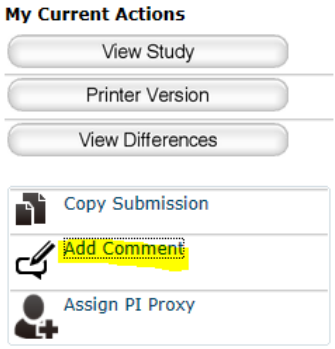
3. The PI will be prompted to certify the following statements. After certification, the research application will be formally submitted and enter the FRC Initial Review state.

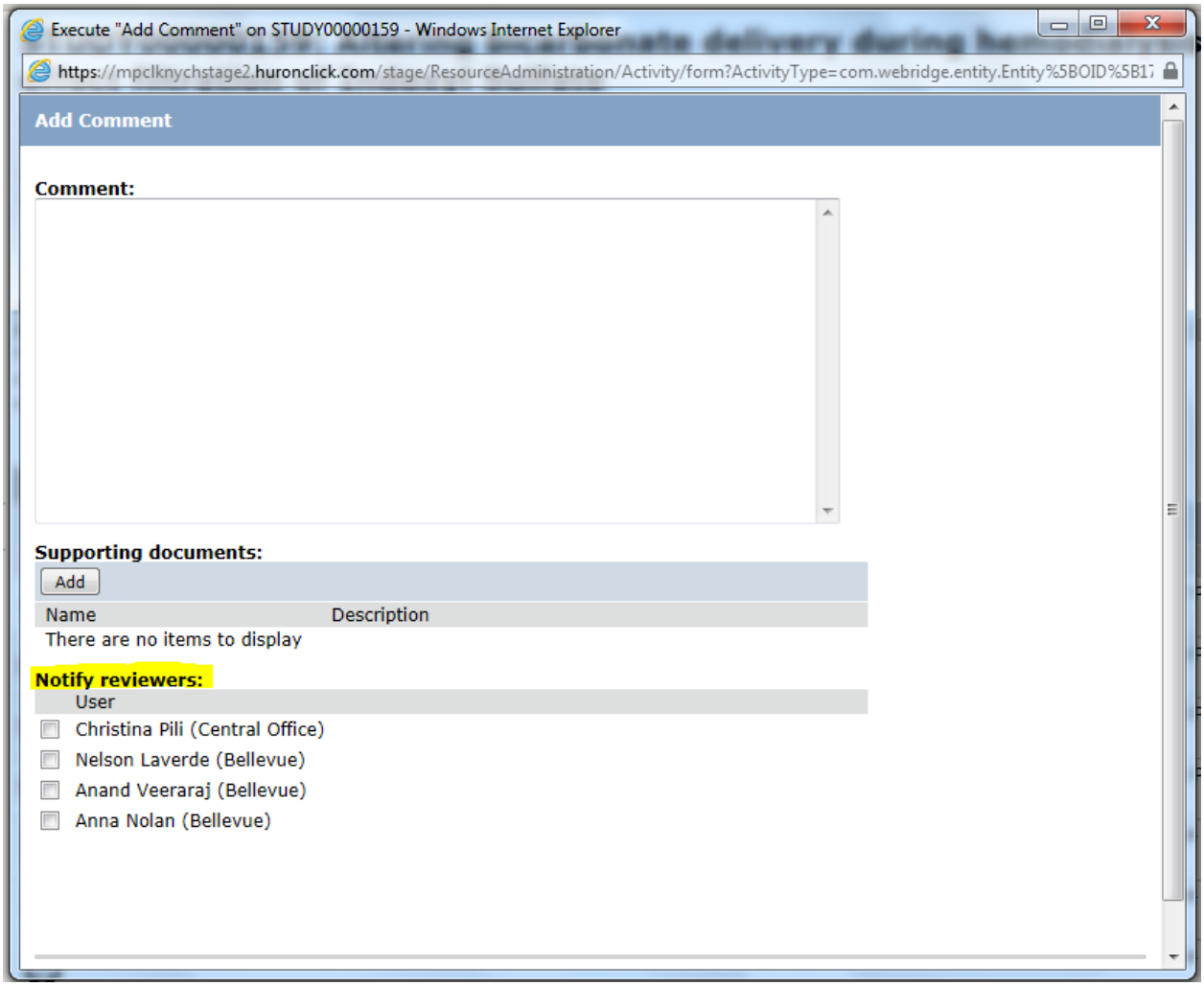


Communicating with the Reviewers

Adding Comments

After submitting your application, if you need to correspond with Reviewers, you can use the **Add Comment** activity from the study record page. If the message is for a specific reviewer, you can select to notify that reviewer. The selected reviewer(s) will receive an email notification that there is a comment for them in the system.





Receiving Comments

When a reviewer sends or responds to a comment, the PI (and any assigned proxies) will receive an email notification from the system.

V) MULTI SITE STUDIES

When a project has multiple arms at two or more HHC facilities, the project is considered a multi- site study. There are two kinds of multi-site studies:

Type 1: A single-site study with HHC approval (or currently under review at the FRC stage or later) that seeks expansion to other HHC facilities. Typically, the expansion to other HHC facilities was not part of the original implementation plan.

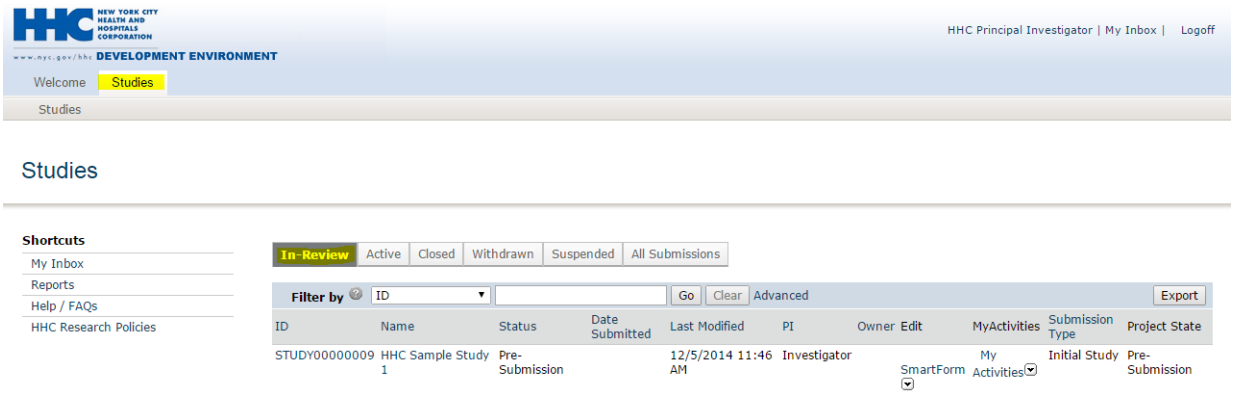
There are two options to submit an application of this type: **1)** the PI can copy the existing application or **2)** the PI at the additional facility (site PI) can start a new application (see directions for the entering a single site study, **Section IV**).

Type 2: A study that is intended to start as multi-site project prior to applying for HHC approval.

> **TIP:** If the PI has not yet submitted the application for review, follow directions for Type 2.

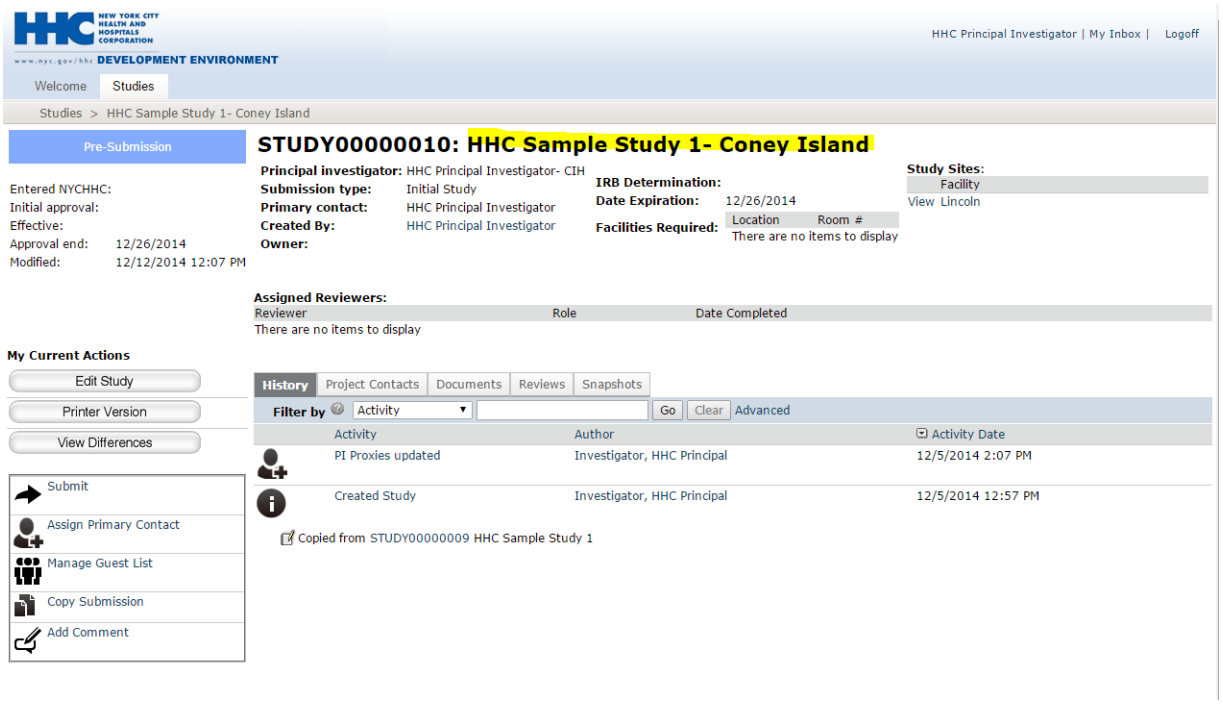
Type I- Completing the STAR APPLICATION for Multi-Site Studies

1. From **My Inbox**, go to the Studies tab and locate the study under the appropriate tab.



2. Click on the title.
3. On the left-hand side, select **Copy Submission**.

4. Name the title using this format: Original Title_Additional_FacilityName. For the following example, the copied submission will be named "HHC Sample Study 1_Coney Island."



5. When a site PI is elected for the additional facility, the PI must enter the name of the site PI in the copied submission (Basic Information page, question #3). Please note the site PI must be registered in the system.
6. Save and exit the application.
7. The application will appear in the site PI's **My Inbox**.
8. The site PI can now tailor the application to their facility.
9. Once the site PI completes the customization, the application is ready for submission.

> **Important!** Remember that each leg of a multi-site study receives HHC approval individually through STAR. Ex: If a study that will take place at Lincoln and Coney Island are both under HHC approval review, and Lincoln receives HHC approval first, Lincoln can engage in study activities as soon as HHC approval is granted.

Type II- Completing the STAR APPLICATION for Multi-Site Studies

Type II applications are intended to be multi-site *prior* to seeking HHC approval/study implementation. When a multi-site application is submitted, it is routed to Research Administration (RA) at Central Office so RA can assist with the coordination of the project.

1. Click on **Create New Study** from **My Inbox** page.
2. An initial application will be created.

> **Important!** The initial Type II application should provide an overview of the project. After RA performs a preliminary review, the application will be copied and sent to each FRC at the impacted facilities. The site PI can then tailor the application to their facility before continuing the review process.

3. Complete and submit application for RA review.

> **Tip**: **IRB Used**
>
> When multiple IRBs are used, upload documents from the IRB that provides oversight for the most impacted facilities. This will save time for when the Site PI tailors the application to their facility.

> **Important! Personnel**
>
> The person completing this initial multi-site application must list the site PIs in the personnel section and then grant them PI access.

4. RA will contact the PI and will let you know if they have questions regarding the coordination of the project. They will loop in the FRCs at this point as well.

VI) Modifications, Continued Approval and Closeouts

Modifications

After a study has received HHC approval, it is the PI's responsibility to upload any updated documents to STAR that have been modified and subsequently approved by the IRB after HHC approval was granted.

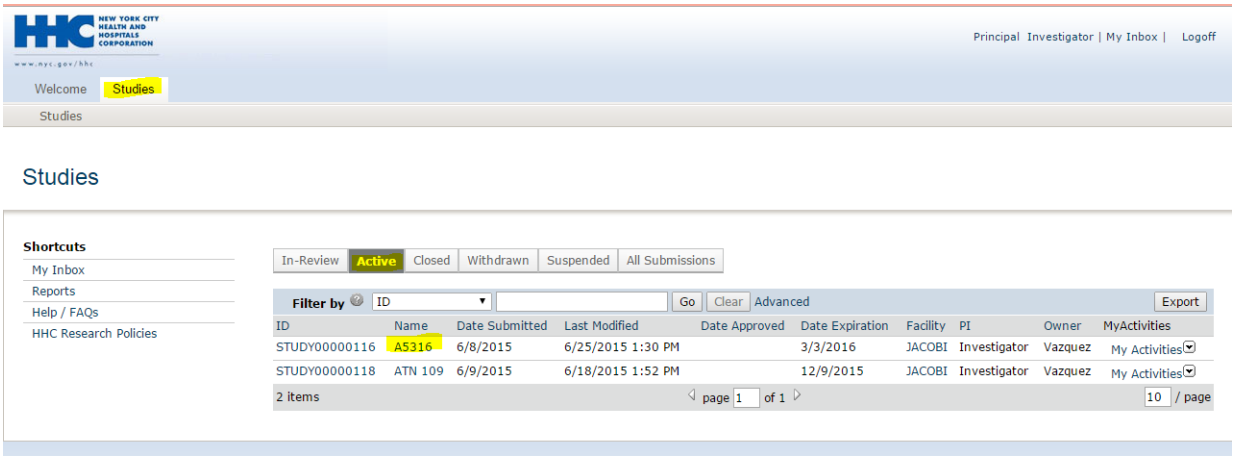
What is considered a modification?

A modification is any change to a protocol that has been approved by the IRB during the period the approval was given. This includes any changes in study personnel, study procedures, the consenting process or any other change in the implementation of the study that differs from what was originally approved by the IRB.

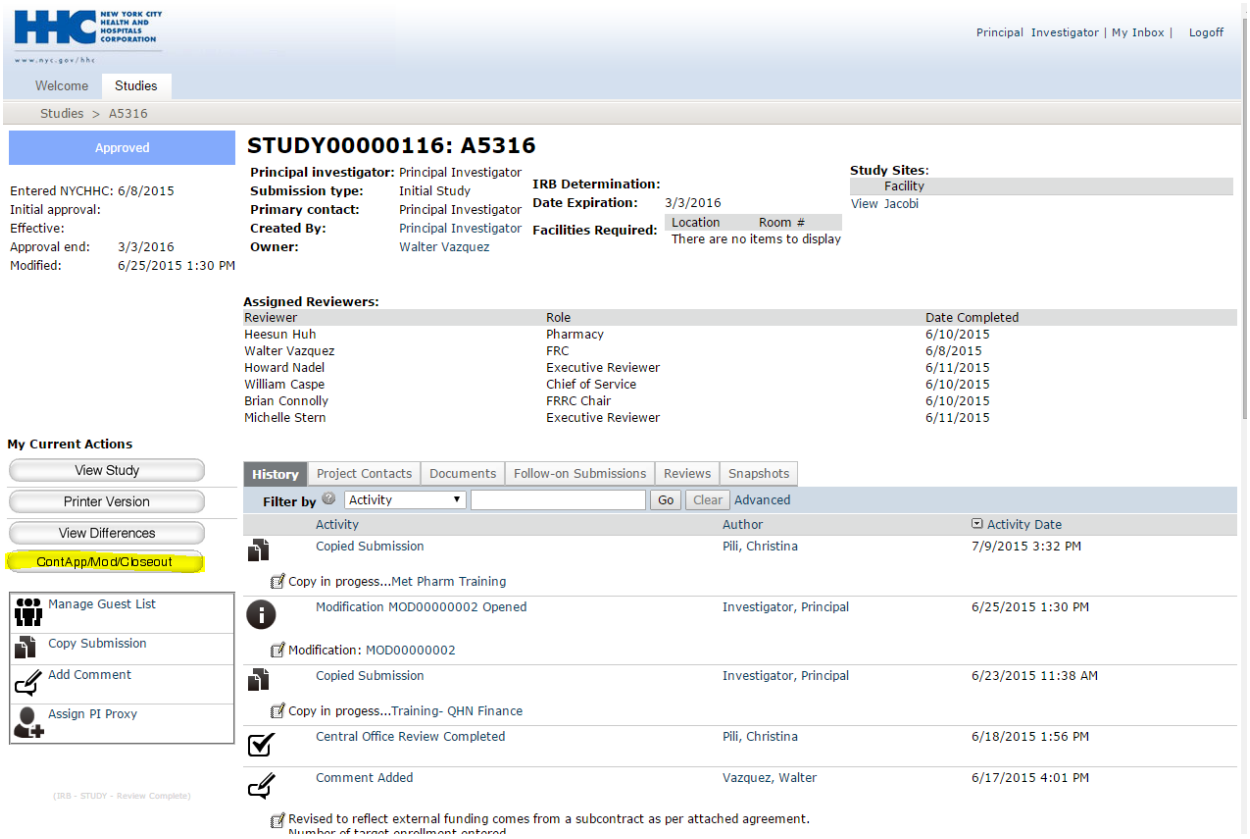
> **Important! Some modifications are automatically approved.**
>
> When a document has been approved by the IRB, it is unnecessary for an FRC to review and approve a modification. However, if a PI has indicated that the project will undergo major operational, contractual or financial changes, or the scope of the project is changing, review by the FRC will be necessary. In some cases, a new application for HHC approval will be required.

To submit a modification:

1. From your homepage, click on the **Studies** tab, then the **Active** tab, then the **Name** of the study.



2. Click on the **Cont App/Mod/Closeout** button to the left.



3. Select **Modification**.
4. Indicate which sections need to be modified. If you answered "yes" to question #2, please explain the changes.
5. After pressing **Continue**, you will be brought to your original application. Update the sections that need to be modified.
6. **Submit** your modification application.

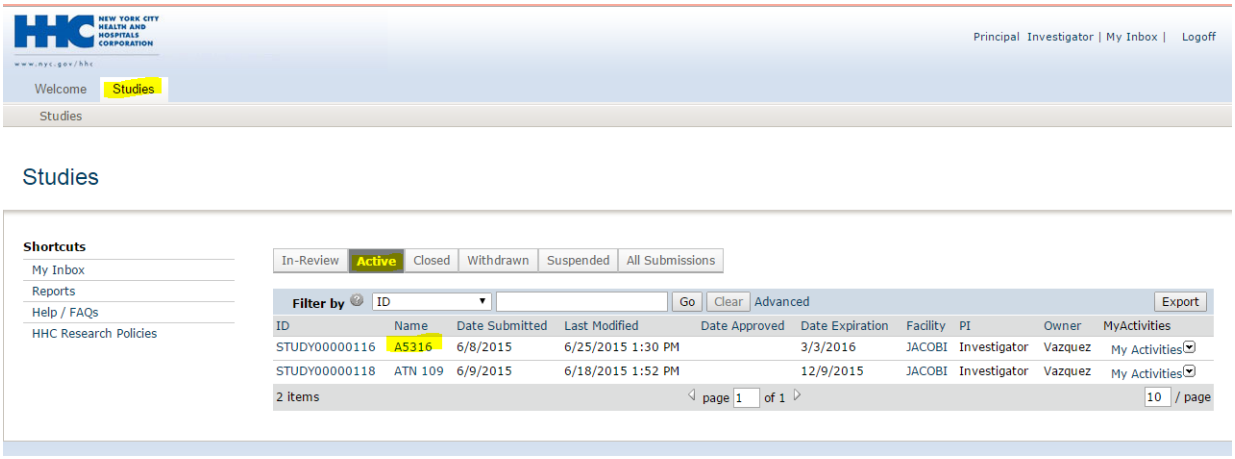
Continued Approval

For expedited and full board studies, HHC approval is valid only when Continued Approval has been granted by the IRB and STAR has been updated to reflect this renewal.

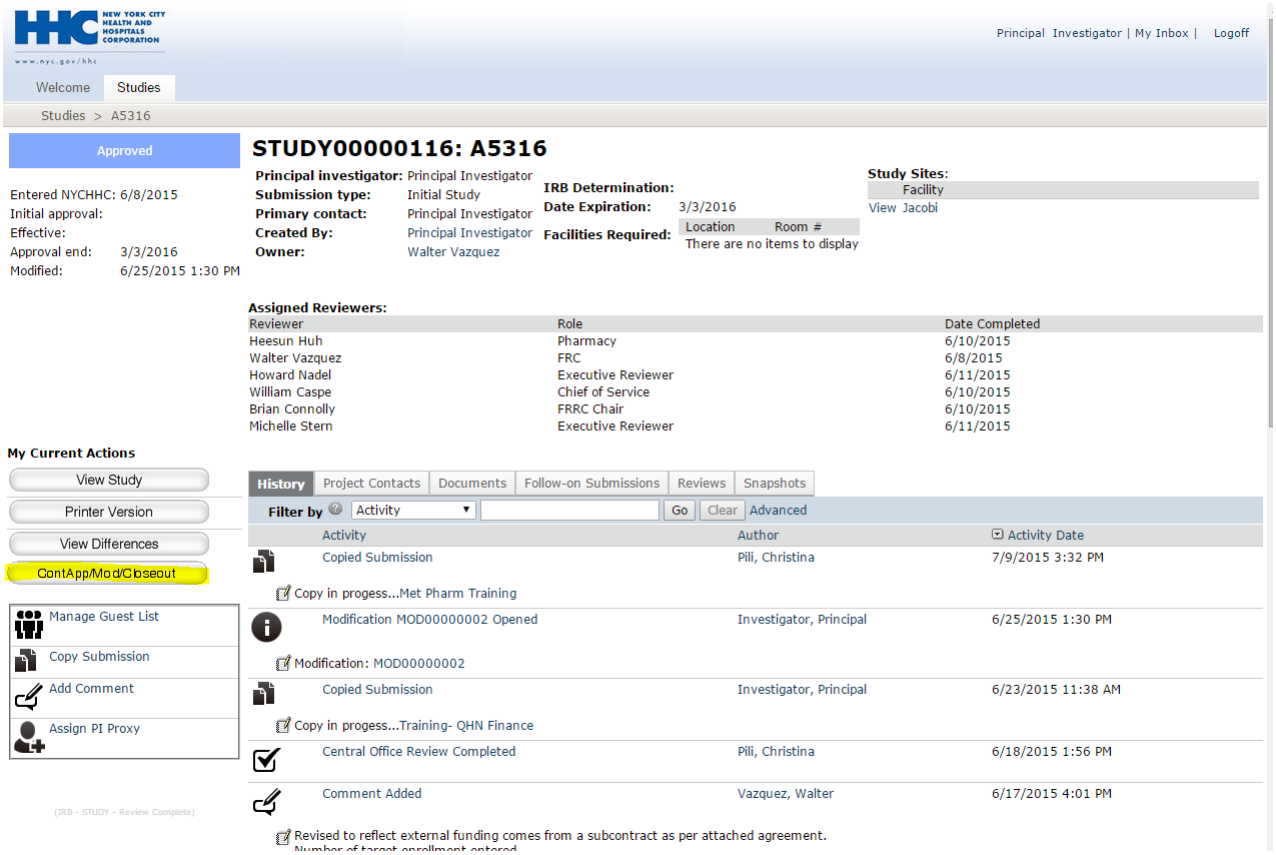
> **Important! STAR will suspend studies if a PI has not submitted their Continued Approval application within 10 business days of the study's IRB expiration date. If a study has been suspended, this means HHC approval is no longer valid and all study activities must stop.**

To submit an application for Continued Approval:

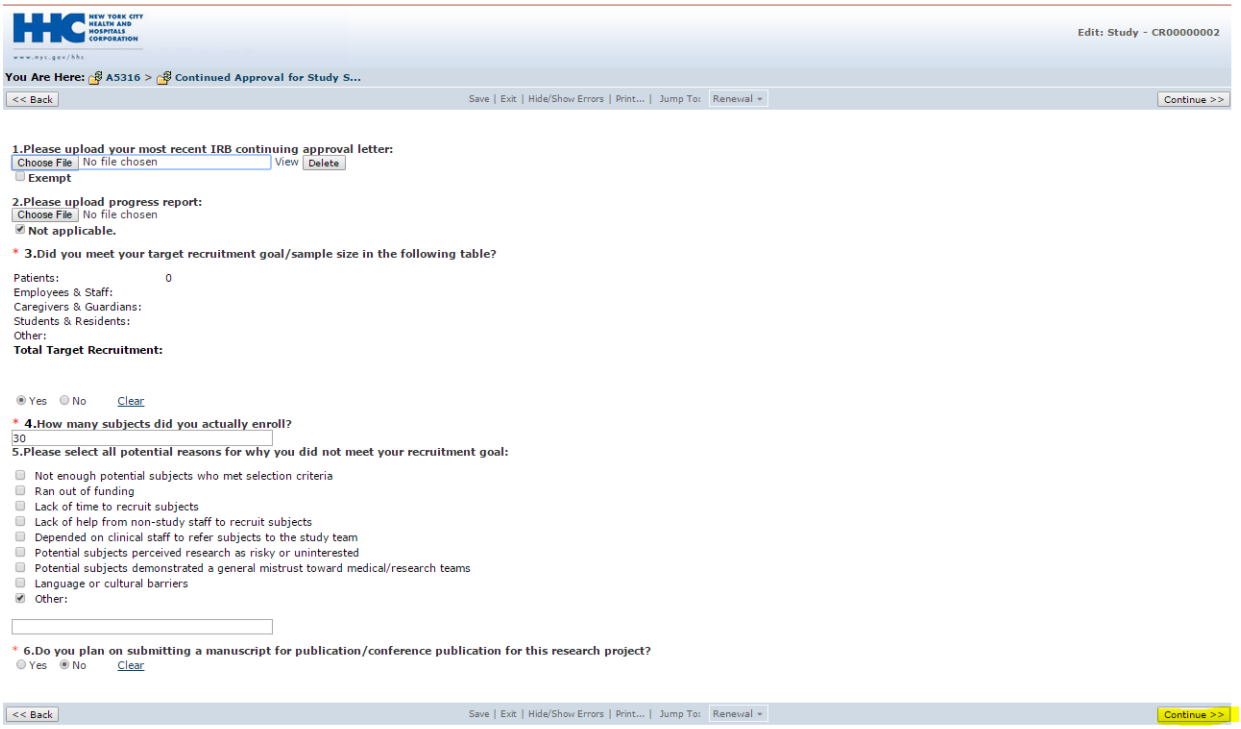
1. From your homepage, click on the **Studies** tab, then the **Active** tab, then the **Name** of the study.



2. Click on the **Cont App/Mod/Closeout** button to the left.



3. Select **Continued Approval.**
4. Complete Continued Approval application
5. Press **continue**, then **submit** your Continued Approval application.



Combined Modifications and Continued Approval

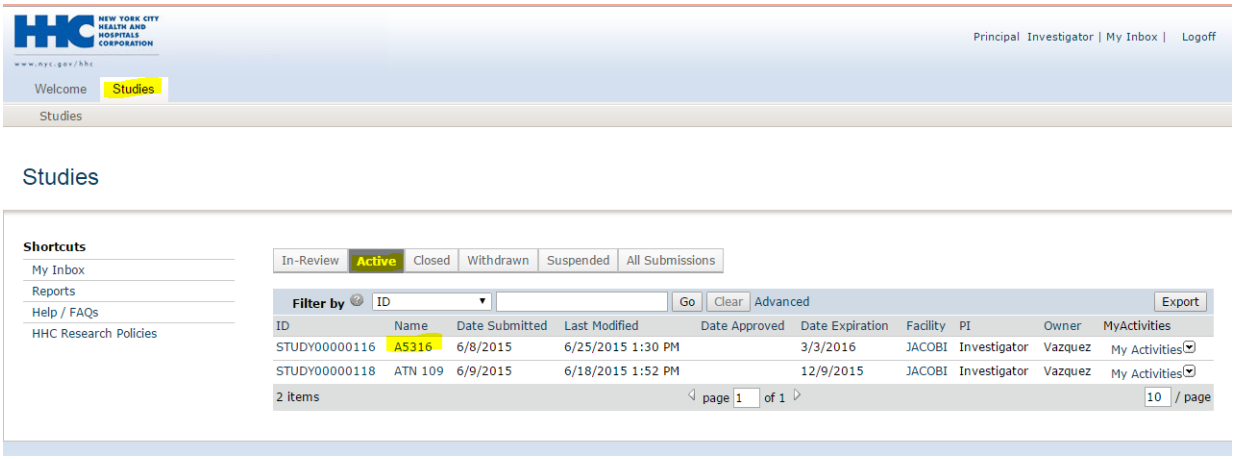
If you need to submit a modification and indicate that Continued Approval has been granted by the IRB, you have the option of completing both tasks simultaneously.

Closeout

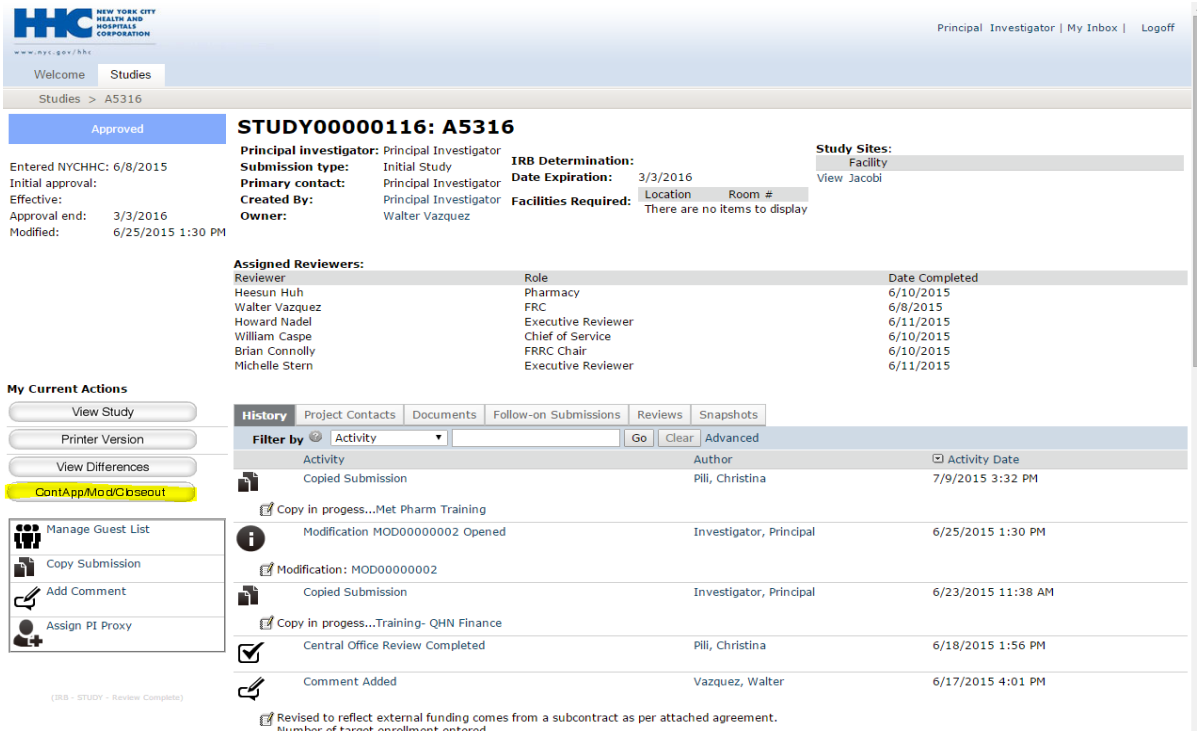
If you have completed your study or if the IRB, the Research Administration Office or any other authorized entity has closed out your study, you must formally close out the project in STAR.

To close out your study:

1. From your homepage, click on the **Studies** tab, then the **Active** tab, then the **Name** of the study.

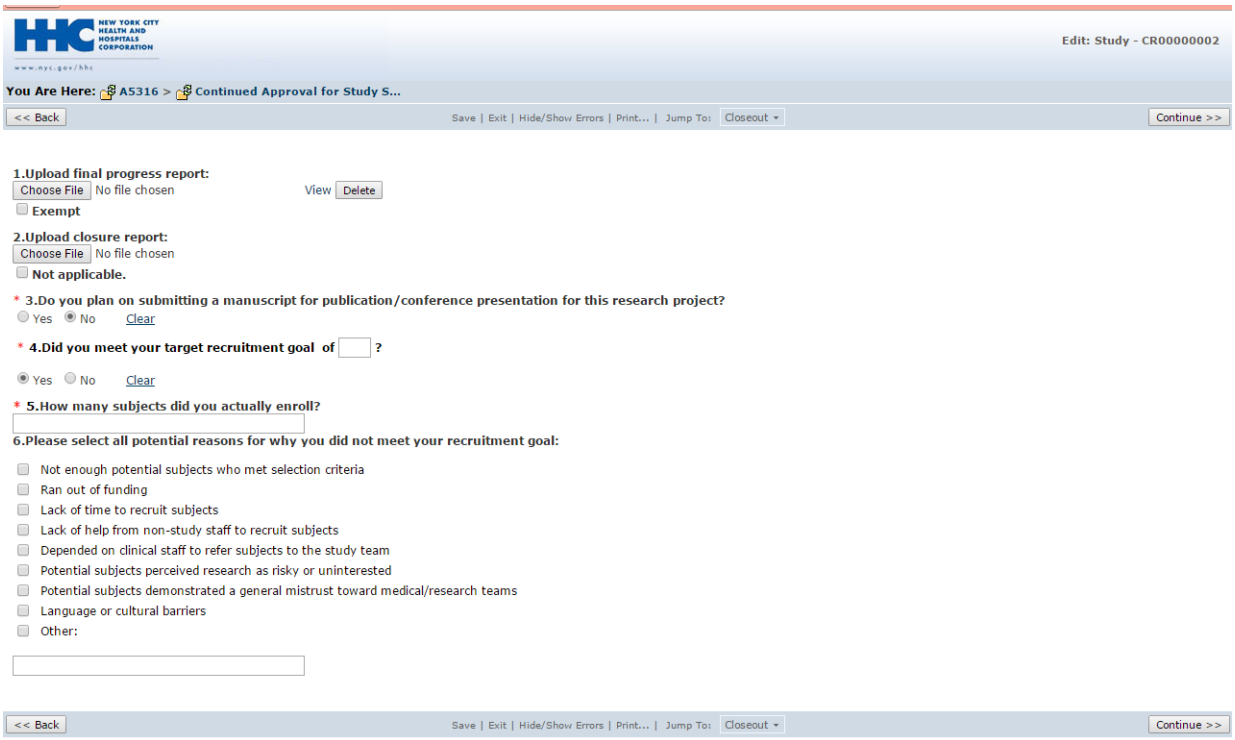


2. Click on the **Cont App/Mod/Closeout** button to the left.



3. Select **Closeout.**

4. **Complete application below. You will need the following documents: IRB Closeout letter and final progress report, if applicable**



Discarding applications

If a study is withdrawn, the study will return to **My Inbox** and remain in the Pre-Submission phase.

1. If there is no intention of re-submitting, from the study record page, under **My Current Actions**, click on **Discard**.
2. The application will be removed from **My Inbox** and will be permanently deleted.