

Create a New Study:

1. On the “My Inbox” page (this should also be your home page), click the “Create New Study” button on the left side of your page.



2. Basic Study Information:
 - a. Input basic study information as prompted. Be sure to click on the question mark buttons for further clarification.
 - b. When attaching protocol, please also be sure to also attach the protocol summary if the study is multisite.

Basic Information ⓘ

1. * Title of study:
2. * Short title: ⓘ
3. * Brief description: ⓘ
4. * Principal Investigator: Rebecca Simms (pi) ⓘ
5. * Does the investigator have a financial interest related to this research? ⓘ
 Yes No [Clear](#)
6. * Will an external IRB act as the IRB of record for this study? ⓘ
 Yes No [Clear](#)
7. * What kind of study is this? ⓘ
 Multi-site study (More than one site will conduct the entire study)
 Collaborative study (each site will conduct a portion of the study)
 Single-site study
[Clear](#)
8. * Attach the protocol: ⓘ

Document
 New-Investigator-tip-sheet FINAL 9-2018.doc(0.01)

3. Funding Sources:
 - a. Add a funding source if applicable. If the funding source is not in the system, please contact the IRB at 404-785-7555 or at Meredith.Capasse@choa.org

Funding Sources ⓘ

1. Identify each organization supplying funding for the study:

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
There are no items to display			

4. Study Team Members:

- a. In section 1, click “Add” to add study members and fill out information as prompted by the pop-up window. If a study team member has a CHOA network ID and cannot be found in the eIRB system, please contact the IRB at 404-785-7555 or at Meredith.Capasse@choa.org

1. * Study team member: ?

2. Role in research: (check all that apply)

- Co-investigator
- Data Analyst
- Research Assistant
- Statistician
- Lay Observer

3. * Is the team member involved in the consent process?

Yes No [Clear](#)

4. * Does the team member have a financial interest related to this research? ?

Yes No [Clear](#)

* Required

OK OK and Add Another Cancel

- b. In section 2, please add all external (those who do not have a CHOA network ID) study team members using the external team member spreadsheet. To access the spreadsheet, click on the question mark icon and click on the spreadsheet link in the pop up window.

Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research: ?

+ Add

Name	Roles	Financial Interest	Phone
There are no items to display			

2. External team member information: ?

+ Add

Name
ExternalStaffListing.xls

Upload Revision

1. Click question mark icon

2. Download spreadsheet to add external team members

External Team Member Information

An External Team Member is someone that does not have an eIRB user ID. Please complete the [spreadsheet](#) to list all external team members.

5. Study Scope – Answer questions as prompted.
6. Local Research Locations
 - a. Add all local research locations. Click the ellipses to see if the research location is already in the system.

Add Research Location Information

Click for list of research locations already in the eIRB system.

1. Select the research location:

- b. If the research location is not in the eIRB system, fill out the bottom section of the pop up window as best you can.

If you cannot find the research location in the list above, enter its information here:

a. Location name:

b. Location address:

Address line 1

Address line 2

Address line 3

City

State or province

Postal code

Country

c. Contact name:

d. Contact phone:

e. Contact e-mail:

7. Drug Information (if applicable)
 - a. This section will appear if you indicated that a drug will be used in the “Study Scope” section.
 - b. Provide drug name, IND information (if applicable), and any supporting documents, such as Investigator’s Brochures, FDA letters, etc.

Drugs

1. * List all drugs, biologics, foods, and dietary supplements to be used in the study:

Generic Name	Brand Name
There are no items to display	

2. * Will the study be conducted under any IND numbers?


Yes No [Clear](#)

3. Attach files: (such as IND or other information that was not attached for a specific drug)

Document	Category	Date Modified
There are no items to display		


8. Device Information (if applicable)

- a. This section will appear if you indicated that a device will be used in the “Study Scope” section.
- b. Provide device name, IDE information, and any supporting documents (manuals, FDA letters, etc.).


Devices 

1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:

+ Add	
Device	Humanitarian Use Device
There are no items to display	

2. * Device exemptions applicable to this study: 

- IDE number
 - HDE number
 - Claim of abbreviated IDE (nonsignificant risk device)
 - Exempt from IDE requirements
- [Clear](#)

3. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device) 

+ Add		
Document	Category	Date Modified
There are no items to display		

9. Local Site Documents

- a. In section 1, include consent documents (informed consent form, assent, revocation letter etc.)
- b. In section 2, add recruitment materials if applicable. This would include recruitment letters, flyers, etc.
- c. Other Attachments
 - i. Attach departmental approval here. This is required. If you also have approvals from outside departments, please also include here. This applies if you are enrolling subjects for your study from a department that is not your own (i.e. enrolling subjects that are not your patients).
 - ii. Attach any other documents that are relevant to the study (questionnaires, DSMB reports, departmental approvals, outside department approvals, etc.)

10. To submit your study:

- a. Review the submission form to make sure information is correct and all relevant documents have been attached.
- b. Click “Finish” on the last page of the submission form. You will be redirected to the main page of the study.
- c. **Important:** On the main study page, please be sure to click “Submit” on the left side of the page. Your study will not be submitted to the IRB if you do not click “Submit”. To double check that the study has been submitted, the study status should note that the study is in Pre-Review.

Next Steps

- Edit Study
- Printer Version
- View Differences
- Submit**
- Assign Primary Contact
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Add Comment
- Copy Submission
- Discard

submission type: Initial Study
Primary contact: Rebecca Simn
PI proxies:

Pre-Submission → Pre-R
 Clarifi Requ

History Funding Conta

Filter by ? Activity

Activity

- Study Created

Submitting a Modification:

1. Go to the main page for the study requiring modification.
2. On the left side of the page, click "Create Modification/CR". Please note that if you already have an open modification, you cannot submit a new modification until the open modification has been approved or withdrawn.

Approved

Entered IRB: 9/5/2018 1:40 PM
 Initial approval: 9/5/2018
 Initial effective: 9/5/2018
 Effective: 9/5/2018
 Approval end: 9/4/2019
 Last updated: 9/20/2018 9:46 AM

Next Steps

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

STUDY0000004

Principal investigator: Rebecca Simn
Submission type: Initial Study
Primary contact: Rebecca Simn
PI proxies:

Pre-Submission → Pre-Rev
 Clarifica Reques

History Funding Contac

Filter by ? Activity

Activity

- Modification MOD00000017 O
- Modification: MOD00000017

3. Select “Modification/Update” and select the scope of your modification (you can select both scopes if applicable). NOTE: If you are making changes to study team members and need to update any study documents (protocol or consents), you must also click Other Parts of the Study as well as Study Team member Info.

Modification / Continuing Review / Study Closure

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

- Continuing Review
 Modification / Update
 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

4. Fill out the Modification Information page.
- Please note that sections 1 and 2 of this page are not required. You can skip these sections if they are not relevant to the modification.
 - In section 3, please be sure to list all changes being made to the study as part of the modification.

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)

- 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

3. * Summarize the modifications: ?

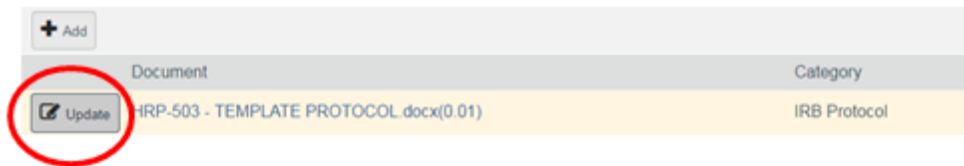
Note all changes being made to the study



|

- The modification will now take you through every page of your initial submission form. Make the modifications where applicable.

*** If updating study documents that have already been approved, please be sure to click the “Update” button next to the currently approved document to add the new version of the document. If updating an approved document for the first time, update the approved document with a clean version of the document and add a tracked version. The tracked version can be updated with subsequent tracked versions for future updates.



- To submit your study:
 - Review the modification form to make sure information is correct and all modifications have been made.
 - Click “Finish” on the last page of the modification form. You will be redirected to the modification page of the study.
 - Important:** On the main modification page, please be sure to click “Submit” on the left side of the page. Your study will not be submitted to the IRB if you do not click “Submit”.

Pre-Submission
Last updated: 1/31/2019 12:09 PM

Principal investigator: Rebecca Simms (pi)
Submission type: Modification
Primary contact: Rebecca Simms (pi)

IRB office: Office for Human Subject Protection
IRB coordinator:
Regulatory authority: Pre-2016 Requirements

Next Steps

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

MOD00000018: Modification #1 for Study Most Important

Flowchart: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete. Clarification Requested and Modifications Required are shown as feedback loops between Pre-Review, IRB Review, and Post-Review.

History: Contacts, Documents, Related RNIs, Snapshots

Filter by: Activity [Enter text to search for] [Add Filter] [Clear All]

No data to display.