

Click IRB ReferenceGuide

Changing the Principal Investigator



How will this guide help me?

This guide will walk you through changing the Principal Investigator (PI) for a Single Site or Multi-Site Study where Seattle Children's is serving as the single IRB. For all external IRB studies, please review the external IRB guide for help in changing the PI.

How to Change the Principal Investigator

NOTE: The current Principal Investigator (PI), and not any assigned PI proxies, is the only one who can submit a modification to change the PI. If the current PI is no longer at Seattle Children's and/or does not have access to Click, please contact the [IRB](#) for assistance.

Step 1 Current PI logs in Click IRB

Click
a Huron solution

Login with your Seattle Children's user name and password.

User Name:

Password:

Remember me

After signing into this site, you are bound by the terms and conditions set forth when you received your account.

Trouble Logging in? Need [Help?](#)

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Step 2

- After logging into Click, find the desired study (See Navigating Click IRB Quick Guide for help finding your study)
- Click the **Create Modification/CR** button in the Next Steps menu on the left side of the study page.

Approved STUDY00002737: 2018.10.22 Polek Test Study

Entered IRB: 10/22/2018 3:45 PM
Initial approval: 10/22/2018
Initial effective: 10/22/2018
Effective: 10/22/2018
Approval end: 10/21/2019
Last updated: 10/22/2018 3:47 PM

Principal investigator: PI NI
Submission type: Initial Study
Primary contact: PI NI
PI proxies:

IRB office: HSPP (IRB Office)
Study Code:
IRB coordinator: Tara Polek
Letter: Correspondence_for_STUDY00002737.pdf(0.01)
Regulatory authority: Pre-2018 Requirements

Next Steps

- View Study
- Printer Version
- View Differences
- Create Modification/CR** 1
- Report New Information

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested (between Pre-Review and IRB Review, and between IRB Review and Post-Review)

Modifications Required (between Post-Review and Review Complete)

History: Funding, Project Contacts, Documents, Follow-on Submissions, Reviews, Snapshots

Filter: Activity (dropdown), Enter text to search for, Go, + Add Filter, X Clear All

Activity	Author	Activity Date
Letter Sent	Polek, Tara	10/22/2018 3:47 PM
Correspondence_for_STUDY00002737.pdf		

Step 3

- Choose **“Modification”** from the options
- Always select **“Other Parts of the Study”** to change the PI (since the PI is found on the Basic Information SmartForm)
- Consider selecting **“Study team member information”** if you need to move the current PI to a study team member role or if you need to remove a study team member who is being promoted to PI
- **Important!** Make these selections carefully; once you move forward from this screen, you cannot change the type or scope of the modification.

Modification / Continuing Review / Study Closure

Please choose carefully; you cannot change your responses once you click Next.

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

- Continuing Review
- Modification
- Modification and Continuing Review

Check this box if you need to change study staff along with changing the PI (e.g. removing someone who is being promoted to PI and/or moving the current PI to a study staff role)

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

Modification scope:

- Study team member information
- Other parts of the study

Changes to the PI will always require this box to be checked

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Step 4 Complete the **Modification Information** SmartForm:

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 Other attachments section of the Local Site Documents page.

3. * Summarize the modifications: **?**

Changing the PI of the study; PI will become a study staff member

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Step 5

- Click **Continue** to access the **Basic Information** SmartForm.
- In the **Principal Investigator** section, click the box next the the current PI's name and choose the new PI.

Basic Information ?

1. * **Title of study:**
2018.10.22 Polek Test Study

2. * **Short title:** ?
2018.10.22 Polek Test Study

3. * **Brief description:** ?
2018.10.22 Polek Test Study

4. * **Principal investigator:**
PI NI ... **Click here to change the PI**

5. * **Will an external IRB act as the IRB of record for this study?** ?
 Yes No [Clear](#)

6. * **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](#)

7. * **Attach the protocol:** (Templates available in the [Library](#)) ?

+ Add
Document
Update HRP 503 - Protocol.docx(0.01)

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Step 6

- Click **Continue** and navigate to the **Study Team Members** SmartForm.
- Make the needed changes to the study team listing.

Study Team Members

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

Click here to remove study staff as desired

Select this button to add the PI as current staff if desired

Name	Roles	Disclosure Status	Involved in Consent	E-mail	Phone
Anthony Pena	Co-PI			Anthony.Pena@seattlechildrens.org	206-884-8161

Select this button to change current staff

Step 6

- Make the desired modifications to the remaining pages (e.g., update your study SmartForm record, which could include updating consent forms or other study documents)
- Click Save and Exit.

Step 7

- From the Modification Workspace, click **Submit** in the Next Steps menu.
- The request to change PI will be effective once the modification request has been approved by the IRB.

Important! Only the PI, and not his/her proxy can click Submit for a Modification to change the PI.

Pre-Submission MOD00004694: Modification #1 for Study 2018.10.22 Polek Test Study

Last updated: 10/22/2018 4:11 PM

Principal investigator: Anthony Pena
 Submission type: Modification
 Primary contact: PI NI

IRB office: HSPP (IRB Office)
 IRB coordinator:
 Regulatory authority: Pre-2018 Requirements

Next Steps

Edit Modification/CR
 Printer Version
 View Differences

Submit **1**
 Manage Ancillary Reviews
 Add Comment
 Discard

History | Contacts | Documents | Related RNIs | Snapshots

Filter: Activity | Enter text to search for | Go | + Add Filter | X Clear All