This quick guide provides information about how to designate, update, or remove a Principal Investigator (PI) Proxy. A PI Proxy can submit the study to the IRB, submit clarifications requested, and submit modifications and continuing reviews. A PI Proxy also receives the Click system generated notifications that are sent to the PI. While more than one individual can be designated as a PI Proxy on a study, the PI Proxy designation is specific for each study.

WHO:

- Principal Investigators (PIs)
- Study Teams

WHEN:

- Designating, updating, or removing a PI Proxy.

HOW:

**Designate a PI Proxy (Initial Study Submission)**

1. Create a new study submission and identify the PI on the “Basic Information” SmartForm page.

   ![Basic Information Form](image)

   **NOTE:**

   - While any individual on the study team may create the study submission, only certain individuals may serve as PI on an IRB submission. See HRPP Manual Section 4-9, Designation as PI, for who can serve as PI on an IRB submission.
2. Identify key project personnel on the “Study Team Members” SmartForm page. Be sure to save this page if you intend to exit the submission. Once the study team is identified, the PI can then designate PI Proxy(ies).

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Roles</th>
<th>Phone</th>
<th>Email</th>
<th>Involved in Consent</th>
<th>HRPP Training</th>
<th>GCP Training</th>
<th>GCP Expedited Data</th>
<th>Financial Interest in Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>ns1</td>
<td>Study Coordinator</td>
<td>yes</td>
<td></td>
<td>no</td>
<td></td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ns2</td>
<td>Project Personnel</td>
<td>yes</td>
<td></td>
<td>no</td>
<td></td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ns3</td>
<td>Co-investigator</td>
<td>yes</td>
<td></td>
<td>no</td>
<td></td>
<td>no</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Alternate phone number for relevant study team member(s) (optional):

Note:
- See HRPP Manual 4-10, Designation as Key Project Personnel on Non-Exempt IRB Projects for who must be listed on non-exempt IRB projects.

3. To designate PI Proxy(ies), the PI logs into Click and navigates to the study submission’s workspace (if they were not the individual creating the study submission).
4. The PI selects “Assign PI Proxy.” This activity is only visible to the PI and only the PI can perform the “Assign PI Proxy” activity.

5. The PI selects the individual(s) to act as PI Proxy by checking the box next to the individual(s) names. More than one individual may be designated as PI Proxy.

NOTE:
- While the PI Proxy can submit the study to the IRB, submit clarifications requested, and submit modifications and continuing reviews, the PI maintains the responsibility for oversight and conduct of the study and are responsible for all actions taken by the PI Proxy.
Quick Guide

How to Designate, Update, or Remove a PI Proxy

6. Once the individual is designated as PI Proxy, that individual can perform the actions of “Submit” and receive Click system generated notifications sent to the PI.

Update or Remove PI Proxy Designation

1. The “Assign PI Proxy” action can be taken by the PI at any point in the study. To do so, the PI would access the study workspace, select “Assign PI Proxy,” and make the changes to the “Assign PI Proxy” list. To remove a PI Proxy, unselect the checked box next to that individual’s name.

NOTE:

- Removing an individual as PI Proxy does not remove the individual from the study; to remove an individual from the Study Team, a MODIFICATION must be submitted.
- If a PI wants to designate a PI Proxy who was not listed in the initial study submission, a MODIFICATION would need to be submitted to add the individual to the study. Only after the MODIFICATION is approved may the PI then designated the new individual as PI Proxy.
- The “Assign PI Proxy” activity is only available on the STUDY workspace; it is not available on a MODIFICATION or CONTINUING REVIEW workspace. The PI must navigate to the main STUDY workspace to perform the “Assign PI Proxy” activity.