

SOP#: RPS-2

Protocol PI Proxy in PROTECT

Version #: 1.0

Next Review Date: 01/2025

Approved Date: 01/2023

Review Interval Period: Biennial

NCI Clinical Director Signature/

Effective Date:

POLICY

A proxy is a member of the study team listed on the PROTECT application/system that the PI designates to act on their behalf. The proxy can do all the same actions in the system that the PI can with the exception of submitting the Scientific Review. The PI MUST submit the Scientific Review in the system.

Anyone listed as a local study team member on the IRB study application can be a proxy. These are the only personnel you will be able to choose on the Assign Proxy activity. Only the PI can assign/remove a proxy.

Protocol Support Office Staff:

The PSO Director and the assigned protocol PSO Manager(s) must be assigned as PI Proxy for the protocol to allow the PSO to appropriately act on behalf of the PI to initiate/prepare and respond to certain actions in PROTECT, based on PI input.

The PSO staff can initiate response actions that have received initial PI/PI Proxy signoff and submission to the IRB (e.g., response to pre-review comments or stipulations) as well as submit directly back to the IRB responses to non-Board actions (e.g., response to pre-review/IRBO Analyst comments) and response to IRB stipulations for administrative clarifications/corrections (e.g., informed consent grammatical changes/edits, typographical error fixes). The PSO staff will not be allowed to be the only signoff to submit any actions for the first time to the IRBO.

Protocol Associate Investigators:

The person(s) assigned on the delegation log to assume PI responsibilities should also be assigned PI Proxy role in PROTECT.

RESOURCES

- NIH PROTECT Help Center [website](#)
- NIH IRB PROTECT Migration Information and FAQs [website](#)
- PROTECT [login site](#)