PROTECT Tip Sheet:
"PROTECT User Accounts & Permissions"

Overview

PROTECT is a permissions-based system, meaning what an account holder can see, do, or experience in the system is based on their account *permissions*. Permissions are given to account holders by the PROTECT system admins as well as by members of the study team - depending on what the user needs to do in the system.

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Who needs a PROTECT account?

Principal Investigators (PIs) – PIs always need an account.
Principal Investigators always need an account as they are responsible for the conduct of the study and need access to view, edit, or perform actions on their study submissions. This applies to NIH PIs as well as participating site PIs.

Study Team Members – Study team members usually (but not always) need an account.
Study Team Members who need to log into PROTECT to view, edit, or perform actions on submissions need to have an account.

Study Team Members who do NOT need to log into PROTECT to view, edit, or perform actions on a submission do NOT need an account to be added to the study team section of the application (as long as they are active in NED).

"Other" System Users (Committee Staff/Committee Reviewers/Ancillary Reviewers, etc.)
Other System Users who will need to log into PROTECT to view, edit, or perform actions on submissions need to have an account to be able to do those duties.

How do I request a new PROTECT account for myself/someone else, or modify an existing account?

You can request a new PROTECT account, or edit an existing one by going to our NIH IRB Help Desk and request the type of account creation or account modification that you need (New NIH user, New Non-NIH user, or addition of permissions to an existing account). The ticket form will walk you through providing us the information we need to create or modify the account. It will also guide you through choosing an account approver for your Institute/Center (IC).

What kind of training do PROTECT users need?

Once a new account ticket request is received by our PROTECT Trainer(s), we will be in touch with the user about the type of system training they need to perform their duties in the system. All of our training is done face-to-face, virtually, and either in a group or 1:1 with a PROTECT trainer.

Why is system training needed for new and modified users?

We train each system user because the PROTECT system is compliant with FDA regulations on electronic records and electronic signatures (21 CFR 11). The guidance the FDA provides for this subpart describes that "persons who develop, maintain, or use electronic systems have the education, training, and experience to perform their assigned tasks". To be compliant with this guidance, effective September 20, 2023, we began requiring all new PROTECT system users attend a live virtual training with one of our PROTECT Trainers before we activate your account.

How long do PROTECT accounts remain active?

Accounts will remain active so long as you continue to login to the system regularly (at least once every 365 days). As part of NIH security requirements, any PROTECT accounts for users who are NOT PIs or Proxies and who have not logged into the PROTECT system in 365 days will have their accounts inactivated. This also means that system notifications will no longer go out to these inactived users. We intentionally will not deactivate user accounts if they are a PI or Proxy on any studies, because they still need to receive system notifications and perform actions on their submissions.

Any users we inactivate will remain on any of their existing submission forms, as their accounts do not "go away" in the system. Their account is just toggled to "inactive". If you have any users who report no longer being able to login to PROTECT and need their account reactivated, please submit a help desk ticket to request this and we will take care of it for you right away. Re-training is not required in this case.

Who must be listed as a Study Team Member on the study application?

All personnel who are engaged in Human Subjects Research (HSR) who are working under the supervision of the NIH PI should be listed under the "Local Study Team Members" section of the study application. Additionally, the statistician must be listed on the study application even if that person is not engaged in HSR as they require review for Conflicts of Interest. If you have a Protocol Navigator(s) who needs to edit and/or perform actions PROTECT submissions, they must also be added to the study team list. Even though they are not engaged in the research, they do go into PROTECT and process/edit/view submissions for the research team, and adding them to the study team is how this is accomplished.

NED STUDY TEAM MEMBERS

NIH study team members WITH NED accounts who are engaged in the research are added to question 1 of this page (see below).

NOTE: The person does NOT need to have a PROTECT account to have their name be available for selection here as long as they are an active NED user. If they have an active NED account but will NEVER need to log into the system or perform any actions on the submission, their name can still be selected here and added to the NIH study team list (even though they do not have a PROTECT account).

NON-NED STUDY TEAM MEMBERS

NIH study team members <u>WITHOUT</u> NED accounts who are engaged in the research are added manually to question 2 of this page (see below).

They are not system account holders so they will never have an account or login or be able to view/edit/perform actions on the study.

Proxies

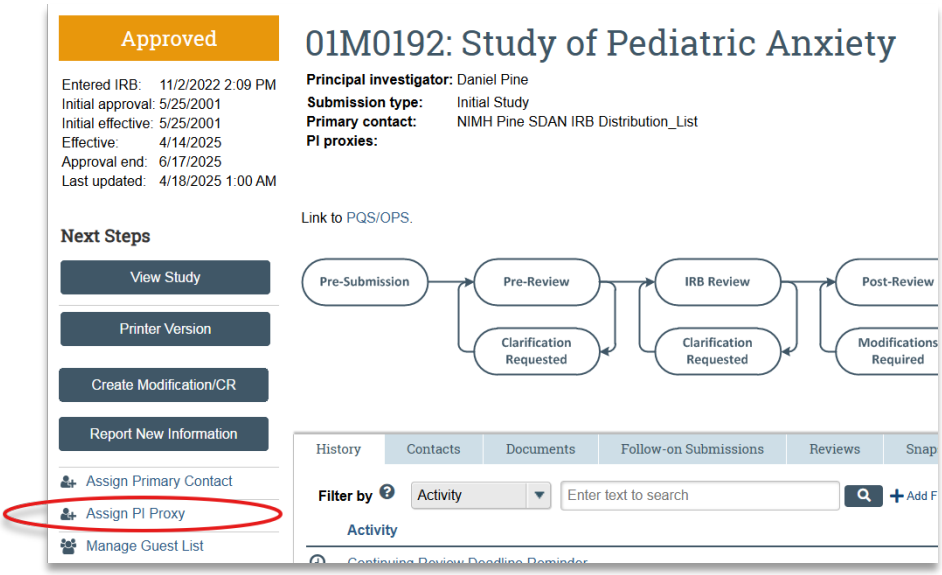
A proxy is a member of the study team that the PI designates to act on their behalf for certain tasks, like submitting projects in PROTECT. The proxy can do all the same actions in the system that the PI can do with the exception of submitting the Scientific Review. The PI MUST submit the Scientific Review in the system.

NOTE: It is really important that PIs consider what, if any, proxies they would like to add to the study as soon as the new study application is created so that should the PI be unavailable, there is someone on the study who can act on the PI's behalf. This will potentially prevent delays in the submission of continuing reviews and modifications, as well as responses to clarifications, etc.

Who can be a proxy?
Any person listed on the study application as local study team members can be added as a proxy. These are the only personnel you will be able to choose on the "Assign PI Proxy" activity. There can be multiple proxies on a study.

Who can assign/remove a proxy?
Only the PI can assign/remove a proxy.

How does one assign/remove a proxy?
The PI will log into PROTECT, navigate to the study workspace, and click the "Assign PI Proxy" activity listed on the left side to add or remove proxies:



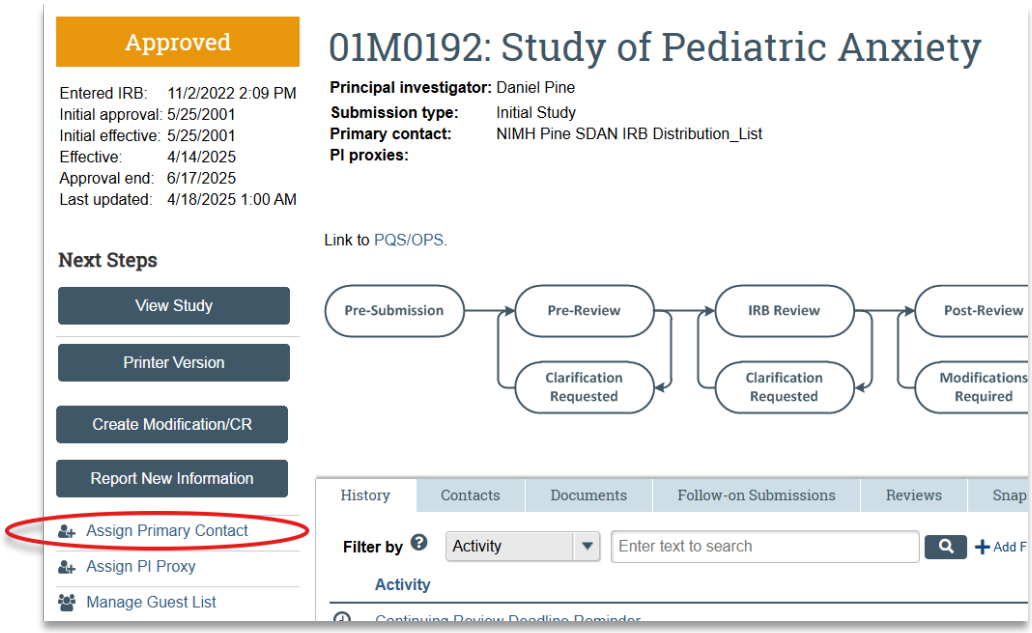
Primary Contacts

The Primary Contact should be someone accessible, knowledgeable about the study, and able to answer clarifications the IRB might have in a timely manner. They also receive all study notifications. They have read-only access to the project.

Who can be a primary contact?
Any system account holder with a NED account can be added as the primary contact on a study. They do not even need to be on the study. Only one person can be designated as a Primary Contact. If you need the primary contact to be a shared inbox instead of a single person, see the section below titled, "How do I set our Primary Contact to be a shared email inbox so my group receives all study notifications?

Who can assign/remove a primary contact?
Any system account holder listed on the study team can assign/remove a primary contact.

How does one assign/remove a primary contact?
The study team member will log into PROTECT, navigate to the study workspace, and click the "Assign Primary Contact" activity listed on the left side to add or remove primary contacts:



Guests

A guest is a PROTECT system user who is given read-only access to a study (e.g., for audit or monitoring purposes).

Who can be a guest on a study?

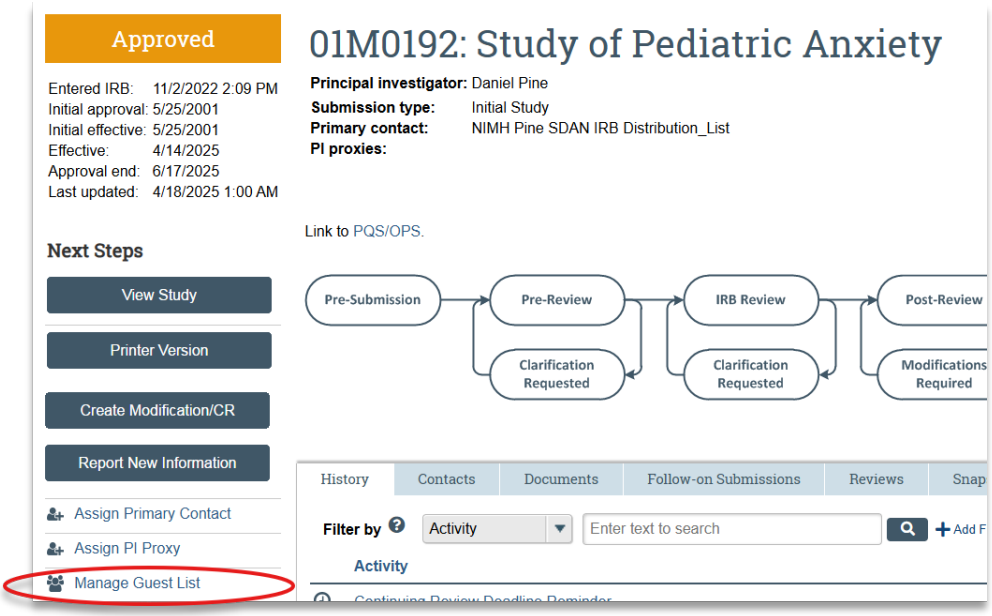
Any system account holder with a NED account can be added as a guest on a study. They do not even need to be on the study. There is no limit to the number of guests that can be added.

Who can assign/remove a guest?

Any system account holder listed on the study team can assign/remove a guest.

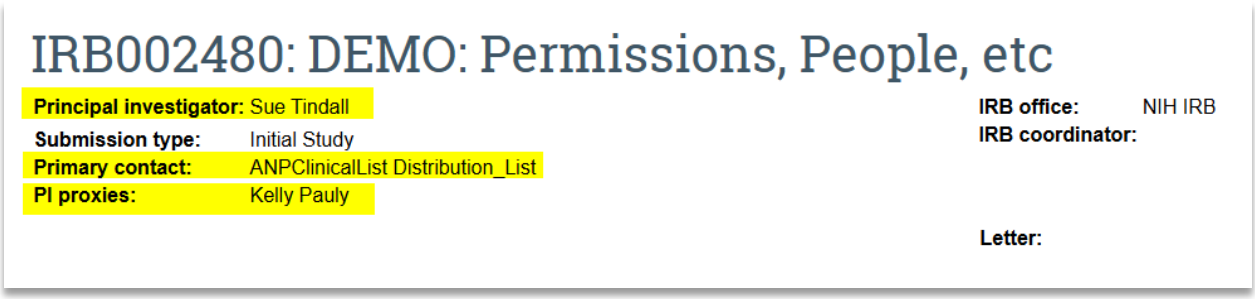
How does one assign/remove a guest?

A study team member can log into PROTECT, navigate to the study workspace, and click the "Manage Guest List" activity listed on the left side to add or remove people from the guest list:



How do I ensure someone receives email notifications on a study?

Notifications go out in the system at important milestones during the study. The users who receive notifications for a study are the PI, Primary Contact, and Proxies. If you wish for someone to receive study notifications, they can be added to one of these three groups, that are also shown on the study workspace:



How do I set our Primary Contact to be a shared email inbox so my group receives all study notifications?

At times, research groups want study notifications to go to a shared inbox, instead of a single primary contact. If you need multiple people to receive all notifications for a study, you may want to go to the NIH IT Service Desk and request to set up a group email address/account in Outlook. Once you have that email account set up, you can go to our PROTECT Help Desk Support system and request that we create a "dummy" PROTECT user account for you that uses that group email address. That "dummy" PROTECT user account can then be set as the Primary Contact for any study in PROTECT to receive all milestone notifications about the study(ies). Please do not submit requests to PROTECT Help Desk Support to set-up dummy accounts for individual studies. This option should be used for groups/offices needing notifications for *multiple* studies (e.g., notifications to go to all Protocol Navigators within an IC).

What if none of the above methods of assigning permissions works for us and we need wider access? How do we request to give someone wider access to many protocols?

There are circumstances where a user might need read-only access to a broader selection of studies for their duties. For example, they might need to view all of the studies in a specific Institute or Center. To request this, go to our NIH IRB Help Desk and request the type of account modification that you need. Describe in the request what you need to perform in the system and the access you are requesting (e.g., All-IC Access). The ticket form will walk you through providing us the information we need to revise the account permissions for your user. It will also guide you through choosing an account approver for your institute.

NOTE: Additional approval required – *The Clinical Director (CD) or their designee of the IC you are requesting access to needs to approve in writing this level of access. Please provide this documentation from your CD in writing and attach it to the ticket, or it will be requested during the approval process.*

Questions/Support

For additional questions, please submit a PROTECT Help Desk ticket and our IT staff will assist you.