

User Guide: pSITE User Account Creation - for Core Site

Intended Audience	Study Teams at NIH.
Summary	This guide will outline how to obtain PROTECT accounts for the pSITE Principal Investigator and the pSITE Study Coordinator at an external institution that will be serving as a pSITE and relying on the NIH IRB.
Date	04/25/2023

Terms

1.	pSITE (Participating Site)	An external site participating in an NIH led study and relying on the NIH IRB.
2.	pSITE PI (Principal Investigator)	The Principal Investigator at the pSITE.
3.	pSITE Study Coordinator	The Study Coordinator at the pSITE.
4.	pSITE User	The pSITE PI or an additional pSITE user such as the pSITE Study Coordinator.
5.	NIH Study Contact	The NIH PI or their designee in the study team, such as the NIH Study Coordinator, who will work with the pSITE to facilitate access to PROTECT.

Instructions

The pSITE PI is required to have a PROTECT account and other additional pSITE user(s) (e.g., pSITE Study Coordinator) may also have an account if the PI would like to add another person(s) as a proxy in the system. The following steps need to be completed for EACH pSITE User.

- 1. The NIH study contact will submit a ticket requesting a PROTECT account for the pSITE user
- 2. This will be done by going to http://ohsrp.helpdesk.nih.gov/.
- 3. The button "PROTECT Accounts" should be chosen as seen below.

To Access PROTECT you m	ust be connected to NIH VPN
TO ACCESS PROTECT you III	ust be connected to Nin VFN.
OHSRP Help Center	
OHSRP IRB PROTECT	Help Desk Support
Nelcome! You can raise a OHS	RP IRB PROTECT Help Desk Support request from the options provided.
To request access to the sp	acific studios, plazes contact research teams directly. Do not submit
requests here.	echic studies, please contact research teams directly. Do not submit
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What do you need help with?	
What do you need help with? Search	Q
What do you need help with? Search	Q
What do you need help with? Search	Q Search help
What do you need help with? Search PROTECT Accounts	Search help
What do you need help with? Search PROTECT Accounts	PROTECT User Account Modification Choose this form if your job role has changed and you require a
What do you need help with? Search PROTECT Accounts PROTECT Support	PROTECT User Account Modification Choose this form if your job role has changed and you require a new role
What do you need help with? Search PROTECT Accounts PROTECT Support IRB Scheduler Support	Search help PROTECT User Account Modification Choose this form if your job role has changed and you require a new role Request Account in PROTECT (NIH user)
What do you need help with? Search PROTECT Accounts PROTECT Support IRB Scheduler Support	PROTECT User Account Modification Choose this form if your job role has changed and you require a new role Request Account in PROTECT (NIH user) Choose this form if you are affiliated with NIH IC
What do you need help with? Search PROTECT Accounts PROTECT Support IRB Scheduler Support	Request Account in PROTECT (NIH user) Choose this form if you are affiliated with NIH IC
What do you need help with? Search PROTECT Accounts PROTECT Support IRB Scheduler Support	Q Search help PROTECT User Account Modification Choose this form if your job role has changed and you require a new role Provide Request Account in PROTECT (NIH user) Choose this form if you are affiliated with NIH IC Request Account in PROTECT (External Participating Site
What do you need help with? Search 'ROTECT Accounts 'ROTECT Support RB Scheduler Support	Request Account in PROTECT (NIH user) Choose this form if you are affiliated with NIH IC Choose this form if you are affiliated with NIH IC Choose this form if you are affiliated with NIH IC

- 4. Next the NIH study contact will click Request Account in PROTECT (External Participating Site User)
- 5. The NIH study contact will continue to complete the form.
- 6. For the field **pSITE PI or Study Coordinator Email Address**, the email address the pSITE user has provided in their email to the NIH Study Contact (institutional email address) will be entered.
- 7. Once the form is completed, the NIH study contact will click submit to complete the ticket.
- 8. The NIH Study Contact will then send the pSITE user the "User Guide pSITE User Account Creation for pSite" available on the <u>IRBO website</u>.
- 9. The pSITE user should complete the steps in the guide provided to create their account request.
- 10. OHSRP IT will receive the ticket and notify the NIH Study Contact when the pSITE user account has been created.
- 11. The NIH Study Contact should notify the pSITE user when the account has been created and tell the user that the next step is to wait for an **invitation** from the PROTECT system asking their site to join as a Participating Site. This will be issued to the pSITE user identified by the NIH study team in either the Initial Study Form, or Modification Form, depending on when the NIH protocol in question is becoming multi-site.