Organization Access (Org User) in Study Tracker

Study Tracker has two access levels: study access and Organization (Org) access. Study access is granted to a Study Team member for a specific study once they are added to the study's IRB Protocol. Organization (Org) access is granted to a user who has an administration role for a department and needs to manage any study associated with their department. This level of access omits the need for the user to be added to each study's individual IRB Project Contacts list and is used for oversight on multiple studies. This handout will focus on the Organization (Org) access level and how to utilize this permission to manage your department's studies and monitor their compliance.

How to Obtain Organization (Org) Access

Organization (Org) access can be requested for those administrators who have completed CITI Training and have a NU NetID. New Org User requests should be sent directly to Study Tracker Support along with the following information: Name and NU NetID, proof of CITI Training completion, and the Department Name for which the Org User addition is being requested (the full list of FSM Departments and Centers can be found in Study Tracker under 'Affiliations').

Each department is assigned an Org Admin and serves as the main contact for the Org. The Org Admin must approve the addition of a new Org user to the Org. Once the new Org User has been added by Study Tracker Support, the Org Admin must then set the permissions for each access level for all Org Users. The Org Admin is the only Org User with the ability to adjust the permission levels. Org Admins also have the responsibility of notifying Study Tracker Support when an Org User must be removed from the Org.

Q Reports P Users E Budget codes Permission levels Org Access 🕜 Q Search \times + Admin? Actions Name Study settings Subject access Study budget access Potential subjects access

Northwestern Memorial HealthCare

For each access level the Org Admin must select the permission level, Read/Write/None, for each category.



| Study Settings | Includes the individual study details recorded under the following sections in Study Tracker: Study Properties, Financial Settings, Public Recruitment, Study Contacts, Affiliations, Support Services, Epic, Activities, ClinicalTrials.gov, Study Schedule, Study Documents, and Advanced Properties. |
|---------------------------|---|
| Subject access | Includes any participant details including participant profile (PHI) and participant enrollment details including consent. |
| Study budget access | Is specific to the \$Finances tab and budget setup details. |
| Potential subjects access | Grants access to the MyChart Recruitment feature if enabled. |

How to Locate Organization (Org) Access

Upon Login your dashboard will display all studies in which you are listed on the IRB on for a specific study in Study Tracker under the 'Studies' tab.

| Alerts Studies | Orgs | | | |
|--------------------------|------------------------|-----------------|----------|---------|
| Don't see your study? 😮 | | | Search: | |
| Study Compliance | IRB number | Name | Status | Accrual |
| ✓ Showing 1 to 1 of 1 | STUXXXXXXXX entries | Demo/Test Study | Approved | 43 |

To access the Organizations in which you have Organization (Org) access for, you must select the 'Orgs' tab.

| Alerts Studies Orgs | | |
|----------------------------------|-------------|--|
| Name | Study Count | |
| Northwestern Memorial HealthCare | 3398 | |
| Northwestern Memorial Hospital | 3406 | |
| Northwestern University | 6015 | |
| Bluhm Cardiovascular Institute | 140 | |
| Northwestern Medical Group | 3400 | |

Types of Organization (Org) Reports

Various reports will display upon opening an Organization (Org) from your dashboard. These reports will only include studies in which this specific Org was recorded for in Study Tracker. For example, if NUCATS was not checked off under Institutes for study number STUXXXXXX, then STUXXXXXX will not be listed in the study count for that department and an Org user for NUCATS will not see this study or have access to it. The PI or Coordinator must ensure that the affiliation is recorded at the study level in order for an Org user to be able to access the study.

| Q Reports | | |
|---------------------------------|--|--|
| Name | | |
| Budget Support Service Provider | | |
| Compliance Report | | |
| Study Enrollments | | |
| Recruitments | | |
| Study Properties | | |
| NMHC research statements | | |
| Study Budgets | | |
| EDW Exceptions | | |
| Study Users | | |
| Affiliated Studies | | |
| Disease Dictionaries | | |
| Diseases | | |

All of the reports can be exported/downloaded to view outside of Study Tracker:

| Budget Support Service Provider | This report provides a glance at the current study list's budget status and Epic sync status. It |
|---------------------------------|--|
| | allows you to quickly identify the studies that are missing a locked budget and/or have not |
| | synced with Epic. |
| Studies | This report provides a more focused look at compliance allowing you to quickly identify what |
| | compliant related information may be missing for a study. If a study is missing policy |
| | required information it will display the status in red. By clicking on the non-compliant status |
| | it will take you to the section of the study in which the information is missing. |
| Recruitments | This report allows you to quickly identify the studies that have 'recruiting' enabled and the |
| | associated recruitment information recorded in Study Tracker. When enabled, the |
| | recruitment information recorded in Study Tracker is what is fed to publicly facing websites |
| | like FSM. |
| Study Properties | This report is a collective view of the information found under the "Study Properties" |
| | section. This section is required to be filled out for all studies. |
| NMHC research statements | Studies that have NMHC medical services performed can locate all issued NMHC study |
| | invoices here. The list displays all studies and the associated invoice pdf file. |
| Study Budgets | Highlights budget related totals including incoming and outgoing invoice totals for financial |
| | snapshots. |
| EDW Exceptions | Lists the studies that have an EDW Exception submitted and highlights the exception details, |
| | I.e. status, reasons, and date. |
| Study Users | Lists all of the contacts for defined roles associated with the study. |
| Affiliated Studies | Lists all of the studies associated with the department allowing you to quickly access a study |
| | from the list. |

For further questions on Study Tracker usage please contact the Study Tracker Support Team at

studytracker@northwestern.edu or visit the Study Tracker FAQ.