

Accrual Access Requirements and Rules - Include v4.5

Requirements for granting/denying access include the following:

- **Processing status** – Must be at least "Verified" (response or no response). See [Trial Processing Statuses](#).
- **Site recruitment status** – Must not be "Withdrawn" nor "Not yet Recruiting". The participating site must have accrued patients at some point in the past, or is accruing patients currently.
- **Action** – You can grant or deny access to the accrual site only when abstracting or validating the study for which access is requested.

Once assigned, users can submit accrual data for all studies associated with their affiliated organization or organization family members. For Complete studies (Institutional and Externally Peer Reviewed), the organization must be a lead; for Abbreviated studies (Institutional), the organization must be a participating site.

Assignment at the organization or family member organization level pertains to studies that the organization has registered in CTRP and extends to those that it will register in the future.

The table below outlines the access and study assignment rules for Complete (Institutional and Externally Peer-Reviewed) and Abbreviated studies.

Access/Assignment	Complete Study	Abbreviated Study
Who can assign access?	A registered user logged in as the Lead Organization's Site Administrator	A registered user logged in as the Site Administrator
Who can be assigned access?	Any registered user affiliated with the Site Administrator's organization, or family member organization (including the Site Administrator)	Any registered user affiliated with the assigner's organization (including the site administrator)
What types of studies can be assigned?	Complete studies for which the assigner's organization is the lead organization	Abbreviated studies for which the assigner's organization is the Lead Organization or participating site
How is access assigned?	<ul style="list-style-type: none"> • By study • By Organization • By Organization Family member ¹ 	<ul style="list-style-type: none"> • By study • By participating site
Who can submit accrual data?	Any assigned user, for any organization studies for which the assigner's organization is the Lead Organization	Any assigned user affiliated with the participating site
Which trials can the Organization Family Accrual Submitter submit accrual data to?	<ul style="list-style-type: none"> • All Complete studies registered by the submitter's organization or family member organization • Studies currently registered in CTRP • Studies that the organization registers in CTRP in the future, once abstracted 	<ul style="list-style-type: none"> • All Abbreviated studies registered by the submitter's participating site <i>only</i> • Studies currently registered in CTRP • Studies that the organization registers in CTRP in the future, once abstracted
What are the default Accrual Reporting Types when studies are registered?	Subject	Summary
How can the Accrual Reporting Type on a study <u>with</u> accrual Data be updated?	<ul style="list-style-type: none"> • Can be updated by CTRO from Subject to Partial Subject, after review/approval by CCCT, without the need to nullify existing accrual. • Can be updated by CTRO to Summary, after review/approval by CCCT, and accrual data has been nullified for that study. 	Can be updated by CTRO from Summary to Subject or Partial Subject, after review/approval by CCCT, and accrual data has been nullified for that study.
How can the Accrual Reporting Type on a study <u>without</u> accrual Data be updated?	<ul style="list-style-type: none"> • Interventional - Can be updated by CTRO from Subject to Partial Subject or Summary, after review/approval by CCCT. • Non-Interventional - Can be updated by users and/or CTRO from Subject to Partial Subject or Summary accrual. 	Can be updated by CTRO from Summary to Subject or Partial Subject, after review/approval by CCCT

1. The system automatically assigns the Organization Family Accrual Submitter access to any study registered by new organizations added to an organization family in the future. The system withdraws access if the Organization Family Accrual Submitter's organization is removed from the organization family in the future.

