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WASHINGTON STATE
U N I V E R S I T Y

CLINICALTRIALS.GOV PROTOCOL REGISTRATION AND RESULTS SYSTEM (PRS) ADMINISTRATOR'S QUICK REFERENCE

Overview

This document provides a summary of responsibilities of an organization's ClinicalTrials.gov Protocol Registration and Results System (PRS) Administrator. New administrators may wish to use the PRS Quick Start Guide to learn the basics of creating and maintaining records before reading this guide.

Create User/Administrator Accounts

Create accounts for users and other administrators in your organization as needed, using the New User Account option from the Accounts menu on the Home page.

- Users create and modify their own records, but normally cannot access other users' records. Administrators have full access to all records within the organization.
- Study investigators can be given either user or administrator accounts at the discretion of each organization.
- The PRS automatically sends email with the PRS web address and login information to the user/administrator upon account creation.

Review/Approve/Release Completed Records

Whenever a user marks a new or modified record as Entry Completed, the administrator is responsible for reviewing the record. Open the record and review all content, making corrections as needed. Follow instructions in the Next Step box on the Record Summary page to Approve and Release the record for PRS Review.

- **Important**: Pay special attention to recruiting status and contact information when reviewing records, as the accuracy and timeliness of this information is extremely important to patients and health care providers.
- All records must be free of error messages in order to be released.
- **Exception:** If the Investigator is designated as Responsible Party for a study, that individual has the authority (and responsibility) to Approve and Release the record even if not an administrator. In that case administrators can Approve the record but cannot Release it. More information on Responsible Party is accessible from the Edit Sponsor/Collaborators page.

Ensure That Records Are Kept Up To Date

The administrator has overall responsibility to ensure that the organization's records are verified, updated, and re-released as needed (at least yearly while a study is active). Email messages are automatically sent by the PRS to administrators for significant user actions, such as completing data entry for a record or modifying a previously Released record.

Check For Problems

Use the Problems column on the Home page to identify important issues, such as records that were updated but never Released or records that are missing information required by the U.S. FDA Amendments Act (FDAAA 801). Work with the owner of each problem record as needed to address the issues, following instructions in the Next Step box on the Record Summary page to complete the process of updating the record

Maintain User Accounts

Reset passwords, update email addresses or make other user account modifications via the Accounts menu on the Home page.

Disable User Accounts

Disable a user's account using the Enable/Disable User Account option under the Accounts menu on the Home page. This is often necessary when a user leaves the organization or no longer requires access to the PRS.

Optional: Maintain Access Lists For Records

A record owner or PRS administrator can optionally grant access to a record, to one or more additional users within the same organization, using the Edit Access List link on the Record Summary page. Users granted access to a record in this manner have the same privileges as the record owner, except for modification of the Access List.