Best Practice

Transferring a ClinicalTrials.gov Record Between Institutions

Susan Hwme, City of Hope Comprehensive Cancer Center
Maureen Olmstead, Virginia Commonwealth University
Scott Patton, Stanford University
Sarah Snider, Medical University South Carolina

Purpose

When the sponsor of a study changes or the responsible party for a record moves to a new Institution, transfer of the ClinicalTrials.gov record to another PRS account may be needed. If the responsible party is no longer affiliated with your Institution, the record should be transferred to the responsible party's new Institution, even if research activities continue at your Institution (for example, your Institution is still a site in the study).

Best Practice

When to Transfer a ClinicalTrials.gov Record

- Institution ClinicalTrials.gov policy should include criteria for transferring study records when the responsible party leaves the Institution.
- Arrangements for management and transfer of the record should be made with the investigator *prior* to the responsible party changing Institutions
- In general:

- If the study is ongoing and will continue at the new Institution, the ClinicalTrials.gov record should be transferred to the new Institution. Example: An awardee or Principal Investigator (PI) of a federally funded grant is transferring to a new Institution and the grant will be transferring with the PI.
- If the study is completed, and will not continue at the new Institution, the record should be completed in the PRS account of the Institution where the research took place, otherwise it would appear that the new Institution was the sponsor of the study even though it was not associated with the study. This will mean allowing the departing Investigator to retain access in the departed Institution's PRS account until such records are completed. For collaborative studies, the responsibility for maintaining the ClinicalTrials.gov record should be delegated to one of the Investigators in a written contract, and the record should be maintained in the PRS account of that Investigator's Institution.

Coordination Between the two Institutions is Critical

- ClinicalTrials.gov indicates that "If the receiving organization has (PRS) Administrators, they are responsible for coordinating the transfer. For organizations without (PRS) Administrators, the Responsible Party and Record Owners (RO) must coordinate the transfer." This means communicating any necessary details between Institutions prior to emailing ClinicalTrials.gov to initiate the transfer.
- If the PRS Administrators at both Institutions are included in the transfer request, then PRS staff can transfer the record without the additional step of obtaining confirmation from the receiving Institution that they will accept the transfer.

Collect the Information you will Need

- You will need to provide the PRS Administrators the following information
  - Name of the receiving organization
  - Username of the new Record Owner
  - NCT number of the record

Send an Email to register@clinicaltrials.gov Requesting the Record Transfer

- In the subject line put “Transfer [NCT#] [to/from] [other Institution]
- In the text include the necessary information
- Copy the responsible party/parties and at least one PRS Administrator at the receiving Institution. If the Institution does not have a PRS Administrator, copy the new Record Owner.
- Either Institution can email the transfer request.
    - If the email is sent by the Institution the Investigator is leaving, state in the email that *the transfer has been agreed upon by the PRS Administrator at the new Institution, copied on the email*.
    - If the email is sent by the receiving Institution, state that *the Institution agrees to the transfer, and the PRS Administrator at the prior Institution is copied on the email*. Correspondence between the Institutions can be included, but it is not required.
    - If the information provided does not include all parties, PRS staff will respond to the email with a request for confirmation from the receiving institution.
- In the email body, include the NCT number of the record to be transferred, and indicate who will be the new Record Owner at the new Institution.
- Once the transfer is complete, PRS staff will reply to the email request confirming that the record has been transferred.
    - **Note:** Records that have been *Released* for ClinicalTrials.gov QC review cannot be transferred until review has been completed.
    - **Note:** If the record has any problems (not updated, anticipated date in the past, etc.). the transfer can’t occur until the problems/errors have been resolved and resubmitted back to PRS staff.

Record will need to be Updated Once it is Received by the New Institution

- The record will be automatically flagged with some area's requiring update
- Areas requiring update may include:
    - Unique Protocol ID
    - Overall Status
    - Sponsor
    - Responsible Party
    - Collaborators
    - Human Subjects Review
    - Contacts/Locations

Glossary

ClinicalTrials.gov Protocol Registration and Results System: (https://register.clinicaltrials.gov/)

- **HR:** Human Resources
- **PI:** Principal Investigator
- **PRS**: Protocol Registration and Results System
- **RO:** Record Owner

Document History:

- 10 April 2021 draft written by Susan Hwme, City of Hope
- 29 July 2021 reviewed by Maureen Olmstead, VCU
- 10 October 2022 reviewed by Scott Patton, Stanford
- 12 January 2023 reviewed by Sarah Snider, MUSC
- 23 April 2023 Final Draft by Susan Hwme, City of Hope
- 5 September 2023 Final Accessibility Review by Meredith Rhodes, UW-Madison