SOP#: RPS-26	**Results Reporting for Research Studies on ClinicalTrials.gov**
Version #: 1.0	**Next Review Date: 09/2024**
Approved Date: 09/2022	**Review Interval Period: Biennial**
NCI Clinical Director Signature/ Effective Date:	James Gulley Digitally signed by James Gulley Date: 2022.09.26 08:15:54 -04'00'

POLICY

The Center for Cancer Research (CCR) reports results data on all applicable clinical trials on ClinicalTrials.gov per the Food and Drug Administration Amendments Act of 2007 (FDAAA). In addition, CCR reports results data per NIH Policy Manual 3007. Results data should be entered into the ClinicalTrials.gov Protocol Registration and Results System (PRS) within one year of the protocol primary completion date.

When the primary outcome is met, ownership of the study's ClinicalTrials.gov record is transferred from the NIH Clinical Center [administered via Office of Protocol Services (OPS)] to the study PI. The PI is the "responsible party" for reporting research results, with the assistance of the NCI FDAAA/ ClinicalTrials.gov Database Administrator (NCI DB Administrator) Lisa King.

Investigators must be in compliance with the FDAAA and the NIH Policy Manual 3007 and be familiar with consequences of not following the law and policy.

DEFINITIONS (NIH Policy Manual 3007)

- *Responsible Party:* the sponsor of the clinical trial (as defined in 21 CFR 50.3) or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.

  Note: For the CCR, the responsible party for reporting research results is the study PI, except for studies with industry sponsors. For industry sponsored studies, the responsible party for ClinicalTrials.gov activities is the study sponsor.
- *Primary Completion Date:* the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.

PURPOSE

To identify the process for reporting research results on ClinicalTrials.gov and the study PI's responsibilities.

RESOURCES

- NIH Policies
  - NIH Policy and Regulation on ClinicalTrials.gov Registration and Reporting
  - NIH Policy Manual 3007 – Clinical Trial Registration and Results Information Reporting
- ClinicalTrials.gov Resources
  - Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT)
  - How to Submit Data into the ClinicalTrials.gov Protocol Registration and Results System (PRS)
  - FAQs on the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11)
- FDA
  - Food and Drug Administration Amendments Act (FDAAA) of 2007
  - Public Law 110-85 September 27, 2007

PROCEDURES

STEP 1: PI Review of ClinicalTrials.gov Reporting Requirements

- PI should review the information in the ClinicalTrials.gov website about reporting research results and be familiar with the requirements.

STEP 2: Update Office of Protocol Services (OPS)

- The PI/designee must report the primary completion date (PCD) to the OPS within 30 calendar days after the clinical trial reaches its actual primary completion date. OPS is the administrator of ClinicalTrials.gov records on behalf of the NIH CC.
- If the study has two primary outcome measures report the PCD when the second primary outcome reaches the primary completion date.

STEP 3: Notify PI that Study Results are Required

- OPS will send an email to PI that:
  - Protocol Registration and Results System (PRS) user account has been created for the PI, if the PI does not already have a user account
  - Primary completion date was met, and results are required to be reported on ClinicalTrials.gov.
  - Ownership of record transferred to PI ("Responsible Party") with access given to the NCI DB Administrator
- NCI DB Administrator will also email the PI to inform them that protocol(s) # XX-C-XXXX will be reviewed and will request additional information.

STEP 4: Enter Data in PRS

- NCI DB Administrator will enter data into PRS

STEP 5: PI Data Review

- NCI DB Administrator will email a copy of the data entered into PRS to the PI for review with a due date for return of changes, or approval if no changes.
- NCI DB Administrator will make changes to PRS as needed and email the PI for final review and approval to submit results data

Please note: To allow adequate time for review and updates on the PRS, the PI must return the information to NCI DB Administrator by the due date in the email.

IMPORTANT: Per regulation and NIH policy, the PI **must** report results data within one year from primary completion date.

STEP 6: Submit Data

- Following PI/designee approval, the NCI DB Administrator will submit the data on the PRS

STEP 7: PI Approval and Release ClinicalTrials.gov Record

- ClinicalTrials.gov will email the PI to approve and release the record
- NCI DB Administrator will also email the PI to log into PRS to approve and release the record
- Record will go for ClinicalTrials.gov Quality Control (QC) review

STEP 8: Respond to ClinicalTrials.gov Quality Control (QC) Comments

- After the QC review, the PI may receive an email that issues have been identified during the QC process that must be addressed. The NCI DB Administrator will also get this email.
- NCI DB Administrator will log into PRS, review comments and work with the PI to answer comments as needed

Please note: To allow adequate time for review and updates on the PRS, the PI must return the corrections at least one week prior to the ClinicalTrials.gov deadline.

IMPORTANT: The PI **must** return corrections by the date required by ClinicalTrials.gov to remain in compliance.

STEP 9: Annual verification of Record and Other Record Updates after Record is Registered on ClinicalTrials.gov

- NCI DB Administrator will update the record verification date when prompted on the PRS and email the study PI to verify information as needed.

- The PI/designee must notify the OPS (CC_Protocol_Services@cc.nih.gov) about any protocol updates (e.g., PI changes, study status updates such as study completion/study closure with IRB). Following notification to the OPS, the OPS will notify the NCI DB Administrator who will work with the PI/designee as needed, to ensure the ClinicalTrials.gov record updates are done.

Note: The study PI is responsible for reviewing the updated ClinicalTrials.gov record to ensure accuracy.