Best Practice

ClinicalTrials.gov Registration Record
PRS Administrator Review - Permissions

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Context

This document offers a best practice for [PRS administrators] with edit access to [Institutional] ClinicalTrials.gov Records to review records populated by Research Groups (RG). It suggests edits that the [PRS Administrator] can make prior to releasing the record without seeking permission from the Research Group.

Best Practice

The [email] service inbox receives a notification when a new ClinicalTrials.gov Registration Record is marked 'Complete'. The [PRS Administrator] reviews the record per the PRS Review Criteria making relevant changes to enable faster PRS Review and/or contacts the study team to clarify the registration record prior to its release. Prioritize review of records with earlier anticipated study start dates.

The following is a list of suggested edits the PRS Administrator can make without study team approval:

- Change the tense of the record (third person; most commonly ‘we’ to ‘the investigators’)
- Reformat the Eligibility Criteria into a bulleted list
- Expand/Define Acronyms
- Remove duplicate information (most commonly word for word text in the Brief Summary and Detailed Description)
- Check Spelling and correct spelling errors
- Spell out symbols (percentage rather than %, number rather than #)
- Use “Participants” instead of “subjects” or “patients” where relevant
- Remove periods from outcome measure titles
- Remove study design terms from the Brief Title
- Change Record Owner per Institutional Policy, as relevant
- Change sponsor to [institution]
- Addition of PI department and protocol version date as a Secondary ID
- Remove bibliographic references from text
- Addition of key personnel to the ‘access list’

The following are examples of edits that require study team approval prior to release:

- Any Outcome Measure-relevant question
- Study Design queries
- FDA-Regulatory / Oversight questions
- Clarification of primary and study completion dates relative to Outcome Measure time frame (such that the study team understands how they are defined)
- Addition/removal of Sponsor/Collaborators and corresponding grant/funding award identifiers
- If IPD Sharing Plan is unanswered or ‘undecided’ suggest ‘No’ at registration if this would otherwise slow down assignment of an NCT number. The Research Group can update the plan as it evolves. OR, recommend the following template language:

Plan to Share IPD: Yes

> Individual participant data collected during the trial, after deidentification will be available to researchers for independent verification of study outcomes or to conduct subsequent secondary research whose proposed used of the data has been approved by an independent review committee identified for this purpose.

Supporting Information: Study Protocol, Informed Consent Form, Clinical Study Report

Time Frame: Beginning 9 months after publication of primary outcomes, and ending 5 years after that date

Access Criteria: Proposals should be directed to [PI email address]. If approved after review by regulatory counsel, requestors will enter into a formal data sharing agreement. Data will be shared via encrypted single-user file transmission protocol.

Document History

- 29 April 2021: initial draft written by Meredith Rhodes, UW-Madison
- 13 May 2021: review by Sarah Snider, MUSC
- 1 March 2024: review by Ilija Atanasovski, Albert Einstein College of Medicine
- 2 April 2024: Accessibility Review by Meredith Rhodes, UW-Madison