Best Practice

PRS Administrator Workflow: Records Never Released

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Purpose

To ensure records started in ClinicalTrials.gov Protocol Registration and Results System (PRS) are completed and posted to the public site in a timely manner or deleted when appropriate. This document describes general points to consider when developing Institutional processes to support researchers with registrations that have been started but never released to ClinicalTrials.gov for Quality Control (QC) review.

Best Practice

1. **Administrative Considerations**: For compliance purposes, the initial record must be submitted before the study start date per the International Committee of Medical Journal Editors (ICMJE) or within 21 days of start (Applicable Clinical Trials (ACTs) per FDAAA Law or NIH clinical trials within scope of the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information). For this reason, it is important for the PRS Administrator to have a mechanism to understand the study status, like access to a Clinical Trial Management System (CTMS), for example. If access to such a resource is unavailable, the following considerations apply:
    a. Establish a timeframe for review of unreleased records in your Institution's PRS account (monthly, quarterly, etc.).
    b. Set a "look-back" time frame, i.e., what is a reasonable length of time since an unreleased record was updated before PRS administrator should contact the team?
    c. Set frequency for follow-up contact (e.g., monthly, quarterly, etc.). A staggered follow-up contact frequency may be appropriate (e.g., 1st and 2nd follow-up after two weeks each, 3rd follow-up after 1 more week – consider an Escalation Policy)

d. Consider setting a time frame or number of follow-up contacts before administrative removal of incomplete records in the case of non-responsive Record Owners (RO) or the Responsible Party (RP).
e. Determine services to be offered, depending on resource allocation. These may include:
    i. Send notification(s) to the RO, RP, and/or study team
    ii. Provide education or educational materials
    iii. Provide direct assistance to resolve individual record

2. Identify Records for Potential Notification (PRS Administrator)

a. Prioritize follow-up for ACTs and NIH trials within scope of the NIH Policy.
b. In the PRS, select ‘Custom Filter’ and under ‘Problems’ (far right box) check ‘Never Released’
c. If ‘Last Update’ column is not visible, click on ‘Show/Hide Columns’ and check the box next to ‘Last Update’ to show column.
d. Click on ‘Last Update’ to sort by date updated to more easily identify studies which fall into the “look-back” time frame.

3. Notify Study Team or otherwise Take Action (PRS Administrator)

a. If a study has not been updated within the “look-back” timeframe, contact the RO or the RP.
    i. See ClinicalTrials.gov PRS Email Communications Best Practices for suggestions.
    ii. If the PRS administrator has access, consider looking up the study’s Institutional Review Board (IRB) or CTMS record to determine whether the study has started, been withdrawn, or is on hold indefinitely. Having that information prior to contacting the RO or RP may speed up the process.
    iii. Offer services as determined based on resource allocation (see Administrative Considerations).
b. If the study will not move forward (e.g., study canceled or withdrawn from the IRB), the record can be deleted by the RP or a PRS Administrator. Note: a PRS Administrator can undelete a record if needed at a later time.
    i. If administrative deletion of the record is allowed and considered the best course of action, the final follow-up prior to deleting the record should clarify that the record can be undeleted if needed.

4. **Helpful hint:** Reminding the RO or RP that, unlike IRB applications, ClinicalTrials.gov records can be easily edited, as relevant. They may be submitted pending initial IRB approval. This may encourage timely submission for PRS review to meet relevant registration requirements.

Document History:

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