ClinicalTrials.gov Registration and Results (CTRR) Taskforce

Best Practice

Email Communication among PRS Administrators, Record Owners, and Primary Investigators

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Purpose

Maintaining compliance with trial registration, record maintenance, and results reporting is extremely important, and non-compliance with federal requirements regarding registration and results reporting can have serious consequences such as loss of funding or civil monetary penalties.

Communication between ClinicalTrials.gov Protocol Registration and Results System (PRS) Administrators and Record Owners is a vital component in helping to ensure compliance. Records that require updates can be proactively revised or updated to prevent them from becoming problem records. The following are best practices to facilitate timely and productive email communications with Research Groups.

Best Practice

- **Proactively communicate before the record becomes a 'problem'.**
    - Use the Planning Report, or similar mechanism, to identify applicable studies with upcoming Anticipated Study Start and Completion dates, Annual Verification dates, or Result Reporting due dates.

        - Keep in mind the PRS does not currently have a mechanism to track results reporting for studies subject to the NIH policy that are not Applicable Clinical Trials (ACTs). An alternate mechanism should be used to track results reporting compliance for these studies. For example, in the Planning Report, look for study records that are Interventional (study type column), initiated on or after 01/18/2017 (study start date column), and have an entry in the “NIH Grants” column; search in the institution's grant processing system or in the study's IRB applications.

- **Build email templates to create efficiency.**
    - Indicate what action is needed in the email subject line along with the reason for the email, the unique institutional study identifier, and NCT number. For example:
        - Response Requested: Confirm or update Primary Completion Date for [study name], [NCT number]
        - Corrections Expected 6/10/2021: Please submit results corrections for [study name], [NCT number]
    - In the body of the email prior to the greeting, summarize the intent of the email and the action requested in one sentence, for example:
        - Please reply to this email indicating whether you would like to use the Clinical Research Office centralized service for assistance in reporting results to ClinicalTrials.gov.
        - Please log into the PRS to verify that the public record for [study name], [NCT number] accurately reflects the current protocol and study status by end June 2021.
    - In the body of the email following the greeting, indicate any outstanding questions regarding the study record, or specific actions needed to bring the record into compliance.

- **If you offer consultative services or assistance to Record Owners, include that date and time in the email to indicate when you are available to help**.

    - If possible, use an Institutional central service (or “generic”) email address, ideally one that uses ClinicalTrials.gov Compliance in the name. Response rates may be improved if someone in a leadership position is willing to add their name to the email address used to send messages regarding updates that are required, results due etc. For example, “Dr. John Doe - ClinicalTrials.gov Compliance”. This inbox will be monitored by the PRS administrator.

- **Follow an Escalation Process.** If the Record Owner, Principal Investigator, or their delegate does not respond after 2 attempts, escalate per your Institution's Escalation Policy or see the CTRR Taskforce Best Practice document "ClinicalTrials.gov Sample Escalation Policies" if help is needed in creating an escalation plan.

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