ClinicalTrials.gov Registration and Results (CTRR) Taskforce

Guidance Document

Email Script to Study Team Once NCT Number has been assigned

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Purpose

To manage expectations of the Study Team to provide study status and protocol updates to maintain legal and policy-driven ClinicalTrials.gov record compliance once the National Clinical Trials (NCT) number has been assigned.

Proposed Email Script

Hello, {relevant Point of Contact (POC)},

The NCT number for [IRB no, Study Title] has been assigned.

ClinicalTrials.gov Identifier: [NCT] – If applicable, please enter this number into OnCore > PC Console > Main > Details > NCT Number (or relevant CTMS)

[NOTE: Include Institution-specific directions here about how to add this study to relevant databases or search engines as required]

After you register a study on ClinicalTrials.gov, the record requires regular maintenance updates throughout the duration of the study. Regular record maintenance helps ensure the information for your study is reliable and accurate on the public site. Our office will assist you in keeping this record in compliance.

*****The very next record action will be to (indicate next expected record requirement here, such as IRB approval or study status change) *****

Now that this study is registered, here's a review of other updates to keep in mind:

- Information from approved **Protocol Amendments** that impact the content of the record is required to be updated in the public record within 30 days of approval.
- Changes to the information in the **Study Status** section of the ClinicalTrials.gov record must also be added within 30 days of the change in study. This includes:
    - Updating the Overall Status (for example: Not Yet Recruiting to Recruiting)
    - Updating the Study Start Date from anticipated to actual after the first participant is enrolled
    - Updating the Anticipated or Actual Primary Completion Date (the date upon which data collection is complete from all enrolled participants to answer the Primary Outcome Measures)
    - Update the Anticipated or Actual Study Completion Date (the date upon which data collection is complete from all enrolled participants), typically, last participant off study date – not the IRB Closure date
- **Contacts and Locations**: Primary contact, back-up contact, study official or the PI should be updated as changes occur. Individual Site Statuses for multisite studies should also be maintained.
- Once the study closes to enrollment and the overall status is updated to 'Active, not Recruiting' [or, 'closed to accrual' per OnCore] – the 'Anticipated' enrollment target must be updated to reflect the 'Actual' enrollment total for the study under the '**Study Design**' section of the record.
- The ClinicalTrials.gov record also requires Annual verification even if there are no other changes needed to the record. After review to ensure the ClinicalTrials.gov record is up to date, the annual verification date in the study status section of the record should be updated to the current month and year.
- When trial results are published, any publication can be linked by entering the PubMed Unique Identifier (PMID) of an article or the full bibliographic citation in the References section of the CT.gov record.

[Insert the items below as appropriate depending on study classification]

- **NIH-funded Clinical Trials:** Please make sure the ClinicalTrials.gov record is updated prior to annual reporting. NIH systems automatically source information from the ClinicalTrials.gov record. It is important to note that the RPPR should be adjusted to align with the ClinicalTrials.gov record to help ensure accurate results reporting.
- **Clinical Trials Subject to the** Revised Common Rule supported by one of these Federal departments or agencies must upload one Informed Consent Form that was used to enroll participants to the ClinicalTrials.gov record after enrollment has completed, but no later than 60 days after the last study visit by any subject.
- The Results Module for this study is due [per FDAAA Law or NIH Policy] within one year of the Primary Completion date.

Optional Text Depending on Institutional Process: If you use OnCore [or other CTMS] to curate trial data and would like us to manage the ClinicalTrials.gov record using OnCore, please let us know.

You can find more information on our [insert relevant links to Institutional website or resources here] otherwise, we're available to answer any questions.

Optional Text Depending on Institutional Process: Please consider providing feedback to us about the service you received by completing this very short survey [link to any customer service feedback].

Thank you!
Your friendly Institutional Service

Document History:

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- 6 September 2023: Review by Carlee Brueser, Duke University
- 11 September 2023: Reviewed by Susan Hmwe, City of Hope
- 11 December 2023: Final Review and Accessibility by Meredith Rhodes, UW-Madison