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Clinical Research NEWSFLASH

A Newsletter for Clinical Research Professionals

Clinical Trials Office, Columbia University

Announcements

- The Final Rule has been in effect since January 18, 2017 for clinical trials registration and results submission on *ClinicalTrials.gov*. For assistance, please contact CU Administrators at ClinicalTrialsGov@cumc.columbia.edu.
- The Clinical Trials Office website now has a new informational page on ClinicalTrials.gov.
- The NIH has a new Data Management and Sharing Policy that will come into effect for applications due on or after January 25, 2023. Please click here for more information.

ClinicalTrials.gov Requirements for NIH-Funded Trials

A report was recently released by the Office of Inspector General (OIG) regarding an audit performed on the National Institutes of Health (NIH) to determine whether NIH ensured that NIH-funded intramural and extramural clinical trials complied with federal reporting requirements.

The report covered 72 NIH-funded clinical trials that were required to have results reported in 2019 and 2020 and concluded that the NIH did not ensure that all clinical trial results were reported in accordance with the federal requirements.

As a reminder, clinical trials that are funded wholly or partially by the NIH and are initiated on or after January 18, 2017 must comply with the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information. This policy requires that interventional (also includes behavioral) NIH-funded clinical trials be registered on ClinicalTrials.gov in accordance with the Final Rule, which was issued on September 16, 2016.

NIH-funded interventional clinical trials that require registration must follow the timelines that are outlined in the Final Rule, which include the following:

Milestone	Deadline
Trial Registration	Within 21 days from the first enrollment (i.e., date of when consent was obtained from the first participant)
Results Reporting for the Primary Outcome Measure	Within a year from the Primary Completion Date
Results Reporting for Secondary Outcome Measure(s)	Within a year from the Study Completion Date
Reporting of Adverse Event (AE) Information	Within a year from the final date of AE data collection

Updates to record information should also follow the deadlines that are outlined in the Final Rule such as:

	Timeline
General Updates	At least once per year
Change in the approval or clearance status of a device product not approved or cleared by the FDA	15 calendar days
Any change in the following: • Study Start Date • Intervention Name • Availability of Expanded Access • Overall Recruitment Status • Individual Site Status • IRB Review Status • Primary Completion Date • Study Completion Date • Responsible Party (RP) • Contact for RP	30 calendar days

Enhanced Checks in RPPR

On October 1, 2021 the NIH implemented new system validations for Research Performance Progress Reports (RPPR) for clinical trial registration and results reporting of NIH-funded clinical trials. These new checks could result in an error upon submission of a RPPR when registration and/or results reporting is overdue, or if the information in the ClinicalTrials.gov study record is discrepant from the grant information.

- Grant recipients will now see an error if they are non-compliant with clinical trial registration at 21 days after the enrollment of the first participant, preventing the submission of the RPPR, if they are more than 30 days past this date.
- Grant recipients will now receive an error, preventing the submission of the RPPR, when results are overdue by more than 12 months after the trial's actual primary completion date.
- An error will be issued if the required registration or results reporting information is overdue by more than 30 days after enrollment of first participant for the registration, or by more than 12 months after the trial's actual primary completion date for results reporting at the time of (RPPR) submission. If the requirements are not met at time of award, it will **prevent issuance of the award**.

The specific errors are not identified when the eRA's Human Subjects System detects an error or discrepancy so it is important that grant investigators ensure that the ClinicalTrials.gov record is updated in real-time as changes occur to a study.

Please see NOT-OD-22-008 for more details and contact ClinicalTrialsGov@cumc.columbia.edu for assistance with resolving any identified errors.

Clinical Trials Office (CTO)

Our mission is to facilitate quality clinical trial research by providing the CU research community with comprehensive administrative services that help move trials quickly from initial proposal through contract execution. We also provide regulatory support for FDA-regulated research.

We're on the Web!

Visit us at:
https://research.columbia.edu/clinical-trials-office

CRC Help:
CRCHelp@columbia.edu

IND/IDE Help:
INDHelp@cumc.columbia.edu

PRS Help:
ClinicalTrialsGov@cumc.columbia.edu

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Revised Common Rule - Posting of Clinical Trial Informed Consent Forms

The revised Common Rule (i.e., 2018 Rule or 2018 Requirements) requires one consent form be posted on a publicly available federal website within a specific time frame for any clinical trials* conducted or supported by a Common Rule department or agency.

In order to satisfy this new provision, the following must apply:

- The consent form must have been used in enrolling participants.
- Consent form is posted (1) after a study is closed to recruitment, and (2) where 60 or fewer days have passed since the last study visit.
- An unsigned, IRB-approved copy is posted on either ClinicalTrials.gov or Regulations.gov.

**Clinical Trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.*

This requirement applies to any HHS-conducted or supported research initiated on or after January 21, 2019.

If you have identified a study that requires posting of a consent form, please contact the IND/IDE Assistance Program (IAP) at INDHelp@cumc.columbia.edu for guidance on how to comply. For more information on the revised Common Rule, please visit the HHS website or the HRPO website.