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Clinical Research Newsletter

A Newsletter for Clinical Research Professionals

Announcements

- The Clinical Trials Office website has an 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.
- Previous newsletter editions can be found on the CTO website, as well as previously held Clinical Research Brown Bag sessions.
- An update to the Guidance on Changes in Principal Investigator has been released and is posted on the HRPO website. The updated document defines currently enrolled subjects.

Clinical Trials Office, Columbia University

ClinicalTrials.gov: NIH-funded Projects

It has been almost seven years since the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information went into effect, which states that all NIH-funded awardees and investigators must register and report results for their clinical trials on ClinicalTrials.gov.

The policy (effective January 18, 2017) applies to all clinical trials funded in whole or in part by the National Institutes of Health (NIH) when:

- Applications or proposals were received by the NIH on or after the effective date
- Trials were initiated on or after the effective date

In an effort to enforce the policy, on October 1, 2021, the NIH released eRA Enhancements, which checks for non-compliance or discrepancies between the ClinicalTrials.gov record ("study record") and information provided in the Research Performance Progress Report (RPPR). Grant recipients now receive an error in the eRA (Electronic Research Administration) System if there are non-compliance or discrepancies with reporting timelines. The RPPR can be submitted only when the errors are resolved.

The following **Q&A** provides general information about the process. Answers may vary depending on specific circumstances.

FREQUENTLY ASKED QUESTIONS

Q1. How do I determine if my NIH-funded study needs to be registered on ClinicalTrials.gov?

A. If your study meets the NIH definition (decision tool) of a **clinical trial** and the PRS definition (checklist) of an **Applicable Clinical Trial (ACT)**, then you must comply with registration regulations and policies.

According to the NIH, a clinical trial is 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 those interventions on health-related biomedical or behavioral outcomes*." A common misconception is that if a study does not include a placebo or control arm, it would not be considered to be a clinical trial.

Your Notice of Award (NoA) will also state the requirements if the NIH-funded research meets the NIH's definition for a clinical trial. *NOTE: Non-NIH federal agencies may have ClinialTrials.gov requirements that differ from those for NIH awardees. Check your NoA for specifics regarding ClinicalTrials.gov registration and results reporting requirements. All ACTs, regardless of funding source, are dictated by the timelines outlined in the Final Rule/FDAAA.*

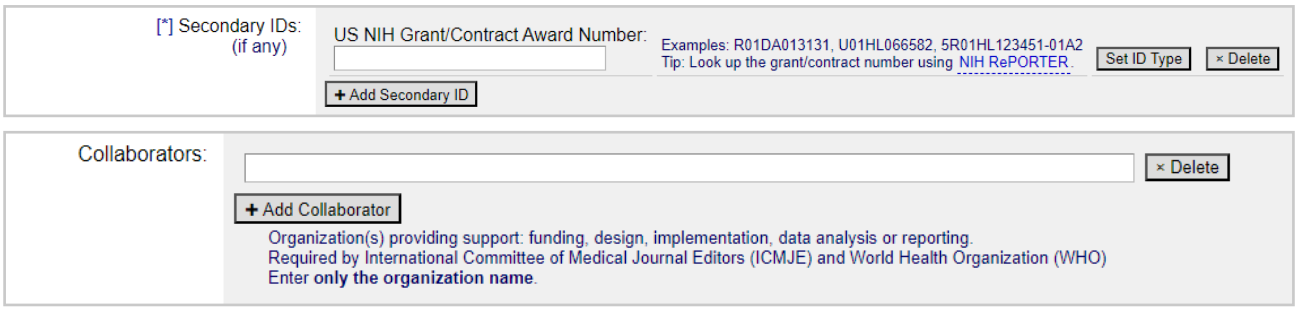
Q2. Who is the responsible party that should be registering and submitting results for a NIH-funded study?

A. Typically, the prime recipient of the grant award that funds the study is responsible for registering the study. The prime awardee may designate another individual or entity (such as a subrecipient) as the responsible party if they: 1) have access to the required study information and results to complete the record; and 2) have the ability to meet all of the requirements under the regulation for submitting and updating of clinical trial information.

When someone other than the prime awardee registers the study, please ensure that the prime awardee is at minimum listed under the Contacts/Locations > Study Officials section of the study record as a "Study Chair" or "Study Director" for appropriate representation.

Q3. Can I register a study if I am still waiting for my funding decision?

A. Yes. The responsible party of the study may register the clinical trial at any time. We recommend waiting to register the study until after you have received your NoA. There is also a chance that a newly assigned grant number may not be available on the NIH RePORTER or recognized in the Protocol Registration and Results System (PRS) yet. Please set a reminder to update the study record as soon as the grant number becomes available. The grant number(s) should be listed under Secondary IDs and the federal agency providing the funding should be listed under Collaborators (as shown below).



This also applies for projects that may become NIH-funded at a later time or receive additional support from a grant mid-project. Check this field at least once a year, or recommended every 6 months for active studies, to ensure the information is complete and update to date. It is also important to check and update the funding section of your Rascal Datasheet so that your IRB and department is aware of any changes.

Q4. What is the deadline for registering and entering results for NIH-funded trials on ClinicalTrials.gov?

A. Registration and results reporting for NIH-funded clinical trials follow the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information, which is in accordance with the timelines outlined by the Final Rule.

Registration is required no later than 21 days after the first participant is enrolled (i.e., consented). The Study Start Date within the study record captures the date when the first participant signs the study informed consent form. Results reporting is due no later than one year from the Primary and Study Completion Dates. These dates capture when the last participant was examined, received intervention or contacted for follow-up either for the primary outcome or the entire study.

The table below outlines the specific milestones and deadlines.

Milestone	Deadline
Trial Registration	Within **21 days** from the **first enrollment**, defined as the date consent was obtained from the first participant.
Results Reporting: Primary Outcome Measure(s)	Within **a year** from the **Primary Completion Date**, defined as the date the final participant was examined or received an intervention for purposes of data collection for the primary outcome.
Results Reporting: Secondary Outcome Measure(s) Adverse Event (AE) Information	Within **a year** from the **Study Completion Date**, defined as the date the final participant was examined or received an intervention for purposes of data collection for primary outcome(s), secondary outcome(s), and adverse events.

Q5. My funded grant supports multiple clinical trials with various research aims. Do I register all of the aims or just some of them under one record?

A. Registration is done per study and not per grant. If your grant covers multiple trials and projects, you need to register each trial or project separately in PRS. Each study record should be tied to a unique protocol ID (i.e., CUIMC IRB Number) and only contain the study-specific aims or outcome measures outlined in the study protocol.

Q6. I received notification that my funds will remain frozen due to discrepancies with the information in eRA Commons and ClinicalTrials.gov. How do I resolve this issue?

A. The grant PI should be in communication with the Project Officer (PO) in Sponsored Projects Administration (SPA) that is assigned to the award, as well as the PO at the NIH to confirm the issue causing a pause on funding. If a discrepancy between the clinical trial information in eRA Commons and the ClinicalTrials.gov record exists, both sources will need to be reviewed and compared to ensure that the information is consistent. Once the information is verified and updated as needed, the grant PI should notify the SPA and NIH POs.

Q7. What is the best way to identify a discrepancy between the study information in eRA Commons and ClinicalTrials.gov?

A. Compare the information provided in eRA Commons Human Subjects System (HSS) and the RPPR against the ClinicalTrials.gov record as the details and dates should match across the report and both systems. The error message provides a general note regarding the nature of the discrepancy, e.g., Primary Completion Date or Study Design are not consistent. Any unresolved discrepancies between the HSS system/eRA Commons and ClinicalTrials.gov may prevent the submission of the RPPR and timely issuance of the award.

Q8. I am a new investigator at Columbia University and I am in the process of transferring some NIH-funded awards from another institution. What do I do with the ClinicalTrials.gov records for those awarded trials?

A. Once the awards are fully transferred to Columbia, the ClinicalTrials.gov record(s) for the studies covered under the awards can be transferred to Columbia University's institutional PRS account. To coordinate the transfer, email ClinicalTrialsGov@cumc.columbia.edu with the grant number(s), former institution name, the National Clinical Trial (NCT) number(s), and the contact information for the PRS administrator at the former institution, if known.

TIPS FOR SPECIFIC DATA ELEMENTS

Field: Secondary IDs

TIP: Ensure the listed grant number(s) correctly correspond to the study being registered on ClinicalTrials.gov. In addition, if the study is supported by more than one grant, ensure each grant number is listed. You can search for the grant number using the NIH RePORTER link located in the study record.

Field: Study Start Date, Primary Completion Date, Study Completion Date

TIP: Check periodically to see if these dates match the anticipated time frame in your RPPR, especially if they need to correspond to specific dates referenced in your grant application or progress report.

Field: Collaborators

TIP: List the federal agency that is granting the award.

Field: Study Description > Detailed Description

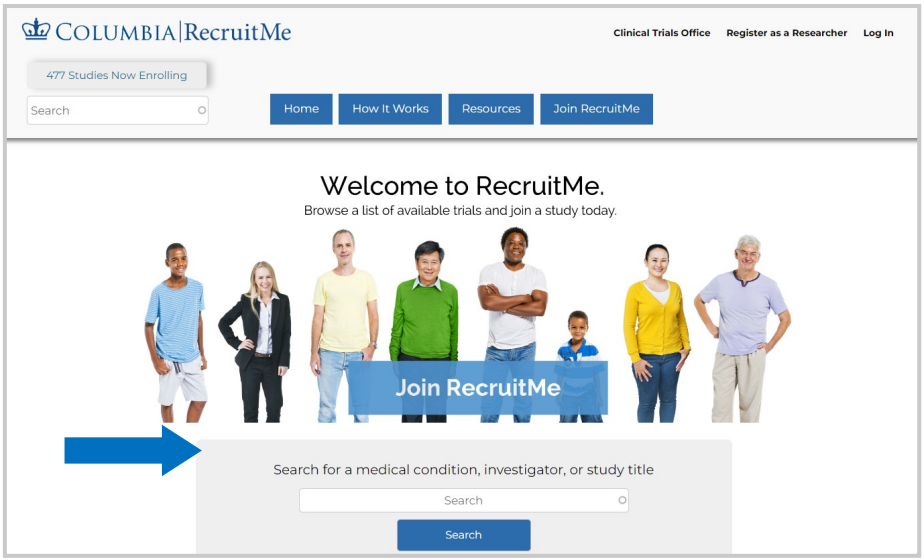
TIP: If you study is being funded by the FDA Office of Orphan Products Development (OOPD), you are expected to mention it under this section and not under Collaborators.

See the Protocol Registration Data Element Definitions for descriptions and examples of the information to be submitted.

RecruitMe UPDATES

RecruitMe now features a streamlined search functionality allowing researchers and the general public to search by condition, investigator, or study title. In addition, enhanced filtering allows for selection of open or closed studies as well as the option to search for studies from multiple areas of interest.

Visit the new RecruitMe informational page for FAQs, list of services, and training materials.



Research Funny

What did the study coordinator wear to impress the study participant when obtaining consent for genetic testing?

Designer genes

Why are chemists great at handling research problems?

They have all the solutions

What type of dogs do research pharmacists own?

Laboratory retrievers

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

RecruitMe:

recruitme@columbia.edu