March 30, 2015
Volume 4, Issue 1

Clinical Research Newsletter

A Newsletter for Clinical Research Professionals

Clinical Trials Office, Columbia University

Announcements

- The next CR Brown Bag Session is on April 15th in P&S-16, Room 405 from 12-1pm on *RecruitMe*. To attend, please RSVP.
- Version 5 (June 2014) of the Clinical Research Handbook is now available. To access the handbook, please visit our website or EVPR's website.
- The CTO website is currently being updated. Please visit us at our new address.
- Columbia University is currently participating in *ResearchMatch*.

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For CRC Training, please visit RASCAL:

TC0098 – Clinical Research Coordinator Mandatory Training

For those who are interested in S-I Training, please visit RASCAL:

TC0096 – FDA Requirements of Sponsor-Investigator Studies

What Is ClinicalTrials.gov?

ClinicalTrials.gov is a national registry – the largest searchable clinical trials database – of federally and privately supported research studies managed by the United States National Library of Medicine (NLM). It serves as a central location where patients, clinicians, journal editors, officials and institutional review boards can obtain study information. As of July 2014, ClinicalTrials.gov lists 186,597 studies with locations in all 50 states and receives an average of more than 57,000 unique visitors per day.

Why Is Registration Important?

- Federally mandated as per Section 801 of the Food and Drug Administration Amendments Act of 2007, also known as FDAAA 801
- Required by the International Committee of Medical Journal Editors (ICMJE) as a condition for publication of research results
- Promotes transparency to the public about clinical trials
- Aids in enrollment and facilitates systematic reviews

Which Trials Must Be Registered?

All Applicable Clinical Trials (ACTs) must be registered on ClinicalTrials.gov according to FDAAA 801. The definition of ACT includes:

- Trials of Drugs and Biologics: Controlled clinical investigation (except Phase 1) of a product subject to FDA regulation
- Trials of Devices: Controlled trials with health outcomes of a product subject to FDA regulation (except small feasibility studies) and pediatric postmarked surveillance studies

For an elaboration of the definition, please visit PRS Info.

⇨ **Does FDAAA801 only apply to industry- sponsored trials?**

No. FDAAA 801 applies to any clinical study that meets the definition of an ACT. FDAAA801 does not distinguish between types of studies or funding sources in establishing requirements for registration and results submission.

⇨ **If I have an observational trial, do I have to register it on ClinicalTrials.gov?**

FDAAA 801 does not require registration for observational trials. Researchers may still use trial registration to satisfy a publication requirement or to garner interest for the study. For more details, please visit the ClinicalTrials.gov information page.

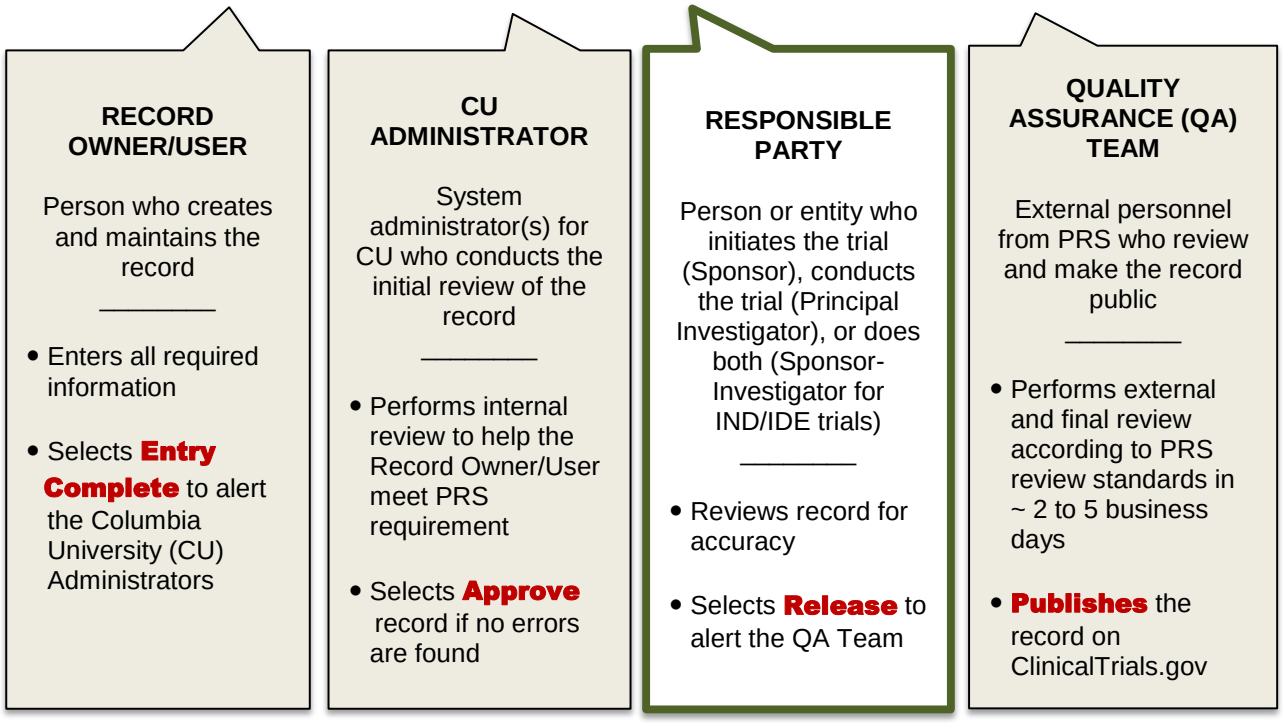
Where and How Does Registration Occur?

Trials are registered as individual records in the Protocol Registration and Results System (PRS), which is a secure web-based data entry network. In order to create a new record, one must request a user account to log on to PRS. Researchers at Columbia University may obtain a user name and password by contacting Columbia University Administrators.

⇨ **What is the timeline and process of registration?**

ACTs need to be registered no later than 21 days after the first subject signs an informed consent form. A newly created record, as well as an updated/modified record, undergoes the following record statuses before it is published on ClinicalTrials.gov.

In Progress ➔ Entry Completed ➔ Approved ➔ **Released** ➔ PRS Review ➔ Public



Do Records Need to Be Updated, and If so, How Often?

Yes. The frequency of record updates depends on the Recruitment Status:

Recruitment Status	How often should I update the record?
Not yet recruiting	Every 6 months
Recruiting	
Enrolling by invitation	
Active, not recruiting	
Completed	Every 12 months* **until the record is complete (i.e., protocol and results sections have been completed and made public)*
Suspended	
Terminated	
Withdrawn	
Change in recruitment status, recruitment information or completion date	Within 30 days of the change

⇨ I updated my record, but I cannot see the changes on clinicaltrials.gov. Why don't they appear on the website?

Changes to the record will only appear in the Record Owner/User's view until the Responsible Party releases the record. Once changes are released by the Responsible Party, the QA Team will need to review and approve the changes in order for them to be made public.

⇨ I updated my record, but I received a notification that my record is outdated. What am I missing?

PRS sends automated messages when a record is outdated based on the *Record Verification Date* field. Researchers who have successfully updated and released their records can still receive these automated messages if they do not update the *Record Verification Date* data field.

Can the Responsible Party Delegate the Task of Releasing the Record to a Designee?

No. The release function is solely reserved for the Responsible Party and will not appear on a record for anyone other than the Responsible Party of a record.

Submitting Results: When and How?

⇨ Am I required to submit to ClinicalTrials.gov the results of a clinical trial that is not an Applicable Clinical Trial?

Results submission is not required under FDAAA 801 for a clinical trial that is not an ACT. If a Responsible Party chooses to voluntarily submit results for such a trial, however, the Voluntary Submissions (PDF) provision of FDAAA 801 may apply.

⇨ When must I submit results?

In general, results of an Applicable Clinical Trial of a drug, biologic, or device that is approved, licensed, or cleared by FDA must be submitted by the Responsible Party no later than 12 months after the *Primary Completion Date* that is provided on the record.

⇨ How do I submit results information if the trial is terminated (that is, stopped prematurely) and no data were collected for one or more Outcome Measures?

If no participants have been consented to participate in the study, set the Overall Recruitment Status to "withdrawn", and no further results information will be needed.

If participants have been consented to participate in the study, provide any available* data in the results section.

*If no data are available for any of the Outcome Measures:

- Specify zero ("0") for the Number of Participants Analyzed in each Arm/Group, and leave the data fields blank.
- Provide an explanation in the Analysis Population Description for why zero participants were analyzed.
- Submit the available data in the Participant Flow, Baseline Characteristics, and Adverse Events modules.

⇨ **If I'm not ready to submit my results, what can I do?**

The Responsible Party may submit a written request for an extension that demonstrates good cause and provide an estimate of the date on which the results will be submitted. An explanation and a projected results submission date are required when submitting a request in PRS. The Director of NIH will evaluate the request and may grant an extension.

NOTE: Pending publication is not considered good cause for an extension.

⇨ **Can anyone help me enter in the data?**

Yes. The Responsible party can delegate results entry to personnel who they consider to be knowledgeable in the study outcomes and data. For example, the study statistician may obtain a clinicaltrials.gov account to enter the results on behalf of the investigator or the Responsible Party. However, the Responsible Party must still release the record in order for the results to be submitted and to appear on a record.

⇨ **Are there any resources that are easily accessible and helpful with understanding how to submit results?**

You can visit the ClinicalTrials.gov information page for short and easy tutorials:

Results: Participant Flow Module
Results: Baseline Characteristics Module
Results: Outcome Measures and Statistical Analyses Module
Results: Adverse Event Module

In addition, you may contact the Columbia University Administrators for further assistance:

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Diana Kim	ddk2133@cumc.columbia.edu

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:

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