University of CINCINNATI

NIH / clinicaltrials.gov Mandates: Required registration of NIH funded studies and posting of study results

Thursday, January 19th, 2023

REMINDER: Invitation to participate in a survey about CRP Job Satisfaction and Retention

Researchers at OSU, Duke University and University of Cincinnati are conducting a brief 15-minute anonymous survey of fellow clinical research professionals (CRPs) to better understand current job satisfaction and retention of CRPs.

If you are a professional working in clinical research (Clinical Research Professional - CRP) You are invited to participate in a research survey to evaluate factors associated with CRP job satisfaction and job retention.
Please click on the following URL to access the informed consent and survey.

https://osu.az1.qualtrics.com/jfe/form/SV_bdemU52sO9W2Qaa

Your effort and time is greatly appreciated!

The Survey is open until February 3rd, 2023

SOCRA CRP CERTIFICATION EXAMINATION
Hosted by CCHMC
Monday, March 20th, 2023

Please visit the SOCRA website for more details.

The Registration Deadline is Tuesday, February 13th, 2023

Register Here

Open review sessions:

CCHMC CRP will be hosting open review sessions prior to the exam date in February 2023
(Dates and times TBD)
Hosted on Microsoft Teams
(link will be provided once dates and times are established).

For any questions or further information, please contact the CCHMC CRP Group at CRP@cchmc.org
or Nate Harris at harrisnl@ucmail.uc.edu

Friday, February 3rd, 2023

Black History Month Presentation:

Black Doctors and the Jim Crow Health Infrastructure of Cincinnati

Carolette Norwood, Ph.D.

Professor and Department Chair of Sociology and Criminology

Howard University

University of CINCINNATI

Today's Presentation:

NIH / clinicaltrials.gov Mandates: Required registration of NIH funded studies and posting of study results

As of October 1st, 2021, the NIH mandates that all clinical trials with any NIH funding register on clinicaltrials.gov. Annual updates of records as well as posting study results are required. Letters of non-compliance are being issued when updates are not complete for each individual applicable study. Failure to comply jeopardizes funding to the PI and the institution. Please join us for a discussion of this important requirement and a "How To" walk through of the process

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CLINICALTRIALS.GOV

WHAT IS IT?

ClinicalTrials.gov is a public database containing information about federally and privately supported clinical trials.

The service is a collaboration involving the U.S. National Library of Medicine (NLM) at the National Institutes of Health (NIH) and the Food and Drug Administration (FDA).

Registration is done through the Protocol Registration and Results System (PRS) at http://register.clinicaltrials.gov

APPLICABLE TRIALS

NIH applicable studies:

- Involve human participants
- Prospectively assign participants to an intervention
- Which are designed to evaluate the effect of the intervention on participants
- Will evaluate a health-related, biomedical, or behavioral outcome

APPLICABLE TRIALS

FDA applicable studies:

- Involves an intervention
- There is at least one study facility in the U.S. or applicable territory OR the study is conducted under a U.S. FDA IND/IDE OR the study involves a drug, biological or medical device product manufactured in and exported from the U.S. for study in another country.
- The study evaluates at least one drug, biological, or medical device regulated by the U.S. FDA.
- The study is other than a Phase I trial of a drug and/or biological product or is the study of other than a device feasibility study.

WHO IS RESPONSIBLE?

(1) the "sponsor" of the clinical trial, OR

(2) the principal investigator of such clinical trial if designated by a sponsor, recipient, contractor, or awardee

MILESTONES

Ensure study is registered no later than 21 days after enrolling the first participant.

Ensure updates are made to the record at least every 12 months.

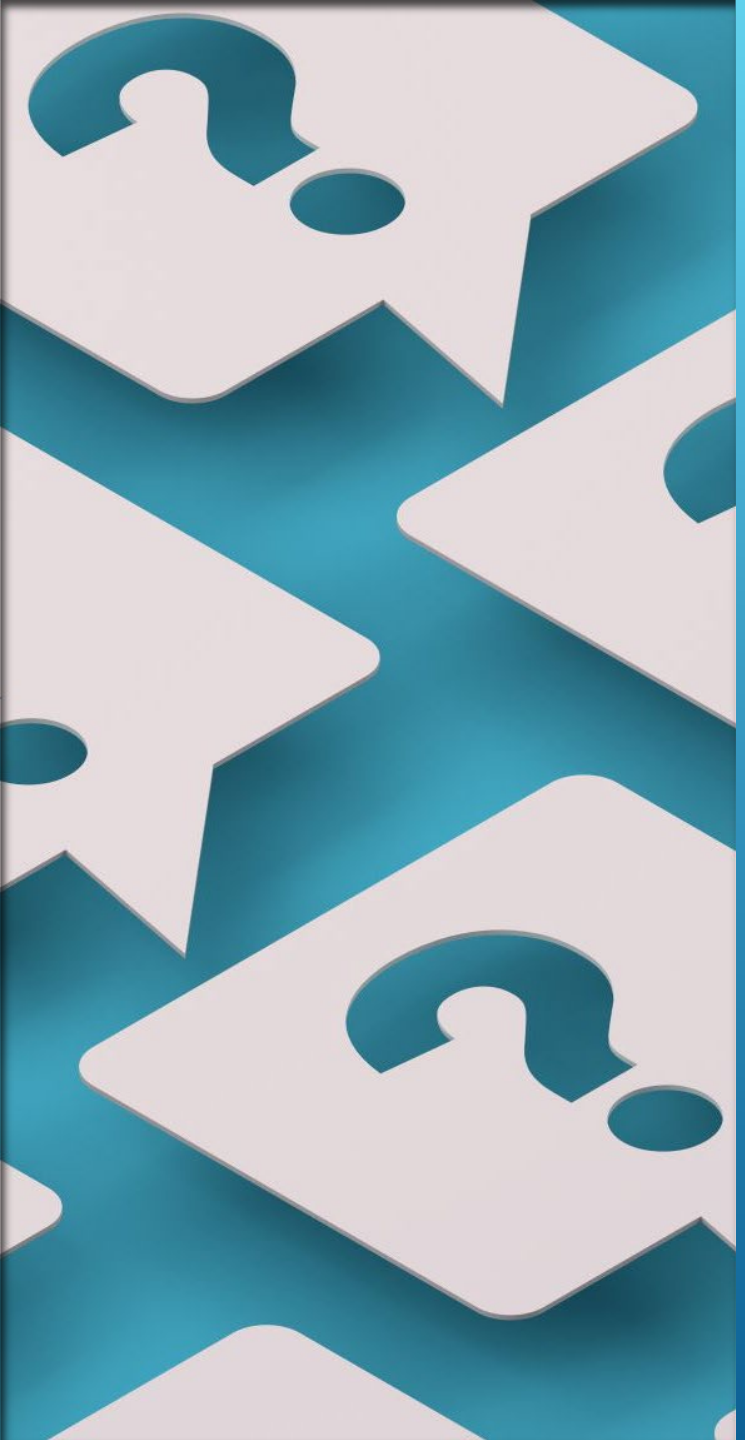
Ensure results are reported no later than a year after the study completion date. 42 CFR Part 11 describes several circumstances under which the results reporting submission for an ACT may be extended past one year.

Respond to PRS Major Comments within 15 calendar days (registration information) or 25 calendar days (results information) of the date on which PRS Staff sent the notification. The Corrections Expected date is indicated in the Record Status box on the Record Summary page.

RECORD OWNERS & THE ACCESS LIST

Record owner

- Role assigned to the person who created the record.
- The primary contact for a study record.
- Can maintain the record or give one or more users access to a record in order to make changes.
- Can be the same as the responsible party, but doesn't have to be the same.
- Receives (not able to opt out of) notifications from PRS system the same as the responsible party.



- The system is designed to detect incomplete, incorrect, and inconsistent entries.

  ERROR messages indicate serious issues that must be addressed.

  WARNING messages indicate potentially serious issues that should be reviewed and addressed as needed.

  NOTE messages indicate potential issues that should be reviewed and addressed as needed.

- Error messages must be addressed in order to release the record for PRS review. The other messages should be evaluated carefully and may lead to issues later if not addressed.

ERRORS, WARNINGS & NOTES

PRS REVIEW & CORRESPONDENCE

- On the main page of the PRS record is a section called PRS Review with a link to the review history
- Event (publish, release, reset), User/Reviewer, date/time, review comments
- Utilize the contact link in the upper right section of the screen to ask questions.

TIPS

- Use the decision trees and read the fine print.
- Review the results data requirements before you submit the study.
- Save a record of PRS correspondence.
- Save a record of changes to the study record.
- Keep the responsible party engaged in the process of record maintenance.
- Keep important milestones in your calendar.

Navigating New Mandates ClinicalTrials.gov An Investigators Perspective

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Research Professor of Medicine
Director, Transplant Clinical Research
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Understanding the Different Demands of the Investigator

Goals of a Grant

- Obtain funding to test hypothesis
- Provide human subject protocol in a concise manner
- Novel science is typically the driving force
- Intellectual ideas are potentially still fluid

Goals of clinicaltrials.gov

- Collect and share significant summary protocol information before and during the trial
- Summarize results and adverse events
- Provide transparency to patients, investigators, sponsors to build public trust.

How to Homogenize these Goals

- Collaborate with a clinical trialist EARLY
- If trial is multicenter, collaborate with a clinical trial organization or equivalent
- Interpret protocol as written in the grant into a clinical trial protocol for regulatory purposes, study implementation, and clinicaltrials.gov reporting.
- Simplify primary and secondary endpoints and use tertiary endpoints for exploratory outcomes

Current Disconnect

- In an effort to obtain grant funding, novel science is prioritized.
- To stay within budget limits, the human subject portion of the grant is woefully underfunded and tends to be an after thought.
- The full cost of human subject research is under estimated and not fully understood.
- Budgeted funds directed toward human subject study are disproportionately utilized by data management to meet mandates such as clincaltrials.gov, etc

Entering Study

- ClinicalTrials.gov is designed to cover ALL clinical studies, therefore, as a user, you will think “my study doesn’t fit”. You have to make it fit☺

http://www.ClinicalTrials.gov/beta/manage-recs/fdaa#WhenDoINeedToRegister-

- User pearls
  - Proper entering of a trial impacts downstream events
  - Enter your study in the most basic and simple form as possible
  - REALISTICALLY enter study start and study completion dates.
  - “Estimated” primary outcome completion endpoint (***date the last participant was examined or received intervention and data collected***) Of note….has NO relation to timing of data analysis.
  - Determination of intervention arms AND Arms/Groups are important because all results must be reported based upon this delineation
  - Responsible party identified as the sponsor or PI
  - Reporting requirements will change. When they change, they are retroactive to ALL active studies. Close studies in a timely manner.

Reporting Results

- Results and Adverse events must be reported within 12 months of the “actual” data of primary outcome completion endpoint, but you will receive queries based upon estimated date.
- Results must be reported within 30 days of FDA approval.
- Other reporting elements must be current, ie overall study status, actual completion date (in the past), enrollment
- User pearls
  - Overall study status must be consistent with study start/completion dates and can not be “recruiting” or “not yet recruiting”
  - Enrollment must be actual and the SAME as the number “started” in participant flow
  - Results section must be consistent with Intervention Names in protocol
  - Results section must be consistent with Arms/Groups in protocol

http://prsinfo.clinicaltrials.gov/results_definitions.html

Closing a Study

- Reporting requirements will change.
- When they change, they are retroactive to ALL active studies.
- Close studies in a timely manner.
- ???

Disseminating Results

- Historically, the investigator was focused on
  - Final report to sponsor
  - Manuscript publication in a high impact journal
- Now, additionally focus on results in clinicaltrials.gov

It is the gift that keeps on giving (or taking)☹