

ClinicalTrials.gov Compliance Reminders

When clinical trial registration information should be submitted to ClinicalTrials.gov as required by
42 CFR Part 11

Registration:

Applicable Clinical Trials (ACTs)* and NIH funded trials are required to register on ClinicalTrials.gov **within 21 days of enrollment of the first subject.**

i.e., date of when the 1st participant signs a study consent form.

Updates:

An active study record should be updated **at least every 12 months**, or within 30 calendar days of a change to protocol information, including recruitment status or primary completion date.

- ! Even if nothing has changed in the study, the record requires yearly review and approval.

Results Reporting:

Study results of ACT studies (42 CFR 11) and/or NIH-supported clinical trials are required to be reported **no later than one year after the primary completion date.**



The date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measure. Whether the clinical study ended according to the protocol or was terminated does not affect this date.

*An ACT refers to a trial involving drugs, biologics, or devices that must be registered and have results posted on ClinicalTrials.gov. The criteria defining an ACT are outlined here: [ClinicalTrials.Gov ACT Checklist.pdf](#)

If you need assistance with ClinicalTrials.gov registration or results reporting, please contact the University's ClinicalTrials.gov administrators at OQC@utah.edu