

Required ClinicalTrials.gov Record Updates under the Final Rule (42 CFR 11)

Data Element Changes	Deadline for updating
Record verification date	Any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months , even if no other updated information is submitted at that time. CU/NIH policy: Update this at least once every 6 months while actively recruiting.
Study Start Date	30 calendar days after first subject is enrolled
Availability of Expanded Access	30 calendar days after expanded access becomes available
Overall Recruitment Status	30 days after a change in overall recruitment status
Individual Site Status	30 days after a change in status of any individual site
IRB Review status	30 days after a change in IRB status
Primary Completion Date	30 days after a clinical trial reaches its actual primary completion date
Enrollment	At the time the primary completion date is changed to “actual” the actual number of participants enrolled must be entered
Study Completion Date	30 calendar days after the clinical trial reaches its actual study completion date
Responsible Party	30 days after a change in the official title of the responsible party
Responsible Party Contact Information	30 days after a change in the contact information for the responsible party