

ClinicalTrials.gov Guidance

Protocol type	Criteria	Registration deadline	Results submission required (with protocol application and Statistical Analysis plan)	Consent form upload required and when
Applicable Clinical Trial	<p>FDA regulated Clinical Trial of a drug or device. Use checklist to determine.</p> <p>Does not include Phase 1 clinical trials</p>	<p>Registration must be submitted within 21 days after the first human subject signs the informed consent form and begins trial participation in accordance with the protocol.</p> <p>Reference</p>	<p>Yes, no later than 1 year after the primary completion date of the applicable clinical trial.</p> <p>Reference</p>	No, optional submission.
NIH Clinical Trial	<p>Funded in part or in whole by the NIH and a Clinical trial (Definition)</p> <p>Includes Phase 1 clinical trials</p>	<p>Must be registered in ClinicalTrials.gov no later than 21 calendar days after the enrollment of the first participant</p>	<p>Yes, no later than 1 year after the primary completion date of the applicable clinical trial.</p> <p>Reference</p>	Yes , after recruitment is closed and no later than 60 days after the last study visit with a subject
Non-NIH Clinical Trial subject to Revised Common Rule	<p>Clinical Trial with (non-NIH) Federal Funding by a Common Rule Agency</p> <p>Does not include Phase 1 clinical trials</p>	None	No	Yes , after recruitment is closed and no later than 60 days after the last study visit with a subject.
Non-FDA and Non-Federally funded study meeting the NIH definition of a Clinical Trial	Is not regulated by the FDA or subject to the Revised Common Rule regulations	None	None	N/A

If you are required to register your clinical trial on ClinicalTrials.gov, please notify RegulatoryServices@uta.edu when you are ready to register your clinical trial. Our office will be responsible for creating an account for you. Once your account has been created, you will then need to create a 'New Record' with details about your clinical trial. For questions about submitting a new record, please use the guidance found [here](#).