Albert Einstein College of Medicine

OFFICE OF HUMAN RESEARCH AFFAIRS
CLINICALTRIALS.GOV FAQ

1. **Which studies need to be registered on clinicaltrials.gov**
   Any clinical trial that meets the below definition:

   If your study is NIH funded: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

   If your study contains an FDA drug, biologic or device:
   - Trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation.
   - Trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.

   It is always better to register your study if you are not sure.

2. **Timeline Requirements/Recommendations**

Event	Timeline	Notes
Registration	**Required:** No later than **21 days** after the first subject is enrolled **Required:** ICMJE requires that registration is complete **prior** to first subject enrollment.	A study is considered registered once the responsible party releases the record to PRS for review.
Actively enrolling studies	**Recommended:** Update/verification every **6 months**	The record must be verified even if no changes need to be made.
Actively enrolling studies, studies closed to enrollment or pending results	**Required:** Update/verification **annually**	The record must be verified even if no changes need to be made.
Change in study status	**Required:** Within **30 days** of status change	

Results submission	Required: No later than **1 year** after the primary completion date	Delayed submission of results is permitted in certain circumstances. See 42 CFR 11.44 for details.

****It is highly recommended that you set your calendar to check your records in CT.gov every 30 days**

3. **Who is responsible for clinicaltrials.gov registration?**

   The Responsible Party for a clinical trial must register the trial and submit results information. The Responsible Party is defined as:

   - The Sponsor of the clinical trial (e.g., Industry Sponsor, Federal Sponsor

   Or

   - The Principal investigator (PI) of a clinical trial if it is an Investigator-initiated study or if designated by a sponsor, grantee, contractor, or awardee, so long as the PI is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of FDAAA's requirements for the submission of clinical trial information.

4. **My study is not yet IRB approved. Can I enter it on ClinicalTrials.gov?**

   Yes, you can! ClinicalTrials.gov will allow registration of the study prior to getting IRB approval if the Overall Recruitment Status of the study is “Not yet recruiting.” IRB approval must be obtained before the study’s Overall Recruitment Status is changed to “Recruiting”. When IRB approval is obtained, update the protocol registration and release the study to ClinicalTrials.gov for review and processing.

5. **Can I submit my study to the IRB before receiving an NCT number?**

   Yes, you can! In the box where it asks for the NCT number type in “pending” and move forward with your submission. You will be required to enter an NCT number before you receive the IRB approval letter.

6. **Can I register a study after it has started, has closed to recruitment, or has completed?**

   Yes, you can! A study can be registered on ClinicalTrials.gov at any time. However, FDAAA Section 801 requires applicable clinical trials to be registered within 21 days of enrollment of the first participant. ICMJE journals (and other journals) require registration of all clinical trials before enrollment of the first participant.

7. **What is the organization code?**

   Generally, if your payroll is at Montefiore the organization ID is MontefioreMC and if your payroll is at Albert Einstein the organization ID is Albert_Einstein

8. **What number do I enter in the protocol ID section?**

   Please enter the Einstein IRB number. If you have not created an application, please do so prior to submitting the study on clinicaltrials.gov.

9. I received a PRS comment during the registration process that involves the outcome measures section and I don't understand what to do?

As a rule of thumb:

- Please include ALL primary and secondary outcome measures/endpoints and label as such. Tertiary and exploratory outcomes are not captured as part of FDAAA.
- Outcome measures must be specific and indicate what is being measured and is (or planned to be) reported-include scale, score, number or percentage. For example, instead of writing simply 'headache relief' you should state 'number of participants who have sustained headache relief'. Instead of saying 'safety' you should say 'safety, as measured by number of subjects with at least one AE'.
- Omit verbs. Instead of writing '*to determine* the maximum tolerated dose of drug…' write it this way "Maximum tolerated dose of drug…'
- List the outcomes separately. For example, Do not list 'all-cause mortality, hospitalization, ER visits' together. It should be written in 3 separate columns as Number of deaths, Number of hospitalizations, Number of ER visits. **Exception:** if a composite score of multiple measures will be used (i.e., Count of individuals who experience any of the following: all-cause mortality, hospitalizations and ER visits)
- Time Frame should always include a number. For example baseline, week 2; during hospitalization, approximately 5 days; or post intervention, week 12.
- If multiple time points are included and you are measuring change between the time points, add the word "change" to the title and if not measuring a change each time point should be listed as a separate outcome measure.
- If using a scale include the scale and meaning of he scores. (i.e., The Numeric rating Scale (NRS-11) is an 11-point scale for patient self-reporting of pain. Scores range from 0-10, with higher scores meaning the worst pain possible (0=no pain to 10=worst possible pain).
- Feel free to reach out to the PRS administrator, Shakira Forde at Shakira.forde@einsteinmed.org or the PRS team directly at register@clinicaltrials.gov for further clarification.

10. I was requested to make a change and determined that changes are not needed or appropriate for an issue, what can I do?

- If it involves an "Advisory issue"-no action is needed from you and you do not need to respond.
- If it involves a "Major issue"-email register@clinicaltrials.gov with the NCT number and the clarification or justification for why it is not needed.

11. I am not sure what 'phase' to choose for my behavioral trial or device trial?

For studies that do not involve a drug or biologic, such as behavioral interventional studies or device trials, select 'Not Applicable'.

12. Am I required to submit the results of non-applicable clinical trials to ClinicalTrials.gov?

Results submission for non-applicable clinical trials is not required (for example, a behavioral study).

13. What about results entry if my trial is terminated and no participants were enrolled?

If no participants were ever enrolled on the trial, results are not required. Remember to change the Overall Recruitment Status to "Withdrawn."

14. What happens if my trial is terminated, and no data was collected for one or more outcome measure?

For a trial that terminated early after participants were enrolled, provide any available data for Participant Flow, Baseline Characteristics, Outcome Measures, and Adverse Events. 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 and, if appropriate, provide information in the Limitations and Caveats module. You must still provide data for Participant Flow, Baseline Characteristics, and Adverse Events.

15. The primary outcome of our trial has been completed, but secondary outcome data is still being collected. When do I need to report results?

ClinicalTrials.gov generally advises completing data entry right away but no later than 12 months after data collection has ended for that measure. If data collection is ongoing, it is a good idea to provide the anticipated posting date for that measure so it is clear to the public when the information will be made available.

16. It is time to report the results of our trial on ClinicalTrials.gov, but the principal investigator is still analyzing the data and writing the manuscript and does not want to publicly disclose the results until accepted for publication. What should we do?

The data must be reported on ClinicalTrials.gov. Results reporting for Clinicaltrials.gov should come first. The International Committee of Medical Journal Editors has indicated that they do not consider publishing to ClinicalTrials.gov as "pre-publication." Here's a link to their FAQs that may be useful. http://icmje.org/faq_clinical.html

You can ask for an extension/delay in disclosing results by contacting the ClinicalTrials.gov PRS staff (register@clinicaltrials.gov), but the request would need to meet their definition of "good cause" and publication issues are generally excluded from that definition.

Communication with the journal regarding the legal obligatory requirements may also be useful. It's unlikely that the journal would refuse a manuscript when the institution/investigator is mandated by law to disclose publicly. However, if the trial was not registered according to the ICMJE journal requirements (prior to enrollment of first participant), the journal may take issue with that and reject the manuscript on that basis.

17. Are exempt research studies excluded from registration and results reporting?

Because most exempt research studies are not considered clinical trials, or involve an FDA-regulated intervention, they would not need to be registered or reported on ClinicalTrials.gov.

However, if your exempt research involves any of the following, the ICJME may have a different opinion:

- drugs;
- surgical procedures;

- devices;
- behavioral treatments;
- dietary interventions;
- process-of-care change;
- biomedical or health-related measures including pharmacokinetic measures and adverse events.

You should register your study in clinicaltrials.gov if it involves any of these.

If you have any additional questions, you can contact our PRS Administrator, Shakira Forde at 718-430-2643 shakira.forde@einsteinmed.org or you can email the PRS team directly at register@clinicaltrials.gov. The PRS team responds to all questions within 24 hours.

You can also refer to ClinicalTrials.gov FAQ page for additional information https://clinicaltrials.gov/ct2/manage-recs/faq