UNIVERSITY of SOUTH FLORIDA

Guidance for registering with ClinicalTrials.gov

1. **What is ClinicalTrials.gov?**
   ClinicalTrials.gov is a protocol registry and results database of publicly and privately supported research studies conducted in the United States and around the world. Sponsors or investigators of certain clinical trials are required by U.S. law to register their trials and submit results to ClinicalTrials.gov.

2. **What is a Clinical Trial?** (See CT.gov glossary of common terms)
   A *Clinical Trial* is defined in the Federal regulations as a clinical investigation or a clinical study in which human subject(s) are **prospectively** assigned, according to a protocol, to one or more **interventions** (compared to no intervention, standard of care, etc.) to evaluate the effect(s) of the intervention(s) on biomedical or behavioral **health-related outcomes**. Applicable Clinical Trial (ACT) vs. Clinical Trial (CT):
   - NIH funded *Clinical Trials* (CT) must be registered in the CT.gov Protocol Registration and Results System (PRS) database.
   - An *Applicable Clinical Trial (*ACT) is a clinical trial evaluating an FDA regulated product being studied in the US or a US territory or for which the investigational product is manufactured in the US or a US territory (see FDA ACT checklist for more details and exceptions).

3. **Why register and submit my results?**
   - Among other reasons, this act of transparency fulfills ethical obligations to the research community and participants, reduces bias, and promotes efficient allocation of research funds.
   - The Food and Drug Administration Amendments Act (FDAAA 801) requires Responsible Parties to register and submit results of clinical trials with ClinicalTrials.gov.
   - The International Committee of Medical Journal Editors (ICMJE) often requires trial registration as a condition of the publication of research results generated by a clinical trial. Their policy requires a data disclosure statement and a disclosure plan as of 2018 and 2019, respectively.
   - Pursuant to NIH policy, NIH funded clinical trials (biomedical and behavioral) must be registered and results reported as a term/condition of award.

4. **Who has the responsibility to register the information**?
   The *Responsible Party* for a clinical trial must register the trial and submit results information. In most cases, the Responsible Party is/will be the author of the protocol. The Responsible Party is defined as:
   - The industry sponsor of the clinical trial or

- The principal investigator (PI) of the clinical trial, if so 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, and has the right to publish the results of the trial.

5. **How do I find the registration site?**
   You can access the registration site directly at: https://register.clinicaltrials.gov/.
   For additional information on the registration process, including rules, regulations, checklists, and definitions; please go to http://prsinfo.clinicaltrials.gov/.

6. **Are there penalties for non-compliance?**
   Yes; failure to register your trial and/or submission of false or misleading information to ClinicalTrials.gov may result in having to face the following:
   - Civil money penalties (see FDA guidance) and,
   - The withholding of grant funds for federally funded studies.

7. **What types of trials must be registered with ClinicalTrials.gov?**
   Registration is required for all NIH funded Clinical Trials (CT) and trials that meet the FDAAA 801 definition of an Applicable Clinical Trial (ACT) [see definitions above]. In addition, any funding can come with a stipulation to register as part of the contract.

8. **How do I register my Clinical Trial with ClinicalTrials.gov?**
   You will need a Protocol Registration and Results System (PRS) user account. Before applying for a PRS account, you should ensure that you are the appropriate individual to submit clinical study information to ClinicalTrials.gov. To avoid duplicate registration, studies should be registered only by the Responsible Party. USF has a Sponsor Organization account (***USflorida***) for trials completed by USF faculty, staff, and students. Moffitt Cancer Center and James A. Haley VA have their own accounts.

   To get a USF user ID, contact QA-QI@usf.edu or complete a request at https://clinicaltrials.gov/ct2/contact-org-admin. A short tutorial in canvas is required in order to obtain an active PRS account.

   After the Clinical Trial record is submitted by the Responsible Party and released by the USF Administrator, a PRS staff member will review the study record. Before the clinical trial is published on the ClinicalTrials.gov public website, you may be asked to clarify items or make corrections to the record. Please note that the initial submission review process and each subsequent update may each take several days.

   After the registration record is accepted by the PRS review staff, the record, including its NCT Number, is usually publicly available on ClinicalTrials.gov within 2–5 business days.

9. When do I register my trial?

The Responsible Party (that is, the Sponsor or designated PI) must submit the required clinical trial information no later than 21 days after enrollment of the first participant. Some publishers may require registration *prior* to enrolling the first participant (See ICMJE requirements). Your clinical trial can be registered prior to or concurrent with IRB approval. Review the Final Rule Training Webinars, PRS Guided Tutorials (BETA) and example studies for details.

10. What information must be provided?

ClinicalTrials.gov has specific data elements that must be included when registering. You can follow the PRS Guided Tutorials, which provide step-by-step instructions for entering results.

Responsible Parties must update their records within 30 days of a change to any of the following:

- *Recruitment Status* and *Overall Recruitment Status* data elements on ClinicalTrials.gov
- *Completion Date* (See *Primary Completion Date* and *Study Completion Date* data element definitions on ClinicalTrials.gov.)

Other changes or updates to the record must be made at least every 12 months. It is recommended that the *Record Verification Date* be updated at least every 6 months for studies that are not yet completed, even if there were no changes to the record.

It is important to note that the registration information must be written in a manner that can be understood by the general public, who may have no familiarity with sophisticated medical terminology or complicated clinical procedures. Contact information should also be included so, if interested, the general public can contact the study team directly to learn more information about participation.

11. Who do I contact for questions?

- Contact register@clinicaltrials.gov for Protocol Registration and Results System (PRS) questions.
- Contact QA-QI@usf.edu for USF specific questions.

12. TIPS:

- When possible, use your IRB number for the *Protocol ID* when registering on the CT.gov PRS.
- Be consistent with the use of terms and titles between the protocol, consent, CT.gov registration, and any other documents.

- Include the CT.gov registration language in your consent form. This language can be found incorporated in our USF consent templates.
- When registering, do not use first or second person language (i.e. use the "investigator" instead of "I" or "subjects" instead of "you").
- Chrome and Firefox browsers seem to work better.
- Define all acronyms.
- Some fields in CT.gov are made public and others are not.
    - If you use a study design that requires certain details be withheld from study participants, use caution when selecting what fields you enter those details into (e.g. designs with deception, certain exclusion criteria that participants may choose to lie about, and/or things that may affect your data integrity).
- Start date and completion date will initially be estimated; consider including only the month and year in your record. Once the date passes, update it with the actual full date.
- Update your record often enough to stay in compliance. Update a minimum of annually and 30 days after changes such as IRB approval of protocol amendments and recruitment status. The verification date field needs to be manually changed with each update.
- The enrollment number entered should equal the number of subjects expected to sign the informed consent form, unless otherwise indicated in the protocol (i.e. subjects who fail screening after signed consent will not be included in the enrollment number).
- Review the "What's New" page on clinicaltrials.gov often for FAQs and notifications about changes or guidance.