What is ClinicalTrials.gov?

What are your responsibilities as the Investigator?

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   This is a data bank established by the Federal Government which provides to the general public (patients, their family members, health care professionals, etc.) an easy avenue to obtain information on all clinical trials involving a wide range of diseases and conditions conducted nationally. Registration with ClinicalTrials.gov will ensure increased awareness of interventional and observational clinical trials sponsored by NIH, other federal agencies, private industries and nonprofit organizations. ClinicalTrials.gov offers information about those studies that are currently open for recruitment as well as those that are no longer recruiting study participants.

2. What specific trials must be registered with ClinicalTrials.gov?
   - Trials initiated after September 27, 2007 or that were initiated on or before that date and were still ongoing as of December 26, 2007
   - Controlled clinical trials (other than Phase I) of FDA regulated drugs or biologics
   - Controlled trials with health outcomes of FDA regulated devices (excludes small feasibility studies) and pediatric postmarket surveillance
   - Generally, trials with one or more arms of FDA-regulated drugs, biologics, or devices that meet one of the following conditions:
     o Have more than one site in the US
     o Are conducted under an FDA investigational new drug application (IND) or investigational device exemption (IDE)
     o Involve drugs, biologics, or devices that are manufactured in the US or its territories and are exported for research

3. Who has the responsibility to register the information?
   - Principal Investigator for single site studies
   - Lead Principal Investigator or sponsor for multi-site studies
   - Sponsor of the clinical trials (federal agencies or a private industry)
   - For clinical trials involving INDs and IDEs – the holder of IND or IDE should be responsible for registering the information.
   - For NIH sponsored clinical trials involving no INDs or IDEs, registration should be coordinated with the sponsoring NIH Institute or Center to avoid duplicate registration.
4. **Why register and submit results?** Registration of clinical trials is a **FEDERAL MANDATE** as outlined in Section 113 of the FDA Modernization Act, effective December 26, 2007. Additionally, Section 801 of the Food and Drug Administration (FDA) Amendments Act mandates that responsible parties register and submit study results of clinical trials with ClinicalTrials.gov.

5. **Finding this site?** You can access this site directly from: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). To register your clinical trial and find additional instructions on the process, please go to [http://prsinfo.clinicaltrials.gov/](http://prsinfo.clinicaltrials.gov/).

6. **Are there penalties for non-compliance?** Yes. Failure to register your trial and/or submission of false and misleading information to ClinicalTrials.gov may result in having to face the following penalties:
   - Significant civil penalties (up to $10,000 per day in violation),
   - Withholding of grant funds,
   - Recovery of grant funds,
   - Data made ineligible for publication

7. **When do I register my trial?** Your clinical trial can be registered prior to or concurrent with USF IRB approval; however the trial must be submitted no later than 21 days after enrollment of the first participant. Additionally, if a trial is submitted prior to obtaining IRB approval, the recruitment status must be listed as ‘Not yet recruiting’ until IRB approval is obtained.

8. **What Specific Information must be provided?** A summary including the following information of the study must be registered:
   - Summary of the purpose of the study
   - Recruitment status
   - Inclusion criteria
   - Location of the clinical trial
   - Specific contact information of the study team
   - Adverse events
   - Basic results

Refer to the ClinicalTrials.gov ‘Review of Protocol Submissions’ document ([http://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf](http://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf)) for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted. It is important to note that the information must be registered in a manner that can be understood by the general public who may have no familiarity with the sophisticated medical terminology or complicated clinical procedures. Upon review of the information on ClinicalTrials.gov, if a member of the general public becomes interested in participating in the clinical trial direct communications can be made with the study contact to learn the specifics.
9. **How do I Register My Clinical Trial with ClinicalTrials.gov?**

Registering with ClinicalTrials.gov involves two simple steps as follows:

A. If you do not already have one, you will need a Protocol Registration System (PRS) user account. If the study will be registered at USF, you may contact the USF PRS administrator by calling 813-974-5638. Important: first check with your study sponsor to determine if an account for the clinical trial has already been established. If your study sponsor has already obtained an account, then visit [http://prsinfo.clinicaltrials.gov/contactRequest.html](http://prsinfo.clinicaltrials.gov/contactRequest.html) to contact the appropriate PRS administrator.

B. Follow the steps below to register your clinical trial.
   - Log into the PRS system by accessing [https://register.clinicaltrials.gov/](https://register.clinicaltrials.gov/) (Note: Enter USflorida in the Organization box)
   - View the ‘Quick Start Guide’. All features that you will need to know in order to register your trial are available via ‘PRS User’s Guide’.
   - Complete all the ClinicalTrials.gov data elements by providing accurate, up-to-date information.

If the submission is complete and without errors, the PRS administrator will forward the submission for quality assurance (QA) review by ClinicalTrials.gov staff. Once the QA review is approved, the Responsible Party can release the record. Information about your clinical trial can be viewed by anyone within 2-5 business days after it is released.

10. **When am I required to update a ClinicalTrials.gov record?** When there is a change in recruitment status or to the completion date, you must update the record within 30 days of the change. Other changes to the protocol or record must be made at least every 12 months and for studies that are not yet completed, the Record Verification Date be updated at least every 6 months, even if there were no changes.

11. **When am I required to submit results of a trial with ClinicalTrials.gov?** Generally, the results of a trial involving a drug, biologic, or device that is approved, licensed, or cleared by FDA must be submitted by the Responsible Party no later than 12 months after the Completion Date (date final subject was examined or received an intervention).

12. **Questions related to registration with ClinicalTrials.gov?** You may contact Research Integrity and Compliance at (813) 974-5638 for additional information or to obtain a PRS user account. You may also contact ClinicalTrial.Gov staff for assistance via email at [register@clinicaltrials.gov](mailto:register@clinicaltrials.gov).