ClinicalTrials.gov Guidance (CT.gov)

January 2017

Background:

To promote protection of human subjects and the ethical conduct of research, under federal law the National Institutes of Health (NIH) maintains the public database of applicable clinical trials, and the U.S. Food and Drug Administration (FDA) is authorized to enforce statutory requirements. The ClinicalTrials.gov Protocol Registration System (PRS), a web-based data-entry system, provides public access to a directory of federally and privately supported clinical trials that test the effects of drugs, biologics, devices and procedures on medical diseases and conditions as well as trials testing effects of behavioral and educational interventions. PRS allows organizations and investigators to register and post results of clinical trials as required by law and to meet the requirements for publication in member journals of the International Committee of Medical Journal Editors (ICMJE).

Q: Are there penalties for not complying with CT.gov requirements?

As of December 31, 2007, all ongoing applicable clinical trials and those registered after that date must report final results one year after the primary completion date of the study. As of March 12, 2012, each PRS record that is delinquent for posting results will be assessed fines of $10,000 per occurrence and $10,000 a day if the record is not brought into compliance within 30 days. Additionally, NIH can withhold, withdraw, or require UF to return some or all NIH grant funding. Responsibility for assessed penalties rests with the Investigator and the Investigator’s department and college.

Q: How do I register and maintain compliance with the requirement?

Division of Sponsored Programs, College of Medicine Research Administration and Compliance, Clinical and Translational Science Institute and Institutional Review Boards collaborate to assist UF faculty and staff in the registration of all applicable clinical trials and to maintain FDAMA and FDAAA compliant records.

UF faculty, administrators and staff can access detailed information regarding applicable clinical trials and step-by-step guidance to register those trials into the PRS system and to maintain such records in compliance with FDA laws and regulations on the Research Administration and Compliance website at: http://rac.med.ufl.edu/manage_study/guide-clinicaltrials-gov/

Q: Is there training required?

UF offers training modules and direct assistance to UF Investigators and study staff regarding all aspects of ClinicalTrials.gov PRS protocol record management from registration to maintaining compliant records, and ultimately to posting final results. All training modules and registration instructions can be accessed at the RAC website: http://rac.med.ufl.edu/training/ctgov/
Q. Who can I contact if I have questions or need more information?

DSP PRS Administrators are available to assist throughout the life of the ClinicalTrials.gov PRS Protocol Record:

- **Gainesville:**
  - Anthe Hoffman: antheh@ufl.edu
  - Elizabeth Piantadosi: epiantadosi@ufl.edu and at UFCT-gov@ufl.edu

- **Jacksonville**
  - Tina Bottini: tina.bottini@jax.ufl.edu (904) 244-9478