New Clinical Trials.gov Requirements

On 9/16/16 the DHHS issued a final rule that has 2 aims:
1) to set forth changes to the legal requirements for registration and results submissions at ClinicalTrials.gov and
2) to clarify requirements that were previously set forth by the law

Some key changes to the law described in the final rule include:
• Additional registration and results information must now be submitted to ClinicalTrials.gov (i.e., the full protocol must be submitted at the time of results submission).
• Trials involving FDA-regulated products that have not yet been approved, licensed, or cleared by the FDA are now required to submit results to ClinicalTrials.gov

The final rule became effective on 1/18/2017 and trials that are required by law to be registered must be in compliance with the final rule by 4/18/2017. The new registration requirements described in the final rule will apply to trials initiated on or after 1/18/2017 and the new results submission requirements will apply to trials that reach their primary completion date on or after 1/18/2017.

Additionally, the NIH issued a notice of a revised ClinicalTrials.gov policy. It is in most ways similar to the final rule except that NIH now requires that all NIH funded clinical trials register and submit results, whether or not the trial is required to register by law. The NIH policy became effective on 1/18/2017 and expectations for compliance will be included in the terms and conditions of NIH awards.

ClinicalTrials.gov is a national web registry of federally and privately supported research studies conducted in the US and around the world. The Ochsner Human Research Protection Program (HRPP) acts as the system administrator for ClinicalTrials.gov for Ochsner. Please contact Stephanie Gaudreau at sgaudreau@ochsner.org or 504-842-3563 if you have any questions.

Links to Resources
News Release on changes to law and NIH policy
Summary of Changes to law and NIH policy

Updated Consent Form Templates
The following updated consent form templates are now posted in ERSA
• Updated Main ICF Template
• Registry Specific ICF Template
• ICF Addendum Template

Some highlights of the update include updated help text and a significant reduction in HIPAA and Greenphire ClinCard required language.

You may start to use the updated templates immediately. This change is applicable for the creation of new consent documents going forward. If you are already in the process of negotiating a consent form with a sponsor you do not need to start over with the new template unless you would like to change out the HIPAA section or Greenphire language for the shortened version.

Consent forms currently uploaded to ERSA DO NOT need to be revised with the new template. Previously approved consent documents DO NOT need to be amended, nor do subjects need to be re-consented.
Plan to attend the Tuesday, April 11th presentation in the Responsible Conduct in Research Lecture Series. It will be held in Monroe Hall at noon. CME and CNE credit and lunch will be provided.

FDA Compliance Corner

This Warning Letter demonstrates failure to ensure that an investigation was conducted according to the investigational plan (21 CFR 312.60). Per protocol, Visit 1 could include the screening visit and randomization if the subject satisfied all eligibility criteria. However, subjects without key lab results to verify eligibility at visit 1 would require a repeat visit to randomize.

- Subjects were randomized at visit 1 without recent serum creatinine and eGFR values. These tests results not only determined eligibility, but also determined the dose of investigational drug. As a result, ineligible subjects were randomized and administered study drug while others were overdosed.
- Subjects whose consecutive eGFR values decreased during the course of the trial were to have their study drug down titrated. Several subjects continued to receive their same dose of study drug though eGFRs values indicated a dose reduction was necessary.

The FDA concluded these failures to follow the investigational plan jeopardized subject safety and welfare, and compromised the interpretability of the data collected at the site.

QUARTERLY RESEARCH FORUM

Tuesday, March 14, 2017 • Noon • Monroe Hall

“Sodium and its Multiorgan Targets”

Speaker

Edward D. Frohlich, MD
Alton Ochsner Distinguished Scientist
Ochsner Clinic Foundation
New Orleans, LA

Objectives
1. To demonstrate evidence that Salt-excess provides further structural and functional deleterious effects other than blood pressure elevation.
2. To demonstrate the structural and functional effects of salt excess on heart, blood vessels, and kidneys.
3. To demonstrate that the foregoing structural and functional effects of salt-excess may be prevented through inhibition of local renin-angiotensin systems.

Purpose Statement:
We will present recent experimental and clinical data from our studies and those of others to explain the deleterious effects of salt excess in hypertension.

Accreditation
The Ochsner Clinic Foundation is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Designation
The Ochsner Clinic Foundation designates this live activity for a maximum of 1 AMA PRA Category 1 Credit™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Conflict of Interest: The speakers, their spouses or partners, have no actual or potential conflict of interest in relation to this program or presentation.

Lunch will be served in Monroe Hall