TTUHSC El PASO

Regulatory Lite ✓

A hint of research compliance tips for your everyday life

What is ClinicalTrials.gov and why is it important to me?

ClinicalTrials.gov is a registry of clinical trials that currently holds registrations from over 230,000 trials from 195 countries. It is run by the United States National Library of Medicine (NLM) at the National Institutes of Health, and it is one of the largest clinical trials databases in the world. In 1997, the FDA amended an act that required the NIH to create and operate a public information resource to track drug efficacy studies resulting from approved investigational drug applications. The primary purpose of Clinicaltrials.gov was to improve access of the public to clinical trials where individuals with serious diseases and conditions might find experimental treatments.

Today, researchers are asked to add any "qualifying" clinical research to ClinicalTrials.gov as an FDA mandate. Qualifying clinical trials may consist of any the following criteria, but are not limited to just the following:

- Use of a biologic agent
- Use of an investigational drug or an investigational device
- Use of an investigational/interventional procedure or a behavioral intervention
- Partially or fully funded by an NIH grant
- Plan to publish study on a journal that follows ICMJE guidelines or is part of ICMJE

If your study meets any of the criteria listed above, you may want to look into these requirements further. More information can be found on the following webpage: https://elpaso.ttuhsc.edu/research/compliance/clinicaltrials.aspx

If you have any question, you can also submit them to the Research Compliance Unit.