

On September 27, 2007, a new law was enacted that expands the type of clinical trials that MUST be registered in Clinical Trials.Gov. There are penalties for non-compliance with the law. Publishers do not accept for publication and report the submission to the clinical trials monitoring agencies. A description of the law and the requirements for registration is attached. Please read the description of the law to meet the requirements. A simple trifold brochure of the registration information can also be downloaded from <http://prsinfo.clinicaltrials.gov/registering.pdf>

## **REGISTRATION AND FAQs**

Please use the link below to find a complete list of answers to the most common questions regarding registering your clinical trial.

<http://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered>

**If you have determined that you are the party responsible for registration with clinicaltrials.gov, please contact a representative from Human Research Protection so that we may submit your contact information to clinicaltrials.gov that will allow you to generate a username and password for the system. You may contact HRP at 215-255-7857 or [HRPP@drexel.edu](mailto:HRPP@drexel.edu)**

Below are answers to two of the most common questions we receive regarding registration.

### **Who Is Responsible for Registering Trials and Submitting Results?**

The Responsible Party for a clinical trial must register the trial and submit results information. The Responsible Party is defined as:

- The sponsor of the clinical trial; or
- The principal investigator (PI) of such 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, has the right to publish the results of the trial, and has the ability to meet all of FDAAA's requirements for the submission of clinical trial information.

For complete statutory definitions and more information on the meaning of "responsible party" and "sponsor," see [Elaboration of Definitions of Responsible Party and Applicable Clinical Trial \(PDF\)](#). See also the [Responsible Party data element](#) on ClinicalTrials.gov.

### **Which Trials Must Be Registered and Have Results Submitted to ClinicalTrials.gov? Registration**

Registration is required for trials that meet the FDAAA 801 definition of an "applicable clinical trial" and were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007. Trials that were ongoing as of September 27, 2007 and reached the Completion Date (see [Primary Completion Date data element](#) on ClinicalTrials.gov) before December 26, 2007, are excluded. "Applicable Clinical Trials" include the following:

- **Trials of drugs and biologics.** Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation
- **Trials of devices.** 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) [pediatric postmarket surveillance](#) required by FDA

"Applicable clinical trials" generally include interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions:

- The trial has one or more sites in the United States
- The trial is conducted under an FDA investigational new drug application or investigational device exemption
- The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research

For complete statutory definitions and more information on the meaning of "applicable clinical trial," see [Elaboration of Definitions of Responsible Party and Applicable Clinical Trial \(PDF\)](#).

- [FAQ: Does FDAAA 801 only apply to Industry-sponsored studies?](#)
- [FAQ: Does the definition of Applicable Clinical Trial under FDAAA 801 only include studies conducted under an FDA Investigational New Drug Application \(IND\) or Investigational Device Exemption \(IDE\)?](#)