

## Amended informed consent regulations (FDA)

**The following paragraph must be included (per FDA regulation) in all consent forms for studies which are required to be registered with [clintrials.gov](http://www.clinicaltrials.gov).**

“A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

**If you are not sure if the study in question needs to be registered, see FDA requirements and guidance below:**

### General Requirements

[U.S. Public Law 110-85](#) (Food and Drug Administration Amendments Act of 2007 or FDAAA), Title VIII, Section 801 mandates that a "responsible party" (i.e., the sponsor or designated principal investigator) register and report results of certain "applicable clinical trials":

**Trials of Drugs and Biologics:** Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation;

**Trials of Devices:** Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies.

"Applicable clinical trials" generally include interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the U.S, involves a drug, biologic, or device that is manufactured in the US (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE). For the complete statutory definitions and more detailed information on the agency's current thinking about their meaning, see this [pdf document](#).  
<http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>