

**New Law on Mandatory Registration of Clinical Trials on ClinicalTrials.gov
Public Law 110-85**

Which trials must be registered under the new law?

- Trials of Drugs and Biologics (other than Phase I investigations)
- Trials of Devices

Who is responsible for registering trials?

- Generally, the sponsor is required to register the clinical trial. However, the sponsor can delegate this duty to the principal investigator. You should check with your sponsor to see if this duty has been delegated to you.
- Principal investigators who are the holder of an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) may be responsible for registering these clinical trials.
- Principal Investigators who receive funding to conduct extramural trials in which there is no IND or IDE holder may be responsible for registering these clinical trials.

When must I register?

- Trials that are initiated after 9/27/07 or trials that are ongoing as of 12/26/07 must be registered by the later of: **12/26/07** or **21 days after the first patient is enrolled**
- Trials that were ongoing as of 9/27/07 and do not involve a serious or life threatening disease or condition must be registered by 9/27/08

What are the penalties for failing to register?

- Failing to register a clinical trial or providing false or misleading information in connection with a clinical trial carries penalties, including monetary penalties of up to \$10,000.
- For federally-funded trials, the withholding of grant funds is a possible penalty.

How do I register?

- JHSPH has an organizational account with ClinicalTrials.gov. To register your clinical trial, go to the following webpage: <https://register.clinicaltrials.gov>. Under Organization, enter JHSPH. Then enter your username and password. If you are unsure of your username and password, contact Margi Joshi at 410-502-0433 or mjoshi@jhsp.edu.
- Once you have entered all the required fields, you must indicate that the record status is "complete" in order for the record to be approved and released to the ClinicalTrials.gov website.
- Remember to update your account as required.
- If you have already registered your trial, we recommend you update your account ASAP to include all the registration fields required under the new law.
- If you have any questions or need assistance in registering, contact Margi Joshi at 410-502-0433 or mjoshi@jhsp.edu.