

To all clinical investigators:

Congress recently passed the FDA Amendment Act of 2007, which includes new requirements for registration of clinical trials on the ClinicalTrials.gov website. Some of the requirements of the new law **must be enacted by December 26, 2007.**

Please read this announcement carefully to see whether your trial(s) are affected by these changes, and what (if any) actions need to be taken by you to ensure your trial(s) are in compliance.

New requirements

Congress expanded registration requirements for clinical trials to most trials of drugs, biologics, and devices subject to FDA regulation. More information is now required in the registration record including:

- primary and secondary outcome measures
- study start and anticipated completion dates
- target number of subjects

Please note: In the future (various time points within the next three years) postings will need to include adverse events and results from completed clinical trials.

How this may affect your trial(s)

For all PI-initiated research: The DF/HCC clinical trials team is in the process of updating the existing registration record of each DF/HCC-initiated trial posted on ClinicalTrials.gov. You may be contacted by the Clinical Trials Education Office (CTEO) to access the trial registration record and verify that the new information is correct. These updates must be finalized on ClinicalTrials.gov by December 26th.

For all Sponsored research: For these types of trials, you must contact the sponsor to determine who will handle the required updates. Again, these updates must be finalized on ClinicalTrials.gov by December 26th. (Note: Please make every effort to make this the responsibility of the sponsor. For future trials, a sponsor will be required to do this unless it is explicitly written into the agreement.)

For help or more information

Please contact **Michele Copersino** (617-582-8422) or **Shannon Nelson** (617-582-8310) in the Clinical Trials Education Office (CTEO).

I appreciate your attention to this very important matter.

Beverly Ginsburg-Cooper, MBA

Associate Director of Administration