Guidance on New Law (Public Law 110-85) Enacted to Expand the Scope of ClinicalTrials.gov: Registration

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Key Dates

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A new law has been enacted to expand the scope of ClinicalTrials.gov. This notice provides information for NIH grantees on new responsibilities related to the first part of the law, the registration of clinical trials.

New Law Enacted to Expand ClinicalTrials.gov:

Public Law 110-85, which was enacted on September 27, 2007 [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf] amends the Public Health Service Act to expand the scope of clinical trials that must be registered in ClinicalTrials.gov. It also increases the number of registration fields that must be submitted, requires certain results information to be included and sets penalties for noncompliance. This notice provides information for NIH grantees and contractors on new responsibilities related to the first part of the law, the registration of clinical trials. Additional information will be forthcoming.

Which Trials Must be Registered?

The trials that must be registered are called "applicable clinical trials." Under the statute, these trials generally include: (1) Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance. You should review the statutory definition of applicable clinical trial to identify if any of your trials must be registered to comply with the law [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf] *See* PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)). NIH encourages registration of ALL trials whether required under the law or not.

Who is responsible?

The entity responsible for registering is the "responsible party." The statute defines the responsible party as:

(1) the sponsor of the clinical trial (as defined in 21 C.F.R. 50.3)
[http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2003/aprqtr/pdf/21cfr50.3.pdf], or

(2) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee (provided that "the principal investigator 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 the requirements" for submitting information under the law.) [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf] *See* PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

How do you determine if you are a responsible party?

Investigators are encouraged to consult with their sponsored research office, institutional counsel, or other partners to determine if they are the "responsible party" for registering a trial. It is your responsibility to determine if you are obligated to register any of your clinical trials.

1) If you are the Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) holder, you may be the "sponsor" as that term is defined in the FDA regulations found at 21 C.F.R. 50.3. For studies that are conducted under an IND or IDE,

the "sponsor" is identified in the course of filing the IND (commonly called the "IND holder" or the "part 812 sponsor") OR

2) You may not be the sponsor, but if you are the Principal Investigator you may have been delegated registration duties by the sponsor provided the other conditions for access and control over information are met. OR

3) For extramural trials, where there is no IND or IDE holder, NIH would not be the responsible party. The funding recipient may be a "responsible party" as that term is defined in the Act, depending on the unique circumstances of the trial.

When Must I Register My Trial?

1) Trials initiated after 9/27/2007, or trials that are ongoing as of 12/26/2007 must be registered in full by: The later of 12/26/**2007** or21 days after the first patient is enrolled.

2) Trials that were "ongoing" as of as of 9/27/2007 and do ***not*** involve a "serious or life threatening disease or condition," must be registered by 9/27/**2008**.

3) Trials that were "ongoing" as of as of 9/27/2007, do involve a "serious or life threatening disease or condition," and are completed (meaning, not "ongoing") by 12/26/2007 are not subject to these requirements, though they may be subject to pre-existing registering requirements.

("Ongoing" in this context means a trial had one or more patients enrolled, but had not examined the final subject or provided the final subject an intervention for the purposes of final collection of data for the primary outcome as of 9/27/2007.)

What are the penalties for failing to register an "applicable clinical trial?"

Penalties for responsible parties who fail to register, or provide false or misleading information in connection with, applicable clinical trials are significant and may include civil monetary penalties and, for federally-funded trials, the withholding or recovery of grant funds. *See* PL 110-85, Sections 801(a), (b), (adding new 42 U.S.C. 282(j), and new 21 U.S.C. 331(jj)).

Obtaining Assistance from NIH:

Existing mechanisms established by NIH ICs to assist funding recipients in registering trials with ClinicalTrials.gov can continue to be used to assist responsible parties with the new registration requirements. A list of IC liaisons is provided below. While the NIH anticipates the continuation of this service, it is important to remember that the IC cannot in any way substitute for the responsible party in fulfilling its statutory duties. When requesting registration assistance from an IC, you are responsible for ensuring that all necessary information is provided to the IC in sufficient time to review and coordinate before the statutory deadlines described above for submission to ClinicalTrials.gov are triggered. You will need to stay in contact with the IC liaison to ensure that your information has been registered properly. Submission of registration information to an IC is not sufficient to satisfy the statutory obligations for submission to ClinicalTrials.gov. Alternatively, you may register your trial directly by following the procedures outlined at http://prsinfo.clinicaltrials.gov/.

Additional information on the new registration requirements is available on the PRS Web site http://prsinfo.clinicaltrials.gov/.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

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