

MEMORANDUM # 07-27

Date November 19, 2007

To Council of Deans
Council of Teaching Hospitals
Group on Business Affairs
Group on Research and Development
Compliance Officers

From Darrell G. Kirch, M.D.

Subject Clinical Trials Registration Requirements

In the Food and Drug Administration Amendments Act of 2007, Congress significantly expanded the scope of clinical trials that must be registered in ClinicalTrials.gov, as well as the number of specified data elements that must be posted. The expanded clinical trial registration responsibilities fall on sponsors of clinical trials and on the principal investigators of such trials. Some of these requirements must be met by **December 26, 2007** and necessitate prompt compliance by responsible parties. Within medical schools and teaching hospitals and health systems, compliance will require close coordination among your investigator community, legal counsel, sponsored research office, compliance officials, and specific clinical trial funders and sponsors.

NIH posted its initial Guidance on these provisions on November 16 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html>. Trials that must be registered generally include Phase 2 - 4 trials of drugs and biologics (controlled clinical investigations other than Phase 1 investigations, of a product subject to FDA regulation) and trials of devices (controlled trials with health outcomes, other than small feasibility studies and pediatric postmarketing surveillance). NIH states in its guidance that it encourages registration of all trials, regardless of whether required under applicable law, and AAMC lends its support to this recommendation.

Registration responsibilities are technical in nature but in general fall on the sponsor of a clinical trial or on the principal investigator if certain key conditions are met. The NIH Guidance, and its underlying references, must be consulted for specifics, but it is especially important to note that **principal investigators have the responsibility to determine whether they are obligated to register their trials in accordance with the law.** They should be encouraged to consult with their sponsored research office and other appropriate institutional offices, and for NIH funded trials, with the funding institute, to determine the extent of their responsibilities.

Key deadlines are December 26, 2007, and September 27, 2008. **Trials initiated after 9/27/07 or ongoing as of 12/26/07 must be registered in full 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 serious or life threatening diseases or conditions must be registered by 9/27/08. Penalties for failing to register applicable trials are serious. The NIH Guidance offers certain assistance to its funding recipients, and should be carefully reviewed.

I encourage you to bring this information to the attention of your relevant institutional offices as soon as possible.