

NLM Board of Regents Working Group on Clinical Trials
Teleconference, March 17, 2009
2:00-3:00 p.m.

Participants: Tom Bradley, Rob Califf, Sherrilyne Fuller, Rick Kuntz, Frank Rockhold, Lou Rossiter, Alastair Wood. NLM Staff: Jerry Sheehan, Tony Tse, Becky Williams, Deborah Zarin.

Summary

1. **Public Meeting.** The public meeting required by FDAAA has been scheduled for April 20th on the NIH campus. Although the Working Group (WG) had previously considered having a role in the public meeting, it was agreed during the March 17 conference call that the primary goal of the meeting should be to provide an opportunity for public input. Since such meetings are not generally a forum for debate or decision making, it was agreed that the WG would not have a formal role to play on April 20th. Of course WG members are welcome to attend the meeting or listen via the webcast, but they may also choose to wait for the summary of the oral and written comments that will be provided in time for a future meeting of the WG. Written comments submitted to NIH/NLM will be posted in the public docket, No. NIH-2009-0002, which is available at <http://www.regulations.gov>.

Details about the public meeting are now available on the ClinicalTrials.gov website at <http://prsinfo.clinicaltrials.gov/public-meeting-april09.html>. As discussed at the February 9th WG meeting, NIH would appreciate your support in disseminating information about the public meeting and the related request for comments to interested parties that might wish to attend the meeting or submit comments. To that end, we attach a copy of the meeting announcement as it was published in the Federal Register on Monday, March 23.

2. **Request for Extensions of Deadline for Submitting Results.** The WG discussed the types of extension requests that have been submitted to ClinicalTrials.gov thus far and agreed to review a proposed set of categories that might be used to guide NIH's decision-making process when determining whether or not to grant requested extensions. As background, submission of results information is generally required within 12 months of the last data collection for the primary outcome measure. In certain cases (related to studies of unapproved products), "certifications" can be submitted to delay the deadline. In addition, the Director of NIH is authorized to grant an "extension" of the deadline if the responsible party submits a written request that demonstrates "good cause" for the extension and provides an estimate of the date on which information will be submitted [additional background information about this provision is available at <http://prsinfo.clinicaltrials.gov/DelayedSubmission.html>]. As discussed during the teleconference, the goal of the proposed categories is to allow NLM to recommend a streamlined process to the Director that will identify generic types of requests that should qualify for extensions (of a specified amount of time) and those that should not.