ACRP
ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS

MISSION:
ACRP promotes excellence in clinical research.

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National Institutes of Health
Office of Management Assessment
6011 Executive Boulevard
Suite 601
MSC 7669
Rockville, MD 20852

In reference to docket number: **NIH-2011-0003-0003**

The Association of Clinical Research Professionals (ACRP) is the primary resource for clinical research professionals in the pharmaceutical, biotechnology and medical device industries, and those in hospital, academic medical centers and physician office settings. ACRP was founded in 1976 to address the educational and networking needs of research nurses and others who supported the work of clinical investigations. Almost 40 years later, ACRP is a global association comprised of individuals dedicated to clinical research and development. Our mission is "ACRP promotes excellence in clinical research." The Academy of Physicians in Clinical Research (APCR) is an affiliate of ACRP and is the leading professional organization, exclusive to physicians, that supports and addresses these unique issues and challenges of all physicians involved in clinical research.

ACRP appreciates the opportunity to provide the NIH with our comments on the Notice of Proposed Rulemaking Clinical Trials Registration and Results Submission as this issue has a significant impact on our membership. The attached document provides detailed comments, suggestions, and recommendations on specific sections of the draft guidance.

We applaud the NIH's efforts on this important issue and hope that our feedback helps improve the final version of the document. Please let me know if you have any questions regarding our comments, or if we may otherwise serve as a resource on issues related to clinical research.

Sincerely,

Terri Hinkley, RN, BScN, MBA, CCRC
Interim Executive Director

NIH-2011-0003-0003 : Notice of Proposed Rulemaking Clinical Trials Registration and Results Submission			
Page Number	**Text Line**	**Reference** *(if applicable)*	**Comments**
NA	NA	General	ACRP would like to request the Agency include a requirement that clinical trial results posted on clinicaltrials.gov include a lay language summary for the public. Oftentimes clinical trial summaries are written scientifically and as a result, are difficult for the general public to understand. In the pursuit of informing the public, we strongly advocate that these summaries be written in a manner that is easily understandable to everyone, preferably at an 8th grade reading level, which is the suggested reading level for informed consent documents.
6	Expanded Access Paragraph		We commend the agency for permitting 'linking' to an existing expanded access record for a drug studied in multiple clinical trials rather than requiring a new expanded access record for each trial of that same drug.
7	Adverse Events paragraph		Since we still struggle with sponsors who do not recognize that they need to collect ALL adverse event information in order to evaluate whether or not a given event is unanticipated, we are pleased to see that FDA will require reporting of all AEs both anticipated and unanticipated. We hope this will raise awareness that all AEs must be recorded, and now they must also be reported if they meet the 5% threshold.
40	#1		For sponsors of nonsignificant risk device clinical trials, there will be no IDE number, even though there may be a qualifying trial which requires registration. Therefore there would also not be an issuing Center to enter. How has this been addressed? Will adding the IRB registration information for the IRB that approved the research as a nonsignificant risk device study suffice in lieu of an IDE #and Center identificaiton from FDA in these situations?
50	NA		We applaud efforts to harmonize data requirements between EudraCT and ClinicalTrials.gov
277	Paragraph 2		Requiring 'country-of-residence' information would not add a burden and could be an important data point to make available.
332	NA		With regard to the Agency's specific request for comment regarding reporting falsification of data, we feel there would be at least 2 potential advantages to requiring notification within 15

			days of confirming the falsification of the data followed by a second report on the impact. For one, notification of data falsification could motivate sponsors to investigate and reanalyze data more rapidly since there would be public knowledge of the event. It might also be possible for sponsors of other trials to assess their studies if they discover that they are using a site where falsification of data could have occurred. The risk is that all investigative sites participating in that trial could come under a cloud of suspicion for having committed fraudulent activities since it could be known that it had to have happened at one of the sites identified as taking part in the study.