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Intramural Correspondence**

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TO: School of Medicine Faculty
FROM: Glen Gaulton, Ph.D.
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DATE: August 31, 2005
SUBJECT: SoM Web-posting and Publication of Penn Clinical Research Trials

As many of you know, highly visible recent events in the assessment of drug efficacy and safety have stimulated a dialogue among the scientific, regulatory, corporate and public communities regarding the awareness, rights of information, and access to clinical trials. We write here to summarize current perspectives, and to outline the School of Medicine approach to these issues. The primary operational goal is to ensure that the conduct and results of your clinical trials may progress and be published in an expeditious fashion with minimal additional burden.

ICMJE requirements & deadlines

The International Committee of Medical Journal Editors (ICMJE), which represents many key medical journals for our faculty, recently published requirements and deadlines for posting information on clinical trials that may be submitted for publication in these journals^{1,2}. According to these requirements, basic information about clinical trials must be registered on a website supported by a non-profit organization and easily accessible. This requirement applies only to those trials that include a comparator arm, e.g., active therapy or placebo. For a summary of the required study information to be displayed, see De Angelis et. al. Ann Intern Med. 2004;141:477-8 (web link noted below in reference 1).

The following summarizes the ICMJE clinical trial posting deadlines.

CLINICAL TRIAL TYPE	POSTING REQUIREMENT
Ongoing Trials (<i>i.e. started before July 1, 2005</i>)	By September 13, 2005
New Trials (<i>i.e. started after July 1, 2005</i>)	Before enrollment of the first subject

Federal requirements and FDA and NIH recommendations

The ICMJE action was predated by the FDA Modernization Act (FDAMA) of 1997 which required sponsors to publicly post clinical trials for drugs designed to treat "life-threatening diseases and conditions". The ClinicalTrials.gov web-based registry was developed as a means to implement this requirement. NIH is using this site to post NIH-funded clinical trials, and some corporate and academic sponsors are posting trials on this site as well. Although there are no restrictions on publication rights imposed by FDAMA, the ClinicalTrials.gov site includes all data elements required by the ICMJE requirements, and additionally those recommended by the WHO. Posting on this site is the responsibility of the sponsor and often lags well behind initiation dates; in addition, only the sponsor is permitted to modify individual fields. This may create a significant problem for academic faculty as many industry-sponsored clinical trials contractually prohibit public dissemination of trial information.

The SoM trial posting plan

Our goal is to have all clinical trials conducted at Penn Medicine posted publicly in a timely manner regardless of, phase, sponsor or IRB review categorization. We believe that this approach honors our responsibility to the public to maximize awareness of, access to, and participation in clinical research at Penn., Therefore, effective the week of August 22, 2005, we have launched a Penn website called "[ClinicalTrials@Penn](http://www.clinicaltrials.med.upenn.edu/)" (<http://www.clinicaltrials.med.upenn.edu/>) for posting of clinical trials at Penn Medicine. This site incorporates the posting requirements of ClinicalTrials.gov, and thereby meets all federal and ICMJE requirements and most WHO recommendations.

ClinicalTrials@Penn will utilize information available from the IRB database and thus will not require faculty initiation. Where available we will also utilize information already posted on ClinicalTrial.gov. However, as the current IRB data fields comprise only a subset of the required trial posting information and many current trials are not yet posted on ClinicalTrials.gov, Principal Investigators or their designees may be contacted to supply additional information to fully populate the Penn fields. We are working with the IRB to modify the IRB submission data so that the posting sites can be fully populated electronically in the future.

To facilitate the timely implementation of this process and to honor our existing obligations to corporate sponsors we have adopted a phased approach to the implementation of this site.

Phase 1: Posting of all NIH funded clinical trials (protocols with full IRB board reviews): week of August 22, 2005

Phase 2: Posting of all other clinical trials except corporate-sponsored: September 12, 2005

Phase 3: Posting of all new corporate-sponsored trials: fall 2005*

Phase 4: Posting of all existing corporate-sponsored trials: winter 2005*

In summary – your obligations to publicly post clinical trials to ensure publication will be met by the institution. You will be contacted if we need your assistance to complete this process. If you have any questions concerning the need to register your trials or the process of registration, please contact the Office of Human Research:

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or

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References:

1. De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *Ann Intern Med.* 2004;141:477-8. Epub 2004 Sep 8. [PMID: 15355883] (www.icmje.org/clin_trialup.htm)

2. Members of the ICMJE:

- Annals of Internal Medicine
- Canadian Medical Association Journal
- Croatian Medical Journal
- Journal of the American Medical Association
- Nederlands Tijdschrift voor Geneeskunde
- New England Journal of Medicine
- New Zealand Medical Journal
- The Lancet
- The Medical Journal of Australia
- Tidsskrift for Den Norske Llegeforening
- Ugeskrift for Laeger
- U.S. National Library of Medicine

* The posting of industry-sponsored trials may utilize modified data fields so that contractual obligations can be met. Discussions with corporate sponsors are currently in progress to identify these needs so that Penn faculty are not disadvantaged in developing industry collaborations.