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Department of Epidemiology
Department of International Health

Department of Medicine
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(Monday) 18 December 2000

Memorandum

To: Center faculty, staff, and friends

Fr: Curt Meinert

Re: The obligation to publish in clinical trials

This is the first in a series of memos concerning issues in the presentation and publication of results from trials.

One can argue that one assumes a moral obligation to publish in return for the privilege of being able to "research" upon human beings and that failure to publish is a violation of a public trust.

The 2nd item in the Nuremberg Code specifies that:

The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

One can argue that it is not possible to generate *fruitful results for the good of society* unless results are published. Trials that are not published cannot benefit society because the information generated is, for all intents and purposes, lost.

Research, in the purview of IRBs, is defined as:

...systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Office for Protection from Research Risks: *Code of Federal Regulations, Title 45: Public Welfare, Part 46: Protection of Human Subjects;* (revised) 18 June 1991.

There is no contribution made to "generalizable knowledge", in the societal sense of usage, if the results of the research are not made available to the public via publication or some other appropriate means when the work is done.

The obligation to publish is implicit when persons are approached for study. The obligation is made explicit if inducement to participation includes the promise of benefits accruing to

others as a result of the research. Indeed, one can even go so far as to argue that IRBs should not allow investigators to use "horizon" promises as inducements for enrollment unless investigators promise to publish.

The commitment to publication in clinical trials exists regardless of the nature or direction of the results. It exists whether the results are negative, nil, or positive. It comes into existence as soon as a trial starts and is not discharged until publication is achieved.

The commitment extends to trials that are aborted because of inadequate sample size or because of inadequate performance and extends, as well, to results-based protocol changes. The commitment carries a requirement to proceed to publication as soon as is practical once a trial is finished or when the protocol is changed.