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(Tuesday) 19 December 2000

Memorandum

To: Center faculty, staff, and friends

Fr: Curt Meinert

Re: Investigator right of primacy

This is the second in a series of memos concerning issues in the presentation and publication of results from trials. The first in the series dealt with the obligation to publish in clinical trials.

Right of primacy is (*Clinical Trials Dictionary: Terminology and usage recommendations*; Meinert, 1995) *the right to be first; in regard to trials, the right of study investigators to be the first to present or publish results of the trial, to be able to do so as they see fit and in the absence of external restraint or control, and to be able to exercise that right before being required or made to provide data to the study sponsor or to agencies, persons, or parties external to the trial for presentation or publication.*

Clearly, the obligation to publish, as discussed in a previous memo, cannot be assured if investigators do not have the right of primacy.

The right of primacy does not exist if the sponsor has the right to approve a publication or has the power to dictate when results are published. The right can be assumed to be in question if the sponsor "owns" the data or is in a position to control access to study data. The right of primacy should be assumed to not exist in sponsor-initiated trials unless made explicit in funding agreements or in a policy of the research group that specifies the requirement of primacy as a condition for proceeding with the trial.

It is the responsibility of investigators to make certain that the right exists before embarking on a trial. Determining whether, indeed, investigators have that right may not be easy. Sponsors may be loathe to provide that right and may be "coy" in making policy explicit in regard to limits on the right. Ironically, it is sometimes NIH-sponsor-initiated, contract-funded trials, where issues regarding primacy are thorniest. The tendency, in regard to a high profile, big ticket, NIH trial is for the Institute Director to want to control dissemination and publication of results. That desire will not be made explicit without probing by investigators.

The reasons for ensuring the existence of the right before proceeding with a trial is implicit in the ethical codes underlying research on human beings. All codes, starting with the

Nüremberg Code, are clear on the requirement that the research performed must be conducted by

> *scientifically qualified persons and under the supervision of a clinically competent medical person* (item 8 in the Nüremberg Code; item 3 in the World Medical Association Declaration of Helsinki; 1964; revised Tokyo 1975)

One can argue that the requirement for proper and competent supervision does not exist if the persons doing the research do not have the right of primacy in regard to the analysis and reporting of results.

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