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Memorandum

To: Center faculty, staff, and friends

Fr: Curt Meinert

Re: Limits to investigator right of primacy

This is the third memo in a series concerning issues in the presentation and publication of results from trials. The first in the series dealt with the obligation to publish. The second dealt with investigator right of primacy. This one deals with limits to that right.

If investigator right of primacy is essential to the conduct and reporting of trials, does it exist in perpetuity? Or does there come a point when that right is secondary to the "right" of society? If so, what is that point?

In theory, one might argue that the investigator right of primacy is always secondary to the right of society to be informed. After all, it is "society" that accords investigators the privilege of "researching upon human beings". Is it, therefore, not reasonable to argue that the "right" of "society" should be preeminent in regard to access to results and data from trials?

Perhaps, but "society" has practical reasons for respecting rights of investigators. The citizenry benefit from trials by the knowledge they produce. Therefore, "society" has a selfish interest in ensuring an environment conducive to maintaining a cadre of people willing to undertake the rigors and risks of trials. It is doubtful that it would be possible to maintain such a cadre if its right of primacy was secondary to the right of society to be informed.

The FOIA (Freedom of Information Act) was born of societal demands for access to information and data generated under the purview of Federal agencies. That Act has been variously invoked by the media, special interest groups, and private individuals in attempts to gain access to unpublished results and data of trials. The relatively low "success rate" of such requests provides indirect evidence of a society willing to respect investigator rights of primacy.

Perhaps, the most celebrated case for access under the FOIA after results were published is from the UGDP. Opponents of that trial distrusted the results and wanted access to raw data to perform their own analyses. Ultimately, that request went to the US Supreme Court (see Chapter 7 of Meinert and Tonascia; *Clinical Trials: Design, Conduct, and Analysis*; Oxford University Press, 1986) where it was denied (5-4 opinion; narrow ruling). The fact that the project was NIH grant-funded, that the NIH sponsoring agency did not have the raw data in its

possession, and that the NIH sponsoring agency had never requested such data, figured in the ruling against the request.

Presently, there are no operational limits on the right, hence, no "statute of limitations" for the right. The question is whether there should be? Here one can argue here that, perhaps, the answer should be yes.

Therefore, when planning trials, it is wise to specify the "statue of limitations" on investigator right of primacy. On their own, investigators are not likely to recognize any limit because they always expect to write yet one more paper, even if they have been dormant for years!

Drafting such policy serves to underscore the duty of the group to publish with reasonable speed and aplomb and, at the same time, to remind them that there will be a clock running against their right.

Operationally, the right might be regarded as "expired":

- After passage of a specified period of time following the close of the trial (eg, 3 years)
- When funding for paper writing and analysis ends
- When there is no visible means of support for analysis or paper writing; none proposed; none being sought
- When the group has gone dormant in regard to analysis and paper writing (eg, no activity in the last 12 months)
- When the research group has disbanded
- When the research group abrogates its right of primacy

The policy should be punctuated with policy that commits investigators to deposit of finished datasets in a public archive, as discussed in a subsequent memo in this series.