

(Thursday) 9 December 2010

## Memorandum

To: CLM

Fr: Curt Meinert

Re: Data sharing

Your memo of a few days back raises the question as to whether we, as custodians of data, have the right to give them to people outside of a research organization without knowledge of those studied.

The work-around for doing so is de-identification and data use agreements. But those work-arounds will not help in front of IRBs if a study subject files a complaint for breach of privacy.

De-identification is not foolproof. It does not eliminate the chance of identification. The saving grace with IPD (individual patient data) distributions is that recipients are not interested in identification and sign statements indicating that they will not attempt identification. However, once data are distributed there is the chance of them coming into hands of persons not bound by use agreements and then all bets are off.

I am struck by the dual standard of the NIH regarding data security and privacy protections. A coordinating center responsible for web-based data collection is expected to meet exacting standards for data encryption and security during data collection. Yet that same center is pressed by the NIH to make IPD datasets available without much concern regarding study subject privacy.

I am coming to the position that, as coordinating centers, we should not be making de-identified data available outside the research group without consents informing study subjects of the intent to do so and that informs them of the risks of identification by doing so. Failing such consents (so far as I know, none of the studies we coordinate have consents containing such statements), I believe we should not undertake preparation of IPD datasets without:

1. A letter from the NIH sponsor requesting such distribution and that acknowledges the risk of such distribution to a study subject's privacy,  
and
2. IRB review of the de-identification procedures proposed and acknowledgment of the IRB that the procedures are deemed sufficient to render the risk of identification minimal.