

(Monday) 13 December 2010

Memorandum

To: Curt Meinert

Fr: CLM

Re: The ethics of data sharing

Have you lost your mind? If something is wrong it is wrong! It does not matter what the NIH says or what your IRB is willing to approve. If an order is wrong your duty is to not follow it. How do the steps outlined in your 9 December memo make data sharing OK if you do not have consents informing study subjects of such sharing and of the risks it entails to their privacy?

De-identification to rationalize data sharing is a ruse. Does anyone believe it is possible to de-identify people in study datasets, even if they involve thousands of study subjects?

The "collapsing" and "combining" required for de-identification has the effect of rendering datasets useless for analysis. The need to adjust to improve the precision of estimates of treatment effects in trials or of risk factors in observational studies requires values of variables specific to the persons studied. Collapsed values for groups of people for de-identification are not helpful.

The census bureau collapses and combines for subgroups of 100 or fewer people in their public use datasets. The subgroup of people in ADAPT (enrollment 2,528) who are female ranges from 330 to 488 for the different study treatments, from 318 to 484 for people aged 75 or greater on entry, and from 180 to 315 for people not married, widowed, separated, or divorced. Crossing those variables with an identifier to indicate where persons are studied produces groups of one or two people in various cases. So much for de-identification.

It is odd that IRBs are fastidious in making certain that consents in IND trials include statements informing people that the FDA has the right to review study records, but that those same IRBs are OK with sharing data outside the study even though such sharing is not mentioned in consents.

Likewise, it strikes me as odd that you have certificates of confidentiality in SOCA for protecting patient privacy but that you are willing to risk privacy by sharing data. How can you be sure that protections provided by such certificates apply once data are deposited outside the SOCA investigatorship?

You keep saying you hope to exit this life without having to dance in front of IRBs. Indeed, I have often heard you say when someone is dancing, "there, but for the grace of God, go I". Perhaps you need to re-read the court case involving consents and the Havasupai Indian tribe in Arizona to see how you could be dancing because of data sharing and specimen use (NEJM 363, 15 July 2010, Mello & Wolf; Lancet 13 July 2010, Caplan & Moreno). Keep in mind that you are dealing with diseases that have stigmas.