

(Monday) 20 December 2010

Memorandum

To: Center and related faculty

Fr: Curt Meinert

Re: NIH applications and data sharing

As noted in an earlier memo (CLM: 4 December 2010), applicants for NIH funding are expected to address data sharing in applications with budgets of \$500,000 or more in direct costs for any year of support. Investigators are expected to outline plans for data sharing in investigator-initiated applications unless they have compelling reasons as to why data sharing is not planned. Sponsor-initiated studies, via requests for proposals (RFPs) or requests for applications (RFAs), will, most likely, require respondents to outline plans for data sharing.

Rule 1: Distinguish between data sharing internal to the investigator group and that external to the group. Assume that references to data sharing in NIH documents and instructions are to data sharing external to the investigator group.

Comment: Data sharing within a research group is assumed. The expectation is that investigators will have access to raw study data for analysis and paper writing and will be supplied with datasets containing identified data when the study is finished.

Rule 2: Distinguish between voluntary data sharing (VDS) and mandated data sharing (MDS).

Comment: VDS is by agreement of study investigators and requestors with investigators having power to decide whether to honor outside requests for data. Depending on the agreement, requestors may receive identified data and perform their own analyses or may arrange for the data center to carry out desired analyses with costs covered by requestors. Typically, the investigator group will require review of uses of data and statements based on data supplied prior to presentations or publications by requestors.

MDS involves transmission of de-identified data to requesting parties without investigator reviews or constraints on how data are used, analyzed, or presented. The requests and data transmissions may be handled by the sponsor, a third party custodian, or the study data center.

Both forms of sharing involve signed statements by recipients to not identify study subjects and IRB approvals of requestors' IRBs as conditions for receipt.

Rule 3: Assume that MDS involves providing de-identified data for distribution to requestors.

Comment: See CLM memo of 4 December 2010 for de-identification.

Rule 4: Recognize that the NIH policy allows latitude in when de-identified data are provided.

Comment: NIH recognizes that the investigators who collect the data have a legitimate interest in benefiting from their investment of time and effort. We have therefore revised our definition of "the timely release and sharing" to be no later than the acceptance for publication of the

main findings from the final data set. NIH continues to expect that the initial investigators may benefit from first and continuing use but not from prolonged exclusive use.

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>) See CLM memo of 4 December 2010 for discussion of "main findings" and "final dataset".

Rule 5: Do not commit to MDS if the finished dataset is likely to be too small to make de-identification viable.

Comment: As NIH stated in the March 1, 2002 draft data sharing statement, the rights and privacy of people who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data sharing is limited, applicants should explain such limitations in their data sharing plans.

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>) Size is a matter of judgment, but it is reasonable to assume that datasets involving only a few hundred people are too small for de-identification precluding *deductive disclosure of the identity of individual subjects*.

Rule 6: Do not commit to MDS in funding applications without intent to require consent forms indicating data will be shared outside the investigatorship and that such sharing carries risks to study subjects' privacy.

Rule 7: Recognize that disclosure regarding external data sharing required in consents under Rule 6 may make recruitment more difficult.

Rule 8: Keep in mind in investigator-initiated applications that *Reviewers will not factor the proposed data-sharing plan into the determination of scientific merit or priority score.*

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>)

Comment: Operationally, the statement means that refusal to MDS cannot be used by reviewers to downgrade a proposal. However, the statement is akin to a judge's instruction to a jury to ignore an incriminating reply by a witness.

Rule 9: Do not commit to MDS in funding applications without a budget to cover costs associated with MDS.

Comment: The trouble with budgeting is twofold. First, one rarely knows at application time when a study ends and, hence, will not know where to show the costs since budgets are by year. Second, a realistic budget is likely to be seen as "excessive" and may threaten the entire project because of cost. People not familiar with the process of de-identification and quality control checks required in relation to it are likely to think it is a simple matter of programming.

Rule 10: The default in projects funded without plans for MSD should be no MDS. Likewise, the default should be no MDS if consent forms do not indicate sharing of data outside the study investigatorship.

Rule 11: Assertion of ownership of data by the funding agency as a basis for requiring MDS should be rejected absent explicit statements of data ownership in funding awards.

Comment: Typically, ownership implies authority to dictate how results are analyzed and reported. It is unlikely that academic institutions will accept funding with ownership being ceded to the funding agency, public or private, if ownership carries those implications.

Rule 12: If consent statements do not include disclosure of intent to engage in MDS, and the funding agency is urging MDS, follow the steps outlined in the 9 December 2010 memo to CLM.
