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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: IRB questions concerning analysis and data sharing

Usually, coordinating centers, by design or default, have responsibilities for guiding clinics in regard to IRB submissions. Typically, this means that they implement procedures to make certain clinics have IRB approvals before starting data collection and for making certain amendments to the protocol during the study are approved before implementation.

By and large, it is clear as to what is required by way of IRB submissions and approvals during a study, but what about when data collection is finished? A previous posting entitled "When to terminate IRB approvals in trials" (posted 9 October 2012) offered recommendations pertinent to maintaining approvals after cessation of data collection. But what does one need by way of IRB submissions and approvals in the limbo period between when data collection ends and all activities cease.

For example, does one need IRB approval simply for data analysis and paper writing? Does the coordinating center need approval to share data with other study investigators? Do people receiving data need approvals to receive data?

The questions below are relevant to issues of analysis and data sharing.

Question 1: As director of a coordinating center, do I need IRB approval to supply study investigators in clinical centers in a multicenter trial with study datasets?
Comment: No, assuming consent statements indicate that the trial is multicenter and that all investigators, regardless of center, have access to study data.

Question 2: Does the data in the datasets have to be deidentified?
Comment: No, assuming consent statements as indicated in Question 1.

Question 3: As an investigator in a clinical center in a multicenter trial, do I need IRB approval to receive study datasets from the coordinating center?
Comment: No, assuming consents as indicated in the answer to Question 1.

Question 4: Do I need IRB approval to supply deidentified study data to a person with whom I have no connection or involvement?
Comment: Technically no, but as seen from a recent posting on coded private information on trialsmeinertsway.com, the transmitting investigator is not free to make that decision and, hence, has to submit the request for a determination by an independent body. That body, absent one created specifically for that purpose, will be one's IRB.

Question 5: As a recipient of data from a study in which I am not involved, do I need approval of my IRB to analyze the data?
Comment: Yes, if the data are not deidentified. Probably not if the transmission involves coded private information as discussed in the posting mentioned in Question 4 and the recipient does not have access to the code identifying data to specific persons, but IRBs vary.

Question 6: Do I need IRB approval to supply deidentified data to a repository for data sharing?
Comment: Probably not, but I would not supply such data without knowledge of my IRB.

Question 7: Do I need IRB approval to receive deidentified data?
Comment: No

Question 8: Do voting members of treatment effects monitoring committees (aka data and safety monitoring committees) need IRB approvals to receive and review study data?
Comment: Answered by prevailing practice, no, but one can argue that the question should be answered yes. Members of monitoring committees are involved in analysis of study data and likely see data identified to persons for adverse events.

Question 9: Are deidentified human research data still human research data if the recipient does not have access to codes linking data to persons?
Comment: Conveniently no by OHRP reasoning; see previous posting concerning coded private information.

Question 10: Do I need IRB approval to supply coded private information to a person (see 15 October 2012 posting to trialsmeinertsway.com for definition)?
Comment: Yes, if the information is supplied to the person in relation to a collaboration. No under OHRP guidelines if the recipient does not have access to codes linking data to specific persons but, as seen in the answer to Question 4, some independent body will have to make the determination if the data qualify as not involving human research.

Question 11: Would you share data under the OHRP guidelines pertaining to coded private information without HIPAA-like deidentification?
Comment: This director would not. The deidentification is minimal under the OHRP guideline. The enforcers of HIPAA regulations – the Office for Civil Rights – does not have a sense of humor regarding data breaches of HIPAA-protected information. Just check with authorities at Massachusetts Eye and Ear Infirmary (slapped with a $1.5 million fine for a stolen laptop containing HIPAA-protected information; http://www.hhs.gov/news/press/2012pres/09/20120917a.html; 17 September 2012).

Disclaimer: Just because I say it does not make it so. I considered getting a read from my IRB as to answers given, but I abandoned the idea for two reasons. First, because IRBs are not given to crispiness when it comes to answers with the most likely answer being "It depends". Second, IRBs vary, so even with a reading here the answers may well be different for other IRBs. These things said, the best advice I can give is "if in doubt, check with your IRB".