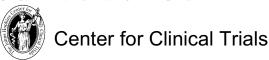
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7 November 2012

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: More about IRB questions concerning analysis and data sharing

I posted a memo entitled *IRB questions concerning analysis and data sharing* to <u>trialsmeinertsway.com</u> on 5 November 2012. In relation to that effort, I was interested in knowing how others would answer the eleven questions in the memo. Accordingly, I sent the questions to colleagues here and elsewhere knowledgeable in activities of coordinating centers a few weeks back. I received nine replies. The results are summarized below.

Question 1: As director of a coordinating center, do I need IRB approval to supply study clinics with finished datasets?

- (5) Yes
- (4) No

Question 2: Does the data in the datasets have to be deidentified?

- (6) Yes
- (3) No

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?

- (5°) Yes
- (4) No
- **Question** 4: Do I need IRB approval to supply deidentified data to a person with whom I have no connection or involvement?
 - (5) Yes
 - (4) No
- **Question** 5: As a recipient of data from a study in which I am not involved, do I need approval of my IRB to receive and analyze the data?
 - (7) Yes
 - (2) No
- **Question** 6: Do I need IRB approval to supply deidentified data to a repository for data sharing?
 - (5) Yes
 - (4) No

Question 7: Do I need IRB approval to receive deidentified data for analysis?

- (3) Yes
- (6) 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 results?
 - (2) Yes
 - (7) No
- **Question** 9: Are deidentified human research data still human research data if the recipient does not have access to codes linking data to persons?
 - (5) Yes
 - (4) No
- **Question** 10: Do I need IRB approval to supply coded private information to a person (see 15 October 2012 posting to <u>trialsmeinertsway.com</u> for definition)?
 - (4) Yes
 - (4) No
- **Question** 11: Would you share data under OHRP guidelines pertaining to coded private information without HIPAA-like deidentification?
 - (1) Yes
 - (8) No

Observations

- 1. There is no question answered the same by all nine respondents. To be fair, some of the answers were accompanied by qualifying comments, but, that said, it is clear that judgments differ.
- 2. The question answered no with one exception is Question 11. The replies indicate that most would not be willing to share data outside the investigator group with the minimal deidentification allowed with OHRP's definition of coded private information.
- 3. The rules and regulations regarding research on human beings are largely clear. They are considerably less clear when it comes to sharing data and analysis of data.
- 4. The variation in replies underscores the fact that there is no yellow brick road for coordinating centers in advising clinics regarding data sharing and analysis.

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