Reviewer's report

Title: Legal Obstacles to Sharing Clinical Research Data Under United States Law

Version: 1 Date: 28 July 2010

Reviewer: Heather Piwowar

Reviewer's report:

This commentary addresses an issue that is timely, important, and relevant. Sharing clinical research data is complex: clinical investigators would benefit from more discussion about the obstacles to data sharing and what can be done to overcome them.

The submission makes a good start in this regard, articulating two issues and arguing that the US Congress needs to take action. However, the commentary needs more grounding in related literature to back up this claim and more detail on what specifically Congress should do.

Major Compulsory Revisions

This commentary touches on several areas where there is an active related literature. The commentary needn’t reference all of them, but should be specific in its arguments and recommendations in light of these discussions.

#1 First, several groups have attempted to align HIPAA and privacy/consent regulations with data sharing proposals. In what ways are these approaches insufficient or problematic, such that there is still a legal hurdle? How would the proposed modifications to HIPAA help?

#2 Second, there is an active and ongoing discussion about appropriate copyright of scientific datasets. For example, many parties believe that copyright for datasets is neither necessary nor appropriate. The author needs to relate his position to this literature, and argue why copyright for datasets is necessary. Some reading in this area includes:


#3 Third, the commentary needs to highlight the tradeoffs between privacy, copyright, incentives, and future research progress. A great start is:

#4 The author also needs to incorporate detailed suggestions about what Congress should do. Reference 12 apparently includes detail on HIPAA details. What specific copyright modifications do you propose? Please include a summary of these recommendations within this commentary, both in the body of the work and in the abstract.

#5 Finally, clearly delineate what is opinion or speculation and what is fact. For example, to my knowledge it has not been demonstrated that a lack of copyright currently dissuades investigators from sharing data; if there is such evidence, please provide a reference when stating that "lack of clarity in the copyright rules ... leads investigators to be cautious." Also, please provide a reference for the statement "The perception among clinical investigators, however, is that deidentified data is often of limited value ..."

Minor Essential Revisions

#6 The third paragraph of the discussion states "apparently there is no evidence on how often final research data from research conducted under an NIH grant is actually made available for sharing with independent investigators." I do happen to know of some, and therefore shall commit the grave sin of pointing you to my own publication:
1. Piwowar HA, Chapman WW. Public sharing of research datasets: A pilot study

If this does not illuminate your intended point, perhaps you could rephrase your statement?

In conclusion, I think this commentary will be a useful addition to the discussion on clinical data sharing, but needs a firmer grounding in the ongoing dialog and more concrete suggestions for Congress.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Declaration of competing interests:**

I declare that I have no competing interests.