Reviewer's report

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

Version: 1 Date: 5 August 2010

Reviewer: Andrew Vickers

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The commentary is very vague and has a red herring that needs to be abandoned (copyright protection for databases). The commentary would need to be rewritten from scratch. The essential question for a researcher like me is whether publishing or sharing raw data could put me in legal trouble. I need a point by point discussion e.g.

- What is the exact wording of HIPAA?
- What are the legal sanctions for HIPAA violations?
- If I deidentify data, is this a complete protection from legal trouble?
- What if there is inadvertent HIPAA violation? E.g. what if I follow what is considered best practice on deidentification, but some clever hacker manages to re-identify my data?
- In what way does IRB approval or otherwise affect my legal status?
- If I get IRB approval for something, but it violates HIPAA, am I protected?
- If I don't get IRB approval, am I in legal danger even if I make sure of deidentification?
- What are some actual cases involving HIPAA? Are any related to research or data sharing?
- Are there any cases of researchers getting into legal trouble?