Reviewer's report

**Title:** Sharing Clinical Research Data in the United States Under the Health Insurance Portability and Affordability Act and the Privacy Rule

**Version:** 2  **Date:** 28 September 2010

**Reviewer:** Andrew Vickers

**Reviewer's report:**

This is a much improved version. The author was very responsive to our suggestions. We can accept this with one very small amendment. The author should point out that the NIH policy states only that grantees should have a “plan” to share data, not that they actually do so. For example, the plan might be that investigators seeking access to the raw data have to complete a five page application form to be reviewed by a committee. Of course, in practice, the committee can decline any such request at will.