

Revising Federal Human Subjects Protections:

An Introduction to Notable Proposed Changes

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On Tuesday, July 26th, 2011, the Department of Health and Human Services published in the *Federal Register* (Vol. 76, No. 143) advanced notice of proposed rulemaking (ANPRM), an invitation to comment on a list of nearly twenty significant revisions to 45 CFR Parts 46, 160, and 164 under consideration. The comment period is open until September 26th, and a few of the major changes that have caught attention will likely garner much public input.

Social scientists are largely pleased about the proposed new category of research labeled “excused,” much like the currently exempt category that many Institutional Review Boards (IRB) have interpreted more broadly than some like. The proposed excused category is to be more clear that research based on surveys, interviews and observation should be considered minimal risk and not fall under the oversight of IRBs, unless there is significant risk to privacy, in which case data security protection requirements would need to be met. It is further proposed that IRB application requirements for projects using such methodologies (the list of which is also under review) be reduced to something more like a declaration of intended research, which could then proceed immediately after filing. (See author of *Ethical Imperialism*, Zachary Schrag’s blog for an up-to-date review of responses and coverage from the perspective of historians, in particular, as well as social scientists: <http://www.institutionalreviewblog.com>).

A second major proposal which has drawn many cheers is one which says that multi-site studies should be managed by only one IRB, eliminating many headaches and much time eaten up by the review process at multiple institutions. The rationale for the change cited by the HHS is exceedingly logical: “There is very little evidence that having multiple IRBs review the same study is increasing protections to subjects. By diffusing responsibility for that review, it might actually be leading to weakened protections” (“Comparison of Current Rule Requirements and Proposed Changes,” <http://www.hhs.gov/ohrp/humansubjects/anprmchangeable.html>). This is a theme echoed throughout most of the changes, which seem to demonstrate an earnest intention to rationalize the regulations and ensure that they are actually increasing protections to human subjects, rather than merely serving as an impediment to research.

A proposal to improve consent forms so that they are more concise and less confusing seems likewise promising, though it remains to be seen what revisions could achieve such a goal, while still meeting the strict requirements for information.

Another major proposal expected to incite much comment—though possibly not so positive as those already mentioned—proposes that ALL research at institutions receiving any federal money should fall under federal regulations, regardless of the funding status of any individual project. The growing number of institutions that have taken advantage of the option of “unchecking the box” over the last few years would find all of their research again subject to the federal rules and procedures (See “Human

Research Protections Prerule Mandates Regs for Non-Govt. Studies,” in *Report on Research Compliance*, Vol. 8, No. 8, Aug 2011, p.1).

Finally, a proposal that all research done on existing deidentified biospecimens must have written consent raises the specter that there will be a dramatic drop in the availability of biospecimens used for research. Current deidentification practices simply do not meet the reality of today’s technology, which can quickly identify patients based on very few data markers. Such research, as well as others relying on deidentified data and previously considered exempt, would now be subject to data security protections under IRB review, as well.

In summary, the proposed revisions clearly demonstrate intention to reduce red-tape, eliminate unnecessary oversight, and reemphasize commitment to subject safety and privacy. Whether these measures will satisfy researchers and the public will become more clear in the coming days.

Read the whole ANPRM at <http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm>.