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Symposium Articles

SYMPOSIUM

Human Subject Protection

Guest Edited by Carl H. Coleman

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The revised Common Rule adopts the reasonable person standard to guide research disclosure. Some members of the research community contend that the standard is confusing and ill-suited to the research oversight system. Yet the revised rule is not as radical as it might seem. During the 1970s, judges started using the standard to evaluate negligence claims brought by injured patients who said doctors had failed to obtain informed consent to the harmful procedures. In its influential *Belmont Report*, the National Commission recommended application of a "reasonable volunteer standard" to guide IRBs evaluating research disclosures. Evidence also suggests that IRBs often invoke the reasonable person standard in deliberations about consent forms. But past application of the standard has been informal and uneven. Robust application of the reasonable person standard will require researchers and IRBs to learn more about what ordinary people want and need to know about the studies they are invited to join. Input from people with personal experience as study participants could be particularly useful to this effort.

Informed consent in clinical research is widely regarded as broken, but essential nonetheless. The most recent attempt to reform it comes as part of the first revisions to the Common Rule since it became truly "common" in 1991. This change, the addition of a "key information" requirement for most consent forms, is intended to support and promote a reasoned decision-making process by potential subjects. The key information requirement is both promising and problematic. It is promising because it encourages clarity and honesty about research participation, creativity in information disclosure, and mutual learning through the investigator-subject relationship. It is problematic because those goals — which have remained aspirational since the beginning — may be difficult to achieve in what has become an excessively compliance-oriented regulatory regime.

The revised Common Rule includes a new option for the conduct of secondary research with identifiable data and biospecimens: regulatory broad consent. Motivated by concerns regarding autonomy and trust in the research enterprise, regulators had initially proposed broad consent in a manner that would have rendered it the exclusive approach to secondary research with all biospecimens, regardless of identifiability. Based on public comments from both researchers and patients concerned that this approach would hinder important medical advances, however, regulators decided to largely preserve the status quo approach to secondary research with biospecimens and data. The Final Rule therefore allows such research to proceed without specific informed consent in a number of circumstances, but it also offers regulatory broad consent as a new, optional pathway for secondary research with identifiable data and biospecimens. In this article, we describe the parameters of regulatory broad consent under the new rule, explain why researchers and research institutions are unlikely to utilize it, outline recommendations for regulatory broad consent issued by the Secretary's Advisory Committee on Human Research Protections (SACHRP), and sketch an empirical research agenda for the sorts of questions about regulatory broad consent that remain to be answered as the research community embarks on Final Rule implementation.

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Independent Articles

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Columns

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A Symposium Guest Edited by Spencer Phillips Hey

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