



Perspective

The Common Rule, Updated

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For the first time since it was issued in 1991, the Common Rule — the set of federal regulations for ethical conduct of human-subjects research — has been updated. Most of the new

requirements, many of which increase flexibility, will go into effect in 2018, which gives institutions a year to work toward implementation.

The public saw the beginnings of this effort in 2011, when the Department of Health and Human Services issued an Advance Notice of Proposed Rulemaking, signaling an interest in modernizing the regulations by enhancing protections for human research participants and reducing unnecessary burden and ambiguity for researchers.¹ In September 2015, a Notice of Proposed Rulemaking (NPRM) identifying numerous proposed changes was released for public comment, generating a robust and energetic discussion of the proposals' merits.² More than 2100 comments were submitted, from a fairly wide swath of the

public, including individuals, institutions, organizations, and societies. These comments, and influential reports including one from the National Academies of Sciences, Engineering, and Medicine,³ led to a long process of deliberation and discussion. The result is a final rule that differs significantly from what was initially proposed.

Most notably, the new rule does not adopt the proposal to cover researchers' use of unidentified biospecimens (such as leftover portions of blood samples) and to require informed consent for such research. This proposal generated far more comments than any other, and by a substantial margin those comments opposed the proposal. Commenters in every category — institutions, researchers, people working in programs

that protect research participants, and people with no employment connection to the research world — expressed concern that implementing this proposal could significantly harm the ability to do important research, without producing any substantial off-setting benefits. The public response was particularly noteworthy, given that the premise behind the proposal was specifically tied to public sentiment: the NPRM had stated that continuing to allow research on unidentified biospecimens without consent would place “the publicly-funded research establishment in an increasingly untenable position because it is not consistent with the majority of the public's wishes.” That premise now seems questionable. Accordingly, the proposals that would have made it harder to do research with unidentified biospecimens are not included in the new rule.

The rule also does not include proposals that were unpopular at least in part because they were dependent on additional rules or cri-

teria that were not yet developed (and thus could not be evaluated), such as government templates for broad consent, a standardized set of privacy and security safeguards, and an online decision tool that could be used by anyone to determine whether a research project fit under an exemption from the rule's requirements. Commenters' complaints about the complexity of some proposals also shaped the final rule, including the federal agencies' decision not to adopt the proposal to extend the Common Rule to clinical trials that are not federally funded.

On the other hand, some of the NPRM proposals received substantial public support. One of these related to improving informed consent so that people would be better informed when making decisions about whether to participate in particular research studies. It has long been recognized that under the current rules, consent forms have been growing longer and can be difficult to understand. They too often appear to be designed more for protecting the legal interests of institutions conducting research than for helping someone make a decision about participation.

To improve consent forms and the process of obtaining consent, the new rules adopt a series of provisions that were in the NPRM or modified in response to comments. Among other things, they will require that prospective participants be given the information that a "reasonable person" would want to have in order to make a decision about participating (a standard that is commonly used for consent to clinical care); that sufficient detail be provided regarding the research; and that the consent form be organized to facilitate

understanding of why one might or might not want to participate.

The new rules also adopt a slightly modified version of the NPRM proposal with regard to the information's presentation. To combat the growth in length and complexity of consent forms, which too frequently means that the most important information ends up buried, informed consent will be required to begin with a "concise and focused" presentation of the key information that will most likely help someone make a decision about whether to participate in a study. So, for example, in a complicated randomized cancer clinical trial, this section of the consent form would probably include information about the most important risks, similar to what a doctor would commonly say to a patient in the clinical setting. The pages of tables that often include hundreds of risks, ranked according to likelihood and severity, which are commonly used in current consent forms, could still be included in the form but could not be part of this initial concise presentation of key information. Another complementary new provision is a requirement, made more flexible than was proposed in the NPRM, to post online one version of a consent form used to enroll participants in federally funded clinical trials.

Other proposed reforms preserved in the new rule represent significant improvements in the oversight system that aim to reduce unnecessary regulatory burden and enhance protections for research participants. Many observers argue that human research participants could be better protected if less time and effort were devoted to the oversight of low-

risk studies, so that institutional review boards (IRBs), administrators, and researchers could focus on ensuring appropriate protections in higher-risk studies. The new rule facilitates this shift in a number of ways. For example, it creates additional exemptions for low-risk studies, eliminates the need for continuing review for many studies, and provides a new option for facilitating the screening of potential participants so long as researchers keep information confidential.

In addition, the rule includes an option permitting researchers to seek broad consent, which allows participants to agree to researchers' using their identifiable private information or identifiable biospecimens, originally obtained for other purposes such as clinical care, for future, yet-to-be-specified research studies. We envision that broad consent may enhance people's opportunity to decide whether their identifiable private information or identifiable biospecimens may be used by researchers for secondary research studies in circumstances in which investigators might have previously chosen to remove personal identifiers before conducting a study or to seek a waiver of consent from an IRB. The latter two options are still available under the new rule, in contrast to the NPRM's proposals with respect to biospecimens. At the same time, we expect that broad consent, which has been made more flexible than it was in the NPRM, will at least sometimes be the preferred option for both participants and researchers.

The new rule also adopts the proposal to generally require single-IRB review for multi-institutional studies conducted in the

United States. In response to public concerns, while the rule establishes single-IRB review as the default, it allows any federal agency supporting or conducting research to determine that the use of a single IRB is not appropriate for a particular context (in contrast to the NPRM's proposal to require that such determinations be made on a study-by-study basis). The goal of encouraging the use of single-IRB review in this way is to empower that IRB to better protect all human participants in a given study, while eliminating the time and effort associated with multiple IRB reviews and the need for reconciling different IRB determinations.

As institutions, IRBs, and researchers integrate the new rules into their practices, we hope that

the greater protections provided to research participants will result in greater trust in the research enterprise and that the new flexibility offered to researchers and IRBs will foster creative and innovative ways of further improving the oversight of the human-subject protection system. For many years, observers have said that the Common Rule would never be changed. Change has now occurred, we believe for the better. And when the research enterprise evolves further and additional changes are warranted, the new rule is proof that positive regulatory reform is indeed possible.

The views expressed in this article are those of the authors and are not necessarily those of the Department of Health and Human Services or the Office of the Assistant Secretary for Health.

Disclosure forms provided by the authors are available at NEJM.org.

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