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Final rule enhances protections for research participants, modernizes oversight system

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Significant changes made in response to public comments
The U.S. Department of Health and Human Services and 15 other federal agencies today issued a final rule to update regulations that safeguard individuals who participate in research. Most provisions in the new rule will go into effect in 2018.

The new rule strengthens protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research. It also allows more flexibility in keeping with today's dynamic research environment.

The current regulations, which have been in place since 1991, are often referred to as the "Common Rule." They were developed at a time when research was conducted predominantly at universities and medical institutions, and each study generally took place at a single site. Since then, research with human participants has grown in scale and become more diverse and data has become digital.

In September 2015, HHS and the other Common Rule agencies published a Notice of Proposed Rulemaking (NPRM), which drew more than 2,100 comments. In response to concerns raised during the extensive review process, the final rule contains a number of significant changes from the proposed rule, including the removal of a provision that would have required researchers to obtain consent before using a study participant's non-identified biospecimens. The final rule maintains the current practice with respect to oversight of these specimens.

The final rule will now generally expect consent forms to include a concise explanation – at the beginning of the document – of the key information that would be most important to individuals contemplating participation in a particular study, including the purpose of the research, the risks and benefits, and appropriate alternative treatments that might be beneficial to the prospective subject.

"Over the years, many have argued that consent forms have become these incredibly lengthy and complex documents that are designed to protect institutions from lawsuits, rather than providing potential research subjects with the information they need in order to make an informed choice about whether to participate in a research study," said Jerry Menikoff, MD, who directs the HHS Office for Human Research Protections, which led the government's efforts to overhaul the regulations. "We are very hopeful that these changes and all the others that reduce unnecessary administrative burdens will be beneficial to both researchers and research participants."

Important elements in the final rule issued today include:

- The requirement for consent forms to provide potential research subjects with a better understanding of a project's scope, including its risks and benefits, so they can make a more fully informed decision about whether to participate.
- Requirements, in many cases, to use a single institutional review board (IRB) for multi-institutional research studies. The proposal from the NPRM has been modified, however, to add substantial increased flexibility in now allowing broad groups of studies (instead of just specific studies) to be removed from this requirement.
- For studies on stored identifiable data or identifiable biospecimens, researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement. As under

the current rule, researchers will still not have to obtain consent for studies on non-identified stored data or biospecimens.

- The establishment of new exempt categories of research based on the level of risk they pose to participants. For example, to reduce unnecessary regulatory burden and allow IRBs to focus their attention on higher risk studies, there is a new exemption for secondary research involving identifiable private information if the research is regulated by and participants protected under the HIPAA rules.
- Removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects.
- Requirement that consent forms for certain federally funded clinical trials be posted on a public website.

The final rule differs in important ways from the proposed rule. Some examples of proposals that, based on feedback from the public, are not being adopted, include:

- The final rule does not adopt the proposal to require that research involving non-identified biospecimens be subject to the Common Rule, and it does not require that consent be obtained in order to conduct such research. In general, researchers can continue to use such biospecimens in the way they are currently using them.
- To the extent that some of the NPRM proposals relied on tools or standards that had not yet been proposed, the final rule either does not adopt those proposals or includes revisions to eliminate such reliance. Examples of items that were not included in the final rule include a template to be used for broad consent forms, and a decision tool to be used for making exemption determinations.
- The final rule does not expand the policy to cover clinical trials that are not federally funded.
- The final rule does not adopt the NPRM's proposed concept of "excluded" activities. Generally, activities proposed to be excluded are now described as not satisfying the definition of what constitutes research under the regulations or are classified as exempt.
- The final rule does not include the proposed standardized privacy safeguards for identifiable private information and identifiable biospecimens. Instead, in most respects, it retains the current approach to privacy standards.
- The final rule does not adopt the proposal for more stringent criteria for obtaining a waiver of the consent requirements for identifiable biospecimens.

Medical advances would not be possible without individuals who volunteer to participate in research. Oversight and protection of research participants is an important safeguard and essential to advancing the research enterprise. Today's action reaffirms the federal government's commitment to all those who participate in research studies.

To view the final rule, click here.

This article was originally posted by the US Department of Health & Human Services and can be found here.

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