ISSUE SUMMARY

The design and conduct of ethical research with human subjects is essential to scientific and medical progress to improve the lives and health of all. Recent efforts to update and rethink the regulations concerning federal oversight of human subject research present significant opportunities and challenges, as the relevant agencies have revisited these rules for the first time in 25 years. Proposals to redefine “human subject” and change the nation’s approach to conducting research on biospecimens could dramatically increase institutional burden and stifle research without an appreciable increase in providing individuals with meaningful information or choice about their participation in research.

Issue

Research with human subjects is an essential driver of scientific progress that improves health and medical care, from interviews and surveys in the social sciences to clinical trials that evaluate the safety and efficacy of drugs and devices. The cornerstone of this research is its ethical conduct, which requires not only that the research itself is ethical, but that its conduct reflects a respect for the individual participants in that research. The regulatory framework for the oversight of research with human subjects, known as the “Common Rule,” is based on sound ethical principles but was last updated 25 years ago. The design and conduct of research has changed in the ensuing years, in the settings where research occurs; the volume of data collected, used, and shared; the technology employed; and the level of public engagement in and understanding of research. The Department of Health and Human Services (HHS) published a Notice of Proposed Rulemaking to revise the Common Rule in September 2015, and the AAMC, along with numerous other stakeholders, provided extensive comments on the proposed approach.

Background

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research released the landmark Belmont Report, which set forth three basic principles for research with human subjects: respect for persons, beneficence, and justice. Respect for persons is the obligation for researchers to treat individuals as autonomous agents capable of self-determination and to protect those lacking this capacity; the principle of beneficence is the duty to minimize harm and maximize benefits, both at the individual and societal levels; and justice refers to the fair distribution of the benefits and burdens of the research process, considering the question of who ought to enjoy the benefits of research and who ought to bear its burdens.

With its ethical foundation firmly rooted in the principles of the Belmont Report, the Common Rule provides the regulatory requirements for research involving human subjects that is funded or overseen by the 15 federal agencies that concurrently adopted it, from the National Aeronautics and Space Administration to the Environmental Protection Agency. Research subject to the Common Rule must undergo ethical review by an Institutional Review Board (IRB).

In 2011, the Office of the Secretary of Health and Human Services, with the Office of Science and Technology Policy in the Executive Office of the President, began the process of revising the rule. The revision process stems from broad consensus that the decades-old regulations were not adequate for the interconnected and advanced research landscape of today. Due to advances such as genetic sequencing, bioinformatics, and “big data” analysis, the capacity to conduct new types of research has been greatly expanded, and the dividing line between research and care delivery in a learning health care system is less clear.
Since July 2011, when an Advance Notice of Proposed Rulemaking (ANPRM) was published indicating HHS’s intention to revise the Common Rule, the broad research community has been actively engaged in this process. There were over 1,000 public comments to the ANPRM, and after the subsequent September 2015 Notice of Proposed Rulemaking (NPRM), HHS received over 2,000 comments, many critical of the proposed approach.

Concerns about the proposed revisions to the Common Rule focused on the change to the definition of “human subject” to include biospecimens (biological materials taken from the body such as blood or tissue), even those without any associated data about the individual from whom those specimens were obtained. This represents a fundamental shift in how research with unidentified biospecimens is now conducted and would potentially increase the complexity and cost of this critical research significantly without a commensurate benefit for or increased information to individuals.

On June 29, 2016, the National Academies of Sciences, Engineering, and Medicine (National Academies) released the second part of a report titled Optimizing the Nation’s Investment in Academic Research: A New Regulatory Framework for the 21st Century. In this congressionally requested report, the National Academies recommended the immediate withdrawal of the proposed rule and the creation of a new national commission to recommend to the president, Congress, and the federal agencies “how the basic ethical principles governing human subjects research should be applied to unresolved human research questions and novel human research contexts.”

**AAMC Policy Recommendations**

- The AAMC disagrees with proposals to define research with de-identified biospecimens as human subject research and to require all individuals whose biospecimens might be used in future research to sign a generic “broad consent” document. Instead, the AAMC proposes the creation of a “robust notification” requirement, which would require institutions to give individuals access to important information about how their biospecimens might facilitate research to advance medical knowledge and treatment.

- As described in its January 2016 comments on the proposed changes to the Common Rule, the AAMC continues to urge HHS to substantially revise the proposal and take advantage of the “unique opportunity to reframe and modernize the Common Rule and to capture the promise and potential of research breakthroughs while recognizing that individuals want to understand the commitments and contributions they are making to move science and health forward.”

**Related Issue**

- Research Regulatory Burden

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**Web Resources**

**AAMC Resources on the Common Rule**

www.aamc.org/commonrule

**The Office for Human Research Protections**

www.hhs.gov/ohrp

**Optimizing the Nation’s Investment in Academic Research: A New Regulatory Framework for the 21st Century**

www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory