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# Bioethicists urge less regulatory burden for low-risk comparative effectiveness research

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In an opinion article published in this week's theme edition of the *Journal of the American Medical Association* focusing on comparative effectiveness research, a team of Johns Hopkins University bioethicists argues forcefully for streamlining federal restrictions on at least some low-risk clinical comparative effectiveness research, instead of easing them – as is now proposed – solely for low-risk social and behavior research involving surveys, interviews and focus groups.

Writing in the journal's new Viewpoint opinion section, the team supports many of the recently proposed changes to long-standing federal rules governing human subjects research that would allow research oversight to focus more on higher-risk research and streamline oversight for lower risk research. The team asserts, however, that much comparative effectiveness research is also of low-risk to patients and also should be subject to streamlined oversight. Indeed, the proposed regulatory changes ignore this growing and critically important category of low-risk clinical research that compares the effectiveness and safety of different treatments already approved by the U.S. Food and Drug Administration.

"The American public wants and needs to know which of different widely used medications is better for the medical problems they have," says co-author Nancy Kass, Sc.D., Phoebe R. Berman Professor of Bioethics and Public Health at the Johns Hopkins Berman Institute of Bioethics. "Doing this type of comparative study poses little if any additional risk to the patients who take part compared to their getting

usual medical care. We need to make sure the regulatory environment makes it straightforward for doctors, patients, and research institutions to want to do more of this kind of clinical research, " says Kass.

The failure of the proposed changes in human subjects protections, known as the "Common Rule," to include clinical comparative effective research "serves to perpetuate the view that all clinical research…involves more than minimal risk," the Viewpoint article states. Kass' co-authors are Ruth Faden, Ph.D., M.P.H., director of the Berman Institute, and Sean Tunis, MD, MSc, President and CEO of the Center for Medical Technology Policy, a non-profit organization that brings stakeholders together to identify key topics for comparative effectiveness research.

In July 2011 the Department of Health and Human Services (DHHS) issued an advance notice of proposed changes to the Common Rule, and asked for comment on suggested ways to modernize regulations governing any use of human subjects in any kind of research. "This is the first significant proposed change to regulations governing human subjects research in 20 years, so it is crucial that the growing field of clinical comparative effectiveness research, which helps doctors and patients make better treatment choices, is addressed now as well," says Nancy Kass.

The Viewpoint article says revising longstanding federal regulations to focus more on high-risk research and allowing more streamlined oversight for lower risk research ultimately will better provide patients the careful protection they need in that smaller body of science that poses higher risk. The absence of attention to clinical comparative effectiveness research (CCER) in thinking through how ethics oversight should be organized in the future, however, stands to put barriers in the way of these important studies. "Doctors and patients alike have voiced a need for more CCER studies that compare the relative safety and

effectiveness of existing and widely used medical options for prevention, diagnosis or treatment," Kass says.

The proposed rule changes currently exclude CCER, the authors say, despite the fact that "many prospective studies of comparative effectiveness are of a low-risk equivalent to that posed by many behavioral and social science research studies" using surveys, interviews and focus groups. Noting an increase in federal investment recently in comparative research of this sort, the authors agree that "significant advances in CCER will depend on reducing the intensity and burden of oversight."

One example of the kind of CCER research that could be subject to streamlined review if changes to regulations included CCER, the authors say, would be a study in which patients treated for hypertension were asked at their regular clinical appointment to respond to a detailed set of questions about their lifestyle and how they think their medications are working.

"The timing of the reconsideration of the Common Rule with the rapid increase in investments in comparative effectiveness research highlights the importance of seizing this opportunity to advance the shared interests in ensuring that CCER evolves rapidly and ethically," the authors state. "Crafting a framework that promotes an appropriate level of oversight for CCER studies that closely simulate routine clinical practice will be essential for the efficient generation of the real world evidence that patients and clinicians require."

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