

Report on Research Compliance Volume 18, Number 9. August 26, 2021

Community Representation, Better Study Design, Subject Payments Can Foster Justice in Research

By Theresa Defino

“Injustice has no place in human subjects research and undermines public trust in science.”

So begin the recommendations issued by the HHS Secretary’s Advisory Committee on Human Research Protections (SACHRP), more than a year in the making, to help address both flagging respect for research and acknowledge gaping health disparities laid bare by COVID-19.^[1]

“Researchers and many others recognize human subjects research as a primary human activity dedicated to objectivity and empiricism; however, it continues to be marred by unjust policies, practices, beliefs, and systems of power,” according to SACHRP. “It is time to reconsider and reestablish justice as a core principle in biomedical and social-behavioral research, reflecting the reality that the science of people must be accountable to people to be legitimate.”

The recommendations reflect “a balance between articulating large and important problems and providing recommendations that were practical as well as aspirational,” said former SACHRP Chair Stephen Rosenfeld, who also told *RRC* he is “very happy” with the final document.

The initial recommendations, “largely a theoretic and technical parsing” of the foundational Belmont Report, “evolved into something that I believe is responsive to real and urgent needs,” he said. Rosenfeld initiated the writing of the recommendations^[2] and shepherded them to approval in July as a member of SACHRP’s Subcommittee on Harmonization after his leadership term ended in January.

Rosenfeld, head of the institutional review board (IRB) consulting firm Freeport Research Systems LLC, also praised the work of the committee, which included a new chair and a number of members who joined after drafting had begun. “We brought together a number of disparate and sometimes conflicting perspectives, and learned from one another through discussion and debate to come up with a recommendation that everyone could endorse,” he said.

RRC asked Rosenfeld how he hopes IRBs and institutional officials and staff will use the recommendations.

“First, I hope that IRB members feel they are able to access and use the committee’s guidance,” he said, without it being referred to them by administrators first. “I would hope this document would be read by all members of the ethical oversight community. It is, despite our best efforts, the product of a relatively small group of people, and solutions to the problems we raise will come from others. Addressing the problems we discuss is something that we’ll all do together.”

Rethinking Exclusions

Asked to highlight critical sections in the recommendations, Rosenfeld said it is “important to articulate the inequities in our health care delivery system as problems for the research enterprise, not simply something to be

reluctantly accepted. It was also important to give the research and IRB communities the message that they *should* be looking at issues of justice, even in the face of so many barriers to change. I hope that the recommendations themselves can give researchers and IRB members license to raise and discuss these issues.”

He also warned “how fraught it could be to do this the wrong way.” For example, research protocols may “explicitly” require data collection “on race and ethnicity. Scientists will analyze the data they have, and there is a risk that associations with race and ethnicity or age and gender will be misinterpreted as causal,” Rosenfeld said. He added that “the call for a research agenda that directly addresses the social determinants of health is critical.”

Rosenfeld called it “significant” that the recommendations also argue for a reinterpretation of the impact of the Belmont Report on protections from inappropriate inclusion or exclusion.

“There’s an adage that’s used ironically in the IRB community that the best way to minimize risk is not to do the research. There is a risk that we’ll use the same approach to make sure there are no inappropriate inclusions. If there is a possibility that the circumstances of a particular group could be used to exploit them, the answer is not to exclude them from the research, but to put measures and oversight in place to ensure that they are not exploited,” he said. “This is the same problem IRBs have with compensation or payment for research subjects. Both problems are hard, in that there is not going to be a single set of standards or checkboxes that will work for all situations. But that is the work of the IRB. If all our decisions could be reduced to compliance checkboxes, there would be no reason to have a diverse committee to review research.”

This document is only available to subscribers. Please [log in](#) or [purchase access](#).

[Purchase Login](#)