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SACHRP: Secretarial Waiver Needed to Transplant Organs Subjected to Research

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Federal officials should begin the process of creating a national board to review studies involving organs subject to research interventions that will be transplanted into living recipients, and of establishing a waiver of some informed consent requirements, according to HHS's highest ranking panel on human subjects research.

Earlier this summer, the Secretary's Advisory Committee on Human Research Protections approved recommendations regarding deceased donor intervention research (DDIR), one of two actions by SACHRP members at the meeting.[1] SACHRP also finalized comments to NIH regarding its proposed data-sharing policy. Additionally, members discussed issues of social justice in research and public health surveillance activities but did not yet have formal recommendations on these topics.

SACHRP has been examining DDIR since January 2019 as requested by the Office for Human Research Protections (OHRP), but the issue dates back to criticisms consumer advocacy group Public Citizen leveled against the Department of Veterans Affairs (VA) in 2016.[2]

At that time, Public Citizen accused the VA and the Health Resources and Services Administration, as well as investigators from the University of California, San Francisco, and Oregon Health & Science University, of sponsoring and conducting unethical research it said also violated the federal Common Rule.

National Academies Offered Framework

At issue was a study comparing the functioning of kidneys once transplanted that had been stored at lower than usual temperatures. Results of the study (the cooler kidneys did better) were published in *The New England Journal of Medicine*.[3] Investigators did not obtain informed consent from the organ recipients because the institutional review board (IRB) had concluded it was minimal risk research and waived the consent requirement.

The concerns raised by Public Citizen also led the National Academies of Sciences, Engineering, and Medicine to empanel a committee, which published *Opportunities for Organ Donor Intervention Research: Saving Lives by Improving the Quality and Quantity of Organs for Transplantation* in 2017.[4]

The National Academies' report called for the "use of a centralized oversight framework that consists of three affiliated entities: (1) a centrally administered and standing Donor-Research Oversight Committee; (2) a single IRB for organ donor intervention research; and (3) study-specific data and safety monitoring boards."

Authors of the report also said that the "single IRB should require informed consent for research participation, unless it determines in appropriate cases that the criteria for alteration or waiver of informed consent are met." They proposed a two-step process that would prepare a patient for the possibility of receiving such an organ and then seek consent if one ultimately came available.