

Report on Research Compliance Volume 19, Number 5. April 21, 2022 SACHRP: IRBs Should Broaden Safeguards for Research Participants' Families, Communities

By Theresa Defino

In 1997, an article in the September issue of the *Archives of General Psychiatry* discussed a study involving “34 younger brothers of convicted delinquents.” According to the abstract, “There is evidence of relationships among serotonin, aggressive behavior, and a childhood history of socially adverse-rearing conditions.”^[1]

Although published more than two decades ago, mention of the article has found its way into a new series of recommendations the HHS Secretary’s Advisory Committee on Human Research Protections (SACHRP) recently submitted titled, “The Protection of Non-Subjects from Research Harm.”^[2]

A “direct effect” of this study of “aggression in younger male siblings of adolescents with a record of juvenile offenses” could be the stigmatization of “family members of any adolescent who has a juvenile record.” Yet, this “could potentially be ameliorated by careful attention to study design and dissemination,” SACHRP said.

The study is an example of the type that can cause harm to individuals who are not enrolled and who, in the view of the highest-ranking federal advisory panel on protections for research participants, need and deserve more attention from institutional review boards (IRBs).

“Although all research stakeholders are responsible for recognizing and addressing risks to non-subjects, SACHRP takes the position that the IRB should assume greater responsibility in protecting non-subjects who may be unknowingly exposed to risk and who cannot take self-protective measures or who may be exposed to experiential harms (e.g. the sexual partner of subject testing an investigational barrier contraceptive, stigma associated with the research results, etc.),” the committee said.

Still, IRBs should be cautious, and assess “different thresholds and distinct characteristics of the risk to the non-subject, namely probability, magnitude, and causal proximity,” according to SACHRP.

Under development by a SACHRP subcommittee for more than a year, the full group approved the recommendations during the March 10-11 meeting, the first of three scheduled for this year. Members expressed hope that the July meeting might be held in person. SACHRP also discussed, but did not vote on, recommendations related to HHS definitions of engagement and support and ethical and regulatory issues associated with research involving artificial intelligence regulated under the Common Rule.

This document is only available to subscribers. Please log in or purchase access.

[Purchase Login](#)