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# Report on Research Compliance Volume 21, Number 5. April 25, 2024 SACHRP: With Careful Review, Research Procedures May Continue After Trial Halt

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An industry sponsor withdraws funding for a trial. An investigator retires or completes training and can't continue with the research. Enrollment or implementation issues cripple a study. A data monitoring committee raises safety or futility concerns about a protocol. A regulatory authority suspends or terminates the research due to violations of regulations or laws.

These are among the myriad reasons that human subjects research may be paused or terminated unexpectedly. When this occurs, is it in participants' best interest to allow some or all of the study procedures, care or treatments to be provided outside of a formal trial? (To clarify, this is not about whether to provide post-trial access to study-related interventions.)

That is the question the HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) pondered in new recommendations requested by the Office for Human Research Protections (OHRP).[1] SACHRP responded with a qualified "Yes," but noted a significant number of important factors that institutional review boards (IRBs), principal investigators (PIs) and others, such as oversight agencies, should consider.

Approved at its March 20 meeting, SACHRP's recommendations are particularly noteworthy because, while the Common Rule is peppered with references to consideration of participants' best interests, it is silent when it comes to this specific circumstance of what to do with subjects in the event a trial pauses temporarily or ends prematurely.

Given OHRP's history of not issuing formal guidance—even on topics it specifically asked SACHRP to address—institutions and IRBs may look to the recommendations for insights and direction on this vexing issue.