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Jennifer Tsui, PhD, MPH
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Department of Population and Public Health Sciences
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Dear Drs. Llanos and Tsui,

I am writing to express my strong support for your proposed modification to the California Committee for the Protection of Human Subjects Institutional Review Board protocol for the ACHIEVE Study. I support your request to remove the requirement for documented (signed) consent and instead implement a waiver of documentation of consent.

As Deputy Director of Cancer Surveillance Research at the Rutgers Cancer Institute and through my work with the New Jersey State Cancer Registry (NJSCR), I have extensive experience in cancer surveillance, registry-based research, and the operational aspects of population-based recruitment through cancer registries. My work focuses on ensuring high-quality, representative data collection while maintaining appropriate ethical standards for research participation.

From both a methodological and operational perspective, requiring signed consent can introduce unnecessary barriers that reduce participation and impact the representativeness of study populations. In registry-based studies, where recruitment often occurs via mail and follow-up outreach, simplifying consent procedures is critical to maximizing response rates and minimizing selection bias.

The use of a waiver of documentation of consent, where participant action (e.g., return of a completed questionnaire) indicates consent, has been effectively and appropriately implemented in studies conducted through the NJSCR. This approach supports efficient study operations while maintaining participant protections for minimal risk research.

Within the ACHIEVE Study, the contrast in consent procedures between the NJSCR and the Los Angeles Cancer Surveillance Program (LACSP) highlights the practical implications of these approaches. Requiring signed consent in LACSP may create additional logistical and perceptual barriers for participants, which can ultimately affect recruitment and data completeness.

Based on my experience, implementing a waiver of documentation of consent is consistent with best practices for registry-based, minimal risk research and is an important step toward improving participation and ensuring more representative data collection across diverse populations.

I strongly support this request and look forward to contributing to the continued success of the ACHIEVE Study.

Sincerely,



Lisa E. Paddock, MPH, PhD
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