OFFICE OF RESEARCH COMPLIANCE
John F. Wolf, MD Human Subjects Committee
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APPROVAL OF RESEARCH

May 06, 2024

Rie Sakai-Bizmark, MD, MPH, PhD
310-222-2327
rsakaibizmark@lundquist.org

Dear Dr. Sakai-Bizmark:

On 05/06/2024, the John F. Wolf, M.D. Human Subjects Committee (1) reviewed the following protocol:

Type of Review/Submission:	Expedited/Initial Submission, Reference #059629
Study Title:	Understanding Disparities in Preventive Care Utilization, Hospitalization and Emergency Department visit Among Children of Deaf and Hard of Hearing Mothers
Investigator:	Rie Sakai-Bizmark, MD, MPH, PhD
IRB No.:	2024-33265-01
Funding:	None
Documents reviewed:	IRB Pre-Review Correction Form (Version 1.0) IRB Application (Version 1.1) Investigator Protocol v1.0 dated 05/06/2024 (Version 1.4) DUA for CO IAPCD (Version 1.0) Abbreviated Institutional Research Project Application (Version 1.0)

The John F. Wolf, M.D. Human Subjects Committee (1) approved the protocol on 05/06/2024 and determined that Continuing Review is not required. The John F. Wolf, M.D. Human Subjects Committee may require an update or "check in" every 3 years until notified that the protocol is no longer active (via submission of HRP-251 Final Report/Study Closure).

As a condition of this approval, you are required to continue to meet all institutional requirements for conducting research with human subjects as outlined in the INVESTIGATOR MANUAL (HRP-103).

As a reminder:

- Modifications to this study must be approved by the John F. Wolf, M.D. Human Subjects Committee in advance of implementing changes to the research.
- New information related to this study must be reported to the John F. Wolf, M.D. Human Subjects Committee in accordance with institutional reporting requirements.
- Close this study once all research activities are complete.

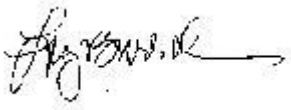
Regulatory Determinations:

- The John F. Wolf, M.D. Human Subjects Committee (1) approved the waiver/alteration of Consent Process under 45 CFR §46.116(f) (2018 Common Rule).

- The John F. Wolf, M.D. Human Subjects Committee (1) approved the above protocol under Child Risk Category 21 CFR §50.51/45 CFR § 46.404.

Important Note: Approval by the IRB does not, in and of itself, constitute approval for the implementation of this research. Other clearance from the Lundquist Institute and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the institute and the entity.

Sincerely,



Signature applied by Elizabeth Burrola CIP on 05/06/2024 04:59:24 PM PDT

Elizabeth Burrola CIP
Office of Research Compliance

cc: Emily Marr, Ph.D., Frank Wu
Office of Research Administration