

APPROVAL OF RESEARCH

September 24, 2024

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

Dear Dr. Sakai-Bizmark:

On 09/24/2024, the John F. Wolf, M.D. Human Subjects Committee (1) reviewed the following protocol:

Type of Review/Submission:	Expedited/Modification, Reference #060415
Study Title:	Impact on Seasonality of Suicidal Behavior Among Adolescents Experiencing Homelessness in the US during the COVID-19 Pandemic
Investigator:	Rie Sakai-Bizmark, MD, MPH, PhD
IRB No.:	2023-33100-01
Funding:	Agency: National Institute of Mental Health Grant ID: 1R21MH137745-01 Grant Title: Suicidal Behavior among Adolescents Experiencing Homelessness in the US during the COVID-19 Pandemic
Documents reviewed:	IRB Pre-Review Correction Form (Version 1.0) HRP-213: Modification (Version 2.1) IRB Application (Version 1.5) Investigator Protocol v1.3 07 31/2024 (Version 1.10)

The John F. Wolf, M.D. Human Subjects Committee (1) approved the protocol on 09/24/2024 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M.D. Human Subjects Committee may require an update or “check in” every 3 years until notified that the protocol is no longer active (via submission of HRP-251 Final Report/Study Closure).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.

See iRIS for the stamped approved consent form and/or other documents. Use copies of these documents to document consent.

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,

A handwritten signature in black ink, appearing to read 'Gina Fierro', with a stylized flourish at the end.

Signature applied by Gina Fierro on 09/24/2024 03:57:31 PM PDT

Gina Fierro
Office of Research Compliance

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