

**DATE:** January 22, 2024

**TO:** Stacie Daugherty, MD, MSPH

**FROM:** Kaiser Permanente - Interregional IRB (KPIIRB)

**PROJECT TITLE:** [1867395-16] Healthcare Organizational Structural Conditions and the Health of People Recently Released from Prison (AKA Structural Conditions and Health After Release from Prison [SCHARP] Study)

**SUBMISSION TYPE:** Continuing Review/Progress Report

**ACTION:** APPROVED

**REVIEW TYPE:** Expedited Review

**EFFECTIVE DATE:** January 22, 2024

**PROJECT RISK:** MINIMAL RISK

**EXPIRATION DATE:** January 21, 2025

**REVIEW CATEGORY:** Expedited Review Category 7a & 7b

Dear Stacie Daugherty:

Thank you for submitting the following materials/documentation:

- Continuing Review/Progress Report - FORM 210 KPIIRB Continuing Review - SCHARP\_12.27.23.docx (UPDATED: 01/8/2024)
- Publication Materials - 2024 ACCJH Abstract - SCHARP.docx (UPDATED: 12/27/2023)

On January 22, 2024, the Kaiser Permanente - Interregional IRB (KPIIRB) reviewed the above referenced submission and granted approval. The KPIIRB continues to accept review authority and oversight for this study for Colorado University - Boulder, Denver Health, and UCHealth University of Colorado.

This study requires continuing review. If you have completed the study, including all analysis of identifiable data, by January 21, 2025, submit a final report and close the study with the IRB. If you have not completed the project by that date, it is your responsibility to submit a continuing review 4-6 weeks prior to the expiration date of January 21, 2025.

All previously approved waivers and determinations continue to apply to this research project.

You must promptly notify the KPIIRB within ONE (1) business day:

- Death of a research participant that is both unanticipated and possibly related to the study
- Unauthorized use or disclosure of confidential subject information or KP information.

In addition, you must promptly notify the KPIIRB within FIVE (5) business days of all other reportable information as stated in the Prompt Reporting Requirements policy.

Changes to approved research may not be initiated without IRB review and approval. If you need to deviate from the protocol in order to protect the rights, safety, or welfare of a participant prior to obtaining IRB approval, you are required to notify the KPIIRB within FIVE (5) business days of this action.

The Principal Investigator is responsible for disseminating information related to the conduct of this study to project staff. If you have questions, please contact the KPIIRB.

Thank you for your commitment to ethical and responsible research.

Sincerely,

Kaiser Permanente - Interregional IRB (KPIIRB)