

Human Subjects Review Office Kaiser Permanente Washington Health Research Institute 1730 Minor Ave, Suite 1600 Seattle, WA 98101

206-287-2919

DATE: November 8, 2017

PRINCIPAL INVESTIGATOR: Gregory Simon, MD MPH

STUDY TITLE: [1135739-1] An Evaluation of the National Zero Suicide Model Across

Learning Healthcare Systems

REFERENCE #: 2017

SUBMISSION TYPE: New Project

ACTION: APPROVED

STATUS DATE: November 8, 2017
EXPIRATION DATE: November 8, 2018
REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category #5

Thank you for your submission of New Project materials for this research study. The Kaiser Permanente Washington Region IRB has APPROVED your submission, including:

- Application Form Application_Record Data Only KPWA_Zero Suicide_Revised.doc (UPDATED: 11/7/2017)
- Budget Zero Suicide Evaluation_SummaryBudget.pdf (UPDATED: 10/10/2017)
- Budget Budget Justification.docx (UPDATED: 10/10/2017)
- Core Data Form Core Data Form (UPDATED: 09/28/2017)
- CV/Resume Sterling Biosketch Zero Suicide.pdf (UPDATED: 10/20/2017)
- CV/Resume Lynch Biosketch Zero Suicide.pdf (UPDATED: 10/20/2017)
- CV/Resume Coleman_Biosketch_Zero Suicide.pdf (UPDATED: 10/20/2017)
- CV/Resume Beck_Biosketch_Zero Suicide.pdf (UPDATED: 10/20/2017)
- CV/Resume Penfold Biosketch.docx (UPDATED: 10/10/2017)
- CV/Resume Simon Biosketch.docx (UPDATED: 10/10/2017)
- Other ZeroSuicideOverview.pdf (UPDATED: 11/3/2017)
- Other Table 1 Evaluation Grid.docx (UPDATED: 10/10/2017)
- Proposal SPECIFIC AIMS.docx (UPDATED: 10/10/2017)
- Proposal RESEARCH STRATEGY.docx (UPDATED: 10/10/2017)

Determinations:

The primary reviewer determined that the overall study design is reasonable, the risk/benefit ratio is reasonable, and the confidentiality protections are adequate.

NOTE: The IRB Office has required that you update the application (using track changes) with any future modifications. Similarly, the IRB Office required that you update Table 1 in track changes (submitted as a separate document in this package) with any future modifications.

All research must be conducted in accordance with this approved submission.

The IRB has approved one or more consent waivers and a waiver of authorization per HIPAA. Please see the additional waiver approval document(s) for details.

You will be required to submit a progress report prior to the following date: November 8, 2018. Prior to this date, you will be prompted to submit the Continuing Review Report, available in the IRBNet library.

This report is documentation of an IRB review. The IRB reviews only the issues related to the protection of human subjects in research. There may be approvals needed by other departments at Kaiser Permanente Washington.

Any revisions to approved research may not be initiated without IRB review and approval unless they are necessary to eliminate apparent immediate hazards to subjects. Please use the IRBNet modification form to request revisions.

Investigators are required to promptly report to the IRB for the following: 1) any modifications in procedures, particularly those affecting risks and benefits to subjects, and 2) any serious and/or unanticipated events or other problems involving risks to subjects or others.

The Principal Investigator is responsible for disseminating this information to project staff.

If you have any questions, please contact the HSRC office at (206)-287-2919 or hsrcoffice@ghc.org. Please include your study title and reference number in all correspondence with this office.

 $\text{FW}00002344 \cdot \text{All}$ relevant regulations and policies are available upon request