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

206-287-2919

DATE:	December 10, 2018
PRINCIPAL INVESTIGATOR:	Gregory Simon, MD MPH
STUDY TITLE:	[1135739-4] An Evaluation of the National Zero Suicide Model Across Learning Healthcare Systems - Opioid Supplement
REFERENCE #:	2017
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVED
STATUS DATE:	December 10, 2018
EXPIRATION DATE:	November 8, 2019
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category #5

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

- Application Form - KPWA_Sub-Study Application_Record Data Only_Zero Suicide Opioid Supplement.doc (UPDATED: 12/7/2018)
- Kaiser Permanente - IRB Core Data Form - Kaiser Permanente - IRB Core Data Form (UPDATED: 11/29/2018)
- Kaiser Permanente - Modification Form - Kaiser Permanente - Modification Form (UPDATED: 11/29/2018)
- Kaiser Permanente - Study Team Form - Kaiser Permanente - Study Team Form (UPDATED: 11/13/2018)
- Proposal - ZS-Opioid_Supplement_FINAL.pdf (UPDATED: 11/13/2018)

Determinations:

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

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.

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.

FW00002344 · All relevant regulations and policies are available upon request