Instructions

- This Application is to be used in conjunction with the IRBNet Core Data Form and Study Team Form.
- Complete items in this application with concise, non-technical language.
- Enter your responses to each question directly below each question in the open text field.
- Define all acronyms.
- Fill out all relevant tables.
- Double clicking on the checkboxes opens a window where you can select "check"
- When completing this application, if a question does not apply to your study then enter "N/A."
- Submit other documents as necessary
- **Guidance:** Red text throughout this application is guidance or special instructions.
- PI signature is required in IRBNet

- If the research includes any of the following activities complete and include the following Supplements (available in IRBNet **Form – IRB Supplements All**):

Consent Wavier/HIPAA Authorization Waiver	**Supplement A**
Research use of electronic media or devices, and/or internet or email	**Supplement B**
Family history or secondary subject data	**Supplement C**
Biological specimens, genetics, and GINA	**Supplement D**
Children	**Supplement E**
Other Potentially Vulnerable Populations	**Supplement F**

Protocol Title & PI

Study/Protocol Title

Reducing CNS-active Medications to Prevent FALLS and injuries in older adults (STOP-FALLS)

Principal Investigator

Benjamin Balderson, PhD

Version Date

December 1, 2022

Form Author

Monica Fujii

Investigator Assurance

Submission of this application in IRBNet indicates that the named PI: Is responsible for the conduct of this research at KP Washington; certifies that the statements herein are true, complete and accurate to the best of his/her knowledge; will report any serious or unanticipated adverse effects, problems, or protocol deviations; will not make changes without prior approval from the IRB; will renew this application with the IRB as directed by the IRB; will conduct the research project in compliance with the IRB conditions of approval; will only implement procedures in the original grant application if they are

also described in this application and approved by the IRB; and will not start the research or use confidential records, data or specimens until the research receives final approval from the IRB.

1. Funding Information

1.1 Funding Source(s).

Provide the following information for current or pending funding source for this research application. Add boxes for each additional source of funding.

Funding Type:	☒ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☐ Other, specify:
Funding Agency:	CDC
Principal Investigator (on proposal):	Elizabeth Phelan, MD, MPH and Shelly Gray, Pharm D
Grant Number:	RNG209845
Proposal Title:	***Reducing CNS-active Medications to Prevent FALLS and injuries in older adults (STOP-FALLS)***
Status:	☒ New ☐ Competing continuation ☐ Non-competing continuation
Start Date:	9/30/2018
End Date:	9/29/2023
Funded:	☒ YES ☐ NO
Is the source of this funding federal?	☒ YES ☐ NO
Is the Department of Defense funding this project?	☐ YES ☒ NO If YES, contact the IRB staff for guidance.
What institution is the prime recipient of these funds?	University of Washington
If KPWA is the prime recipient, list all institutions that will be sub-recipients of funds on this award:	

2. Study Purpose, Overview, & Background

Guidance: This section of the application provides the IRB reviewer(s) with an overview of the project. Detailed descriptions of study procedures, including recruitment and consent processes, are requested in other sections of the application.

2.1 Objectives

Describe in plain language the purpose, specific aims, or objectives and indicate the primary goal(s) of the study (e.g. safety, tolerability, effectiveness, feasibility, pilot study, etc.). State the hypotheses to be tested. State primary and any secondary study endpoints.

The overall objective of STOP-FALLS is to implement a patient-centered medication reduction program that focuses on CNS-active medications to reduce falls and unintentional injury among older adults. Our aims are as follows: **AIM 1: Adapt and Obtain Feedback on** approaches necessary for adoption and implementation of evidence-based medication reduction strategies (intervention) for use in an integrated health care system. **AIM 2: Implement and Evaluate** the intervention using a cluster randomized trail design. **Aim 3: Assess** barriers and facilitators to intervention adoption, implementation, and maintenance.

2.2 Background

a. Scientific Background

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. A short list of references or bibliography must be included as part of this document, uploaded separately, or provide the relevant page number(s) of the grant where references or bibliography can be found.

Falls are a growing public health problem. Falls and fall-related injuries constitute a critical, and growing, public health problem. One in three community-dwelling adults aged 65 and older, and one in two aged 80 and older, sustains a fall each year. About half of all falls result in an injury. Treatment of injurious falls is expensive, costing over $30 billion annually. As the aging population grows, the adverse impacts of falls (fractures, functional dependency, permanent nursing home residence) will occur with increased frequency, and costs will rise substantially. Systems-based approaches that address the prevention of falls are thus urgently needed. An increased emphasis on fall prevention in clinical practice will greatly enhance the quality of ambulatory care of older adults and stem the rising tide of fall-related healthcare use and costs.

Centrally acting medications are a contributor to falls. Medications, particularly those that affect the central nervous system (CNS), have been consistently linked to falls. Common side effects of CNS-active medications include dizziness, sleepiness, and impaired balance and coordination. Use of CNS-active medications is common, with up to one-quarter of older adults in the community taking at least one of these medications. Importantly, research has found that reduction in these medications can reduce falls. Current practice guidelines recommend that prescribers review all medications with their older patients to minimize polypharmacy and the use of CNS-active and other high-risk medications. However, this practice is not routinely followed due to multiple key barriers: lack of (patient, provider, pharmacist) awareness that medications can cause falls, multiple prescribers, multiple pharmacies, guidelines that induce polypharmacy, patient belief in the need for medication, provider reluctance to change prescriptions, even in the face of patients prompting discussion, and lack of sustainable methods to promote interactions between prescribers, pharmacists, and patients.

b. Benefit to Society

Provide a brief description (a few sentences) of the study's potential benefit to society.

The STOP-FALLS Intervention has the potential to reduce falls and fall-related injuries in adults aged 60 and older using a minimal-risk method. This intervention may also reduce other adverse events including unintentional overdoses and motor vehicle crashes. If it proves to be successful, then this simple intervention could be readily disseminated and at a low cost.

c. Preliminary Data

Provide a brief description of the preliminary data/studies. If there are IRBNet files for those studies, please include the title and number.

Best practices for reducing use of CNS-active medications exist but are underutilized. In preparing this project, we completed a thorough review of the literature and identified two interventions with strong evidence for efficacy in reducing CNS-active medications. We describe these just below.

Eliminating Medications through Patient Ownership of End Results (EMPOWER) is a direct-to-patient educational intervention to reduce use of benzodiazepines in older adults. A randomized trial conducted in partnership with community pharmacies that recruited community-dwelling older adults taking a benzodiazepine found a 27% discontinuation rate at six months. The intervention empowered patients to discuss deprescribing of these medications with their physician or pharmacist but did not engage healthcare providers directly. The investigators found that providers tended to dismiss safety concerns about benzodiazepine use in the context of patient-initiated discussions and believe that this explains why higher discontinuation rates were not achieved (C. Tannenbaum, personal communication).

Developing Pharmacist-led Research to Educate and Sensitize Community Residents to the Inappropriate Prescription Burden in the Elderly (D-PRESCRIBE) combined the EMPOWER intervention with a pharmacist-initiated, prescriber-directed, evidence-based decision support tool. This approach achieved a doubling of the six-month discontinuation rate seen with EMPOWER alone.

In summary, evidence suggests that older adults can be educated and empowered to engage in discussions with their providers that result in favorable changes in their medication risk profile (including medications viewed as being difficult to discontinue, i.e., benzodiazepines). Prescriber-directed decision support can also improve the safety of medication regimens. Yet, there remains a need for a pragmatic model that simultaneously engages patients, pharmacists, and prescribers in the context of real-world, daily healthcare delivery to efficiently and safely reduce the use of CNS-active medications. Moreover, models that can sustain prescribing changes over time are paramount to achieve effects on health outcomes such as falls and fall-related injuries, as resumption of medications may otherwise occur.

In STOP-FALLS, we will adapt the EMPOWER patient-directed educational brochure together with the prescriber-directed decision support tool used in D-PRESCRIBE for use within the integrated healthcare delivery system at 9 KPWA clinics. If STOP-FALLS is successful, we expect it to significantly reduce the incidence of falls, fall-related injuries, and healthcare costs for injury care.

d. Data Analysis

Provide a brief description of the main data analysis plan.

Aim 2

Overview. Statistical analyses will be performed using statistical software (R, SAS, or STATA). Descriptive statistics will be computed and appropriate graphical summarizations (histograms, boxplots, scatterplots) will be made for all variables across the intervention clinics and usual care clinics to assess the comparability of the baseline characteristics and follow-up time of each group. Although we stratified our randomization on size and location of clinics and expect the KPWA population to stay relatively stable over the study time period, any patient characteristics which we find to be different (either clinically or statistically at P-value <0.10) between groups at baseline, known to be related to the outcome or likelihood of disenrollment from the health plan will be adjusted for in analyses. We will always include age, sex, and indicator of prior falls in the adjusted models. Statistical significance will be indicated by a P-value <0.05 and all tests and confidence intervals will be two-sided.

Primary Outcome. To compare the primary outcome of reduction in number of medically treated falls between intervention and usual care groups over 12 to 24 months, we will run a Poisson regression model with indicator of intervention or usual care clinic and other adjustment variables. A participant's follow-up time within a clinic will start when they were sent a mailing (intervention group) or comparably for the usual care clinics we will mimic when they would have been sent a mailing if they were in the intervention group and start their follow-up time at that point. To account for differential follow-up time per participant we will include an offset term that is observed follow-up time and accounts for censoring due to disenrollment from the health plan (e.g., offset will be either to the end of the study period between 12-24 months depending on clinic and patient roll-out timing or time enrolled in the health plan over their clinics follow-up periods). To account for cluster randomization at the clinic level we will use generalized estimating equations (GEE) with a robust sandwich variance to account for clinic-level correlation. We will conduct similar models for 6- and 12-month follow-up times which are secondary time points. Further, to explore the timing of when the intervention effect may have occurred, we will run a Poisson model with three indicators of time periods (0-6 months (reference group), 6-12 months, 12-18 months, and 18-24 months) including interactions with time periods and indicator of intervention or usual care clinic. Each participant has up to 4 different outcome measures (less only if censored) in the model and the offset is determined by the time observed in a given time period. To account for multiple outcomes for a participant and cluster randomization we will apply Poisson regression with GEE and a robust sandwich variance.

Secondary Outcomes. To examine the effect of the intervention on unintentional overdose up to 24 months, we will create a binary measure of any healthcare episode for overdose over 24 months. Similar to the analysis of the primary outcome, a Poisson regression model will be used to account for differential follow-up time per participant. We will also examine the effect of the intervention on this outcome every 6 months to explore intermediate trends over time. Motor vehicle crash-induced injuries will also be assessed following the primary outcome analysis. For direct costs of the intervention at 24 months amongst the intervention cohort we will just provide an average cost per patient, standard deviation and range.

Aim 3

Overview. Aim 3 will involve targeted analyses of likely key factors affecting adoption, implementation and maintenance of our intervention. The goal is to generate knowledge that would inform other health systems in their attempts to implement this intervention by obtaining purposely sampled perceptions of delivery system stakeholders (pharmacists, primary care providers, and clinic leadership) of the intervention to inform adoption decisions; describing contextual factors that influence implementation of the intervention; and considering the influence of program costs on intervention maintenance. All data for this aim will be observational (no data collected on patients or providers) to promote feasibility and limit the extent to which self-report measures bias findings, and they will align with established reporting recommendations, wherever possible.

Implementation Strategy Tracking. A published method for tracking strategies will be applied across project meetings to capture information on implementation strategies including: operationalization of each strategy by reporting on the actor of the strategy, the action being performed, the target of the action, temporality, dose, outcome affected, and rationale for strategy selection. We will used structured minute-taking during meetings to capture the information. Strategies will be coded to align with published compilations and reveal novel strategies, consistent with Dr. Lewis' application of this method in an ongoing R01. The richness of the data allows for an understanding of factors affecting implementation, strategies used by whom and how often to achieve what. This information is critical to any form of implementation guide and can allow understanding of any variation in implementation that may be linked to outcomes.

Clinical Leadership. Clinic-level leaders (typically middle managers) are usually the individuals most influential over implementation processes as they are the conduit between high level administrators and front-line providers. Ways in which they shape thinking about and the ultimate form that the STOP-FALLS program takes and how it is integrated into existing workflows will be assessed by ongoing observations of the Implementation Team, with these observations relayed to the research team as part of monthly meetings of the Implementation Team and the research team. Consistent with emerging literature, we will classify the degree to which clinic leaders demonstrate proactive, knowledgeable, supportive, and perseverant leadership for the STOP-FALLS implementation. We will analyze the degree to which these influences helped or hindered intervention adoption and implementation across the KPWA delivery system. We will do this by first classifying clinics as low, moderate, or high performers and then describe leadership characteristics of each clinic group.

Adaptability Analysis. Adaptability of an intervention is important in order to maximize program impact in different settings. We will systematically identify possible adaptations to our intervention and assess whether they might maintain or alter program fidelity, guided by principles of Planned Adaptation. The basic tenet of Planned Adaptation is the imperative to identify core program components, or "elements of a program that fundamentally define its nature and that account for the program's effects", *and* provide information on potential adaptations of the program (i.e., ways in which the program can be adapted and ways in which it should not be adapted; identifying cultural modifications that do not conflict with the program theory). Adaptations at the clinic level will be tracked by the KPWA Implementation Team, with this information relayed to the research team during joint monthly meetings. We will code adaptations according to an established framework for characterizing adaptations of evidence-based practices post implementation to indicate whether an adaptation was made to the

context, content, or implementation support. We will use adaptation resources (adaptation guidelines, fidelity monitoring tools) to facilitate this process. From this analysis we will make explicit the core components of our intervention and describe ways in which it could be realistically adapted for use in different clinical settings and/or with different patient and provider populations.

Implementation Costs. Contemporaneously, information on direct costs to implement the intervention will be tracked. Costs will be categorized as start-up or maintenance. Start-up costs will include costs to adapt the intervention, time needed to bring the delivery system on-board, staff time needed to identify and invite (mailed letters) eligible patients to participate in the program, overhead (space rental, utilities, supplies), equipment, and personnel costs. Pharmacist time to assess and monitor medication regimens of intervention patients as a result of referrals as well as time to interact with providers will be calculated according to methods used previously. Cost information will be estimated from project invoices, Implementation Team discussions with clinical staff regarding time estimates, and administrative records. We will use descriptive statistics and summarize cost data in terms of a mean intervention cost per patient.

2.3 Study Design Overview

a. Overview/snapshot

Describe the overall approach of the study (e.g. prospective, interventional, observational, retrospective, etc.). If your study includes more than one group, arm, or subject population, describe that here (for example, a study of both subjects and their caregivers, or a study with both a prospective interventional arm and a retrospective chart review arm).

The STOP-FALLS Project is a Multi-phase Study that involves 3 distinct phases of activities. Phase 1 activities involve a 1-time web-based survey of KPWA Primary Care Providers (MD, DO, Pa-C, ARNP) who provide care to older adults aged 65+ to assess their attitudes towards and self-efficacy for deprescribing our medications of interest. Phase II involves holding 3 focus groups with patients' representative of our target population to help ensure that the Patient Brochures created and curated by our study team are patient-centered (Aim 1).

Phase III (Study Intervention) is a Cluster Randomized Controlled Trial testing whether providing educational brochures to older adults aged 60+ and their providers has an effect on medication usage, fall-related healthcare use (primary outcome), and other (secondary) injury outcomes (Aim 2). In Phase III (Study Intervention), we will also do a targeted evaluation of key factors affecting adoption, implementation and maintenance of the intervention (Aim 3). We are not collecting any information on individual providers and are not collecting any provider outcomes as a part of Phase II or Phase III activities. To meet our objectives in Phase III, we will collect and analyze patient-level data including automated data in the KPWA Virtual Data Warehouse on health care utilization, prescription medication fills, demographics, and diagnoses. Patient-reported outcomes on symptoms relevant to the medications of interest and their potential deprescribing (pain, depression, anxiety, and insomnia) will also be extracted and analyzed from Clarity and Natural Language Processing of the clinical notes field in EPIC. Additionally, we will collect 3 self-reported questions from all participants regarding the type of brochure they received, it's perceived helpfulness and whether the

participant will initiate a conversation with their doctor. **This current application is seeking permission for Phase II and Phase III activities only because Phase I is already approved in IRBNet (Project ID: 1375781-3).**

For the PHASE II (Focus Groups), we used a focus group model to help ensure that our patient brochures are patient-centered. There are 5 patient brochures (1 for each study medication class; Opioids, Sedative/hypnotic (Benzo), Tricyclic Antidepressants (TCA), Muscle Relaxers, and Antihistamines that will be used in this study, but we will only be vetting 3 of these brochures in patient focus groups (Opioids, TCAs, Muscle Relaxers). The reason for only hosting focus groups for three of our 5 brochures is that these brochures wee created by modifying brochures created by our consultant team members in Canada (the CaDeN Group). Intensive focus groups were held in the making of these brochures, so we anticipated there will be minimal changes required. We submitted any changes as a modification prior to using the brochures in the intervention phase (Phase III). The brochures to be used in the focus groups are:

- 190916_OpiodsPatientBrochure_FG and Intervention_Submitted
- 190916_SMRPatientBrochure_FG and Intervention_Submitted
- 190916_TCAPatientBrochure_FG and Intervention_Submitted

The other 2 patient brochures and ALL provider Evidence-Based Pharmaceutical Opinions (EBPO) are FINAL.

This activity was completed in December of 2019.

This current application is seeking permission for Phase II and Phase III activities only because Phase I is already approved in IRBNet (Project ID: 1375781-3).

b. Study Intervention

If the study includes a behavioral, educational, or other type of intervention briefly describe the intervention or provide a thorough overview of the intervention. Explain whether the intervention is standard of care at KPWA or elsewhere and whether testing the intervention is part of the study design. One paragraph is adequate here, section 7 (question 7.1.d), asks a detailed description of the intervention.

Phase III of the STOP-FALLS Study involves an educational intervention designed to guide safer use of medications by older adults. With the input and assistance from our KPWA delivery system collaborators, the study team created and curated educational brochures for each CNS-active medication class that is a target of the intervention. The target medication classes are: opioids, sedative hypnotics (also known as benzodiazepines and Z-drugs), skeletal muscle relaxants, tricyclic antidepressants (TCAs), and antihistamines as well as fall prevention. For each medication class, we have created a Patient Brochure packet that will be mailed to patients using the medication on a chronic (>3 months) basis and a related decision support tool, referred to as an Evidence-Based Pharmaceutical Opinion (EBPO), that will be sent to the patient's provider. Prior to October 2020, the EBPOs were sent to providers using secure fax. After December 2020, a link to the online version of the EPBO's will be sent to the providers using Epic Staff Messaging. The Patient Brochures contain information about the potential risks of the target medication, alternative, safer methods of symptom management and fall prevention. The brochures also contain a sample tapering schedule which the patient may decide to follow as well as repeated encouragement to

discuss reducing the dose and/or stopping the medication with his/her healthcare providers. The Provider EBPOs describe the risks associated with the medication and alternative evidence-based treatments that could be tried to help the patient reduce their use of the target medication.
Additionally, the study team in collaboration with the clinic will identify, a "Clinic Champion" who will function as a liaison between the STOP-FALLS study team and the clinic. The clinic champion will forward the Deprescribing Pearls (via email) to the providers at the clinic. The Deprescribing Pearls will be sent every 2 weeks for the first 4-5 months of the study (currently we have 15 tip sheets/posters). These contain information drawn from the EBPO's related to medication deprescribing. If they choose, the clinic champion may highlight information from the Deprescribing Pearls in morning huddles/team meetings. Additionally, the clinic champion can communicate with the study team about issues that might come up at their clinic regarding the study.
All patient and provider materials have been carefully cross-referenced with KP Guidelines and reviewed by leaders in the KPWA delivery system so that all information and recommendations are concordant with KPWA Guidelines and the fall prevention brochure has been developed by our funder and is widely available in the public domain.
Approximately 1 month after the brochure is mailed out, participants will receive a follow-up postcard inquiring about the helpfulness of the brochure and whether the participant will initiate a conversation with their provider.
Detailed Steps: Patients are identified as being in the correct age for their medication class, receiving primary care or assigned to a primary care provider at one of our intervention clinics, and taking at least 1 of CNS-active medications of interest on a chronic (>3 month) basis. Patients are mailed an educational brochure about a CNS-active medication class that they are currently taking (verified by KPWA pharmacy data) and a fall prevention self-help sheet. The patient's primary care provider will be sent an Evidence-Based Pharmaceutical Opinion Brochure (EBPO) synchronous with the patient mailing goes out. Additionally, we will mail all participants an antihistamine brochure because there is high utilization of over-the-counter antihistamine use, but prescriptions in automated data sources is low. An associated EBPO will not be sent synchronous with this antihistamine brochure mailing except when the patient is identified as taking prescription antihistamines on a chronic basis. In order to ensure that KP providers are not confused by these communications, we will inform providers at the Intervention Clinics about this study and materials that they can expect to receive through morning huddles and/or brown bag lunches as deemed appropriate by the clinic managers.
Approximately 1 month after the brochure is mailed out, participants will receive a follow-up postcard inquiring about the helpfulness of the brochure and whether the participant will initiate a conversation with their provider.
Patients will receive brochures for each medication class that they are prescribed, with subsequent brochures being mailed out 3 months after the previous one. We anticipate that less than 10% of participants are on 2 or more CNS medication classes. Additionally, we will mail all participants an antihistamine brochure because there is high utilization of over-the-counter antihistamine use, but prescriptions in automated data sources is low.

No other follow-up is conducted by the study team until it is time to pull automated patient data to measure outcomes as described in this application.

c. Flow diagram (if needed)

If the study design is complicated (i.e, has multiple populations, data sources, subject pathways, etc.), insert a flow diagram here or upload it as a separate document if the format is incompatible with this form.

NOTE: Update March 2021 - Due to initial delays due to COVID 19 and changes to procedures based on feedback from our intervention clinics (during both the first two recruitment waves and during our study overview sessions at clinics), our overall study time is going to be delayed significantly including pulling participants and collecting outcomes data, therefore we need to extend the date range for both sample identification and data collection by 1 year. This only applies to PHASE III (Study Intervention):The intervention will be rolled out monthly to clinics and persist for 12 months as depicted in the table below.

Clinic	Apr-2021	May-2021	Jun-2021	Jul-2021	Aug-2021	Sep-2021	Oct-2021	Nov-2021	Dec-2021	Jan-2022	Feb-2022	Mar-2022	Apr-2022	May-2022	Jun-2022	Jul-2022
1	x	x	x	x	x	x	x	x	x	x	x	x				
2		x	x	x	x	x	x	x	x	x	x	x	x			
3		x	x	x	x	x	x	x	x	x	x	x	x			
4			x	x	x	x	x	x	x	x	x	x	x	x		
5				x	x	x	x	x	x	x	x	x	x	x	x	
6				x	x	x	x	x	x	x	x	x	x	x	x	
7			x	x	x	x	x	x	x	x	x	x	x	x		
8					x	x	x	x	x	x	x	x	x	x	x	x
9					x	x	x	x	x	x	x	x	x	x	x	x

2.4 Other IRBNet file(s)

Guidance: If the project has multiple aims or phases that a) do not begin at the same time and have different data sources/sites consult with the IRB on how best to submit the overall project.

Are there other IRBNet files that have activities or subprojects that are part of this grant/contract/study?

☒ **YES** ☐ **NO**

If YES, please attach the form entitled "Summary Table of IRBNet Files for One Funding Source."

3. Study Population

3.1 Study Population Tables

Provide the expected number of subjects for this study. **Complete this/these table(s) or use your own**. If there are multiple subject populations or multiple sub-studies, create separate tables for each population/site.

KPWA Population		
Population	**Anticipated Number of subjects to be screened/invited**	**Anticipated Number of subjects to be enrolled**
Focus Group Participants	400	40- enrollment complete
Cluster Randomized Trial Participants	5000	~5000
	Total: ~5040	Total: 5040

3.2 Secondary Subjects

Guidance: Secondary subjects exist when the study team asks for private information about a third party from the primary study subject. For example, medical history of relatives, or information about patients' providers. If this study includes secondary subjects include them as a population in section 1.3 above and throughout the remainder of the application.

Do you plan to include data from secondary subjects? ☐ **YES** ☒ **NO**
If YES, complete **Supplement C**.

3.3 Inclusion and Exclusion Criteria

a. Inclusion criteria

Specify inclusion criteria (age, health condition, etc.) for each population. If this varies by study site please group sites separately.

Phase II (Focus Group) inclusion criteria:
We will include patients aged 65-80 years of age who are chronic users (defined as pharmacy dispensings that cover at least 70 days of the last 90 days) of 1 or more of the targeted CNS-active medications. We will limit our sample to patients with 1+ primary care visit to KPWA clinics in Seattle (Capitol Hill, Northgate, Downtown) within the last 12 months or who reside (determined crudely with zip code) within 5 miles of KPWA's Capitol Hill clinic (where the focus groups will be held). Phase II work was completed in 2019.

Phase III (Trial) inclusion criteria:
The study sample for each clinic will be identified at the time the intervention (or matched date for control clinic) is rolled out at the clinic.
For opioid and sedative mediations, we will include patients aged 60+ years of age who are chronic users (defined as pharmacy dispensings that cover at least 70 of the last 90 days) of 1 or more of the CNS-active medications of interest (opioids or sedatives) and who are either assigned to a primary care provider or had 1+ visits in the prior year to a primary care provider at one of the 18 KPWA clinics participating in this study.
For benzodiazepines, TCAs and antihistamines, we will include patients aged 65+ years of age who are chronic users (defined as pharmacy dispensings that cover at least 70 of the

last 90 days) of 1 or more of the CNS-active medications of interest and who are either assigned to a primary care provider or had 1+ visits in the prior year to a primary care provider at one of the 18 KPWA clinics participating in this study
Eligible subjects seen in multiple PC clinics will be assigned to the clinic where they had the most PC visits in the prior year. Subjects assigned to an intervention clinic will be considered the Intervention Group and subjects assigned to control clinics will be considered the Control Group. The sample will be static or unchanged throughout the study.

b. Exclusion criteria

Specify exclusion criteria (age, health condition, etc.) for each population. If this varies by study site please group sites separately.

Phase II (Focus Group) Exclusion Criteria:
Patients will be excluded for any one of the following: a) diagnosis of dementia/Alzheimer's disease or a pharmacy dispensing for a medication(s) used to treat dementia (i.e., a cholinesterase inhibitor or memantine); b) reside in a skilled nursing facility; c) cancer diagnosis in the prior 12 months; d) receiving hospice or palliative care; e) legally blind (unable to see print materials); f) unable to read English (unable to understand and comment on the print materials); g) unable to hear and/or speak English (unable to hear focus group questions and respond); h) unavailable at the date/time of the focus group, i) lacking transportation to get to and from the focus group and j) uncomfortable or unwilling to participate in a group discussion.

After inclusion and exclusion criteria are applied for the focus group sample, we will select a random-weighted sample (weighted on age, sex, and race/ethnicity) of 400 potential participants. Phase II work was completed in 2019

Phase III (Trial) Exclusion Criteria:
For the opt-out protocol (July 2020-October 2020)
Individuals will be excluded for any one of the following: a) diagnosis of dementia/Alzheimer's or a pharmacy dispensing for a medication(s) used to treat dementia (i.e., a cholinesterase inhibitor or memantine), b) reside in a skilled nursing facility; c) metastatic cancer diagnosis in the prior 12 months; e) receiving hospice or palliative care; f) legally blind (unable to read print materials); g) indication in the KPWA VDW demographics table that the patient requires a translator (cannot read materials printed in English); h) enrolled in SMART (IRBnet 1220346, PI Larson) or STRIPE (IRBnet 1295096 , PI Boudreau); i) enrolled in KPWA COMET initiative; a pharmacy based initiative to lower opioid dosing.

For the waiver of consent protocol (December 2020-):
Individuals will be excluded for any one of the following: a) diagnosis of dementia/Alzheimer's or a pharmacy dispensing for a medication(s) used to treat dementia (i.e., a cholinesterase inhibitor or memantine), b) reside in a skilled nursing facility; c) metastatic cancer diagnosis in the prior 12 months; e) receiving hospice or palliative care; f) legally blind (unable to read print materials); g) indication in the KPWA VDW demographics table that the patient requires a translator (cannot read materials printed in English); h) enrolled in SMART (IRBnet 1220346, PI Larson) or STRIPE (IRBnet 1295096 , PI

Boudreau); i) enrolled in KPWA COMET initiative; a pharmacy based initiative to lower opioid dosing; i. a code for opioid use disorder

3.4 Equitable Representation

a. gender and minority representation

Will participant population include equitable gender and minority representation?

☒ **YES** ☐ **NO**

If NO, explain.

b. Population oversampling, omission

Will any groups are being oversampled, omitted, or targeted?

☐ **YES** ☒ **NO**

If YES, explain.

3.5 Participant Languages

Is it possible that this study may include non-English speaking participants?

☐ **YES** ☒ **NO**

If YES, list possible language(s) and complete **Supplement F**.

3.6 Minors

Does this study include subjects under the age of 18?

☐ **YES** ☒ **NO**

If YES, list the ages of the children involved in this research and complete **Supplement E.**

3.7 Prisoners

Guidance: If this study includes prisoners you must contact the IRB staff for guidance before completing this application.

Does this study include prisoners?

☐ **YES** ☒ **NO**

3.8 Other Potentially Vulnerable Populations

Does this study include other subjects who might be considered vulnerable? For example, vulnerable populations include, but are not limited to

- Individuals with questionable capacity to consent/decisionally impaired
- Individuals who are seriously or terminally ill
- Native Americans and/or Alaska Natives

- Identifiable communities
- Veterans
- Employees of the institution conducting the research
- People of low socio-economic status

☐ **YES** ☒ **NO**

If YES, list populations and Complete **Supplement F.**

4. Procedures – Identification of Subjects

Guidance: If the study includes multiple populations (patients, providers, care givers, multiple intervention groups, etc.) you must respond to each question for each group. List each group in the answer or create tables for each population as relevant.

4.1 Subject Identification

How will the study team identify potential study subjects? Describe the procedures for identifying potential subjects. If you plan to re-contact participants from a previous or active study, describe these procedures and submit the consent form for that study. Note where in the consent you have permission to (re) contact participants for this new study. (Use active voice and specify who will do what, (e.g., "a KPWA research programmer will identify eligible subjects from the VDW data", etc.)

For Phase II (Focus Groups), a KPWHRI study programmer will identify potential study participants from the KPWA automated data systems (i.e., Virtual Data Warehouse). Phase II work was completed in 2019.

For and Phase III (Trial) a KPWHRI study programmer will identify potential study participants from the KPWA automated data systems (i.e., Virtual Data Warehouse). To exclude participants from STRIPE and SMART, the study programmers on those projects will send the STOP FALLS study programmer a file containing the CHSIDs or MRNs of enrolled study participants on a regular basis until the STRIPE and SMART studies have finished enrolling participants. To exclude COMET participants, the study programmer will receive an email from Melissa Sturgis (KPWA Clinical Pharmacy Operations Coordinator) with a list of MRNs of enrolled COMET participants.

4.2 Data for Identification

List the key information/variables collected from medical records and/or other KPWA electronic sources that will be used to identify potential study subjects. We are expecting to see a robust list or description of the variables. Use the table(s) below or attach a table or chart abstraction form of your own. Indicate the date range of interest. Use the second table (below) if data will be obtained from institutions other than KPWA.

This is applicable to the PHASE II Focus Groups which was completed in 2019:

Data from KPWA, or a KPWHRI Study, to identify potential study subjects		
Source (specify)	**List of electronic data that will be used to identify potential subjects**	**Date Range**

(i.e., from KPWA, or an existing or previous study, etc.)		
KPWA electronic data sources	Healthcare Utilization: Primary care visits (inclusion criteria) Palliative care, hospice care, and skilled nursing facility care (exclusion criteria)	start of health plan enrollment – 12/1/2020
KPWA electronic data sources	Pharmacy Dispensing Data: drug name, date of dispensing, quantity, days supply, and prescriber id for the medications classes of interest (opioids, benzodiazepines, antidepressants, antihistamines, Z-drugs for sleep, other sedative hypnotics) and cholinesterase inhibitors and other drugs used to treat dementia/Alzheimers (exclusion criteria)	11/1/2018 – 12/1/2020
KPWA electronic data sources	Diagnosis Codes: Alzheimers, dementia, cancer, legally blind, and ICD procedure codes for cancer treatment (exclusion criteria)	start of health plan enrollment 12/1/2020
KPWA electronic data sources	Demographics: age, race, sex, and ethnicity	start of health plan enrollment 2/1/2020
KPWA electronic data sources	Tumor Registry: dates of all cancer diagnoses (exclusion criteria)	start of health plan enrollment 2/1/2020
KPWA electronic data sources	Enrollment start and stop dates	start of health plan enrollment – 2/1/2020
KPWA electronic data sources	Referral for nursing homes and/or hospice (Exclusion Criteria)	start of health plan enrollment – 2/1/2020
KPWA electronic data sources	Hospice admissions database (Exclusion Criteria to confirm that these patients are not receiving hospice care)	start of health plan enrollment – 2/1/2020

Providers are not subjects in this research. We are not collecting any individual data on providers.

This is Applicable for PHASE III Intervention:

For the opt-out protocol: (July 2020-October 2020)

Data from KPWA, or a KPWHRI Study, to identify potential study subjects		
Source (specify) (i.e., from KPWA, or an existing or previous study, etc.)	**List of electronic data that will be used to identify potential subjects**	**Date Range**
KPWA electronic data sources	Healthcare Utilization: all outpatient visits, dates, provider id	9/30/2018 – 10/31/2020
KPWA electronic data sources	Pharmacy Dispensing Data: drug name, NDC, strength, quantity, days supply, prescriber id, and date dispensed for all medications of interest (opioids, benzodiazepines, tricyclic antidepressants, Z-drugs, other sedative hypnotics, muscle relaxers, antihistamines) and medications to treat Alzheimers/dementia (exclusion criteria)	9/30/2018 – 10/31/2020
KPWA electronic data sources	Diagnosis Codes: all fall and fracture related diagnoses and dates of diagnoses	9/30/2018 –10/31/2020
KPWA electronic data sources	Demographics: age, sex, race, and ethnicity	9/30/2018 – 10/31/2020
KPWA electronic data sources	Tumor Registry: dates of all cancer diagnosis (exclusion criteria)	9/30/2018 – 10/31/2020
KPWA electronic data sources	Procedures: all fall and fracture related procedure codes and dates of procedure	9/30/2019 – 10/31/2020
KPWA electronic data sources	Enrollment: enrollment start and stop dates	9/30/2019 – 10/31/2020
KPWA electronic data sources	Provider table: provider id, specialty, provider type	9/30/2019 – 10/31/2020
KPWA electronic data sources	Referral for nursing homes and/or hospice (Exclusion Criteria)	9/30/2019 – 10/31/2020

KPWA electronic data sources	Hospice admissions database (Exclusion Criteria to confirm that these patients are not receiving hospice care)	9/30/2019 – 10/31/2020
SMART study	CHSIDs or MRNs of enrolled participants	4/1/2020- 10/31/2020
STRIPE study	CHSIDs or MRNs of enrolled participants	4/1/2020- 10/31/2020
COMET intervention	MRNs of enrolled participants	4/1/2020- 10/31/2020

For the waiver of consent protocol (December 2020-):

Data from KPWA, or a KPWHRI Study, to identify potential study subjects		
Source (specify) (i.e., from KPWA, or an existing or previous study, etc.)	**List of electronic data that will be used to identify potential subjects**	**Date Range**
KPWA electronic data sources	Healthcare Utilization: all outpatient visits, dates, provider id	9/30/2018 – 6/30/2023
KPWA electronic data sources	Pharmacy Dispensing Data: drug name, NDC, strength, quantity, days supply, prescriber id, and date dispensed for all medications of interest (opioids, benzodiazepines, tricyclic antidepressants, Z-drugs, other sedative hypnotics, muscle relaxers, antihistamines) and medications to treat Alzheimers/dementia (exclusion criteria)	9/30/2018 – 6/30/2023
KPWA electronic data sources	Diagnosis Codes: all fall and fracture related diagnoses and dates of diagnoses, all opioid use diagnoses codes and dates (exclusion criteria)	9/30/2018 –6/30/2023
KPWA electronic data sources	Demographics: age, sex, race, and ethnicity	9/30/2018 – 6/30/2023
KPWA electronic data sources	Tumor Registry: dates of all cancer diagnosis (exclusion criteria)	9/30/2018 – 6/30/2023
KPWA electronic data sources	Procedures: all fall and fracture related procedure codes and dates of procedure	9/30/2019 – 6/30/2023

KPWA electronic data sources	Enrollment: enrollment start and stop dates	9/30/2019 – 6/30/2023
KPWA electronic data sources	Provider table: provider id, specialty, provider type	9/30/2019 – 6/30/2023
KPWA electronic data sources	Referral for nursing homes and/or hospice (Exclusion Criteria)	9/30/2019 – 6/30/2023
KPWA electronic data sources	Hospice admissions database (Exclusion Criteria to confirm that these patients are not receiving hospice care)	9/30/2019 – 6/30/2023
SMART study	CHSIDs or MRNs of enrolled participants	4/1/2020- 6/30/2023
STRIPE study	CHSIDs or MRNs of enrolled participants	4/1/2020- 6/30/2023
COMET intervention	MRNs of enrolled participants	4/1/2020- 36/30/2023

Providers are not subjects in this research. We are not collecting any individual data on providers.

4.3 Waiver Requests to Identify Potential Subjects

Are you requesting waivers to identify subjects for this study?

☒ **YES** ☐ **NO**

If YES, complete **Supplement A.**

5. Procedures – Screening and Recruitment

Guidance: If the study includes multiple populations (patients, providers, care givers, multiple intervention groups, etc.) you must respond to each question for each group. List each group in the answer or create tables for each population as relevant.

5.1 Screening Activities

Will you conduct screening or any other research procedures before obtaining informed consent for the main study activities?

☒ **YES** ☐ **NO**

IF YES, briefly describe any data collection/screening or other research procedures that you will use to determine eligibility in the study (e.g., phone screening, chart abstraction, blood tests, wearing activity devices, attending office visits, etc.) before obtaining full informed consent. Also complete the table below.

Brief Description: **Phase II (Focus Group):** Prior to obtaining Informed consent from focus group participants, our KPWHRI study programmer accessed KPWA automated data to assemble our sample of potentially eligible Phase II focus group participants (N=400). We

mailed focus group invitation letters to this group and eligibility was confirmed by Survey Phone Room during a brief phone screening. We expected approximately 10% of potential subjects will participate (N~40) in the 3 focus groups. Phase II work was completed in 2019.

Phase III (Trial):

In this application we describe the procedures for the Opt-Out Protocol (July 2020-October 2020) group and the Waiver of Consent/HIPAA Authorization Protocol (December 2020-) group.

The "Opt-Out Protocol (July 2020-October 2020)" refers to the participants who were recruited during the period of July 2020 until October 2020. During that time, the opt-out rate from the intervention arm was approximately 15% and the study team put recruitment on pause as they worked with the biostatistician to determine if this rate was a fatal flaw, which it turned out to be. At this time, the study team made the decision to change procedures by asking for a waiver of HIPAA authorization and consent for both intervention arm and regular care participants. No participants were enrolled until the waiver requests are granted.

The "Waiver of Consent/HIPAA Authorization Protocol (December 2020-) group" refers to the participants who will be enrolled after the modification for a waiver of HIPAA authorization and consent is granted.

Opt-Out Protocol (July 2020-October 2020)
We are requesting a waiver of documentation of consent for Phase III trial (intervention) activities. Prior to receiving the Study Information Sheet, our KPWHRI study programmer will access KPWA automated data (VDW) and use lists of participants enrolled in the STRIPE and SMART studies and enrolled in COMET, to assemble our sample of Phase III participants. There is no further screening for eligibility or primary data collection. Patients receiving care in clinics assigned to the Intervention Group will be mailed a Study Information Sheet with their first patient brochure. The Information Sheets provide an opt out number to call if patients prefer to not have their data included in the study or they do not want to receive patient brochures.

Waiver of Consent/HIPAA Authorization Protocol (December 2020-) We are requesting a waiver of consent for Phase III trial (intervention) activities consisting of both regular care and intervention arm participants. A KPWHRI study programmer will access KPWA automated data (VDW), and use lists of participants enrolled in the STRIPE and SMART studies and enrolled in COMET, to assemble our sample of Phase III participants. There is no further screening for eligibility or primary data collection. Patients receiving care in clinics assigned to the Intervention Group will be mailed a notification letter about the research study occurring in their clinic, patient brochure and self-help information sheets.

Source (specify)	List of primary data collection that will be used to identify and determine eligibility of potential subjects	Date Range(s)

(i.e., screening phone survey, activity monitor results, lab tests, etc.)		
Phone screening (for Phase II focus groups only)	See attached screening questions and phone script	n/a

5.2 Screening and Recruitment Process

a. Step-by-Step Description

Describe the overall recruitment process, including screening if applicable, for each study population. Include step-by-step detail using active voice to explain where, when and how the study team recruit and enroll participants. Include information about the use of letters, flyers, email message, phone calls, etc. (Upload all recruitment materials documents into IRBNet.)

Phase II (Focus Group):

A KPWHRI Study Programmer will access KPWA automated VDW data to identify potentially eligible participants and randomly select n=400 (weighted-random sample on age (5-year groups), sex (F, M), and race/ethnicity (Caucasian, Black/African American, Asian, Other, Hispanic)). The KPWHRI Programmer transfers the sample to the survey research program programmer. The survey research program prints focus group recruitment letters and mails them to potential participants (n=400). Between 5-10 days post mailing, the survey research program call room staff calls potential participants, explain the study, and reads through the Oral Consent for telephone screening. If the potential participant agrees to answer our focus group screening questions, the survey research program phone room staff will lead the potential participant through the screening questions, which ends in a determination of eligibility for focus group participation. If the participant is eligible and is willing to participate, the survey research program phone room staff will schedule the participant for one of our focus groups. The study project manager will send participants a reminder letter with the details of the focus group. Two days prior to the focus group, the participant will receive a reminder phone call from the study Project Manager and/or focus group facilitator. Informed consent will be obtained in-person prior to the start of the focus group. The goal is 3 focus groups with 8-12 participants per focus group. Phase II work was completed in 2019.

Phase III (Trial):

Opt-Out Protocol (July 2020-October 2020)

At clinic roll-out, the KPWHRI Study Programmer will access KPWA automated data (VDW tables) and receive data files from STRIPE, SMART and COMET to identify the eligible Intervention Group (see section 3.3 for eligibility criteria). The KPWHRI Programmer loads

the sample into the study database. Every month, the KPWHRI programmer updates the medication lists for the Intervention Group and runs an algorithm to select which patients in the Intervention Group are mailed to that month (see Figure in section 7.1.e on the selection of who is mailed to each month). The KPWA survey research program will print invitation letters, study information sheet, and relevant patient brochures and mail these materials to patients.

At the same time, the Research Specialist will print and send, via secure fax, EBPOs on the same medication class to the patient's PC provider. In order to ensure that KP providers are not confused by this communication, we will inform providers at the Intervention Clinics about this study and materials that they can expect to receive through morning huddles and/or brown bag lunches as deemed appropriate by the clinic managers.

One month after the initial brochure is sent, the KPWA survey research program will send out the postcard mailer.

The same process of identifying the sample will occur for usual care clinics at the time the matched intervention clinic goes live, but the Control Group and their respective providers will not receive any of the educational materials.

Waiver of Consent/HIPAA Authorization Protocol (December 2020-)

At clinic roll-out, the KPWHRI Study Programmer will access KPWA automated data (VDW tables) and receive data files from STRIPE, SMART and COMET to identify the eligible Intervention Group (see section 3.3 for eligibility criteria). The KPWHRI Programmer loads the sample into the study database. Every month, the KPWHRI programmer updates the medication lists for the Intervention Group and runs an algorithm to select which patients in the Intervention Group are mailed to that month (see Figure in section 7.1.e on the selection of who is mailed to each month). The KPWA survey research program will print notification letters and relevant patient brochures and mail these materials to patients. At the same time, the Research Specialist will send the Epic Staff Message, a message letting the provider know their patient was included in the study and a link to the EBPO of the same medication class. In order to ensure that KP providers are not confused by this communication, we will inform providers at the Intervention Clinics about this study and materials that they can expect to receive through morning huddles and/or brown bag lunches as deemed appropriate by the clinic managers.

One month after the initial brochure is sent, the KPWA survey research program will send out the postcard mailer.

The same process of identifying the sample will occur for usual care clinics at the time the matched intervention clinic goes live, but the Control Group and their respective providers will not receive any of the educational materials.

Providers:

Providers are not subjects in this research. We are not screening or recruiting providers for this study.

Prior to clinic rollout, the research team will explain the study to providers at team huddles and meetings (whichever individual clinics prefer) and the information to be shared at these huddles/meetings has been uploaded in IRBNet.

Providers are alerted when one of their patients is included in the study. The study RS will contact them by Epic Staff Messaging. We chose this method after receiving feedback from our first clinic, Capitol Hill, that the previous method of faxing and dealing with hard copies not only does not fit in with their usual workflow, but also goes against the current COVID policies for reducing physical paperwork. We have also vetted this process with SERT and the process and accompanying materials have been approved by SERT on 12/1/2020. Although, there is no follow-up from the research team once the staff message has been sent, SERT told us that if providers reply to the staff message with questions, then the study team needs to be able to reply to their questions in Epic Staff Messaging; we cannot force them to call us on the telephone.

b. Recruiter(s)

List position/title of the people who will be recruiting, screening, and enrolling participants.

Kanichi Nakata Research Specialist III
Monica Fujii, Project Manager II
Survey Research Program Staff

5.3 Screening Data

Describe the plan for use/destruction of data collected during screening/recruitment in the event of a screen failure or when a potential subject is contacted but refuses participation or does not respond (e.g. destroyed immediately, destroyed at end of study, retained so that subjects are not contacted repeatedly about participation after they have declined, etc.).

Phase II (Focus Group): Potential participants will be called a max of 6 times after the recruitment letter goes out. A tracking database will be used to record the date of the invite letter, date and number of recruitment calls, whether contact was made, screening status, eligibility, active versus passive refusals, participation, and incentives provided. Potential participants who choose to opt-out will be coded as a refusal and no further data will be collected or calls made. Phase II work was completed in 2019.

Phase III (Trial):

Opt-Out Protocol (July 2020-October 2020)

There is no screening for the trial. Subjects in the Intervention Group that opt out will be removed from the sample, no further data will be collected, and they will not receive the study educational brochures.

Waiver of Consent/HIPAA Authorization Protocol (December 2020-)

There is no screening for the trial.

6. Informed Consent

6.1 Consent and HIPAA Authorization Overview

Which of the following typical consent processes at KPWA will be used for this study? Check those that apply to both eligibility screening and study activities.

	Activity	What to Submit
☒	**If you are requesting a waiver of written documentation of consent &/or a waiver or alteration of HIPAA Authorization.** This will often be the case when a study involves a non-signed consent process (like oral consent, or web screening) and no signed HIPAA Authorization form, plus an information statement (e.g., for eligibility screening)	- **Supplement A** -Information Sheet -Oral consent script (or web screening questions)
☐	**Written informed consent & separate HIPAA Authorization Form** A written signed consent form and separate written signed HIPAA authorization form (Required for more than minimal risk studies)	-Consent form -HIPAA authorization
☒	**Written informed consent & HIPAA Authorization as one document** A written signed consent form that includes HIPAA authorization language in the consent form	-Consent form ***Applicable for Patient Focus Groups Only***
☒	**Waiver of informed consent & waiver of HIPAA Authorization (very rare)** No subject consent or HIPAA Authorization from subjects	-**Supplement A**
☐	**Use of Legally Effective Electronic signature** Only for studies that use legally effective docu-sign software. Consult with IRB if you have questions.	-Certification from issuing company
☐	**Other** (explain):	Contact HRSC staff

6.2 Informed Consent Process

a. Consent Process

Describe the informed consent process for this study in detail (including who will administer the consent, when, and where.) Address each study population separately.

Phase II (Focus Groups): This activity has 2 phases of consent. The first will be to collect Oral Consent for Eligibility Screening. These telephone eligibility questions confirm that the potential participant is available during the hours of our focus group, is comfortable speaking in a group setting, and is able to read materials written in English and hear our focus group questions and participate in discussion. The Study Research Specialist and/or Project Manager will call potential participants who have been sent a recruitment letter to see if he/she is interested in learning more about our study and if he/she is willing to answer 5 questions (see Focus Group Screening

Questionnaire and Script) to find out if he/she is eligible to come to our focus group. Participants who are willing to be screened will be asked our 5 eligibility questions and if eligible, will be scheduled for the focus group appropriate for his/her medication type. The second consent is Informed Consent + HIPAA. Informed consent will be administered by the study RS and/or Project Manager prior to the start of the focus group. This will be done in-person in a private location close to the focus group location. Phase II work was completed in 2019.

Phase III – Intervention Clinic Patients:

Opt-Out Protocol (July 2020-October 2020)

Participants receiving care at our Intervention Clinics will be sent a study information sheet with our study patient brochures. The Information Sheet will explain study procedures and how to opt-out of this study.

Waiver of Consent/HIPAA Authorization Protocol (December 2020-)

All participants (both intervention arm and usual care) are enrolled under waiver of consent and HIPAA authorization.

b. Ongoing Consent

Describe your process to ensure ongoing consent.

Ongoing consent is not applicable for this study.

c. Undue Influence and Coercion

Describe what steps will be taken to minimize the possibility of coercion or undue influence?

Opt-Out Protocol (July 2020-October 2020)

All materials are developed to encourage participation while making it clear that patients do not have to participate and that their choice to not participate will not impact their care or insurance at KP. We engaged the KPWA EAGLEs team to review all study materials and provide suggestions for making the materials more transparent and readable. We provide a modest monetary incentive for participating in the focus groups and provide no monetary incentive for participating in the trial.

Waiver of Consent/HIPAA Authorization Protocol (December 2020-)

All materials are developed to encourage participation while making it clear that patients do not have to discuss the study materials with their providers. We engaged the KPWA EAGLES team to review all study materials and provide suggestions for making the materials more transparent and readable. We provide a modest monetary incentive for participating in the focus groups and provide no monetary incentive for participating in the trial.

d. Consent Form in EHR

Guidance: If study records will be placed in EHR, this information must be included in the consent form.

Will the study place a copy of the study consent form in the subject's medical record?

☐ **YES** ☒ **NO**

6.3 Assent of Children and Parent Permission

Does this study involve assenting/consenting youth and/or parental consent?

☐ **YES** ☒ **NO**

If YES, complete **Supplement E.**

6.4 Non-English-Speaking Subjects

Does this study involve consenting subjects who do not speak English?

☐ **YES** ☒ **NO**

If YES, complete **Supplement F.**

6.5 Decisionally Impaired Subjects

Does this study involve consenting/assenting subject who may be unable to consent due to decisional impairment?

☐ **YES** ☒ **NO**

If YES, complete **Supplement F.**

7. Procedures – Primary Study Activities

7.1 Randomization, Interventions, and Clinical Procedures

a. Randomization

Will subjects be randomized to receive procedures, activities, interventions, etc.?

☒ **YES** ☐ **NO –**

If YES, please describe the randomization.

This is applicable to PHASE II (Intervention) ONLY:

The unit of randomization is at the clinic level (stratified randomization by size and location of clinic), so individuals are not the unit of randomization. However, subjects are randomized to receive the intervention according to their assigned clinic. Of the 18 clinics identified for the trial, 9 clinics will be randomized to the intervention and 9 to usual care. The clinic pairs for the stratified randomization are as follows (approved by delivery system leaders):

Intervention Clinics	Control Clinics
Capitol Hill	Northgate
Veradale	Lidgerwood

Tacoma Medical	Steele St.
Burien	Renton
Bellevue	Redmond
Silverdale	Port Orchard
Lynnwood	Everett
Poulsbo	Federal way
Kent	Northshore

b. Clinical Trial

Is this study a clinical trial as defined by National Institutes of Health (NIH)?

NIH defines a clinical trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

☒ **YES** ☐ **NO**

c. Study Interventions and/or Other Clinical Procedures

Does your study include any behavioral, educational or medical interventions, or any other clinical procedures (e.g., blood draw, blood pressure, training workshops)?

☒ **YES** ☐ **NO**

If YES, continue. If NO skip to **7.2**

d. Summary of Intervention/Clinical Procedures

Please check boxes below and/or summarize intervention activities and/or other clinical procedures. Check all that apply.

☒ Educational/behavioral intervention (e.g., counseling program, clinical decision aid)

☐ Medical intervention (includes prescribing or administering drugs)

☐ Drug or medical device. IF CHECKED, complete **Supplement B**. Also contact IRB Office staff for required additional forms and information and check all boxes below that apply.

☐ FDA-approved drug or device will be used for a purpose consistent with the existing labeling

☐ IND/IDE not required (attach letter from FDA)

☐ Study involves other FDA regulations (e.g., CLIA, mobile devices, etc.): IF CHECKED, please list.

☐ Other (explain):

☐ Study procedures involving radiation (e.g., mammograms, bone density measurements, etc.). If checked, provide assurance that KP Washington's Radiation Safety Committee approval will be obtained.

☐ Other clinical procedures (please describe briefly – e.g., blood pressure, BMI measurements, wearing fitbits, monitoring devices, fasting before glucose test, etc.):

☐ Biological specimen collection (blood, urine, saliva, fecal, etc.):

☐ Other activities not listed above (please describe briefly):

e. Detailed Description of Intervention

Describe the intervention activities in excruciating detail. If there is a separate manual, submit that also.

There is no intervention in **Phase II (Focus Group)**

Phase III of the STOP-FALLS Study involves an educational intervention designed to guide safer use of medications by older adults. With the input and assistance from our KPWA delivery system collaborators, the study team created educational brochures, self-help sheets for each CNS-active medication class that is a target of the intervention and curated a fall prevention self-help sheet. The target medication classes are: opioids, sedative hypnotics (also known as benzodiazepines and Z-drugs), skeletal muscle relaxants, tricyclic antidepressants (TCAs), and antihistamines. For each medication class, we have created a Patient Brochure that will be mailed to patients using the medication on a chronic (>3 months) basis and a related decision support tool, referred to as an Evidence-Based Pharmaceutical Opinion (EBPO), that will be sent via Epic Staff Messaging to the patient's provider. Additionally, we will mail all participants an antihistamine brochure because there is high utilization of over-the-counter antihistamine use, but prescriptions in automated data sources is low. An associated EBPO will not be sent synchronous with this antihistamine brochure mailing except when the patient is identified as taking prescription antihistamines on a chronic basis. The Patient Brochures contain information about the potential risks of the target medication and alternative. The brochures also contain a sample tapering schedule which the patient may decide to follow as well as repeated encouragement to discuss reducing the dose and/or stopping the medication with his/her healthcare providers. The self-help sheets contain safer methods of symptom management and fall prevention. The Provider EBPOs describe the risks associated with the medication and alternative evidence-based treatments that could be tried to help the patient reduce their use of the target medication. All patient and provider materials have been carefully cross-referenced with KP Guidelines and reviewed by leaders in the KPWA delivery system so that all information and recommendations are concordant with KPWA Guidelines

Prior to the start of Intervention activities at each Intervention Clinic, study team members will attend huddles or team meetings (to be chosen by clinic leadership) to explain the

research study and introduce providers and staff to our materials and method of distribution to patients and providers. .
Additionally, the study team in collaboration with the clinic will identify, a “Clinic Champion” who will function as a liaison between the STOP-FALLS study team, and the clinic. The clinic champion will forward the Deprescribing Pearls (via email) to the providers at the clinic. The Deprescribing Pearls will be sent every 2 weeks for the first 6 months of intervention implementation in each Intervention Clinic. If they choose, the clinic champion may highlight information from the Deprescribing Pearls in morning huddles/team meetings. Additionally, the clinic champion can communicate with the study team about issues that might come up at their clinic regarding the study.

The STOP-FALLS patient brochures, self-care sheets, provider EBPOs and Deprescribing Pearls are not currently a part of the standard of care at KPWA, however, our team of clinicians (geriatrician, pharmacists, and clinical psychologist) adapted/developed them in consultation with KPWA guidelines and KPWA delivery system (including primary care and pharmacy) leaders and curated the fall prevention self help sheet from the funder/public domain. Dr. Ben Balderson, a clinical psychologist at KPWPMG, and KPWHRI EAGLES Team also contributed heavily to the development of materials. All recommendations were cross-referenced with KPWA Guidelines so that all information contained within the brochures reflects and does not conflict with KPWA Guidelines and available treatment options.

The patient brochures, but not the fall prevention sheet, were vetted during the facilitated and recorded Focus Groups (Aim 1 of Phase II) where older adult patients who are taking these medications were asked to share their thoughts on the readability, content, and format of the materials as well as their overall impression and suggestions for improvement. The research team summarized recordings and notes from the focus groups and use this information to modify the patient materials accordingly. For examples of these materials, see patient brochures and provider EBPOs that are included with this application.

Eighteen clinics will be randomized to either intervention (n=9 clinics) or usual care (n=9 clinics). Patients meeting the eligibility criteria (see section 3.3) and either assigned to a primary care provider in one of the 9 intervention clinics or receiving primary care in one of the intervention clinics (defined as 1+ visits to the clinic in the year prior to intervention roll-out) are the study intervention group. The study control group will be defined similarly with respect to eligibility criteria and assignment/visits to the usual care clinics. The sample is static (identified once at of the time of study roll-out at the particular intervention clinic and matched usual care clinic) throughout the study.

The intervention will be rolled out at a rate of 1-3 clinics each month (tentative start date of July 2020) and the intervention will persist in each clinic for up to 12 months (see Table in Section 2.3.c for roll-out schedule).

In order to ensure that KP providers are not confused by this communication, we will inform providers at the 9 Intervention Clinics about this study and materials that they can expect to receive (via Epic Staff Messaging) by attending morning huddles and/or brown bag lunches as deemed appropriate by the clinic managers. During the intervention period, intervention

group participants (and their providers) will receive brochure(s) specific to the medication class or classes they are currently taking. A maximum of approximately 35-95 intervention participants per clinic will receive mailings each month for opioids, z-drugs, skeletal muscle relaxers, TCA, and prescription antihistamine users. We refer to this herein as our "max cap" per clinic each month (this number represents ~15% of monthly clinic visits by the intervention sample and has been agreed upon with by the KPWA delivery system). The maximum number has a range because it will vary by clinic according to total eligible patient participants and the expected number of patient visits per month. For the mailing of antihistamine brochures to all participants, except those who already received one because they were identified as prescription antihistamine users, the max cap will not apply. We will mail the antihistamine brochure once to all eligible patients who have not already received an antihistamine brochure due to a chronic (>3 months) antihistamine prescription.

From the intervention group at each clinic, we will sample the max cap number each month over the course of the intervention period opioid, z-drug, skeletal muscle relaxer, TCA, and prescription antihistamine users. We will prioritize which patient in the intervention group at each clinic gets mailed a brochure (and the class-concordant EBPO to the patient's provider) as follows: Patients with a PC visit scheduled in the next 8-38 days will be prioritized in filling the max cap each month. This provides time for the patient and provider to receive and read the materials prior to the visit and optimizes the chances of a discussion about the medication being held as part of the visit (i.e., prepared patient and prepared provider as per the Chronic Care Model). If the max cap is not met for an intervention clinic in a given month, a random sample of the study intervention group will then be selected to fill the max cap for mailings that month.

Patients will receive only one brochure related to a given medication class during the intervention period. Patients taking >1 medication classes of interest will receive no more than one unique patient brochure every 3 months for a maximum of 4 brochures over the 12-month intervention period. If patients are using more than one of the five medication classes, the brochures mailed will be prioritized as 1) opioids; 2) benzodiazepines/Z-drugs; 3) muscle relaxants; 4) TCAs and; 5) antihistamines. Additionally, we will mail all participants an antihistamine brochure because there is high utilization of over-the-counter antihistamine use, but prescriptions in automated data sources is low.

One month after sending the brochure, patients will receive a postcard mailer with 3 self-reported questions regarding the type of brochure they received, it's perceived helpfulness and whether the participant will initiate a conversation with their doctor.

Sending EBPOs to providers are triggered by the mailing of the patient brochure and will follow a similar logic. For the mailing of antihistamine brochures to patients without a prescription for antihistamines, we will have the clinic champion disseminate one final clinical pearl with a link to the EPBO for antihistamines to all providers.

The intent of these materials is to start a conversation between the patient and provider that will improve health outcomes via dose reduction and/or discontinuation of the medication. The process by which deprescribing occurs will be determined by the provider and patient and with the involvement of a clinical pharmacist at the discretion of the patient's PCP.

The process/algorithm for selecting which patients in the Intervention Group receive mailings each month is detailed below.

Opt-Out Protocol (July 2020-October 2020)

1. Every month after clinic launch through 12-months post, update the current chronic high-risk medication use among the Intervention Group.
2. Create a pool of eligible patients to mail to from each clinic's Intervention Group. Pool includes:
    a. Current chronic users of 5 high-risk medication classes of interest with no prior mailing for that medication class. Multiple records per person.
        i. Sort by order of priority of target medication classes (opioid, benzo/z-drug, muscle relaxant, tca, antihistamine) and keep only one record per patient if multiple. For example, a current chronic user of opioids and benzos with no prior mailings of either would go into the mailing selection pool as an opioid user.
    b. No mailings in the prior 3 months.
    c. Exclude anyone who has been withdrawn from the study on file as deceased, or previously had a "bad address".

3. Sample eligible patients for mailings (set max cap at 15% of sample for that clinic).
    a. Prioritize those with a PC appointment to a provider in that clinic in the next 8-38 days.
        i. FaxEBPO to provider the visit is scheduled with
    b. Prioritize those with no prior mailings to fill up the rest of the max cap for mailing.
        i. Mail to the most frequent prescriber of the medication (prior 12-months).

Waiver of Consent/HIPAA Authorization Protocol (December 2020-)

1. Every month after clinic launch through 12-months post, update the current chronic high-risk medication use among the Intervention Group.
2. Create a pool of eligible patients to mail to from each clinic's Intervention Group. Pool includes:
    a. Current chronic users of 5 high-risk medication classes of interest with no prior mailing for that medication class. Multiple records per person.
        i. Sort by order of priority of target medication classes (opioid, benzo/z-drug, muscle relaxant, tca, antihistamine) and keep only one record per patient if multiple. For example, a current chronic user of opioids and benzos with no prior mailings of either would go into the mailing selection pool as an opioid user.
    b. No mailings in the prior 3 months.
    c. Exclude anyone who is on file as deceased, or previously had a "bad address".

3. Sample eligible patients for mailings (set max cap at 15% of sample for that clinic).
    a. Prioritize those with a PC appointment to a provider in that clinic in the next 8-38 days.

i. Send staff message to with link to EPBO to provider the visit is scheduled with

b. Prioritize those with no prior mailings to fill up the rest of the max cap for mailing.
   i. Send staff with message with link to EPBO to the most frequent prescriber of the medication (prior 12-months).

4. After all participants have received their mailing, mail antihistamine brochure to everyone
   a. No mailings in the prior 3 months.
   b. Exclude anyone who is on file as deceased, or previously had a "bad address".
   c. Exclude anyone who received an antihistamine mailing already due to chronic use of prescription antihistamines

f. Alternative Procedures

Guidance: If there are alternative treatments or procedures that might be advantageous to the participant it should be included in the consent form.

Are there alternative procedures or treatments that might be advantageous to the participant?

☐ **YES** ☒ **NO**

If YES, please describe briefly.

g. Denial of Procedures or Treatment

Guidance: If participants are denied access to certain procedures or treatments during the course of the study, this information must be included in the consent form.

Are there any procedures or treatments that the participant will be denied access to?

☐ **YES** ☒ **NO**

If YES, please describe briefly.

h. Relationship to Clinical Care

If this study is a clinical trial, pragmatic trial, or a study that in any way interfaces with clinical care, please describe exactly which procedures will be conducted for the research as opposed to procedures the subjects would undergo (in the exact manner described in the protocol, if there is a protocol) even if they were not participating in the study.

This is applicable to PHASE III (Intervention) ONLY:

The intervention does not directly interface with clinical care. We will send, via staff message with a url to the EBPOs to providers whose patients receive educational brochures for the target medication classes. Our goal is to educate patients and providers on the risks of these medications for older people, to provide guidance about safer alternatives, and to share information about safe deprescribing. The conversations and actions taken by providers and patients as a result of the intervention materials will be determined by the provider and patient. Our materials may result in increases in PC visits at these clinics and potentially referrals to pharmacy for assistance with deprescribing. The delivery system is aware and onboard with this potential uptick in services because it is a KPWA goal to reduce use of these medications by elderly enrollees. We set our max cap of mailings each month to a number that is consistent with delivery system capacity (per conversations and approval of delivery system leaders).

i. Study Records in EHR

Guidance: If study records will be placed in EHR, this information must be included in the consent form.

Will you place a copy of study information (e.g., study participation, study-initiated test results, messages to physicians, genetic test results, incidental findings) in the subject's medical record?

☐ **YES** ☒ **NO**

If YES, describe here what information will be put in the subject's medical record.

j. Return of Results/Lab Tests to Subjects or Providers

Guidance: Sharing results with subjects and/or providers must be described in the consent form.

Will study results, or individual subject results, such as results of standard or research lab tests (and genetic tests) be shared with subjects or their providers?

☐ **YES** ☒ **NO**

If YES, please describe briefly.

k. Patient Initiated Withdrawal

Describe procedures that will be followed when subjects withdraw from the research, including withdrawal from intervention but continued data collection.

Phase II (Focus Group): Because participation in Phase II involves attending a 1-time focus group, the only option for withdrawing from the study is to leave in the middle of the focus group. Participants are allowed to do this if they choose. We will still use any data we have collected in the focus group up to the time they choose to leave.

Phase III (Trial):

Opt-Out Protocol (July 2020-October 2020)

If a participant in Phase III withdraws form the study, we will remove his/her study ID from future data pulls but will keep data previously obtained. This means that although they received the initial brochure, we will not mail future patient brochures (or accompanying EBPOs to their providers) to patients who opt out/withdraw from the study.

Waiver of Consent/HIPAA Authorization Protocol (December 2020-)

Participants will not be able to withdraw from the study. We have included clarifying language in the notification of study letter that they may receive multiple informational brochures and postcards and that they do not have to act on the materials. We have requested a waiver of consent and HIPAA authorization for the collection of the EMR from which participants cannot opt out of.

l. Investigator Initiated Withdrawal

Describe any anticipated circumstances under which subjects could be withdrawn from the research without their consent.

Not applicable for this study.

m. Orderly Termination

Describe any procedures for orderly termination of the study, if applicable.

Not applicable

7.2 Other Research Procedures

Guidance: Activities checked in this section should be included in the consent form.

Check all that apply:

a. Surveys, questionnaires, interviews, focus group

☒ Check if this project includes, surveys, interviews, focus groups.

How will surveys/questionnaires/interviews be done? (CHECK ALL THAT APPLY)

☒ By mail	☐ By mail with telephone follow-up	☐ By telephone
☐ By email	☐ By internet	☒ In-person
☐ Other (Please describe):		

b. Videotaping, audio recording, photography, or court reporter

☒ Videotaping, audio taping, using a court reporter, or photographing study participants:

IF CHECKED, explain what type of recordings you will make, how long you will keep them, how they will be stored, and if anyone other than the members of the research team will be able to see or hear them.

We will audio-record the in-person patient focus groups. These audio-recordings will be stored on the KPWHRI G-drive folder for media storage that is dedicated only to STOP-FALLS Study Team members with a need to access these files for research purposes only.

c. Technology/Devices

☐ Using technological software/devices (e.g., websites, software applications, smart phones, laptop computers, tablets, Fitbits, iPads, etc.)

IF CHECKED, complete **Supplement B.**

d. Specimens

☐ Specimen collection, storage or use

IF CHECKED, complete **Supplement D.**

CHECK ALL THAT APPLY

☐ Existing (i.e. previously collected) specimens, such as stored blood, pathology slides, etc.
☐ Blood draw or collection of other biological specimens (saliva, colon tissue, pap smears, etc.)
☐ Establishing a specimen repository. If CHECKED, consult with the IRB Staff.

e. Genetic Testing

☐ Genetic testing or collection of genetic information including DNA or any sequence of base pairs (i.e., SNPs, RNA, chips, arrays, microsatellites, STRs, etc.)

IF CHECKED, describe this below and complete **Supplement D.**

f. Family Medical History/Pedigree

Guidance: If the study includes family medical history/pedigree be sure to include family member in responses to **3.1** and **3.2** of this form.

☐ Family medical history information obtained from study participants
IF CHECKED, complete **Supplement C.**

g. Observation

☐ Data collection via observation of subjects. Briefly describe:

h. Other

☐ Other data collection from or about subjects, not already described above. Briefly describe:

7.3 Data Collection from EHR and/or Other Records

a. Data Collection for EHR and/or Other Records

Does the study include the collection of information from medical records and/or any other records for ongoing study activities and/or outcomes?

☒ **YES** ☐ **NO**

If YES, continue. If NO, skip to **7.4**

b. Direct Identifiers & CHSID

Check all of the direct identifiers that will be collected or included in the analytic data files, the study linking file, or other study records at KPWA.

☒ Names	☒ Medical record numbers	☐ IP address numbers
☒ Dates	☒ Health plan numbers	☐ Biometric identifiers (e.g., finger prints, voice prints, retina scans)
☒ Postal address	☐ Account numbers	☐ Facial Photos/Images
☐ Geocode	☐ License/Certificate numbers	☒ Any other unique identifier(s) specify: Auditory recordings of focus groups
☒ Phone numbers	☐ Vehicle ID numbers	☐ None
☐ Fax numbers	☐ Device identifiers/Serial numbers	
☐ Email address	☐ Web URLs	
☐ Social Security Numbers		

Will this study use CHSID as a linking file?

☒ **YES** ☐ **NO**

If NO, explain.

c. Data Sources

Check boxes below for each data source that will be used for this study.

☒ KPWA medical records and administrative/warehouse data

☒ KPWA other data collection activities, (e.g., chart abstraction or validation, retrieving scans, etc.)

- ☒ Chart abstraction – chart abstraction form is attached
- ☐ Chart abstraction – chart abstraction form will be submitted as a future modification
- ☒ Chart validation only – no data collection
- ☐ Films (e.g., x-ray, CT scans, etc.)
- ☐ **Other (describe):**

Adverse Drug Withdrawal Chart Validation (Safety Monitoring)

Adverse drug withdrawal events (ADWE) are possible side effects of our intervention if participants decide to taper their medications. For the purpose of safety monitoring, we will conduct medical record review to determine if any serious ADWE's occurred in our study population for both the intervention and usual care group in participants with prescriptions ford opioids and/or benzodiazepines. We define serious as ADWE that require an emergency department visit or hospitalization.

☐ Data from another institution's patient medical records **(specify institution[s]):**

- ☐ Individual medical charts
- ☐ Electronic warehouse/administrative data
- ☐ **Other (explain):**

☒ Data from a previous study

IF CHECKED, specify study title and principal investigator's name and IRBNet #; explain consent provisions; attach the previous consent form.

Data from the SMART and STRIPE studies will only be used to ensure that participants from those studies are excluded from being selected as participants in this study. Data will not be used for any other uses or analyses. Information on SMART and STRIPE below.

Systematic Multi-Domain Alzheimer's Risk (SMART). PI: Larson. IRBnet# 1220346
The consent process for SMART is:

1) SRP staff will administer oral informed consent on the phone for the following: to ask eligibility screening questions, to schedule an in-person baseline visit, and to mail an ActiGraph to be worn one week prior to the baseline visit.

2) At the start of the baseline visit, the research specialist will obtain written informed consent for measurement visits, HE contacts if applicable, and post-study activities.
3) If the participant is randomized to the SMARRT intervention arm, the health coach will mail a copy of the intervention addendum ahead of the first coaching contact. The coach will obtain written informed consent for intervention activities at the first coaching contact.
4) For both SMARRT and HE, if a participant shows possible signs of dementia, we will ask to conduct additional testing, as described in the main consent form.
5) For both SMARRT and HE, if a participant develops dementia and progresses to a point of needing a legally authorized representative (LAR) to assist in their continued participant, the LAR will be asked to sign the LAR addendum for the participant to continue. Study staff will seek assent from the participant as well if s/he is able to provide assent. The LAR will also be asked to sign HIPAA authorization for continued medical record use. The LAR will be given a copy of the consent form and HIPAA authorization that their loved one had signed.

The consent form is included in this package- Consent form at measurement visit-MPE V2 and Consent form addendum intervention MPE v2 2019-08-08

Pain Self Management Training for Opioid Taper (STRIPE). PI: Boudreau. IRBnet# 1295096
The participant receives a study information sheet prior to recruitment calls. At the time of recruitment call the study research specialist reads a script with all the consent element and then obtains oral consent to participate in the study. The second screening script which includes the oral consent language and the information sheet is included in this package- STRIPE Round 2 Screening Script and STRIPE Info Sheet_20190207

☐ Data from non-medical sources (e.g., motor vehicle records, genetic data from dbGAP, school records, etc.):
IF CHECKED, describe the sources.

☒ Other (describe): COMET
The Clinical Pharmacist Opioid Management Team or COMET, is a Kaiser Permanente Washington Delivery System Pharmacy based initiative to lower opioid dose.

d. Key Information/Variables
Guidance: If there are multiple subject populations please provide information and tables for each group.

Use the table(s) below to list the key information/variables collected from medical records and their source. If the tables below cannot adequately capture your data please attach a table or chart abstraction form of your own. Indicate the date range of interest. Use the second table (below) if data will be obtained from institutions other than KP Washington.

Opt-Out Protocol (July 2020-October 2020)

Data from KP Washington or KPWHRI Study		
Source (specify) (i.e., from KPWA, or an existing or previous study, etc.)	**Key Information/Description of Variables**	**Date Range**
KPWA VDW	Diagnosis and procedure codes	6/1/2019 – 6/30/2022
KPWA VDW	All healthcare utilization such as primary care visits, specialty visits, emergency department visits, inpatient stays, nursing homes, etc.	6/1/2019 – 6/30/2022
KPWA VDW	Pharmacy dispensing data data on all medications (drug name, date of dispensing, strength, quantity, days supply, provider id, NDC)	6/1/2019 – 6/30/2022
KPWA VDW	Demographics (e.g., age, sex, race)	6/1/2019 – 6/30/2022
KPWA Clarity	Patient reported outcome scores and dates questionnaire was administered – pain (PEG), anxiety (GAD), depression (PHQ-9), insomnia (ISI)	6/1/2019 – 6/30/2022
KPWA clinical notes in the EMR (extracted with natural language processing)	Mention of symptoms (yes, no) or scores for symptom questionnaires on pain, anxiety, depression, and insomnia. Date of mention or administration of questionnaire.	6/1/2019 – 6/30/2022
KPWA EMR	Date and provider of scheduled PC visits	6/1/2019 – 6/30/2022
KPWA EMR	Referrals to pharmacy (y, n) and date	6/1/2019 – 6/30/2022
KPWA VDW	Provider ID, Specialty, Provider Type, primary practice clinic. Data collected so that we can determine who the patients' PCP is for faxing the EBPO to the correct provider).	Intervention Launch to Intervention End

Waiver of Consent/HIPAA Authorization Protocol (December 2020-)

Data from KP Washington or KPWHRI Study		
Source (specify) (i.e., from KPWA, or an existing or previous study, etc.)	**Key Information/Description of Variables**	**Date Range**
KPWA VDW	Diagnosis codes: For outcomes including: • Injury diagnostic codes • Fall-related diagnostic codes • Motor vehicle crash (MVC)-related diagnostic codes • Unintentional overdose-related diagnostic codes • Adverse drug withdrawal event (ADWE) diagnostic codes For chronic conditions associated with falls, e.g.: arthritis, back pain, knee pain, alcohol use disorder, chronic lung disease, congestive heart failure, diabetes, heart disease, hip fracture, hypertension, obesity, peripheral neuropathy, osteoporosis, Parkinson's disease, stroke, urinary incontinence, impaired vision, impaired hearing, memory problems, non-melanoma cancers, frailty For other diagnoses related to medication prescription for the following conditions: anxiety, depression, insomnia, chronic pain	6/1/2019 – 9/30/2024

KPWA VDW	All healthcare utilization for the outcomes (falls, MVC, overdose, ADWEs) such as primary care visits, specialty visits, emergency department visits, inpatient stays, nursing homes..	6/1/2019 – 9/30/2024
KPWA VDW	Pharmacy dispensing data (drug name, date of dispensing, strength, quantity, days supply, provider id, NDC) for the following intervention target medication classes: benzodiazepines, z-drugs, opioids, muscle relaxants, antihistamines, tricyclic antidepressants. In addition, the following medication classes are needed to examine whether target medications were substituted with equally unsafe medications as a result of the intervention: Gabapentinoids, other sedative hypnotics, other antidepressants, steroids, second generation antihistamines, NSAIDs, topical pain medications, and injectable pain medications (e.g., cortisone injection)	6/1/2019 – 9/30/2024
CESR VDW	CESR Med Order Table information (e.g. instruction for usage, prescription date, medication type)	6/1/2019 – 9/30/2024
KPWA VDW	Demographics (e.g., age, sex, gender, race, marital status)	6/1/2019 – 9/30/2024
KPWA Clarity	Patient reported outcome scores and dates questionnaire was administered – pain (PEG), anxiety (GAD), depression (PHQ-9), insomnia (ISI)	6/1/2019 – 9/30/2024
KPWA clinical notes in the EMR (extracted with	Mention of symptoms (yes, no) or scores for symptom questionnaires on pain, anxiety, depression, and insomnia. Date of	6/1/2019 – 9/30/2024

natural language processing)	mention or administration of questionnaire.	
KPWA EMR	Date and provider of scheduled primary care, physical therapy and mental health visits	6/1/2019 – 9/30/2024
KPWA EMR	Referrals to pharmacy (y, n) and date Referrals to acupuncture (y,n) and date Referrals to COMET (y,n) and date Referrals to pain clinic (y,n) and date Referrals to massage (y,n) and date Referral to mental health (y,n) and date Referrals to sleep clinic (y,n) and date Referrals to pain clinic (y,n) and date	6/1/2019 – 9/30/2024
KPWA VDW	Provider ID, Specialty, Provider Type, primary practice clinic. Data collected so that we can determine who the patients' PCP is for Epic Staff Messaging the EBPO to the correct provider).	Intervention Launch to Intervention End

e. Other Data

Describe any other data collection activities not already mentioned above. For example, using aggregate data to describe the study sample (provide a table for this activity).

7.4 Subject Time Commitment, Payments, and Costs

a. Time Commitment

How much time will be required for subjects to participate in the study? (Include subject's time for all study procedures and data collection activities. Feel free to use your own table. Be sure duration of participation is included in the consent form.)

Phase II (Focus Group)

By mail: 5 minutes
By telephone: 10 minutes
In person: 2 hours
By email: _____
By internet: _____
Other: _____
Total: 2 hours, 15 minutes

Phase III (Trial)

By mail:	30
By telephone:	
In person:	
By email:	
By internet:	
Other:	
Total:	30

b. Deception/Incomplete Disclosure

Does this study include deception or incomplete disclosure?

☐ **YES** ☒ **NO**

If YES, please explain why this is needed and state whether subjects will be debriefed at the end of the study.

c. Subject Costs

What costs will subjects incur as a result of participating in this study? Check all that apply and describe in the consent form. Participants must be informed of these costs prior to their enrollment in the study.

Subjects will be responsible for their own transportation to the focus groups. Parking will be reimbursed.

Any co-pays, co-insurance, or deductibles for mediations or office visits that occur as a result of the educational study materials sent to patients and providers are the responsibility of the patient. This is in the information sheet sent to patients with their first educational brochure.

☐ None
☒ Transportation
☐ Meals
☐ Parking
☒ Co-pays, co-insurance, deductibles
☐ Charges for clinical procedures/treatment (specify type of procedure/treatment)
☐ Other (describe):

d. Subject Payment(s)

Will subjects be paid for their participation in the study?

☐ None
☒ Direct monetary payment (specify amount and timing of incentives(s)): $50.00 for Focus Group Participation
☐ Non-monetary payment (specify type, value and timing of incentives)):

7.5 Sequential Description

Provide a **detailed (excruciatingly detailed) sequential description** of the study activities for a typical subject. The information in this section should describe what will happen (including collecting data from records) **from a research participant's perspective**. Use active voice, "The study team mails an invitation to the potential subject. A research specialist calls the subject…etc." rather than passive voice, "The subject will receive a phone call".

Be sure to:

- Briefly describe of all study procedures, tests, treatments, and collection of data from records
- Explain who will collect data
- Indicate where study activities will take place
- Describe different subject groups or phases separately
- If the study is complex and has multiple sites, populations, or phases include a flow chart.

Phase II (Focus Group):

1) The KPWHRI study programmer creates a study sample per our inclusion/exclusion criteria listed above in Section 3.3 and uploads this sample to our study database.
2) The study team mails an invitation letter to the potential focus group participant.
3) The study team RS or PM calls the potential participant, explains the study, administers oral consent for eligibility, and if potential participant is willing, administers telephone eligibility questionnaire.
4) If participant is eligible and willing to participate, study team schedules participant for the focus group that corresponds to the patient's medication type (e.g., muscle relaxer, tricyclic antidepressant, etc.)
5) 2 days prior to focus group, study team makes a reminder call about focus group time, location (at Central KP on Capitol Hill), and parking
6) Day of focus group, study team greets participant and administers Informed Consent
7) The study team conducts the focus group (See Focus Group Guide), where the following brochures will be discussed:
    - 190916_OpiodsPatientBrochure_FG and Intervention_Submitted
    - 190916_SMRPatientBrochure_FG and Intervention_Submitted
    - 190916_TCAPatientBrochure_FG and Intervention_Submitted
8) The audio recorder is turned on by the study team. A study team member will take notes during the focus group, capturing patient suggestions for editing purposes.
9) At the end of the focus group, the audio recorder is turned off and the study team hands out parking vouchers and $50 incentive.
10) The study team will analyze the focus group data and make changes to patient brochures as necessary.
11) All changes to brochures will be sent to the IRB as a modification

Phase II work was completed in 2019

Phase III (Trial):

Opt-Out Protocol (July 2020-October 2020)

1. In order to ensure that KP providers are not confused by this communication, we will inform providers at the 8 Intervention Clinics about this study and materials that they can expect to receive through morning huddles and/or brown bag lunches as deemed appropriate by the clinic managers.
2. The KPWHRI study programmer creates study sample per our inclusion/exclusion criteria listed above in Section 3.3 and uploads this sample to our study database.
    a. Sample created on the date the intervention is rolled-out (2 of the 8 clinics rolled out each month) to a particular intervention clinic and the matched usual care clinic
3. The study team mails the information sheet, invitation letter, first brochure, and relevant self-care handout(s) to a subgroup of the Intervention Group from each intervention clinic each month. The Control Group receives nothing.
4. Corresponding EBPOs sent via secure fax to the patient's provider.
5. One month after sending the patient brochure, the study team mails the postcard mailer
6. Repeat process for subsample each month for 12-months.
    a. Patients (and accompanying materials to their providers) receive only one brochure per medication class during the study period
    b. Patients taking multiple medication classes of interest will receive no more than one brochure every 3 months for a max of 4 brochures in 12 months.

Extract automated data from table 7.3.d (opt out protocol) from KPWA VDW on Intervention and Control Group to assess outcomes at 24 months post roll-out into the intervention clinic and matched usual care clinic.

Waiver of Consent/HIPAA Authorization Protocol (December 2020-)

1. In order to ensure that KP providers are not confused by this communication, we will inform providers at the 8 Intervention Clinics about this study and materials that they can expect to receive through morning huddles and/or brown bag lunches as deemed appropriate by the clinic managers.
2. The KPWHRI study programmer creates study sample per our inclusion/exclusion criteria listed above in Section 3.3 and uploads this sample to our study database.
    a. Sample created on the date the intervention is rolled-out (2 of the 9 clinics rolled out each month) to a particular intervention clinic and the matched usual care clinic
3. The study team mails the notification of study letter, first brochure, and relevant self-care handout(s) to a subgroup of the Intervention Group from each intervention clinic each month. The Control Group receives nothing.
4. Urls for corresponding EBPOs sent via Epic Staff Messaging to the patient's provider.
5. One month after sending the patient brochure, the study team mails the postcard mailer
6. Repeat process for subsample each month for 12-months.
    a. Patients (and accompanying materials to their providers) receive only one brochure per medication class during the study period
    b. Patients taking multiple medication classes of interest will receive no more than one brochure every 3 months for a max of 4 brochures in 12 months.

Collect deprescribing information.

1. Exploratory work: the KPWHRI study programmer will look in the CESR Med Order Table to ascertain availability of deprescribing information for all participants for the medications of interest.
2. Chart validation: the KPWHRI study programmer and project manager will conduct chart validation on a subset (up to 20%) of study participants to look for concordance between what is in the CESR Med Order Table and what is in the chart.
3. Refine code to collect deprescribing information based on #1 and #2 and pull data to assess outcomes at 24 months post-roll out into the intervention clinic.

Extract automated data from KPWA VDW on Intervention and Control Group to assess outcomes at 24 months post roll-out into the intervention clinic and matched usual care clinic.

Ascertain ADWE for the purpose of safety monitoring. We will conduct medical record review to determine if any serious ADWE's occurred in our study population for both the intervention and usual care group in participants with prescriptions ford opioids and/or benzodiazepines. We define serious as ADWE that require an emergency department visit or hospitalization.

1. The study programmer will identify potential ADWEs using electronic data sources
2. The KPWA chart abstractor will review the medical records to ascertain if a serious ADWE occurred. They will enter information regarding the event into a chart abstraction tool in REDCap.
3. The KPWA chart abstractor will send redacted medical record information about the event to Dr. Elizabeth Phelan using the KPWA secure file transfer site. A material and data transfer agreement will be in place prior to sending this information
4. Dr. Phelan will conduct her own independent review of the potential ADWE and enter the information into the chart abstraction tool in REDCap
5. At the end of chart redaction, the results of the double chart abstraction will be compared. Any discordance in outcomes will be adjudicated by a third party- Dr. Shelly Gray.

8. Risks & Benefits

8.1 Benefits

a. Direct Benefits (For PHASE II Focus Groups):

Check boxes below for all potential **direct** benefits to participants.

☒ None
☐ Potential improvement in physical health due to the following:
☐ Clinical intervention, such as counseling, exercise, etc.
☐ Medical procedure or treatment (not including medications)
☐ Administration of medication(s)
☐ Other (please describe briefly):

a. Direct Benefits (PHASE III Intervention):

Check boxes below for all potential **direct** benefits to participants.

☐ None
☒ Potential improvement in physical health due to the following:
☐ Clinical intervention, such as counseling, exercise, etc.
☐ Medical procedure or treatment (not including medications)
☐ Administration of medication(s)
☒ Other (please describe briefly): As a result of patients receiving the educational brochures and providers receiving the EBPOs, patients may achieve safer medication usage thereby reducing their risk of falls and fall-related injuries.

b. Benefits by Population

If any of the benefits listed in above apply to only certain cases or subgroups within the study, please describe here.

The direct benefits apply only to patients receiving care at primary care clinics randomized to be an Intervention Clinic.

b. Indirect benefits

Check boxes below for all potential **indirect** benefits. **(For PHASE II and PHASE III):**

☒ Increase in scientific knowledge for society
☐ Other (please describe briefly):

8.2 Risks

a. Potential risks (PHASE II Focus Group ONLY):

Check boxes below for all potential study risks

☒ Discomfort at answering personal questions or psychological distress due to research procedures
☒ Breach of confidentiality
☐ Physical adverse effects from the following:
- ☐ Blood draw
- ☐ Clinical intervention, such as exercise program, in-person counseling
- ☐ Medical procedure, such as X-ray, strength measure, screening tests, etc.
- ☐ Medication(s) given as part of research
- ☐ Other (describe briefly):

a. Potential risks (PHASE III Intervention):

Check boxes below for all potential study risks

☐ Discomfort at answering personal questions or psychological distress due to research procedures
☒ Breach of confidentiality
☐ Physical adverse effects from the following:
- ☐ Blood draw
- ☐ Clinical intervention, such as exercise program, in-person counseling
- ☐ Medical procedure, such as X-ray, strength measure, screening tests, etc.
- ☐ Medication(s) given as part of research
- ☐ Other (describe briefly):

b. Unforeseeable Risks

Which procedures, if any, may have risks to the subjects that are currently unforeseeable? Explain

NA

c. Risks by Population

If any of the risks listed in above apply to only certain cases or subgroups within the study, please describe here.

NA

d. High-Risk Methods or Clinical Procedures

Does this study involve any high-risk methods or clinical procedures (e.g., investigational drugs, devices, or procedures; radiation exposure; or other intervention with patients, etc.)?

☐ **YES** ☒ **NO**

If YES, Describe the probability, magnitude, duration, and reversibility of the risks. Describe any physical, psychological, social, legal, and economic risks and how they will be managed?

d. Coordination of Care with Provider(s)

Will the patient undergo any clinical procedures or receive any medications that might require coordination of care with the patient's health care provider(s)?

☐ **YES** ☒ **NO**

If YES, please briefly describe what steps you will take so the study participant's health care is not negatively affected (e.g., how you will track care to follow-up on a research intervention if needed, etc.)

e. Sensitive Topics

Please check whether data will be collected on any of the following topics:

☐ Sensitive aspects of subjects' behavior, such as drug use, sexual behavior or use of alcohol
☐ Any information that could put subjects at risk of criminal or civil liability
☐ Any information that, if disclosed, would likely have negative consequences to the participants or damage their financial standing, employability, insurability or reputation

f. Reporting of Risk of Harm or Abuse

Indicate whether you are collecting, or are likely to learn incidentally, information about the following:

☐ Child abuse, elder abuse, or spouse abuse
☐ Risk of harm to self or others (i.e., suicidal ideation, threats to others)

If you checked either of these items, describe the reporting plan here and, if applicable, in the consent form.

g. Incidental Findings

Does the study carry a risk of incidental findings?

☐ YES ☒ NO
If YES, describe your plan for evaluating these and determining whether and how subjects or their providers will be given this information.

h. Previously Unknown Condition
Is it possible that you will discover a previously unknown condition (disease, genetic predisposition, etc.) in a subject as a result of study procedures?
☐ YES ☒ NO
If YES, explain how you will handle this situation:

i. Electronic Communication(s) and Data Transmission
Will the internet, email, or any other electronic communication, be used to communicate with participants, OR collect and/or transmit data (other than de-identified datasets) inside or outside of KP Washington? (Examples include websites, software applications, smart phones, laptop computers, tablets, Fitbits, iPads, etc.)
☐ YES ☒ NO
If YES, Complete **Supplement B.**
If YES, how will you verify the participant's identity?

9. Adverse & Unanticipated Events

9.1. Management of Adverse/Unanticipated Events
Who will handle any adverse/unanticipated events for this study?
KPWHRI PI, Benjamin Balderson, PhD, and Project Manager Monica Fujii will handle any adverse/unanticipated events.

9.2 Data Safety Monitoring Plan
Is a data safety monitoring (DSM) plan required by the sponsor or otherwise planned?
☐ YES ☒ NO
If YES, Describe the provisions for data and safety monitoring (DSM) to ensure safety of research participants. Please indicate the following details in your DSM plan:
- adverse event (AE) grading scale
- plan for unanticipated AE reporting
- plan for anticipated AE reporting
- plan for safety review (by whom and what frequency)
- plan for ongoing review of results (if appropriate)

9.3 Data Safety Monitoring Board
Is a data and safety monitoring board (DSMB) required by the sponsor or otherwise planned?
☐ YES ☒ NO

If YES, provide details of the DSMB.

9.4 Financial Responsibility for Injury

Guidance: Please make sure that the study contract and/or KP Washington policies support any language regarding physical injuries. If the study is greater than minimal risk, information about who is responsible for treatment of physical injuries caused by the study is required in the consent form.

a. Responsible Party

Who will be financially responsible for treatment of physical injuries resulting from study procedures?

- ☐ Study sponsor
- ☐ Subject or subject's insurer
- ☒ Not applicable
- ☐ Other, explain:

b. Financial Responsibility and Consent Form

Does the consent form explain who will be financially responsible for treatment of physical injuries resulting from study procedures?

- ☒ Not applicable
- ☐ **YES continue**
- ☐ **NO** please explain:

10. Privacy, Confidentiality, Data Storage, & Data Security

10.1 Subject Privacy During Participation

Describe the steps that will be taken to protect subject privacy during recruitment, consent and study procedures (e.g., will subjects be recruited in a private space, where will you keep written study materials, etc.)

Phase II (Focus Group): Patients will have privacy during our study recruitment and screening calls because they will be called at their preferred contact number. Our study staff will always ask if this is a good time for learning more about our study and answering question to see if he/she is eligible to participate in one of our focus groups. If the participant agrees to participate in the focus groups, informed consent will be administered individually in a private room adjacent to the focus group meeting room.

Phase II work was completed in 2019.

Phase III (Trial):
Opt-Out Protocol (July 2020-October 2020)
Study recruitment materials accompanied by a Study Information Sheet, will be mailed to individuals. Potential participants can choose to open the letter at a time that is appropriate for him/her. There are no recruitment or screening calls for this Phase. If a participant chooses to opt out of the study by calling our study line, the participant can choose to make that call at any time when it feels right for him/her. There is no informed consent for Phase III activities, we are asking for a waiver of documentation of consent for these activities.

Waiver of Consent/HIPAA Authorization Protocol (December 2020-)
Study recruitment materials will be mailed to individuals. Potential participants can choose to open the letter at a time that is appropriate for them. There are no recruitment or screening calls for this Phase There is no informed consent for Phase III activities, we are asking for a waiver of documentation of consent for these activities.

10.2 Data Storage at KPWA

a. Storage Location

Where will the data be stored?

All data will be stored on the KPWHRI secure network folders accessible only to research study team members.

Chart review data for ADWE's will be stored on KPWA's REDCap, behind the KPWA firewall.

b. Who Can Access Data?

Who will have access to the identifiers/linking file?

Only the KPWHRI study programmer will have access to the linking file. The KPWHRI study programmer, Research Specialist, and Project Manager will have access to identifiers so that they can recruit patients, mail out study materials, track patients who opt out of the study by refusing to allow their data to be accessed for use in this study and review their medical record in Epic for ADWE chart review.

c. Identifier/Link Destruction Date

When (month/year) will the identifiers, and the link to identifiers, be destroyed?

All identifiers will be destroyed 3 years after the end of the study which is 8/29/2026.

d. Other Security Measures

Describe any other steps that will be taken to ensure security (e.g., password protection, encryption, separation of identifiers from data, certificates of confidentiality, etc.

Computer files will be password protected with access restricted to staff using this information to perform study-related activities. All analytic data files will be password protected. Data tables with any identifiers needed for mailing the patient brochures (i.e., name, address) or recruitment into the focus groups (i.e., name and phone number) will be kept separate from all other study data tables. All employees at KPWHRI routinely sign a confidentiality form that covers access to all data encountered.

10.3 Data Destruction or Retention

a. Destruction or Retention of Data

Describe the plan to destroy/archive or retain data at the end of the study.

We plan to keep de-identified data indefinitely. All identifiers will be destroyed 3 years after the end of the study which is 9/29/2026.

b. Retention beyond 5 years

If you propose to keep identifiers **beyond a limited data set** indefinitely, or for more than 5 years past the study end date (typically the end of the funding period for the grant) provide a justification for this.

NA

10.4 Future Use(s) of Study Data

Guidance: If you plan to create a registry, repository or biobank, consult with the IRB.

Will identifiable or coded data be used for future research after this study is complete?

☐ YES → Describe below ☒ NO→ Continue

11. Disclosure of Identifiable Health Care Information & Data Sharing

11.1 Disclosure and/or Sharing

Will anyone not employed by KP Washington have access to, or be given, any of the identifiers listed below in Question 11.2 (with or without health information)?

☐ **YES** → continue ☒ **NO** → skip to section **12**

11.2 Identifiers to be Released

What identifiers will be released outside of KP Washington? (CHECK ALL THAT APPLY)

☐ 1. Name(s)
☐ 2. Any geographic subdivision smaller than a state (including street address, city, county, precinct, ZIP code, and their equivalent geocodes), except for the initial 3 digits of a ZIP code
☐ 3. Any dates (other than year only) directly related to an individual, (for example, birth date, admission date, discharge date, date of death, visit date, diagnosis date, etc.) and any ages over 89
☐ 4. Telephone number(s)
☐ 5. Fax number(s)
☐ 6. Email address(es)
☐ 7. Social security number(s)
☐ 8. Medical record number(s)
☐ 9. Health plan beneficiary number(s)
☐ 10. Account number(s)
☐ 11. Certificate/license number(s)
☐ 12. Vehicle identifiers and serial numbers, including license plate numbers
☐ 13. Device identifier(s) and serial number(s)
☐ 14. Web universal resource locators (URLs)
☐ 15. Internet protocol (IP) address number(s)
☐ 16. Biometric identifier(s), such as, finger or voice prints, body geometry, iris or retina scans
☐ 17. Full face photographic image(s) and any comparable image(s)

☐ 18. DNA or any identified sequence of chemical base pairs
☐ 19. Geocode
☐ 20. Any other unique identifying number, characteristic, or code (not including a study number assigned for this project as long as the study number is not a combination of identifiable numbers that could be decoded by the recipient)

11.3 External Organizations/Individuals

List which person(s) and/or organization(s) will have access to, or be given, these identifiers and what health information they will have along with the identifiers. List each person and/or organization separately. (NOTE: If you plan to share fully identifiable PHI outside of KPWA, you must talk with the IRB first.)

11.4 Data Transfer

Describe how this information will be transferred securely (for example, Secure File transfer).

11.5 Storage at External Site(s)

Describe how this information will be stored at the other sites and how the site will protect the confidentiality of shared data.

11.6 Consent for Sharing Identifiable Data

Are you obtaining written signed consent for the release and/or sharing of data described above?
☐ **YES** → continue
☐ **NO** → Explain. If you are requesting a waiver of informed consent complete Supplement A. Note that this project may require disclosure tracking.

12. Sharing of De-Identified or Aggregate Data

12.1 Sharing De-Identified or Aggregate Data

Will anyone not employed by KP Washington have access to or be given de-identified or aggregate data?
☒ **YES** → continue ☐ **NO** → skip to section **13**

12.2 External Organizations/Individuals

List which person(s) and/or organization(s) will have access to, or be given, de-identified or aggregate data. List each person and/or organization separately.

University of Washington:
Shelly Gray, PharmD
Elizabeth Phelan, Md, MPH

12.3 Data Transfer

Describe how this information will be transferred and stored securely (for example, Secure File transfer).

We will transfer de-identified analytic dataset to our two UW investigators using our KPWHRI Secure File Transfer Site.

12.4 Storage at External Site(s)

Describe how this information will be stored at the other sites and how the site will protect the confidentiality of shared data.

This de-identified analytic dataset will be stored in a password protected UW file only accessible by the Principal Investigators, Shelly Gray, PharmD and Elizabeth Phelan, MD, MPH.

13. Required Data Sharing & Data Contributions to Repositories

13.1 Required Data Sharing

a. Funder Required Sharing

Is data sharing required by your funding agency?

☐ **YES** ☒ **NO**

b. Contribution to a Repository

Guidance: If you are contributing data to a required repository consult with IRB staff.

Will data from this study be contributed to a repository?

☐ **YES** → continue ☒ **NO** → skip to section **14**

13.2 Data Sharing Plans

a. Overview of Data Sharing Plan

If data sharing is required by your funding agency, or if you plan to establish or contribute information to a repository, please describe plans for sharing final research data for use by other researchers.

b. Confidentiality

Describe the steps that will be taken to ensure the confidentiality of subjects and security of their data (e.g., password protection, encryption, separation of identifiers from data, certificates of confidentiality, etc)

c. Storage

Where will the data be stored and for how long?

d. Access to Data

Who will have access to the data and how?

e. Data Release Procedures

Describe the procedures to release data to other researchers, including: the process to request a release, approvals required for release, who can obtain data, and the data to be provided.

14. Involved Organizations, Investigators, & IRBs

Guidance: If this application includes multiple study phases or subprojects, please answer the following questions separately for each phase or subproject. Note: Sometimes arrangements are possible when multiple IRBs are reviewing the same study. Contact the Human Subjects Office if this seems relevant to your study.

14.1 External Institutions, PIs, and Activities

List all institutions involved in this study and the PI at the site, provide a brief description of activities occurring at each site, and identify which IRB will be reviewing for each site if required. Complete the table below.

List all Institutions Involved	PI at Institution	Briefly describe activities conducted at the site or by site personnel (e.g., study design, recruitment, data collection, consultation, etc.)	List the IRB reviewing for the institution or N/A to confirm that the site PI has determined that no IRB review is needed at that site.
KPWHRI	Benjamin Balderson	Responsible for overall study conduct at KPWA. Participate in study design, recruitment, data collection, intervention implementation, , data analysis and interpretation of results, manuscript drafting, and presentation/dissemination of results	KPWA IRB
University of Washington	Shelly Gray and Elizabeth Phelan	Study design, design intervention materials, participate in data analysis and interpretation of results, manuscript drafting, and presentation/dissemination of results	KPWA IRB

14.2 KPWA Collaborators

List any KP Washington staff persons (outside of KPWHRI) who are collaborating on this project (i.e., KP Washington clinic staff, pharmacy staff, laboratory staff, etc.)

Drs. Kim Painter, Andrea Chun, Angela Sparks, Sharon Burks, Janet Kim, and Paul Brock were involved in helping with study design, materials development, and assisting with clinic selection and intervention feasibility. While these collaborators have been instrumental in helping to ensure this intervention is possible within KPWA, they will not have access to study data or know which patients are participating in this study.

14.3 Other Consultants or Institutions

List any other consultants and/or institutions involved in this study not mentioned above.

NA

15. Training in the Protection of Human Subjects

Guidance: All KP Washington research staff are required to complete training on the protection of human subjects EVERY 3 YEARS. This training may be completed on the web through the CITI training site at www.citiprogram.org by signing in under KP Washington. Instructions for linking your CITI training certificate to your IRBNet profile are available in IRBNet at irbnet.org.

15.1 KPWA PIs, COIs, and PMs

Guidance: All KP Washington investigators, co-investigators, and project managers must:
1) Be listed in the Study Team form wizard in IRBNet and
2) Have their human subjects training records and CVs available in IRBNet via the linking process from IRBNet to CITI

15.2 Non-KPWA PIs, COIs

Guidance: All non-KP Washington investigators and co-investigators, who are relying on KP Washington for IRB review, must:
1) Be listed in the Study Team form wizard in IRBNet and
2) Have their human subjects training records and CVs available in IRBNet. These may be linked to CITI training or an uploaded certificate.

15.3 Other KPWA Study Staff

☒ Check this box to confirm that all other study staff (at KPWA-or at other sites if relying on KPWA for IRB review) who have access to identifiable data, or who interact with participants (e.g., programmers, research specialists, survey interviewers, interventionists, etc.) have up-to-date human subjects training records.

Attachments

Mark the following attachments below:

A = attached (in this application or in IRBNet)

F = will follow later

N/A = not applicable.

Recruitment materials

- NA Recruitment flow chart
- NA Flyers/Brochures/Advertisements
- A Letter to physician(s) concerning patient contact
- A Postcard/email/Letter of invitation to subjects
- A Recruitment script(s)
- Other

Consent/HIPAA Authorization materials

- A Written consent form(s)
- A Oral consent script(s)
- A Consent script for assessing study eligibility
- A HIPAA authorization form for use and release of health information
- A Study Information Sheet
- NA Certification from the source of the electronic signature that the software is compliant with Washington state laws

Data collection instruments

- A Questionnaire or survey questions
- NA In-person interview questions
- A Focus group guide
- A Medical record abstraction form
- A Intervention materials
- Other

Email Communication

- A Scripts (sent via Outlook, Epic secure messaging, etc.)

Other materials

- A **KP Core Data Form Wizard**
- A **KP Study Team Form Wizard**
- A **Summary Table of IRBNet Files for One Funding Source (if relevant)**
- NA **Letters of Support** from KP Washington sponsor or collaborator (if available)
- NA **Emails from KP Washington's Privacy, Security, and Legal** offices with their comments on the use of electronic devices proposed in this application.

[NA] **Email exchange with Tech Risk Review** (including the form you completed, their questions, answers, determinations and any comments on the use of electronic systems or devices proposed in this application) (if relevant)

[A] **Complete grant application/funding proposal** (required)

[NA] **Study protocols** (e.g., suicide risk protocol, high blood pressure protocol, study intervention protocols, etc.)

[NA] **Complete clinical protocol**, case report form, and Investigator's Brochure. This is required if study is FDA regulated.

[NA] **IND/IDE Letter/Email from the FDA** stating that the study is exempt from IND/IDE regulations

[A] **Investigator CV and training linked in IRBNet.** *If KP Washington is the IRB of record for other sites, please also make sure the CV and human subjects training for each lead investigator at those sites is linked in IRBNet.

[A] **Summary Table of IRBNet Files for One Funding Source (if relevant)**

[NA] **Prior approvals. Provide any documentation from prior approvals for this research** (e.g., school, external site, laboratory, radiation safety, biosafety approval, etc.)

[ ] **Other** (describe or list): [ ]