# Outreach to Reduce Depression Disparities

NCT05580406

Last IRB Approval: 08/25/2023

# Study Application (Version 1.5)

## 1.0 General Information

***Please enter the full title of your study::**

Outreach to Reduce Depression Treatment Disparities

***Please enter the protocol number or short title:**

MHRN Pilot Project
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

**Please identify the Study Phase:**

PILOT

**Is this study going to be conducted in multiple locations?**

**Note: Multiple locations refers to KPSC/KPHI sites only. If conducting a data only study, always select No.**

Yes

**Is this Study using Subject Management?**

○ Yes ◉ No

**Please identify the Accrual Target:**

**NOTE: Include the total number of participants/subjects being targeted for prospective or clinical trial research. Please leave blank if conducting a data only study.**

800

## 2.0 Add departments

**2.1 List all departments associated with this study.**

| Is Primary? | Department Name |
|---|---|
| ○ | **KPHI** - Research |

**2.2 List the study location of the Principal Investigator and Co-Investigators.**

| Primary Location | Area Code | Area | Location Code | Location Name |
|---|---|---|---|---|
| ◉ | | Hawaii Region | 30H00 | Kaiser Permanente Center for Health Research - Hawaii |

## 3.0 ■ Assign key study personnel(KSP) access to the study

**3.1 * Please add a Principal Investigator for the study:**

| Name | Role | Training Record |
|---|---|---|
| Simiola, Vanessa L, PhD | PD/PI | View Training Record |

**3.2 If applicable, please select the Research Staff personnel:**

A) Additional Investigators

| Name | Role | Training Record |
|---|---|---|
| Matero, Lisa | External Co-Investigator | View Training Record |
| Simon, Gregory, MD | External Co-Investigator | View Training Record |

B) Research Support Staff

| Name | Role | Training Record |
|---|---|---|
| Angmorter, Judith J | Financial Support Analyst | View Training Record |
| Erickson, Catherine | Research Associate | View Training Record |
| Nie, Sixiang | Research Associate | View Training Record |

**3.3 *Please add a Study Contact:**

| Name | Role | Training Record |
|---|---|---|
| Erickson, Catherine | Study Contact | View Training Record |
| Simiola, Vanessa L, PhD | Study Contact | View Training Record |

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g., The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

## 4.0 Funding Information

**4.1 * Sponsor/source of funding is:**

- ☐ Consortium/Cooperative Group (e.g. Children's Oncology Group (COG), National Surgical Adjuvant Breast and Bowel Project (NSABP), The Cancer and Leukemia Group B (CALGB), The American College of Surgeons Oncology Group (ACOSOG), etc.)
- ☐ Device Manufacturer (e.g. Advanced Cardiovascular Systems, Inc., Vascutek Ltd., etc.)
- ☑ Federal - National Institutes of Health Organizations (NIH), National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID)
- ☐ Federal - Other. (Health Care Related Agencies (excluding Public Health Services and NIH): Centers for Medicare/Medicaid Services, US Dept. of Veteran Affairs, etc.)
- ☐ Federal - Public Health Services. (Agencies within the US public health services: Centers for

Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Indian Health Service (IHS))

- ☐ Foundation (e.g. Children's Hospital of Orange County, Robert Wood Johnston, Bill and Melinda Gates Foundation, National Childhood Cancer Foundation (supports COG), etc.)
- ☐ Government - Local (e.g. Los Angeles Dept. of Managed Health Care, Los Angeles County Dept. of Public Health, etc.)
- ☐ Government - State (e.g. California Dept. of Health and Human Services, California Dept. of Public Health, etc.)
- ☐ Internal Operating Budget (e.g. Departmental Budget). Does not include Regional Research or Internal Research Nursing Committee, select separate RRC/Internal Research Nursing option
- ☐ Internal Research Nursing Committee (RNC)
- ☐ Personal Time / Unfunded
- ☐ Pharmaceutical Company (e.g. Glaxco Wellcome, Pfizer, Merck, etc.)
- ☐ Private - For-Profit (e.g. American Association of Health Plans, etc.) Do not include device manufacturers or pharmaceutical companies as they have their own funding types
- ☐ Private - Not For-Profit (e.g. American Diabetes Association, Children's Hospital of Orange County/Los Angeles, etc.)
- ☐ Regional Research Committee (RRC)
- ☐ University - Private (e.g. The Scripps Research Institute (TSRI), University of Southern California, Los Angeles (USC), Loma Linda University, etc.)
- ☐ University - Public (e.g. University of California, San Diego (UCSD), University of California, Los Angeles (UCLA), etc.)
- ☐ Other

Please indicate "Other" funding below:

## 5.0 Study Type: Research & Application Type

**5.1 * Principal Investigator's Location for this Study**

Center for Integrated Health Care Research 501 Alakawa St Suite 201 Honolulu, HI 96817

**It is mandatory to have the Facility's street address and zip code. If same as PI location above, enter "same".**

Same

**5.2 * Is the Principal Investigator a resident or fellow?**

○ Yes ◉ No

If yes, provide anticipated graduation date:

**5.3 If applicable, Co-Investigator contact information for this study.**

**Include KPSC Co-Investigator contact information (e.g. name and medical center location).**

**Include External Co-Investigator name and external location only if an iRIS shell account has not been created and they have not been added in the previous section.**

| Co-Investigator Name | Medical Center Location |
|---|---|
| Gregory Simon | KP Washington |
| | |

Lisa Matero | Henry Ford

**5.4 * Define the type of research:**

- ○ Clinical Trial (Cooperative Group)
- ○ Clinical Trial (Industry Sponsored or Principal Investigator Initiated)
- ○ Data Only
- ○ Exempt Request
- ○ Humanitarian Use Device (HUD)
- ◉ Interregional Application / Health Care Systems Research Network Research Application (KPSC Lead)
- ○ Interregional Application / Health Care Systems Research Network Research Application (KPSC Non-Lead)
- ○ KPSC Cede Request to External IRB (PLEASE SELECT ONLY AFTER CONSULTATION WITH IRB STAFF)
- ○ Nursing Research (Prospective) VALIDATION REQUIRING NURSING COMMITTEE APPROVAL PRIOR TO IRB
- ○ Nursing Research (Data Only) VALIDATION REQUIRING NURSING COMMITTEE APPROVAL PRIOR TO IRB
- ○ Prospective
- ○ Regional Research Committee (RRC) Funded (Prospective and Clinical Trial Research)
- ○ Regional Research Committee (RRC) Funded (Data Only)
- ○ Single Patient Use
- ○ Treatment Protocol/Expanded Access

## 6.0 Glossary of Acronyms and Abbreviations

***If your application will include any abbreviations/acronyms, please use this section to include, in alphabetical order, a glossary of abbreviations/acronyms.***

**6.1 Please include a glossary of all acronyms and abbreviations, in alphabetical order, which will be used in this study application.**

## 7.0 IRB of Record

**7.1 Information about the Lead Principal Investigator --**

Principal Investigator from Lead Institution:

Vanessa Simiola, PsyD

Address:

501 Alakawa St Suite 201
Honolulu, HI 96817

Department:

Center for Integrated Health Care Research

Phone Number:

(860) 614-9925

Fax Number:

E-mail Address:

Vanessa.L.Simiola@kp.org

**7.2 * List the Proposed IRB of Record and Include Institution's Federal Wide Assurance Number (FWA). If KPSC is the IRB of record, list KPSC.**

SCAL is the IRB of record for the Hawaii Area.

## 8.0 Interregional/HMORN Research Application Questions

**8.1 Information about the Regional Principal Investigator(s) or Local Principal Investigator --**

**Submission of this form by any Principal Investigator listed below (Regional PrincipaI Investigator or Local Principal Investigator) will verify that the submitting regional Principal Investigator accepts responsibility for the information in the research application as it pertains to the conduct of the study in his or her region/site, and that the submitting regional PrincipaI Investigator or Local Principal Investigator agrees to conduct the study within his or her KP region/site in compliance with all applicable federal regulations and KP policies and procedures, including KFRI SOP-004 and SOP HMORN-001.**

| | Regional PI Name | KP Region and Facility | Department | Phone Number | Fax Number | E-Mail (KP Lotus Notes Only) |
|---|---|---|---|---|---|---|
| | Gregory Simon | KP Washington | Research Institute | | | |
| | | | | | | |

## 9.0 General Section: Research Study Summary

## Performance Sites (S1)

**9.1 List the Kaiser Permanente Regions and Facilities in which the study will take place. If this is a data only study, list the KP regions and facilities from which data will be used/abstracted. If data is abstracted by condition and not facility, list Kaiser Permanente Southern California.**

KP Washington
KP Hawaii

**9.2 If this study will be conducted under subcontract to another institution, describe this relationship and name the institution and study sponsor.**

Not Applicable

**9.3 Are other Institutions participating?**

- (•) Yes
- ( ) No

**If yes**, describe their roles:

*Kaiser Permanente Hawaii (KPHI)* serves 225,000 members, over 70% of whom are Asian and/or Pacific Islanders. Approximately 14% are insured by Medicare and 12% by Medicaid. Services are provided throughout the state in 17 outpatient clinics throughout the islands and one hospital on Oahu. KPHI will serve as the lead site for this investigation. During Phase I, programmer /analysts at KPHI will develop distributed code using VDW tables for use at KPHI and Henry Ford Health System. KPHI will use this code to identify eligible participants for Phase II and III of the project (to be conducted at a later time, pending IRB approval).

Henry Ford Health System (HFHS) serves over 1.1 million patients per year, approximately 35% of whom are African American. Approximately 25% are insured by Medicare and 15% by Medicaid. HFHS has more than 40 clinics and 6 hospitals serving South and Southeast Michigan, including the Detroit metropolitan area. HFHS will run the distributed code to identify eligible members for Phases II and III. HFHS will provide limited datasets to KPHI for analyses following the execution of data use agreements between sites.

Kaiser Permanente Washington: Dr. Gregory Simon of KP Washington is the lead for the MHRN Grant for which this project is funded. He will assist in the interpretation of results as well as data analysis and dissemination of findings. He will work with the site investigators (Dr. Vanessa Simiola (KPHI) and Dr. Lisa Matero (HFHS) closely throughout the project and assist with the development of materials. No human subjects research will be conducted at KP Washington. Limited data sets will be shared with KP Washington, following the execution of data use agreements between sites for phase II and III. For phase I, PHI will not be disclosed.

**9.4 Describe the involvement of the external investigator in the study and provide the Federal Wide Assurance (FWA) Number for their affiliated institution. *Note: external refers to anyone not affiliated with KPSC.**

*Kaiser Permanente Hawaii (KPHI)* serves 225,000 members, over 70% of whom are Asian and/or Pacific Islanders. Approximately 14% are insured by Medicare and 12% by Medicaid. Services are provided throughout the state in 17 outpatient clinics throughout the islands and one hospital on Oahu. KPHI will serve as the lead site for this investigation. During Phase I, programmer /analysts at KPHI will develop distributed code using VDW tables for use at KPHI and Henry Ford Health System. KPHI will use this code to identify eligible participants for Phase II and III of the project (to be conducted at a later time, pending IRB approval).

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## 10.0 General Section: Research Study Summary

## Study Abstract (S2)

**10.1 * What is your research question or hypothesis?**

Do outreach messages improve treatment initiation rates (within 60 days of outreach) for racial and ethnically diverse patients who have a new diagnosis of depression?

What type of outreach message is most effective (i.e., e-mail, direct message, telephone)?

What is the acceptability and effectiveness of different communication modalities (online messaging, mailed letters, telephone) among racial and ethnic minority populations?

**10.2 * Summarize your methods.**

PHASE 1 PORTION OF THE STUDY WAS APPROVED BY A SUB-COMMITTEE OF THE SCAL IRB IN

AUGUST 2021.

Phase I involved the identification of eligible participants (see below) for recruitment in Phase II and Phase III of the research study using data previously collected in the electronic health record. During Phase I programmers at KPHI built the distributed code and tested this code between the two recruitment sites for ongoing refinement. No participants were contacted during Phase I of the study (data only).

Phase II: We conducted formative research to inform a pilot trial to evaluate a population-based outreach program to improve rates of depression treatment initiation among traditionally underserved racial and ethnic groups. [Note, this phase and supporting documents were previously approved by the SoCal IRB committee].

Phase III: This phase involves a randomized controlled pilot trial. The trial will involve randomization of 400 participants (200 from each site) into two groups: outreach and standard care. Participants randomized to the outreach intervention will receive outreach messages from our project teams via secure messaging and/or telephone. Participants assigned to standard care will not receive this intervention. This pilot work intends to inform a subsequent full-scale pragmatic trial to examine impact on health disparities.

## 11.0 General Section: Research Study Summary

## Background / Significance (S3)

**11.1 Briefly state why this study is important to Kaiser Permanente Southern California and/or the community. List formal references to appropriate publications that critically evaluate existing knowledge, and specifically identify the gaps that this study is intended to fill.**

*Feel free to either use the text editor or upload a document.*

**Failure to initiate treatment is a major gap in care for depression -** Depression is among the most prevalent and costly health conditions in the US. Despite the availability of several effective treatments, half or more of people with a new diagnosis of depression do not start any formal treatment. A recent Mental Health Research Network (MHRN) study involving more than 240,000 patients in 5 health systems with a new diagnosis of depression in primary care found that only about a third (36%) had completed a psychotherapy visit or filled a prescription for antidepressant medication within 90 days of a new depression diagnosis[1]. This finding was consistent with numerous previous studies reporting sub-optimal depression treatment initiation[2, 3].

**Large racial and ethnic disparities in depression treatment initiation exist** – African Americans, Hispanics and Asian Americans are even less likely to start treatment than are non-Hispanic whites. MHRN data show that the odds of Asians, Non-Hispanic blacks and Hispanics initiating treatment were 30% lower even after controlling for income and education[1]. This finding is consistent with substantial previous evidence[4-7].

Upload:

| Version | Sponsor Version | Title | Category | Expiration Date | Document Outcome | Checked Out | View Document |
|---|---|---|---|---|---|---|---|
| No Document(s) have been attached to this form. | | | | | | | |

## 12.0 General Section: Research Study Summary

## Methods (S4)

**12.1 * What are the study objectives?**

Previous research by Mental Health Research Network (MHRN) investigators and others demonstrates that online messaging and other telehealth technologies can effectively and efficiently address premature discontinuation of depression treatment[23-27]. These interventions, however, have focused on adherence after treatment initiation and have been tested primarily in non-Hispanic white populations. Less is known about the acceptability and effectiveness of different communication modalities (online messaging, mailed letters, telephone) among racial and ethnic minority populations. Implementation of eHealth technologies must take care not to exacerbate health disparities.

**Approval for phase 1 (data only) was obtained in August 2021. Approval for phase II (formative research) was obtained in February 2022.**

We will conduct formative research (Phase II—focus groups) followed by a pilot trial (Phase III) to evaluate a population-based outreach program to improve rates of depression treatment initiation among traditionally underserved racial and ethnic groups. This pilot work intends to inform a subsequent full-scale pragmatic trial to examine impact on health disparities.

**12.2 * Provide a description of the study type, and study procedures (including inclusion/exclusion criteria, recruitment, estimated participant time commitment per study procedure, proposed compensation for study participation and patient population selection including study inclusion and exclusion criteria). For data only studies, include the inclusion/exclusion criteria as part of the study procedure(s).**

**Phase 1 of Study (IRB Approved in August 2021)**

Using a computable EHR phenotype developed and validated in MHRN research, these data warehouses (e.g., VDW, Clarity) at each site will be used to identify adult patients meeting the following criteria:

- New diagnosis of major depressive disorder or dysthymic disorder at a primary care visit ("new" defined as no depression diagnosis, psychotherapy visit or filled antidepressant prescription in the prior year)
- Continuously enrolled in the participating health system for 365 days prior to the eligible diagnosis (to assure capture of prior diagnoses or treatments)
- PHQ-9 depression score of 10 or more within 14 days before to 7 days after the eligible diagnosis
- No filled prescription for any antidepressant medication OR psychotherapy visit attended within 30 days of the eligible diagnosis*
- No recorded PHQ-9 depression score less than 5 since the eligible diagnosis
- At least 18 years of age or older

The KP Hawaii site will only include patients who self-identified (based on EHR data) as Asian or Native Hawaiian or Other Pacific Islander. The Henry Ford site will only include patients self-identified as African American or Hispanic.

Potential participants will be excluded because of:

- Diagnosis of schizophrenia or bipolar disorder in the prior 2 years
- Not registered to use EHR patient portal
- Previously requested to not be contacted for research

Data will be maintained for the federally mandated period, or for at least seven years, whichever is longer. Identifiers (PHI and PII) will be removed as soon as feasibly possible and only retained as needed for meet the study objectives.

Study compenstation will not be offerred

**Phase II (IRB Approved in February 2022)**

Phase II and Phase III are prospective by design. Phase II will involve a formative evaluation by way of focus groups. Phase III will involve a randomized clinical trial.

Phase II: The goal of this formative phase is to refine and adapt outreach methods and messages with the input of racially and ethnically diverse patients, including African Americans, Asians, Native Hawaiians/Other Pacific Islanders and Hispanics. Each site will recruit 3 focus groups of 6-8 members, with KPHI recruiting Asian Americans and Pacific Islanders and HFHS recruiting African Americans and Hispanic patients. An incentive of a $30.00 in the form of a gift card will be offered. We will attempt to contact the participants 4 times in total. One time via postal mail and up to three follow-up calls.

Led by an experienced focus group facilitator, draft methods and messages of the proposed intervention (*Outreach_Messages_For_Focus_Groups.doc*) will be presented to patient participants and feedback elicited on the mode of delivery, content of the messages, and any other thoughts about how to make the intervention effective (*Patient_Focus_Group_Questions.doc*). Themes to be explored will include: varying perceptions of need for treatment, stigma attached to treatment-seeking, concerns about risks of treatment, and practical or logistical barriers. Results from patient focus groups and provider input will be used to revise and adapt the outreach methods and content.

We anticipate the length of each focus group to be between 1.5 and 2 hours per meeting. Focus groups will be audio recorded and transcribed by a professional transcriptionist. All identifiers will be removed during the transcription phase (e.g., names). During the meeting participants will be asked to only use their preferred (first) name.

The perspective of primary care providers about barriers to treatment initiation and integration of outreach interventions with health systems workflow is also important. Ten primary care providers at each site who have made at least 10 new diagnoses of depression during the past year, will be briefly surveyed regarding perceptions of common patient and procedural barriers to treatment initiation (*Provider Survey Questions.doc*). Providers will be contacted either digitally (through e-mail or EPIC portal) to request their participation (*Provider Recruitment Email.doc & Provider_Information_Sheet.doc*). We may provide a small token of appreciation equivalent to no more than $10.00 to primary care providers (e.g., cookies, a gift bag, or a gift card). Providers will be recruited digitally to complete a brief 10-minute survey (*Provider Recruitment Email.doc*). We will work with clinical liaisons within each health system to recruit eligible providers. Invitations to providers will either be sent by the Site-PI or a designated clinical partner (e.g., Dr. Stacey Honda at KPHI). The survey invitation will contain an informational sheet (*Provider_Information_Sheet.doc*) that will be attached to the electronic message and attached as an attachment.

Research Assistants will be informed that they must contact the PI immediately via telephone and email if a participant indicates during any participant contact. The Research Assistant will inform the participant that the Study PI will follow-up with them. Whenever possible, a warm handoff will occur between the Research Assistant and PI. The PI will immediately contact the participant (via telephone or in person depending on when/where distress is indicated) and conduct a risk assessment as well as offer referral resources for that participant within the health care system and the National Suicide Prevention Hotline. The two site PIs are both licensed clinical psychologists with experience conducting and assessing for risk. The risk assessment will include determining if the participant is experiencing thoughts of harming themselves or others, intention to harm self or other, means to harm self or other, past history of self or other harm, as well as protective factors from engaging in self or other harm. If the participant is deemed moderate to high risk (indicates intent to harm self or other, demonstrates acute distress), the PI will remain with the patient until a warm handoff is made to a provider within the health care system. Emergency services, including calling 9-1-1, will be used if indicated to ensure participant safety.

Participants will also be provided with information regarding referral services upon request. These will include services offered within the health care system (i.e., the telephone for behavioral health, health care system approved Apps and digital interventions) as well as national hotlines such as the National Suicide Prevention Hotline

**Phase III:**

The structured outreach and care facilitation intervention will adapt procedures and tools developed and proven successful in the current MHRN automated outreach project as well as other outreach and care management interventions developed and tested by MHRN investigators[10, 23, 29].

A chart review document has been created to facilitate the outreach clinicians in obtaining relevant and tailored information for the outreach messages. The chart review sheet will also be used for quality assurance purposes as it will ensure that information obtained through the algorithm is reflective of what is in the current medical record. The chart review document is included with the modification package (see document Chart Review Document).

Specific components include:

Initial outreach messages – Outreach messages will be sent via health system EHR (Epic) patient portal messaging systems (see document ORDTD Scripts_9.27.22) . This system supports secure and confidential two-way exchange of free-text messages and tracking of read/unread messages. Text for initial outreach messages will be based on messages developed and refined in the ongoing MHRN automated outreach project, further refined using formative feedback from focus groups described above.

Online messaging and telephone follow-up – Following procedures developed and tested in the messaging collaborative care trial and the ongoing Suicide Prevention Outreach trial[30], outreach clinicians will follow a structured protocol for outreach if there is no response to the initial message:

- If initial message is not read – up to three telephone outreach attempts

Based on previous experience, we expect that most telephone outreach would involve leaving telephone message reminders regarding patient portal messages rather than live contact with participants. We have developed a phone script (see document Phone_Script_Outreach). For participants with PHQ-9 score >=15 or response to item 9 >=2, initial contact will be by telephone. For participants with PHQ-9 score less than 15 and a response <2 to PHQ-9 item 9, initial contact will be by online message. Using motivational interviewing scripts and tools developed in previous research programs[23, 30], outreach clinicians will assess readiness and respond with appropriate tailored interventions focused on either motivational enhancement or action planning. Depending on clinical need, outreach clinicians will also assess risk of self-harm, initiate safety planning, and facilitate urgent mental health care (Safety Protocol document).

Monitoring initiation and adherence – Based on experience in the MHRN Suicide Prevention Outreach Trial and Automated Outreach project, outreach clinicians will track reading outreach messages as well as initiation of and early adherence to depression treatment (either medication or psychotherapy) using EHR-based population management tools (Epic Registry and Reporting Workbench functionality).

Outreach clinicians – Outreach clinicians will be either registered nurses or masters-prepared mental health clinicians. Following a typical model for implementation of collaborative care or care management programs, outreach clinicians will receive approximately 8 hours of initial training and will participate in bi-weekly supervision teleconferences during the period of active intervention delivery.

Identification of Study Participants (Phases I and II):

The following criteria will be used to guide identification of participants for the formative evaluation (Phase II focus groups) as well as a clinical trial (Phase III). *However, during the Phase II we will also invite participants who have initiated treatment following a new depression diagnosis to ensure this perspective is also represented in the focus groups.

Using a computable EHR phenotype developed and validated in MHRN research[1], these data warehouses (e.g., VDW, Clarity) at each site will be used to identify adult patients meeting the following criteria:

- New diagnosis of major depressive disorder or dysthymic disorder at a primary care visit ("new" defined as no depression diagnosis, psychotherapy visit or filled antidepressant prescription in the prior year)
- Continuously enrolled in the participating health system for 365 days prior to the eligible diagnosis (to assure capture of prior diagnoses or treatments)
- PHQ-9 depression score of 10 or more within 14 days before to 7 days after the eligible diagnosis
- No filled prescription for any antidepressant medication OR psychotherapy visit attended within 30 days of the eligible diagnosis*
- No recorded PHQ-9 depression score less than 5 since the eligible diagnosis
- At least 18 years of age or older

The KP Hawaii site will enroll only patients who self-identified (based on EHR data) as Asian or Native Hawaiian or Other Pacific Islander. The Henry Ford site will enroll only patients self-identified as African American or Hispanic.

Potential participants will be excluded because of:

- Diagnosis of schizophrenia or bipolar disorder in the prior 2 years
- Not registered to use EHR patient portal
- Previously requested to not be contacted for research

**Pilot Trial Design**

Each week, the computable EHR phenotype described above will be used to identify patients meeting criteria for failure to initiate depression treatment during the prior week. All eligible participants will be randomly assigned either to continued usual care (i.e. no contact from study staff) or to an outreach intervention described above. Engagement in care and recorded clinical outcomes over the subsequent 60 days will be assessed using health system records.

***Intervention Assignment -*** All eligible patients will be randomly assigned (1:1 ratio) to either continued usual care or attempted outreach using a masked table of computer-generated random assignments. Randomization will be stratified by study site and use a permuted block design, with randomly varying block sizes of 4, 6, 8, 10 and 12.

**12.3 * Provide a brief description about the quality management plan for the selection of study participants and integrity of the data. Specify the verification or audit process to ensure data and/or participants meet the study inclusion criteria. Additionally, describe the mechanism to ensure that study data is well secured and accurately entered. (e.g. two staff verification process to ensure entry criteria are met prior to using data or including a participant; safety reports; Data Safety Monitoring Board and/or screening checklists.)**

- All staff will be training in HIPAA privacy rules, human subjects protections, authorization of access by CIHR/HFHS IT, password protection, encryption, physical security, and separation of identifiers from data
- We plan to archive the deidentified data at the end of the study for the federally-mandated retention period or at least seven years, whichever is later.
- A Data Use Agreement will be executed between all sites prior to the transfer of any data. Data exchanged between the sites will contain the minimal information necessary and will be in the form of a limited data set.
- Data will be stored on password-protected encrypted devices and servers.

No identifying information will be linked to the audio-recordings of the focus groups interviews. Participants will not be asked to state their name for voice linking. Audio-recordings will be sent to a professional transcriptionist via secured transfer. Once the transcription is received the audio-file will be permanently destroyed. All data will be transferred from an encrypted computer, which is password protected, to a secured server during data collection. Identifiers will be removed from all data obtained in this study and identifiers will be destroyed following the completion of the study, prior to closure of the IRB protocol.

We will convene a Data and Safety Monitoring Board including:

- A clinician with expertise regarding psychotherapy for depression (Dr. Shiloh Jordan, VA Pacific Islands Health Care Division)
- A clinician with expertise regarding medication treatment for clinician (Dr. Roy Perlis, Harvard University)
- A statistician with expertise regarding effectiveness or pragmatic trials (Dr. MargaretAnne Mackintosh, National Center for PTSD, Palo Alto)

DSMB members will not be affiliated with research centers or health systems participating in this study.

The DSMB will meet three times during the pilot trial portion of the project:

- One meeting prior to beginning enrollment to review all study procedures

- One meeting when approximately half of the planned sample has been enrolled to review enrollment progress, quality/fidelity of intervention delivery, and any adverse events identified by or reported to study staff
- One meeting when the full sample has been enrolled to review enrollment progress, quality/fidelity of intervention delivery, any adverse events identified by or reported to study staff, and quality/integrity of outcome data

The DSMB will have authority to:

- Require changes to study procedures
- Terminate enrollment because of inadequate progress
- Terminate delivery of interventions because of concern regarding effective or safe delivery

Given the sample size, the relatively short recruitment period, and the delay in availability of outcome data extracted from health system records; we do not propose any interim analyses of study outcomes. Interim analyses prior to completion of enrollment would not have adequate power to detect either significant benefit or significant harm from the outreach intervention

**12.4 * Provide a description of the Statistical Analysis Plan (including rationale for number of subjects recruited for the study and the statistical method(s) by which the data will be analyzed)**

Based on previous MHRN research, we presume that 10% of participants assigned to usual care will initiate treatment within 60 days of randomization (after not initiating treatment in the first 30 days after diagnosis) and that only 2% will disenroll from participating health systems (i.e. outcome data not available) within 60 days. A sample size of 200 per group across both sites will afford 90% power (chi-square statistic with 2-sided type 1 error of 5%) to detect an increase from 10% to 22% in those assigned to the outreach intervention. Within any specific racial or ethnic group, the anticipated sample size of approximately 50 per group would afford 80% power to detect an increase from 10% to 33% in those assigned to the outreach intervention. In other words, this pilot study will have adequate power to detect moderate to large increases in treatment initiation and will not have adequate power to examine effects on ultimate clinical outcomes (i.e., HEDIS response and remission rates).

The primary trial outcome will be initiation of formal depression treatment within 60 days of randomization, defined as either at least one filled prescription for any antidepressant medication or attending at least one individual psychotherapy visit. Two secondary outcomes (recording of depression remission or response) will be defined and assessed using NCQA/HEDIS Electronic Clinical Data Systems specifications for depression response and remission[31]. Those specifications identify recorded response (i.e. 50% or greater decrease in PHQ-9 score from baseline) and remission (i.e. any recorded PHQ-9 score of less than 5) among all patients with new diagnoses and baseline PHQ9 scores of 10 or higher. Following HEDIS specifications, failure to record clinical outcome will be considered failure to achieve response or remission.

Descriptive analyses will examine baseline participant characteristics (age, sex, baseline PHQ-9 score, history of prior depression treatment) and examine uptake or acceptance of specific intervention activities, including:

- Proportion of intervention participants reading initial outreach messages
- Proportion responding to initial outreach and completing outreach assessment
- Proportion of those not responding to online messages who respond to subsequent telephone outreach
- Distribution of PHQ-9 responses, perceived need for treatment, and perceived treatment barriers among those completing outreach assessment (by online messaging or telephone).
- Proportion initiating any treatment or specific type of treatment (medication or psychotherapy) according to response to outreach, PHQ-9 score at initial assessment, perceived treatment need at initial assessment, and perceived barriers to treatment at initial outreach.

Sample size permitting, each of these analyses will be stratified by race/ethnicity group.

Analyses of primary outcomes will compare rate of treatment initiation within 60 days (defined above) among all patients originally assigned to the intervention condition to the rate among those assigned to continued usual care, regardless of acceptance of or participation in the outreach intervention (i.e. intent-to-treat analysis). Unadjusted comparisons will use chi-square statistics to compare rates, and adjusted analyses will use logistic regression, adjusting for age group, history of prior depression treatment (medication or psychotherapy), baseline PHQ-9 score, and site. Analyses of secondary outcomes (depression remission and response by HEDIS specifications) will follow the same scheme.

We do not propose any "as treated" or "per protocol" analyses limited to patients who accept or respond to outreach interventions. Because it is not possible to identify usual care patients who would have declined intervention services, any comparison of intervention "accepters" to the full usual care sample would be fundamentally and irreparably biased.

**12.5 * Provide the approximate time needed to complete the research at KPSC.**

| | Year 3 | | | | Year 4 | | | | Year 5 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **TASK** | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| Obtain initial IRB approvals | X | X | | | | | | | | | | |
| Develop focus group recruitment materials and content guide | | X | | | | | | | | | | |
| Develop provider survey guide and finalize methods | | X | | | | | | | | | | |
| Develop and test EHR programming for case ID and secure information exchange | | X | X | X | | | | | | | | |
| Obtain IRB approval for focus group and provider survey protocols | | X | | | | | | | | | | |
| Conduct patient focus groups | | | X | X | | | | | | | | |
| Conduct provider surveys | | | | X | X | | | | | | | |
| Finalize outreach materials and protocol | | | | | X | | | | | | | |
| Obtain IRB approval for finalized outreach materials and protocol | | | | | | X | | | | | | |
| Outreach patient enrollment | | | | | | X | X | X | X | | | |
| Outcomes measurement/data analysis | | | | | | | | X | X | X | | |
| Results reporting | | | | | | | | | | | X | X |

**13.0 General Section: Research Study Summary**

## Special Population (S5a)

**13.1 * Will data on any of the following vulnerable populations be included in your study?**

Groups not identified for inclusion below must be listed in the exclusion criteria under "General Section: Research Study Summary Methods S4 (Study Procedures)"

**NOTE FOR DATA ONLY STUDIES:** If pulling data by condition, select all populations where there is a reasonable possibility that data for this population may be included in the study.

**NOTE FOR NON-DATA ONLY STUDIES:** Select all populations where there is a reasonable possibility that the population may be included in the study.

- [ ] Economically disadvantaged
- [ ] Educationally disadvantaged
- [x] Employees
- [ ] Minors (under age 18)
- [ ] Persons who are cognitively impaired
- [x] Persons who are mentally ill
- [ ] Persons unable to speak and/or read English (If yes, please specify language)
- [x] Pregnant women
- [ ] Other (Please specify)
- [ ] None

Please specify Language and/or Other:

**14.0**

## General Section: Research Study Summary

## Special Population (S5b)

**14.1 Provide either a description of the plans to include pregnant women. If pregnant women will be excluded from the proposed research, present an acceptable justification for the exclusion. Acceptable justification for exclusion is in respect to the health of the subjects or the purpose of the research.**

PHASE 1: Data on pregant women may be collected, however not targeted.

PHASE 2 and 3: Pregnancy is not targeted, however it is possible that women who are pregnant may participate in the focus group if they meet the eligibility criteria and are willing to particicpate.

It is possible that a pregnant woman might be enrolled if she meets other eligibility requirements. We would like to include pregnant women because pregnancy can often be a trigger for depression.

**14.2 * Provide a description of the recruitment methods of pregnant women as subjects.**

Pregnant women will be recruited in the same manner as other individuals. Participation will be voluntary free of coercion and they will be provided the opportunity to opt out at any time.

**14.3 * Provide either a description of the plans to include non-English speaking or minority groups. If non-English speaking or minority groups will be excluded from the proposed research, present an acceptable justification for the exclusion. Provide the percentage of patients that will be potentially excluded based on language selection and how the percentage was determined. Acceptable justification for exclusion is in respect to the health of the subjects or the purpose of the research.**

Phase 1 of this study is data collection only and language is not a targeted data variable.

Phase 2 & 3: We are not planning to enroll non-English speakers because the focus groups and outreach messages will be conducted in English. We anticipate between 2-5% of our sample will be non-English speaking and therefore we will still have adequate representation from diverse populations while excluding these individuals due to language and translation barriers.

**14.4 * Provide a description of the recruitment methods of non-English speaking or racial/ethnic group members as subjects (e.g. translation of documents, use of the short form process, culturally sensitive staff).**

Not Applicable

**14.5 * Provide either a description of the plans to include children. If children will be excluded from the proposed research, present an acceptable justification for the exclusion. Acceptable justification for exclusion is in respect to the health of the subjects or the purpose of the research.**

Children will not be recruited because we are only studying adult depression.

**14.6 * Provide a description of the expertise of the investigative team for dealing with children. Include in response the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.**

Not Applicable

## 15.0 Participants (S1)

**15.1 * If there will be direct contact with human subjects, what will be the method of contact?**

- [ ] In-person
- [x] Internet/e-mail (script required)
- [x] Letter (script required)
- [x] Telephone (script required)
- [ ] Text Messaging (script required)
- [ ] Other (please specify)
- [ ] No direct contact

If other, please specify:

**15.2 * Which subject contact documents are being submitted now for review with this application:**

- [ ] Consent Form
- [x] Internet/E-mail Script
- [ ] None
- [ ] Provider Contact Letter
- [ ] Recruitment Flyer
- [ ] Reply Post Card
- [ ] Study Questionnaire
- [ ] Subject Contact Letter
- [x] Telephone / Text Messaging Script
- [x] Other (Please Specify)

If Other, please specify:

In this current package we are including the following documents, in addition to those marked above: Safety protocol procedures, Chart review document, Crisis response tracking database

Please upload the recruitment documents

| Version | Sponsor Version | Title | Category | Expiration Date | Document Outcome | Checked Out | View Document |
|---|---|---|---|---|---|---|---|
| 1.3 | | Provider_Information_Sheet_Revised_11.16.21 | Participant - Recruitment Materials | | Approved | | 17.03 KB |
| 1.1 | | Provider Recruitment Email_Revised_11.15.21 | Participant - Recruitment Materials | | Approved | | 14.01 KB |
| 1.3 | | 3C Patient_Invitation_Letter_Revised_11.16.21 | Participant - Recruitment Materials | | Approved | | 16.57 KB |
| 1.3 | | Follow-up Informational Letter for Verbal Consent Participants_Revised_11.16.21 | Participant - Recruitment Materials | | Approved | | 25.01 KB |

**15.3 * Is this study Food and Drug Administration regulated?**

○ Yes ◉ No

**15.4 * Will an investigational drug(s) or biologic(s) be used in this study?**

○ Yes ◉ No

Please select drug(s)/biologic(s)

| View Details | Drug Name | FDA Approved | A new drug or a new use of an already approved drug: | IND Number |
|---|---|---|---|---|
| No drugs have been added to this Study | | | | |

If drug(s)/biologic(s) are not available, list the name of investigational agent(s) and Investigational New Drug Application (IND) and filing number. **If you entered a drug in the above field, enter N/A in the text box**:

**15.5 * Will an approved drug(s) be used in this study for a non-approved purpose, delivery, or dosage?**

○ Yes ◉ No

## 16.0 Participants (S2)

**16.1 * Will an investigational device(s) be used in this study?**

○ Yes ◉ No

Please enter the device(s)

| View Details | Device Name |
|---|---|
| No devices have been added to this Study | |

**16.2 * Will a non-investigational device(s) be used in this study?**

○ Yes ◉ No

If yes, enter device(s) names.

**16.3 * Will genetic or pharmacogenomic testing be part of this study?**

○ Yes (Identify the procedures/tests, the organizational affiliation of those who will conduct the genetic or pharmacogenomic testing and the storage and disposal protocol for the genetic material.)
◉ No

## 17.0 Participants (S3)

**17.1 Has a "Certificate of Confidentiality" been obtained for this research study?**

◉ Yes
○ No

## 18.0 Participants (S4)

**18.1 * Will Gene therapy/Gene transfer/Recombinant DNA/Biohazardous agents be a part of this study?**

○ Yes ◉ No

## 19.0 Participants (S5)

**19.1 * Will any research participant be exposed to more than the standard level of ionizing radiation?**

○ Yes ◉ No

If different from standard of care, has the protocol been submitted to the Research Radiation Safety Committee (See SOP KP-201, Radiation Exposure at **http://scalresearch.kp.org/irb/sop.html**)?

○ Yes ◉ No

**If yes,** please upload approval notice from the Research Radiation Safety Committee. **If no,** please continue.

| Version | Sponsor Version | Title | Category | Expiration Date | Document Outcome | Checked Out | View Document |
|---|---|---|---|---|---|---|---|

No Document(s) have been attached to this form.

**19.2 * Check any of the following research procedures that will be conducted:**

- [ ] Alcohol / Drug Testing
- [ ] Cell-line creation
- [ ] HIV Testing
- [x] None
- [ ] Pregnancy Testing
- [ ] STD / Hepatitis Testing

## 20.0 Research Questionnaire (S1)

**20.1 * If existing data / biospecimens will be used in this study, from which sources will data or records be retrieved?**

- [x] Medical record (paper or HealthConnect)
- [x] Disease registry or any database maintained within KPSC, e.g. POINT, Cancer Registry (specify below)
- [ ] Research or non-routine laboratory, radiology, or other reports (specify below)
- [ ] Sensitive patient data, e.g., STD tests, HIV tests, genetic marker tests, etc. (specify below)
- [ ] Data from previous KPSC IRB approved research (specify below)
- [x] Other (specify below)

Specify below:

Virtual Data Warehouse, Clarity

**If any source above is selected, attach a copy of either a case report form, data abstraction sheet or data element form**

| Version | Sponsor Version | Title | Category | Expiration Date | Document Outcome | Checked Out | View Document |
|---|---|---|---|---|---|---|---|
| 1.0 | | Data Abstraction Sheet Template_VS | Study - Data Abstraction Form - Case Report Form | | Approved | | 22.93 KB |

**Please note, you must obtain permission for access to the data from the appropriate KPSC department(s).**

## 21.0 Research Questionnaire (S1a)

**21.1 * Will this study require access to databases, medical records, other automated KPSC electronic data sources or confidential information?**

- (•) Yes
- ( ) No

**21.2 * Please estimate the number of individuals that will be included in your study for data analysis after applying study inclusion and exclusion criteria. This number of individuals applies to all patients *you plan to access data from* using either an electronic database or paper chart. The number of individuals provided here will serve as your sample size for the data component of the study and exceeding this number will result in a protocol deviation unless a modification to increase the sample size has been approved.**

*Please exclude decimal points or commas in your answer.*

448

Specify number of KPSC participants:

448

Specify number of Non-KPSC participants:

0

☐ None, no electronic data, including medical records, will be reviewed for this study

## 22.0 Research Questionnaire (S2)

**22.1 If subjects will be recruited into the study, describe the recruitment method(s). Identify who (organizational affiliation and position) will invite member participation in the study. Append to your application copies of proposed recruitment material (s) (e.g., introduction letter, e-mail, flyers).**

Recruitment methods for Phase II are outlined below:

Phase II:
Focus Groups: During Phase II participants will be sent a letter that incorporates the elements of consent and provides general information about the project and focus groups (Patient_Informational_Letter.doc). When possible, this letter will also be sent via secure messaging though the electronic health record (e.g., Kp.org or MyChart). Participants will be informed in the letter that a member of the study team will call them to invite them to participate, answer any questions they have, and ask them questions about their experiences with mental health treatment, if any. Research assistants will call potential participants up to four times, leaving a call back number if/when possible. The research assistant will review the information that was included in the initial mailing, obtain verbal consent, and confirm the participants response for attendance (Phone_Script_Focus_Group.doc). Focus groups may take place in person (conditions permitting) or via video-teleconferencing. Participants who confirm their interest in attending the focus group will be sent another mailing via e-mail or postal mail (E-Mail or Mailing Reminder for Confirmed Participants.doc), detailing information about the focus group (e.g., time of the focus group, location/link to join, etc.). One week prior to the focus group meeting, a research assistant will contact all confirmed participants to remind them (email/phone per their preference) of the upcoming meeting (Reminder_Call_Script_1-week prior.doc & E-Mail or Mailing Reminder for Confirmed Participants.doc). At this time, the research assistant will offer to answer any questions the participant may have.

We anticipate the length of each focus group to be between 1.5 and 2 hours per meeting. Focus groups will be audio recorded and transcribed by a professional transcriptionist. All identifiers will be removed during the transcription phase (e.g., names). During the meeting participants will be asked to only use their preferred (first) name. The number of recruitment attempts will be limited to 4.

Provider Survey: Providers will be recruited digitally to complete a brief 10-minute survey (Provider Recruitment Email.doc). We will work with clinical liaisons within each health system to recruit eligible providers. Invitations to providers will either be sent by the Site-PI or a designated clinical partner (e.g., Dr. Stacey Honda at KPHI). The survey invitation will contain an informational sheet (Provider_Information_Sheet.doc) that will be attached to the electronic message and attached as an attachment.

Phase III:

Once a participant is determined to be eligible for the study using the algorithm described in previous sections, the participant will be randomized to either standard care or outreach messaging groups. Participants randomized to standard care will not be contacted by the project team. Follow-up data will be collected (see previous section) regarding treatment initiation and depression remission (follow-up PHQ-9 scores) for 60 days after randomization for standard care participants. Participants randomized to the outreach group will receive either an initial phone call or secure message from the study team. For participants with PHQ-9 score less than 15 and a response <2 to PHQ-9 item 9, initial contact will be by online message. For participants with PHQ-9 score >=15 or response to item 9 >=2, initial contact will be by telephone. Up to four outreach attempts will be made per participant. If initial outreach occurs by secure message and it is not read within three days of sending, up to three telephone outreach attempts. Telephone outreach will take two times in one week, and then two weeks following the last attempt.

We propose a waiver of the usual requirement for informed consent to identify potential participants and assign patients to either continued usual care or attempted outreach. We believe that this approach (waiver of consent in such a modified Zelen or randomized encouragement design to evaluate a low-risk outreach intervention) satisfies regulatory requirements and ethical standards for waiver of consent. Use of this approach in similar previous MHRN trials has been vetted with the DHHS Office for Human Research Protections and approved by MHRN health system institutional review boards.

For participants assigned to outreach, the initial outreach message will include abbreviated informed consent information, including (see outreach message consent document):
• Description of the outreach program
• Notification that outreach is part of a research project
• Advice that participation is voluntary and instructions on declining further participation

## 23.0 Research Questionnaire (S2a)

**23.1 Describe the methods you will use to ensure protection of confidential information.**

All staff will be training in HIPAA privacy rules, human subjects protections, authorization of access by CIHR/HFHS IT, password protection, encryption, physical security, and separation of identifiers from data.
We plan to archive the deidentified data at the end of the study for the federally-mandated retention period or at least seven years, whichever is later. A Data Use Agreement will be executed between all sites prior to the transfer of any data. Data exchanged between the sites will contain the minimal information necessary and will be in the form of a limited data set. Data will be stored on password-protected encrypted devices and servers.

**23.2 Describe the mechanism you will use to share, send out or transfer participant identifying information across KPSC departments (e.g. KPSC email, KPSC share drive, KPSC SharePoint) and external to KPSC (e.g., RedCap, US Mail, UPS).**

***NOTE:** KP National Policies prohibit storing personal identifying information (PII) and/or protected health information (PHI) on a personally owned device unless an exception is granted. KP National Policies also prohibit sending PII and/or PHI to a personal email address, even if the email is encrypted during transmission.

Please refer to the following policies

- **NATL.IS.017 Use of Personally Owned Devices Policy**
- **Secure Electronic Communication NATL.IS.010 v.3 (policytech.com)**

A Data Use Agreement will be executed between all sites prior to the transfer of any data. Data exchanged between the sites will contain the minimal information necessary and will be in the form of a limited data set. Data will be stored on password-protected encrypted devices and servers. KP Secure file transfer will be used to transfer data between sites. Encrypted e-mail will also be used within and between sites whenever possible.

**23.3 Describe the personally identifiable information (PII) that will be sent out or transferred across KPSC departments and externally. (e.g. MRN, DOB, Social Security Number, Name) and provide the name(s) of the individuals receiving the information.**

***NOTE:** PII is information that when used alone or in combination with other relevant data can identify an individual.

Only a limited data set will not be shared between non KPS Hawaii sites. PHI will be limited to an as needed basis (e.g., contact information for recruitment purposes) and will only be shared amongst KP Hawaii study staff within each site. Sorry for the confusion, Daria. The contact information will remain within each site and not be shared between sites. As in, if a person is identified as eligible from KPHI (by KPHI analyst), this would be shared with the study personnel within KPHI only (i.e., PI, research assistant) for the purpose of recruitment. Similarly, the same would apply for Henry Ford—we (at KPHI) would not receive any of their participant's contact

information—it would only be accessed by their team and used internally for their recruitment purposes. The limited dataset that would be shared between sites would include elements like date of diagnosis, date of psychotherapy appointment, date of prescription fill. These would be for data analysis purposes.

**24.0**

## Research Questionnaire (S3)

**24.1 * Will a repository be used or developed as part of this research? A repository or "tissue bank" is a collection of biological specimens whose organizers: 1) Receive specimens from multiple sources, 2) Maintain the specimens over time, and 3) Control access to and use of specimens by multiple individuals and/or for multiple purposes, which may change over time.**

- ○ Yes
- ◉ No
- ○ Not Applicable

If yes, describe if it is existing or to be developed and how you are using the repository to support your research plan.

**24.2 * Will the study require a written informed consent document?**

- ○ Yes
- ◉ No

**25.0**

## Waiver of Informed Consent

**25.1 * Please answer the following five questions to determine waiver or alteration of informed consent.**

Does the research involve no more than minimal risk to the subjects?

◉ Yes ○ No

Will the waiver adversely affect the rights and welfare of the subjects?

○ Yes ◉ No

Is the waiver or alteration necessary to practicably carry out the research?

○ Yes ◉ No

If the research involves using identifiable private information or identifiable biospecimens, could the research be practicably carried out without using such information or biospecimens in an identifiable format?

- ○ Yes
- ◉ No
- ○ Not Applicable

Whenever appropriate, will the subjects or legally authorized representatives be provided with additional pertinent information after participation in the research?

- ☐ Yes
- ☐ No
- ☑ Not Applicable

**25.2 * Are you requesting from the IRB a waiver of the requirement so that a participant does not sign a written informed consent document for this study?**

(•) Yes ( ) No

If **YES**, explain how the only record linking the participant to the research would be the consent document and the primary risk would be potential harm resulting from a breach of confidentiality; or the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. An informational sheet will be provided to participants of the focus groups (Phase II). 3. We anticipate that the focus groups will likely take place virtually given the circumstances of the ongoing pandemic as well as the geographic diversity of the Hawaiian islands and broad catchment area of Henry Ford Health System. However, it is possible that if technology issues exist that would prevent participants from attending that we would host a small group at a health care system facility to join the virtual meeting. Given that we at the very least anticipate a blended format, if not entirely virtual it would not be feasible to obtain signed consent from all participants.

We are requesting a waiver of written consent and an alteration to consent (use of abbreviated consent) for Phase III of this study. Participants in the standard care group will not be contacted by participants and only data already collected within the health care record will be used. For participants assigned to the outreach group, we are requesting to include an abbreviated consent in the initial outreach message (via secure message or phone). Participants in this research study are not being asked to complete any study procedures. The intervention is strictly the use of outreach messages. See Outreach Message Consent document.

**26.0**

# HIPAA Privacy Rule (S1)

**26.1 * In the conduct of this study, will you have access to subjects *Protected Health Information (PHI)*? *Protected Health Information (PHI)* is identifiable health information that includes any demographic or other descriptive information that could link the identity of an individual to his or her health information. The Privacy Rule lists 18 identifiers that alone or in combination are components of PHI. (Click here for a list of the 18 identifiers).**

(•) Yes ( ) No

**27.0**

# HIPAA Privacy Rule (S2)

**27.1 * Who within the KP entities (e.g., KFHP, KFH, PMG) within your Region will use (i.e., have access to- see Privacy and Security Glossary) the Protected Health Information (PHI) in the context of this research?**

- [x] Principal Investigator
- [x] Research nurse(s)
- [x] Research assistant(s)
- [x] Programmer(s)/ IT
- [ ] Co- or Sub-investigator(s)
- [ ] Pharmacist(s)
- [x] Statistician(s)/ Analyst(s)
- [ ] Other(s) (please specify)

**If other,** please specify:

**27.2 * Will anyone not on KP's workforce have access to Protected Health Information in the conduct of this study?**

(•) Yes ( ) No

**27.3 * Will a Non-Kaiser Permanente Southern California Co-Investigator have access to Protected Health Information (PHI) in any form (oral, written or electronic) in the context of this research?**

( ) Yes
( ) No
(•) Not Applicable

**If yes,** upload a signed Confidentiality Agreement.

| Version | Sponsor Version | Title | Category | Expiration Date | Document Outcome | Checked Out | View Document |
|---|---|---|---|---|---|---|---|
| No Document(s) have been attached to this form. | | | | | | | |

**27.4 * Does the data being used or created for this study qualify as a *Limited Data Set*? A *Limited Data Set* is health information that can only include dates (e.g., admission, discharge, service dates, birth/death dates and age) and geographic descriptors (e.g. zip codes, state, county, city and precinct, but not street addresses) but must exclude other identifiers. See the HIPAA Research Glossary.**

( ) Yes (•) No

**28.0**

# HIPAA Privacy Rule (S3)

**28.1 * Do you anticipate that your study will have an informed consent form including a Privacy Rule Authorization section for participants to sign?**

( ) Yes, study will include an informed consent form with a HIPAA authorization
(•) No, an informed consent form will not be used

**29.0**

# HIPAA Privacy Rule (S5)

**29.1 * Are you requesting a waiver of the requirement for a signed authorization to use or disclose Protected Health Information either for the entire study or any portion of it (e.g., medical record review to determine eligibility or for recruitment portion of a clinical trial)? Disclosure of Protected Health Information means releasing, transferring, providing access to, or divulging Protected Health Information to individuals not on KPSC's workforce.**

(•) Yes, entire study
( ) Yes, partial waiver (specify the portion below)
( ) No

**If yes** and **partial**, describe portion.

**30.0**

# HIPAA Privacy Rule
# (S5a)

**30.1 Describe why the research could not be done if you were required have each individual sign a HIPAA authorization to allow use of their *Protected Health Information for this study*.**

It would be impractical to have each proposed participant sign an authorization form, given the nature of the research protocol. As a pragmatic trial, we will not be contacting participants prior to randomization in the clinical trial. Participants in the control group will have no contact from the study staff and we will only track outcome data for these participants. Further, the population may be difficult to reach and some individuals may have outdated contact information.

We are requesting a waiver to written authorization for the use or disclose of PHI for Phase III (clinical trial). This will allow our programmer analysts to identify eligible participants using the electronic medical record for randomization and track outcomes already collected within the EHR. It is not feasible to conduct this research without this waiver of authorization. A signed authorization would also be another piece of identifiable information, which we are trying to minimize.

Only CIHR or HFHS programmer analysts who have undergone training in HIPAA privacy will access the data in the EMR (after IRB approval is obtained). Data extracted from the EHR with encrypted patient identifiers will be stored electronically on password-protected encrypted devices.

**30.2 * Does the use or disclosure of Protected Health Information for this study present no more than minimal risk to the privacy of the individuals whose Protected Health Information will be accessed?**

(•) Yes ( ) No

**30.3 * Describe your plan to protect any identifiable information from improper use or disclosure.**

All staff will be training in HIPAA privacy rules, human subjects protections, authorization of access by CIHR/HFHS IT, password protection, encryption, physical security, and separation of identifiers from data.

We plan to archive the deidentified data at the end of the study for the federally-mandated retention period or at least seven years, whichever is later. A Data Use Agreement will be executed between all sites prior to the transfer of any data. Data exchanged between the sites will contain the minimal information necessary and will be in the form of a limited data set. Data will be stored on password-protected encrypted devices and servers.

**30.4 * Describe your plan to destroy any identifiers at the earliest opportunity or provide a rationale for retaining the identifiers.**

Data will be maintained for the federally mandated period, or for at least seven years, whichever is longer. Identifiers (PHI and PII) will be removed as soon as feasibly possible and only retained as needed for meet the study objectives. Information will be maintained for participants who decline participation use a tracking database (e.g., Access or Excel) to ensure they are not subsequently recruited following declining participation. Upon completion of the recruitment phases, this information will be destroyed immediately.

**30.5 * Describe why the research could not be done without access to the *Protected Health Information*.**

As described above, it is not practicable to conduct the research in Phases I, II or III without a waiver of HIPAA authorization. We cannot know which subjects qualify for Phase III until we perform this initial data query.

This study is minimal risk to subjects' privacy. Only CIHR or HFHS programmer analysts who have undergone training in HIPAA privacy will access the data in the EMR (after IRB approval is obtained). Data extracted from the EMR will include encrypted patient identifiers and will be stored electronically on password-protected encrypted devices.

**30.6 * Is the Protected Health Information that you are requesting to use or disclose the minimum necessary to conduct this study?**

- (●) Yes
- ( ) No

**30.7 * How many individuals' Protected Health Information will be disclosed? Disclosure of PHI means releasing, transferring, providing access to, or divulging PHI to any individual or entity outside the KPSC Region." This includes sharing PHI between KP Regions.**

***NOTE:** KP National Policies prohibit storing personal identifying information (PII) and/or protected health information (PHI) on a personally owned device unless an exception is granted. KP National Policies also prohibit sending PII and/or PHI to a personal email address, even if the email is encrypted during transmission.

- ( ) No Protected Health Information will be disclosed
- ( ) Fewer than 50 individuals
- (●) 50 or more individuals

**31.0**

# HIPAA Privacy Rule (S5b)

**31.1 What type of Protected Health Information will be disclosed?**

- [x] Clinical/ Diagnostic
- [x] Health Care
- [x] Demographic

**32.0**

# HIPAA Privacy Rule (S6)

**32.1 * Will you disclose Protected Health Information only as a Limited Data Set?**

- (●) Yes
- ( ) No

**33.0**

# HIPAA Privacy Rule
# (S7)

**33.1 Name of the recipient (individual or entity) receiving the Limited Data Set, including contact name and telephone number:**

Gregory Simon, KP Washington
Henry Ford Institution (Collaborator)

**33.2 Will the recipient be a Service vendor contracting with Kaiser Permanente to support this research, such as mailing, survey, web hosting, data/specimen storage, laboratory service, and radiology services?**

○ Yes ◉ No

**33.3 What service will the recipient provide?**

Collaborating on the research and data analysis

**33.4 Name of the individuals or class of individuals (e.g., data analysts, etc.) permitted to use the Limited Data Set:**

Investigators
External Collaborator

**33.5 What information will be included in the Limited Data Set?**

The limited dataset that would be shared between sites would include elements like date of diagnosis, date of psychotherapy appointment, date of prescription fill. These would be for data analysis purposes.

**33.6 How will the recipient use the Limited Data Set? (e.g., analyze data, produce report, etc.)**

analyze data

**33.7 Will the recipient be permitted to re-disclose the information to a third party and if so, to whom? (names of the individuals or entities)**

No

**33.8 Will the recipient use sub-contractors with access to the Limited Data Set? (specify names)**

No

**33.9 In addition to disclosing Protected Health Information as a Limited Data Set, will you also be disclosing Protected Health Information which does not meet the criteria of a Limited Data Set?**

○ Yes
◉ No

**34.0**

# HIPAA Privacy Rule
# (S9)

**34.1 * If the study is a clinical trial, will participants be required to waive their right to access their Protected Health Information collected during their participation in the clinical trial? (Clinical Trial is a prospective biomedical or behavioral research study of human participants involving a licensed or investigational drug, device, biologic or behavioral intervention and is designed to answer specific questions about biomedical or behavioral interventions (e.g. treatments, devices, drugs, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine, whether new biomedical or behavioral interventions are safe and effective).**

- ○ The study is not a clinical trial.
- ○ Yes, participants will be required to waive their right to access their study records during the clinical trial.
- ◉ No

**35.0**

# HIPAA Privacy Rule
# (S10)

**35.1 Is this clinical trial registered at www.clinicaltrials.gov?**

Provide an attestation that the clinical trial is registered or a plan to register it at www.clinicaltrials.gov along with your application. (See Standard Operating Procedures KPSC-IRB-SOP 12 at **https://irb.kp-scalresearch.org/KPSC%20IRB%20SOP-012.pdf**)

◉ Yes ○ No

IRB Comment: Attestation is required to either confirm registration or plan to register. The IRB will accept any format. Most commonly submitted is a screen shot of registered trial with Clinical Trial.gov and IRB will also accept email communication from sponsor or PI indicating intention to register trial.

| Version | Sponsor Version | Title | Category | Expiration Date | Document Outcome | Checked Out | View Document |
|---|---|---|---|---|---|---|---|
| 1.0 | | Clinical Trials | Study - ClinicalTrials.gov Registration | | | | 480.71 KB |
| 1.0 | | Signed Attestation Clinical Trial Registration | Study - ClinicalTrials.gov Registration | | | | 19.88 KB |

**36.0**

# HIPAA Privacy Rule
# (S11)

**36.1 * Do you assure that you will only use and disclose Protected Health Information as described in this Application (i.e., the Protected Health Information will not be reused or re-disclosed to any other person or entity), except as required by law (any changes in use or disclosure will be approved by the IRB prior to implementation)?**

◉ Yes ○ No

## 37.0 Research Use of the Internet Questionnaire (S1)

**37.1**

**If you plan to use email or the internet, within or outside of KP, to 1) communicate with study participants or 2) to send participant information to a collaborator or contractor, you are required to complete this questionnaire.**

*** Will the internet or e-mail be used to either communicate with participants or transmit Protected Health Information (PHI) inside or outside of Kaiser Permanente Southern California?**

(•) Yes ( ) No

If yes, please indicate if it's **internet**, **email** or **both.**

[x] Internet
[x] Email

## 38.0 Research Use of the Internet Questionnaire (S2)

**38.1**

*** Will participants be asked to provide any information using the internet?**

(•) Yes ( ) No

## 39.0 Research Use of the Internet Questionnaire (S3)

**39.1**

*** What measures will be taken to ensure the Web server hosting the internet site is protected? (e.g., physical security, firewalls, software patches/updates, penetration drills, etc.)**

We will use only KP approved survey hosting software (RedCap) and will send electronic correspondence from within the KP Firewall. We will ensure that all software is updated with appropriate patches.

**39.2**

*** Will a password or other secure authorization method be used to allow access to the web site?**

( ) Yes (•) No

If yes, how will user passwords be distributed?

If yes, how will passwords and Web access be terminated?

**39.3 * Will the user session be encrypted?**

( ) Yes (•) No

If yes, what method of encryption will be used? (SSL, PKI, etc.)

If yes, will a minimum level of 128-bit encryption be used?

- ○ Yes
- ○ No
- ◉ Not Applicable

**39.4**

*** Who will have administrative access to data on the Web server? (provide names, study roles, and organizational affiliations)**

The PI, research assistant, project manager and programmer/analyst at each site will have access to data on the web server.

**39.5**

*** What administrative safeguards exist to restrict unauthorized and unnecessary access?**

KP approved software will be used only. Further, only authorized users with an account name and password designated to the program will be able to access the survey.

**39.6**

*** Who is the application owner (who maintains the application)?**

REDCap (KPSC)

**40.0**

## Research Use of the Internet Questionnaire (S4)

**40.1**

*** Will e-mail be used to contact participants?**

◉ Yes ○ No

If yes, how can participants be assured the communication is from an authorized person?

Only KP email accounts will be used to demonstrate integrity to each participant. No personal email addresses will be used by study staff for contacting or corresponding with participants.

**41.0**

## Research Use of the Internet Questionnaire (S5)

**41.1**

*** Will participants be asked to contact investigators using e-mail?**

○ Yes ◉ No

If yes, how will participants be authenticated to adequately ensure the source of the e-mail communication?

41.2

*** Does the study consent form discuss potential risks to privacy associated with use of e-mail?**

○ Yes ◉ No

## 42.0 Research Use of the Internet Questionnaire (S6)

42.1

*** Will e-mail be used to send study data to investigators, vendors or others inside or outside KP?**

◉ Yes ○ No

If yes, will the e-mail be encrypted?

◉ Yes
○ No
○ Not Applicable

If yes, will attachments to the e-mail be encrypted or password protected?

◉ Yes
○ No
○ Not Applicable

42.2

*** If automated e-mail routing systems are used, what security controls will be in place? Describe your testing and disaster recovery procedures.**

Not Applicable

42.3

*** Will contractors or vendors have access to study participants personal identifiable or confidential information?**

○ Yes ◉ No

If yes, what language will be included in the contract to protect participant privacy?

If yes, what security requirements will be provided to contractors or vendors who are designing or hosting Web based services to the project?

42.4

*** Who is responsible for ensuring that KP policies and procedures for confidentiality and security are followed for this project? Provide the name of the person responsible and his/her professional position and affiliation.**

The study PI, Vanessa Simiola, Psy.D will be responsible for ensuring that KP policies and procedures for confidentiality and security are being followed.

42.5

*** Who is responsible for security administration for the information technology associated with this project? Provide the name of the person responsible and his/her professional position and affiliation.**

The study PI, Vanessa Simiola, Psy.D will be responsible for ensuring that KP policies and procedures for confidentiality and security are being followed.

## 43.0 Non-Kaiser Permanente Collaborator

**43.1 * Will your study require collaboration with a non-KPSC research collaborator? (e.g. investigator, study sponsor, data coordinating center, etc.)**

(•) Yes ( ) No

## 44.0 Risk Assessment Mitigation Process (RAMP)

**44.1 * Click below to start the Risk Assessment Mitigation Process (RAMP). This is a required form.**

### Kaiser Permanente Southern California Principal Investigator's Attestation to Disclose Kaiser Permanente Southern California Protected Health Information from Human Subject Research to a Collaborator Outside of Kaiser Permanente

*** Add Collaborator(s)**

| Collaborator's Information | Please select from the following criteria: |
|---|---|
| Name of Collaborating Institution:<br>Henry Ford | ( ) No, this study does not require the disclosure of Kaiser Permanente Southern California (KPSC) Protected Health Information (PHI) to a collaborator. The study uses a deidentified data set.<br>(•) Yes, this study does require the disclosure of Kaiser Permanente Southern California (KPSC) Protected Health Information (PHI) to a collaborator in the form of a Limited Data Set (LDS). I understand that the LDS can only include: elements of an address greater than street address; dates of birth, death or service. Prior to disclosure of the LDS, |

| | |
|---|---|
| Name of Collaborator /Responsible Person:<br>Lisa Matero<br>Collaborator's Address:<br>1 Ford Pl # 1E, Detroit, MI, 48202<br>Collaborator Telephone Number (xxx-xxx-xxxx) Tie-Line (x-xxx-xxxx):<br>(313) 874-6677<br>Collaborator E-mail Address:<br>lmatero1@hfhs.org | KPSC will execute a Data Use Agreement with the collaborator. I understand that the use of an LDS mitigates risks to the Participant's privacy and security.<br>○ Yes, this study does require the disclosure of Kaiser Permanente Southern California (KPSC) Protected Health Information to a collaborator. I have conducted a thorough and accurate data security risk assessment as required using the Risk Assessment Tool (in the next section). There were no identified risks to data privacy, security, or confidentiality.<br>○ Yes, this study does require the disclosure of Kaiser Permanente Southern California (KPSC) Protected Health Information to a collaborator. I have conducted a thorough and accurate data security risk assessment as required using the Risk Assessment Tool. I have indicated all identified data privacy, security and confidentiality risks on the Risk Assessment Tool. |
| Name of Collaborating Institution:<br>KP Washington<br>Name of Collaborator /Responsible Person:<br>Gregory Simon | ○ No, this study does not require the disclosure of Kaiser Permanente Southern California (KPSC) Protected Health Information (PHI) to a collaborator. The study uses a deidentified data set.<br>◉ Yes, this study does require the disclosure of Kaiser Permanente Southern California (KPSC) Protected Health Information (PHI) to a collaborator in the form of a Limited Data Set (LDS). I understand that the LDS can only include: elements of an address greater than street address; dates of birth, death or service. Prior to disclosure of the LDS, KPSC will execute a Data Use Agreement with the collaborator. I understand that the use of an LDS |

Collaborator's Address:

Kaiser Permanente
Washington Health Research Institute
1730 Minor Ave, Suite 1600
Seattle, WA 98101-1466

Collaborator Telephone Number (xxx-xxx-xxxx) Tie-Line (x-xxx-xxxx):

206-287-2979

Collaborator E-mail Address:

gregory.e.simon@kp.org

mitigates risks to the Participant's privacy and security.

- ○ Yes, this study does require the disclosure of Kaiser Permanente Southern California (KPSC) Protected Health Information to a collaborator. I have conducted a thorough and accurate data security risk assessment as required using the Risk Assessment Tool (in the next section). There were no identified risks to data privacy, security, or confidentiality.
- ○ Yes, this study does require the disclosure of Kaiser Permanente Southern California (KPSC) Protected Health Information to a collaborator. I have conducted a thorough and accurate data security risk assessment as required using the Risk Assessment Tool. I have indicated all identified data privacy, security and confidentiality risks on the Risk Assessment Tool.

## Risk Assessment Tool

**A. DATA STORAGE RISKS**

A1. KPSC Protected Health Information will be stored by the collaborator outside United States.

**PROHIBITED if pursuant to a waiver of informed consent. Modify study protocol.***

○ Yes ◉ No

A2. Unencrypted KPSC Protected Health Information will be stored on a collaborator-owned, portable, endpoint computing device or storage media (e.g., a laptop, iPod, or PDA, MP3 device, flashdrive, other media storage device).

**PROHIBITED if pursuant to a waiver of informed consent. Modify study protocol.***

○ Yes ◉ No

A3. Unencrypted KPSC Protected Health Information will be stored on other collaborator-owned computing devices—e.g., research workstation—that are **not** behind a firewall.

**PROHIBITED if pursuant to a waiver of informed consent. Modify study protocol.***

○ Yes ◉ No

A4. Hard copy KP Protected Health Information will stored by collaborator at a collaborator-maintained facility.

○ Yes ◉ No

**B. DATA TRANSMISSION RISKS**

B1. Transmission of KPSC Protected Health Information will be via ***unencrypted** email communications (note: this can be communications between the collaborator and KP or between the collaborator and the research participant or between the collaborator and other entities).

**PROHIBITED if pursuant to a waiver of informed consent. Modify study protocol.***

○ Yes ◉ No

B2. Transmission of unencrypted electronic KPSC Protected Health Information will be across the Internet – e.g., to a website.

**PROHIBITED if pursuant to a waiver of informed consent. Modify study protocol.***

○ Yes ◉ No

B3. ***Unencrypted** electronic KPSC Protected Health Information will be transported via transportable/removable storage media (e.g., KP will send data stored on a CD via UPS or U.S. mail to a collaborator in another location) between KP, the collaborator, and /or the research participant.

**[*For Secure Electronic storage Policy, see http://kpnet .kp.org: 81/security/best_practices/ses.html to ensure that the storage of member/patient identifiable information (MPII) meets current policy.]**

**PROHIBITED if pursuant to a waiver of informed consent. Modify study protocol.***

○ Yes ◉ No

B4. Mail or messenger services will transport hardcopy files of KPSC PHI (e.g., transport from KPSC to collaborator; from collaborator to KPSC; etc.)

○ Yes ◉ No

B5. The collaborator or researcher personally transports hardcopies of KPSC PHI (e.g., hardcopy files carried by the collaborator from site-to-site).

○ Yes ◉ No

**C. DATA ACCESS RISKS**

C1. Collaborator does not have policies and controls that limit access to KPSC Protected Health Information (hard copy or electronic) to only those individuals who need access to conduct the research.

○ Yes ◉ No

C2. Collaborator does not have mechanisms (e.g., intrusion detection software or regular electronic system activity audits or monitoring) for determining if KPSC Protected Health Information has been inappropriately or illegally accessed, used, disclosed, or modified.

○ Yes ◉ No

C3. Collaborator allows individuals to remotely access KPSC Protected Health Information from home or from other remote, personal workstations, including portable devices.

○ Yes ◉ No

C4. Collaborator allows remote access to KPSC Protected Health Information by individuals working outside the United States boundaries.

○ Yes ◉ No

C5. Collaborator accesses KPSC Protected Health Information on-site at a KPSC facility.

○ Yes ◉ No

* Modify study protocol to eliminate risk, use a Limited Data Set, deidentified data, or informed consent.

Outreach Message Consent Information

The following information will be added to the initial outreach attempt. This will occur via telephone or secure messaging.

Researchers at [insert site] are conducting a study funded by the National Institute of Mental Health (NIMH). The study is called *Outreach to Reduce Depression Treatment Disparities (ORDTD)*. Our research is trying to find ways to improve patient engagement in treatment for depression. One of the ways we are trying to do this is through outreach messages, such as the one you are receiving here. Up to three more outreach attempts may be made by our study team over the next one-month period. These will be over telephone or secure messaging.

Participation in this study is voluntary and you may decline further participation by writing to a member of our study team at [include email address, mailing address] or by calling us at [include phone number]. Whatever choice you make will not have any effect on your relationship with [insert health care system] and will involve no penalty or loss of medical care benefits to which otherwise you are entitled. After we receive your request to withdraw, no further data will be collected or shared. However, data already collected or shared may still be used for the study. Unless you withdraw your authorization, this agreement does not expire.