Protocol Title: Study of Colorectal Cancer Screening Options

Study Protocol: 5/09/2019

PI: Gloria Coronado, PhD

NCT05987709

1. **Protocol**
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2. **Objectives**
   We propose to evaluate Guardant Health's commercially available colorectal cancer screening assay (Guardant SHIELD) in individuals who are not up to date with CRC screening.

   Primary Objective (or Aim)
   Assess colorectal cancer screening completion among patients who are non-adherent after receiving stool test outreach, who have an upcoming clinical appointment, and who are offered a commercially available colorectal cancer blood test versus usual care (i.e. reminder to complete stool testing during their clinical appointment).

   Secondary Objectives (or Aim)
   Assess patients' and providers' perceived confidence in the test (based on available test performance characteristics) and willingness to obtain/offer the test on an on-going basis, based on qualitative interviews; assess preliminary rates of follow-up colonoscopy completion (after an initial abnormal test result) among participants allocated to the blood test vs. usual care condition.

3. **Background Information and Rationale**
   Blood-based tests for colorectal cancer detection are thought to offer many advantages over stool-based and endoscopy-based tests. Such tests can be easily completed during in-person clinic visits and can be combined with other blood draws. Such tests may be particularly acceptable for patients who forgo stool-based testing options due to the 'yuk' factor. While blood-based tests will likely produce greater colorectal cancer screening adherence than stool-based testing and endoscopy options, there is little empirical data to support this claim.

4. **Study Design**
   The study will be a randomized clinical trial comparing the two options for colorectal cancer screening: the commercially available blood test and usual care (reminder to complete FIT). Patients will be randomized (1:1) to receive the offer of a commercially available blood test (intervention) or usual care. Only intervention patients will be consented to the study. Consented patients will be asked to complete a blood draw at the Kaiser Permanente Northwest (KPNW) clinical lab. Our primary analysis will compare rates of colorectal cancer screening (we will consider completion of the blood draw as completion of colorectal cancer screening) in the two study conditions using intention-to-treat data; we will also report the proportion of intervention participants who consent and, among those, the proportion who successfully complete the blood draw.

   We will also conduct qualitative interviews will 20-30 intervention patients and/or providers to understand perceived confidence in the blood test and willingness to receive/offer it on an every-three-year basis. Patients will have been offered the blood test option and will have completed the blood test (completers) or have agreed to take part in the study, but did not show to the blood test visit (non-

completers). Providers will be involved in offering colorectal cancer screening to patients and following up on abnormal results, such as primary care providers and GI specialists.

5. Study Population

a. Number of Subjects

We will prospectively identify and recruit 400 patients from KPNW who received, but did not complete, a FIT in the past 3-9 months, and have an upcoming appointment at a KPNW clinic (within 2 – 6 weeks of eligibility determination). Patient identification will be performed on a weekly basis by a CHR analyst. We will overrecruit by up to 10% to account for participant no-shows and screen-failure.

For the qualitative interview component of this study, 20-30 intervention patients and/or providers will be interviewed.

b. Eligibility Criteria

Inclusion Criteria:

- Age 45-75
- Received a FIT test in the last 3-9 months yet did not return their FIT
- Upcoming appointment or willing to reschedule an appointment at KPNW within 2 - 6 weeks
- Able and willing to provide informed consent if in the intervention arm

Exclusion Criteria:

- On do not contact list
- Having a legal authorized representative
- Non-English speakers

c. Vulnerable Populations

Vulnerable Populations (VPs)	Include/Exclude	Rationale
Pregnant women	Include	Pregnant women aged 45-75 are still eligible for colorectal cancer screening; there are no unique risks to obtaining a blood test among pregnant women.
Children	Exclude	Colorectal cancer screening is not recommended among individuals younger than 45.
Neonates of uncertain viability or nonviable neonates	Exclude	Colorectal cancer screening is not recommended among individuals younger than 45.
Prisoners*	Excluded	The KPNW IRB does not have the appropriate membership to review research involving prisoners.

Other VP	Rationale for Inclusion
Limited English proficiency	We will exclude patients whose language preference is a non-English language.
Decisionally impaired adults	We will exclude patients with a diagnosis of dementia (documented in the electronic health record).

Click or tap here to enter text.

d. Setting

This is not a multi-site study. Study activities will take place at Kaiser Sunnyside Medical Center and KPNW Center for Health Research.

For the qualitative interview component of this study, the interviews with both patients and providers will be conducted via telephone using password encrypted devices and software (e.g. CHR laptop using Microsoft Teams calling functions).

e. Recruitment Methods

The CHR analyst will identify patients eligible for recruitment based on the eligibility criteria outlined above.

1. The eligible population will then be randomized (1:1); randomization will be stratified based on age group (45-49, 50-64, 65+) and colorectal cancer screening history (ever vs. never).

2. Once the patient list has been identified by the analyst, the population will be uploaded into Clinical Conductor for use by research staff to conduct outreach.

3. The research staff will outreach to the patients for recruitment by mail and/or email. The research staff will send an introductory study letter/email and a copy of the consent form to participants allocated to the intervention condition. Research staff will then call the patient for recruitment.
    a. A maximum of three calls will be made

4. Research staff will coordinate meeting the patient prior to or after their clinical visit.

5. Outcomes of patient contacts will be tracked (declined, not able to reach, etc.) outcomes into Clinical Conductor.

6. The project analyst will pull data when the project is complete.
    a. From clinical conductor
    b. From Virtual Data Warehouse (VDW) datasets

For the qualitative interview component of this study, for patient completers of the blood test, we will identify a list of recent completers and reach out via letter and/or email. These

possible interviewees will have been informed of the possible interview at their initial consenting process when participating in the blood test.

For non-completer patients, we will generate a list of those who agreed to participate but did not show for their blood collection visit and reach out via letter and/or email.

In both cases, qualitative staff will follow up with up to 3 phone call attempts to ascertain willingness for the interview or not. The recruitment letter/email provides individuals with study team contact information through which they can opt-out of further contact or outright decline.

For provider interviews, we will work with the CHR study PI and study analysts to generate a list of primary care and GI providers who are involved in offering CRC screening and follow up surveillance. Providers will be sent an email request and study staff will follow up by email or phone up to 3 times to ascertain interest in the interview.

f. Consent

Written consent will be obtained prior to any study procedures, for patients in the intervention arm.

An IRB waiver of informed consent will be obtained for patients in the usual care group. Usual care patients will not be asked to sign informed consent, as it may create unnecessary confusion. Outcome data will be collected through retrospective chart review for participants in both study conditions.

For the qualitative interview component of this study, we request a waiver of *signed* informed consent. Verbal consent will be obtained from the patients and providers for participation in the qualitative interviews.

Informed Consent Process

Patients will be mailed and/or emailed copies of the consent forms prior to the research visit so that they can be thoroughly reviewed and discussed with family and friends, if they choose. Patients are also given contact information so that they can contact research personnel by telephone throughout the study. Patients will be interviewed and consented in private. All discussions with patients will be held in strictest confidence and out of earshot of the general public.

Patients will be fully informed that their participation in the study is voluntary. Patients may decline to be part of the study. Their decision to participate in the study will not affect the care they receive.

For the qualitative interview component of this study, informed consent will be obtained from the patients and providers utilizing an information sheet and consent discussion, but without signed documentation. If, after the consent discussion, an individual agrees to be interviewed their verbal agreement will be documented by study staff. This research does not involve procedures for which

written consent is normally required outside of the research context. This study presents no more than minimal risk of harm to subjects.

Non-English-Speaking Subjects
N/A

Assent of Children and Parent Permission
N/A

Adults Unable to Consent/Decisionally Impaired
N/A

g. HIPAA Authorization – if study will use or disclose Protected Health Information (PHI)
Signed HIPAA Authorization will be obtained from each patient allocated to the blood test intervention. The authorization will be combined into the informed consent form.

Waiver or Alteration of HIPAA Privacy Rule Authorization
For the usual care group, we request a Waiver of HIPAA authorization.

For the qualitative interview component of this study, we request an alteration of HIPAA authorization, removing the requirement for signature. Verbal authorization will be obtained.

6. Communicating with Recruits and Participants

Study staff may call, email, and/or text message potential participants (i.e. recruits) ahead of their scheduled consent and blood draw visit to remind them of their appointment.

In addition, study staff may generally correspond with individual participants or recruits by phone or back and forth email and/or text messaging to address participant questions, concerns, or to coordinate scheduling or meeting up for their visit. Back-and-forth communication by email or text messaging will not be required. Participants will be offered another way of communicating with staff, such as by phone, in case they do not feel comfortable exchanging information over email and/or text. Sensitive study content or protected health information (PHI) will not be included in these emails or texts. A potential participants willingness to take part in back-and-forth communication by email and/or text messaging will be documented in their research record.

7. Study Procedures

Blood Sample Requirements

1. One (1) blood sample will be collected in each of 200 unique patients who (a) received, but did not complete, a FIT in the past 3-9 months, and (b) have an upcoming appointment at KPNW in the next 2-6 weeks.

2. Forty (40) mL of whole blood will be collected per sample using 4, 10mL Streck tubes as part of the Blood Collection Kit (“Kit”) provided by Guardant.

3. Guardant's Test Requisition Form (TRF) will be completed (with the PI information and participant ID number) for each sample and placed in the Kit.

4. Each sample will be packaged and the corresponding TRF included in the Kit. The Kit will be shipped to Guardant overnight using the pre-paid, pre-addressed FedEx Clinical Pak.

5. Samples received by Guardant greater than 7 days from the time of receipt may be subject to cancellation per the CLIA-certified lab protocol.

No identifiable patient information will be placed on the tube – Only a study sample ID will be on the tube when sent to Guardant Health's lab.

Blood Sample Processing (CLIA line)
Once received Guardant will test the blood samples. Guardant will test samples using its colorectal cancer screening assay in its CLIA-certified lab. A final report for each sample will then be provided to the investigator(s) via its online portal within approximately 14 days of sample receipt. Guardant will cover the cost of processing and reporting up to 200 tests.

Data Collection
The study analyst will provide certain clinical data to Guardant (within 120 days of the 200th intervention patient enrolled, and blood sample received), the details of which follow:

- Patient ID
- Age at study entry
- Cohort assigned to
- GH colorectal cancer screening test result (if applicable)
- FIT test result after randomization (if applicable)
- Time between colorectal cancer screening test result offer and screening test completion
- For those with positive screening test, was colonoscopy completed?
    - If yes, time between positive test result and colonoscopy
    - If yes, colonoscopy outcome (CRC, advanced neoplasia, non-advanced neoplasia, negative, incomplete)

Qualitative Data Collection
Qualitative interviews will be conducted among a subset of patients who have (completers) and have not completed (non-completers) the blood test and among providers (20-30 total interviews) who offer colorectal cancer screening to patients. Each participant will undergo a single interview, conducted via telephone, that will last for 45-60 minutes. Each interview will be audio recorded with participant consent.

a. <u>Data Analysis</u>
Data analysis will be conducted at KP CHR will guidance from the statistician at Guardant Health.

Below is a list of primary and secondary endpoints for analyses.

1. Primary endpoint:
    a. Colorectal cancer screening completion (incl. blood test, stool-test or colonoscopy) rate within 3 months of randomization, by study condition (using intention-to-treat design).
2. Exploratory endpoint:
    a. Percent of individuals offered blood-based testing who accepted, percent who complete the test.
    b. Test positivity rate, % of positive individuals who proceeded to diagnostic endoscopy

For those with endoscopy, percent with findings (colorectal cancer, adenoma, negative). Exploratory endpoints will not be statistically powered for comparisons.

Sample size calculation:

Sample size was calculated based on a previous study (Liles, et al 2016). Assuming that the adherence rate of FIT is 88%, a sample size of 200 in each group (FIT and blood test) achieves 91.8% power to detect an adherence rate difference of at least 8% between the two groups.

b. Qualitative Analysis
All interview recordings will be transcribed verbatim. All transcribed interviews will be coded using thematic data analysis and the constant comparative method to identify patterns in interviewees' responses. Code books will be developed for the patient and clinical staff interviews based on an initial review of the transcripts, and the interview guide questions. Codes will be applied to transcripts with the aid of a qualitative software program (e.g., ATLAS.ti) or using a template built in excel. Coding will be an iterative process with the goal of identifying connections and patterns across participants' responses. Emergent themes from the interviews will help us understand both patient and provider acceptability of the blood test as a CRC screening method, and aid in identification of barriers and facilitators to implementing the blood test option within a health system.

c. <u>Sharing of Results with Subjects</u>
Results from the commercially available blood test will be provided to the patient (through mail/email or phone call). A copy of the final report will be scanned into the patients EMR. In addition, participants whose test result is abnormal will be notified by the GI department, whose staff will facilitate the referral and scheduling of a follow-up colonoscopy (a recommended screening at KPNW). Participants whose tests result is normal will receive a letter that includes a number to call if they have any questions.

The blood sample will only be tested for markers of colorectal cancer; there is no known risk of incidental findings. The laboratory conducting the test is Clinical Laboratory Improvement Amendments (CLIA) certified.

d. Data and/or Specimen Banking
N/A

8. Privacy, Confidentiality and Data Security

Information obtained in this study will include protected health information of the patients. The identity of the patients will not be part of the study. No personally identifiable information will be shared outside the clinic. All reports, forms, or articles related to this study will be prepared such that no individual patient can be identified. Samples will be coded with a study ID number to protect patient confidentiality. Only the authorized CHR study personnel will have access to the link between the patient's identifiable information and the study ID.

Collection of sensitive data will not occur as a part of this study.

Describe the plan for storage of data and/or specimens.
In order to minimize the risk of loss of confidentiality, all records related to study data will be kept in locked cabinets. Access to study information will be restricted to authorized research personnel. A password system will be used to control access to all information stored on a secured computer. All residual blood samples will be discarded at the end of the study.

For the qualitative interview component of this study, the interviews with both patients and providers will be conducted via telephone using password encrypted devices and software (e.g. CHR laptop using Microsoft Teams calling functions) and stored behind CHR firewalls within project specific folders. De-identified audio transcripts will be retained indefinitely.

Study data will be retained and destroyed in compliance with the study contract.

Collection of data from subjects electronically
N/A

Does this study involve the disclosure of PHI to a collaborator?
Data for this study will be disclosed to Guardant Health (the funder). In addition to the blood samples sent to Guardant, they will also receive:

- A limited dataset of patient characteristics
- Data will be limited, and identifiers removed. Guardant Health will not receive any Personal Health Information
- Data will be transferred via Secure File Transfer site.

Data Commitments (data and specimen sharing)

Recipient and Description of Materials	**Identifiers*** (note w/an X)	**Health Information**** (note w/an X)	**HIPAA Documentation** (see policy NWRC.PRIV.04)
Guardant	__Fully Identifiable	_x_Yes	__x__Signed Authorization

Blood specimens and a patient characteristic dataset will be sent to Guardant.	_x_Limited Data Set __De-Identified __Aggregate	__No	__Waiver of Authorization _x_Limited Data Set only (DUA Required) __De-Identified or Aggregate Data __N/A, No Health Information

9. Provisions to Monitor Data to Ensure the Safety of Subjects

Because this study will not involve treatment, adverse events are unlikely to occur. However, as a safeguard, the clinical research coordinators, and the principal investigator will review study data; study results (when available); complaints about the research; and will report any adverse events or unanticipated problems involving risk to patients to the Institutional Review Board. Adverse Events of any sort reported to the project team and investigator will also be characterized by type and number. Standard risks associated with blood draws include pain, bruising in the area from where the blood is taken, redness and swelling of the vein, infection, dizziness and a rare risk of fainting. These risks will vary from person to person. The healthcare staff will follow normal clinical practices to ensure sterility and safety. Study participants undergoing the blood draw will be advised to talk to their doctor about any side effects while taking part in this study. Many patients will be getting their blood drawn for non-study purposes, thus, only adverse events associated with study blood draws will be attributed to the study. Adverse events associated with colonoscopy (perforation, bleeding) are extremely rare; any adverse events associated with colonoscopy will not be attributable to the study because colonoscopy is part of standard care.

Plans for the Patients at the End of the Protocol

Patients will continue to follow their schedule of recommended screenings regardless of their participation in the study. Any patient who experiences problems from participating in this study will be provided all appropriate medical care and the study staff will follow their progress and give appropriate recommendations for on-going screening. However, no further contact with patients is anticipated during or after completion of the study (beyond potential recruitment and participation for the qualitative interview component).

10. Risks and Benefits

a. Risks to Subjects

There are minimal risks and discomforts to participating in this study. Collection of blood involves potential risk of pain or discomfort, redness, bruising or localized infection at the site of the needle stick. Patients will be instructed to alert staff for any complications resulting from the blood draw.

Patients may feel uncomfortable with questions asked during the qualitative portion of the study. We will be clear that answering all questions will be optional. There may be risks of data breech.

There are no additional risks or discomforts to patients in this study.

In the unlikely event that a patient experiences physical injury or illness because of participating in this research study, medical care will be made available at the clinical site of sample collection.

b. Potential Benefits to Subjects
Patients will not benefit directly from involvement in the study. However, the general colorectal cancer screening-eligible patient population may benefit from the ease of a blood test. Some patients may benefit from obtaining the blood test and obtaining a follow-up colonoscopy.

11. Economic Burden to Subjects
No cost will be incurred by the subjects for participation in this study.

12. Compensation to Participants
Patients will not be compensated for participation.

Patients participating in the qualitative interview will be offered a $25 gift card as appreciation for their participation.

13. Resources Available
N/A

14. Additional Approvals
N/A

15. Drugs or Devices
N/A

16. Multi-Site Research
N/A

17. Community-Based Participatory Research
N/A

Protocol Title: Study of Colorectal Cancer Screening Options

Informed Consent Form: 10/7/2022

PI: Gloria Coronado, PhD

NCT05987709

Kaiser Permanente Northwest Region

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Title: Study of Colorectal Cancer (CRC) Screening Options

Sponsor: Guardant Health

Lead Researcher: Gloria Coronado, Ph.D.
Kaiser Permanente Northwest
Center for Health Research
3800 N. Interstate Ave.
Portland, OR 97227
(971) 254-1969

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is your choice. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can also agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- Ask all the questions you want before you decide to take part in the research.

Why is this research being done?

This research is being done to see whether people who do not return their colorectal cancer screening stool test, also called a FIT, are willing to have a blood test done instead.

The standard CRC screening option is a FIT test, which is an easy test you do at home. This study gives the option of a blood test for CRC screening, called the Guardant SHIELD test.

The Guardant SHIELD CRC screening test is a commercially available test which works by finding signs of colorectal tumor in the blood of patients at average risk for CRC.

We also want to know how participants and health care providers make decisions about which CRC screening test to use. We will ask up to 20 participants and 10 providers to be interviewed. This interview will be done by phone and will take about 30-45 minutes. The interviews will be recorded and transcribed (written out). If you are selected, it is your choice to take part in the interview. You may choose not to take part in the interview and still participate in the study.

How many people will take part in this study?

About 400 participants will be in this study.

What happens to me if I agree to take part in this research?

If you choose to be in this study, you will sign this consent form and we will ask you to have four tubes of blood (about 3 tablespoons) drawn for testing. We will collect the blood samples at the time you come in for a regularly scheduled visit at a Kaiser Permanente Clinic.

The samples of blood will be labeled with a unique study ID number and shipped to Guardant Health for testing.

We will also collect information from your medical record, such as information about you and any colorectal screening or follow-up care you receive.

Study staff may communicate with you by phone, email, and/or text message while you are participating in this study. Please let the study staff know if you prefer one method of communication over another or if you feel uncomfortable with any of these methods of communication.

Will I receive the results from my blood test?

Yes. If your test result is abnormal, you will be contacted by Kaiser to discuss additional testing (e.g., a colonoscopy). If your test result is normal, you will receive a letter notifying you. A copy of your test result will be included in your electronic medical record.

How long will I be in this research?

If you are selected and agree to participate in a phone interview, your participation in the study will end after your blood draw and interview are completed. If you are not selected to participate in a phone interview, your participation in the study will end after your blood draw is complete. We will collect information from your medical record for up to one year after your test is complete.

Can I stop being in the study?

Yes. You do not have to be in this research study, and you can quit at any time. Just let the study staff know that you are no longer interested. If you decide not to be in this study or to stop being in this study, it will not affect your regular medical care or health benefits.

Risks

Risks involved in this study are minimal. Taking blood may cause pain, bruising in the area where the blood is taken, redness and swelling of the vein, infection, dizziness and in rare situations, fainting.

Benefits

If you decide to be in this study, there is no direct benefit to you. Other people may benefit in the future from the information that is learned in this study. Having the blood test and follow-up colonoscopy may be beneficial for some people.

Alternatives to Participation

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research

Will I be paid for taking part in this research?

You will not be paid for taking part in this research.

Will it cost me money to take part in this research?

You will not have to pay for any costs related to the study blood draw and sample testing. Other parts of your care that are routine (that you would have received if you were not in this study), will continue to be provided and charged to you according to your Kaiser Health plan.

Standard text messaging rates may apply for any messages received as a part of this study. Charges would depend on your cell phone carrier and service plan.

Research-Related Injury

Since the study involves the collection of blood samples only, it is not likely that you will experience injuries. If you have any injury during this study, Kaiser Permanente will provide care for that injury as covered by your usual health benefits.

Payment for such things as lost wages, expenses other than medical care, or pain and suffering is not available. No free medical care or other form of compensation will be offered by Kaiser Foundation Health Plan of the Northwest, Kaiser Foundation Hospitals, Northwest Permanente, PC, or the Kaiser Permanente staff conducting the study. You are not giving up any of your legal rights by signing this form.

Authorization to Use and Disclose (Release) Health Information

If you sign this consent document, you give permission to researchers at Kaiser Permanente Northwest (KPNW) to use and disclose (release) your protected health information (PHI), for the purposes of the research study as described in this consent.

Do I have to give you access to my health information?

Giving access to your health information is voluntary. You get to choose. No matter what you decide, now or in the future, it will not affect your medical care. You can change your mind at any time in the future. However, if you choose not to give us access to your health information now, we will not be able to enroll you in the research study.

To do this study, we will be looking at or collecting information about you and your health, including tests and both clinical and research observations made during your participation in the study. The study doctor may obtain information about your health including:

- Information collected during this research about blood tests
- Past, present and/or future medical records
- Specific information about routine testing and results.

We will not be able to see all the information in your health record. We will use a computer program to find only the data that we need for the study.

If information from this study is presented publicly or published in a medical journal, you will not be identified by name, picture, or any other personally identifying information.

Who might get this information?

Researchers at KPNW will use your health information to conduct the research study. Others at KPNW may access your health information to help coordinate or oversee the research. This may include employees of any of the organizations that make up KPNW:

- Kaiser Foundation Hospitals
- Kaiser Foundation Health Plan of the Northwest, Inc.
- Northwest Permanente
- Permanente Dental Associates

We may disclose (release) the health information described above to others outside of KPNW who are involved in conducting or overseeing research, including:

- Guardant Health (the sponsor of this study and the laboratory processing your samples)
- The Kaiser Permanente Northwest Institutional Review Board, a committee of scientific, non-scientific, and community members who review research to protect the rights and welfare of participants
- Government oversight agencies, such as the Office for Human Research Protections or the Food and Drug Administration
- People from the Kaiser Permanente program office or other Kaiser regions who monitor the research

How is my health information protected?

State and federal privacy laws protect your health information. We will do our best to protect your confidentiality by using standard security measures as required by law. We will also remove or separate information that identifies you (such as your name or address) from the rest of your health information whenever possible. Everyone at KPNW with access to your information has received training in the protection of sensitive information. Still, there is a small chance your information could be released accidentally. There are also certain situations where we may be required by law to release your information.

Once your information has been given to others, it may no longer be protected by state or federal privacy laws. It will be protected by other rules and agreements with the recipients. However, there is still a risk that a recipient could share your information without your permission.

May I withdraw my permission to use my health information?

Yes, you may cancel your permission at any time. If at any time you want to withdraw this agreement, you must notify the lead researcher, Gloria Coronado, Ph.D., in writing at the address below or by email at Gloria.D.Coronado@kpchr.org.

Kaiser Permanente Northwest
Center for Health Research
3800 N. Interstate Ave.
Portland, OR 97227

If you withdraw your permission, we will no longer use your health information or share it with others. We may still use or disclose information about you that was shared before you cancelled your authorization or permission. If you withdraw your permission, you will not be able to continue participating in this research study.

When will this authorization to use my health information expire?

This Authorization will expire at the end of the research study.

Who should I call if I have questions?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (503) 335-6725, CHR_Compliance@kpchr.org if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject

Signature

Your signature documents your consent to take part in this research and your agreement to the use and disclosure of your health information.

A copy of this consent form will be provided to you.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

I attest that I discussed this consent with the participant named above, and the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____

Printed Name of Person Explaining Consent

_____ _____

Signature of Person Explaining Consent Date