ENGAGED 2
TRIAL Recruitment Call

Hello, this is _________________ calling from Kaiser Permanente Washington Health Research Institute. Our name used to be Group Health Research Institute. May I please speak to ______________?

[If respondent not available, arrange an alternate time to call. If respondent available, continue.]

[Reintroduce self if initial identification was made to other than respondent.]

Recently we mailed you a letter for the Engaged 2 study. Did you receive the letter?

[If no, we offer to explain the study, but will send another letter if requested]

(As the letter stated), we are asking you to participate in a study to help us learn the best ways to inform women about breast density and cancer risk. We have created a new website that we hope will be an effective way to do this. The website is designed to be used by women and their doctors to learn about breast density, their personal breast cancer risk, options for screening and prevention and steps they can take to manage their risk. We are comparing this new website to a standard health information website that is already available.

Before I take more of your time, I would like to ask you a few questions to see if you are eligible. If you are, I’ll give you more details about the study. Your participation in this phone interview is completely voluntary. Your answers will be kept confidential as provided by law. These questions are important in helping us determine whether you meet the criteria for the study, but if there is any question that you do not wish to answer, please tell me. This call may be monitored for quality purposes. May I ask you the questions?

[If no, go to refusal script. If yes, continue.]

SCREENING QUESTIONS

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<thead>
<tr>
<th></th>
<th>Question</th>
<th>Eligibility Script</th>
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<tbody>
<tr>
<td>1</td>
<td>Are you age 40 - 69?</td>
<td>If NO, not eligible go to not eligible script</td>
</tr>
<tr>
<td>2</td>
<td>Are you still receiving your care at Kaiser Permanente? As you’ve probably heard, Group Health is now Kaiser Permanente.</td>
<td>If NO, not eligible go to not eligible script</td>
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</table>
| 2a| Do you plan on receiving your care at Kaiser Permanente for the next 12 months? | If NO, not eligible go to not eligible script
<p>|                                                                           | IF YES/NOT SURE, CONTINUE                               |
| 3 | Have you recently had a normal mammogram at Group Health (which is now Kaiser Permanente)? | If NO, not eligible go to not eligible script           |</p>
<table>
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<tr>
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<tr>
<td>4</td>
<td>Have you ever been referred to or received genetic counseling or testing because of your family history of cancer?</td>
<td>If YES, not eligible go to not eligible script</td>
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<tr>
<td>5</td>
<td>Have you ever been diagnosed with cancer other than basal skin cancer?</td>
<td>If YES, not eligible go to not eligible script</td>
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<tr>
<td>6</td>
<td>Do you use email?</td>
<td>NOT CURRENTLY REQUIRED, BUT GET APPROVAL IF WE MAKE IT REQUIRED IN FUTURE</td>
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<td>7</td>
<td>Do you have access to the Internet on a regular basis? This can be via any device – desktop computer, laptop, tablet or smartphone.</td>
<td>NOT CURRENTLY REQUIRED, BUT GET APPROVAL IF WE MAKE IT REQUIRED IN FUTURE</td>
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[If not eligible for Questions 1-5:] CURRENT CRITERIA
We are sorry, but based on the information you have told us, you are not eligible for this study. Since this is a research study, there are certain criteria that everyone must meet.

**If no to either Question 6 or 7 : IF REQUIREMENTS CHANGE**
We are sorry, but because this study involves review of a website and completing online surveys, we are only inviting people that have email and access to the internet.

[If eligible:] You are eligible for the study. Let me tell you a little more. There are a total of three surveys. The first one takes is by phone, and takes about 30 minutes. I will ask you about your overall health practices, including your experiences with mammograms and your thoughts and opinions about breast health.

After that interview, we will ask you to visit the study website. Based on your random assignment, you will be directed to either the new study materials, or to materials on the American Cancer Society website. At the end of the study, everyone in the study will be given access to the new study materials.

We will send you $20 as a thank you for completing the first interview

We will ask that you log into the website within the next 6 weeks, and review it at your convenience. This should take about an hour. [USE ONLY IF NEEDED: You can you use any device to view the website (desktop, laptop, tablet or smartphone).]

You will provide your written consent to participate in the study before you begin to view the contents of the website. If you do not log to the website for whatever reason, we will send paper consents to you in the mail. You can return paper consent documents in a self-addressed stamped envelope we will provide. All women must provide their consent to be part of the study.

We will ask you to complete a follow up survey in 6 weeks, and in 12 months. Each follow up survey will take about 30 minutes, and we will send you $20 as our thank you as you complete each one.
Are you interested in participating?

[If yes, continue. If no, go to refusal script.]

[Record answer and continue]

Would this be a good time to do the first interview? It takes about 20 minutes.

[If yes]
As before, your answers are voluntary and any information you give will be kept confidential as provided by law. Whether you choose to answer the questions will not affect your care or benefits at Kaiser Permanente. May I ask you the interview questions now?

[Go to baseline interview questions. At the end of the interview, continue]

That was the last survey question.

TRIAL Randomization Script

Now I’d like to tell you about the materials we are asking you to review. We believe they will be very valuable in helping you to understand your risks for breast cancer, and ways to manage your risk.

As we said earlier, we have randomly assigned women to two groups- one group to review materials designed for the study, the other to group to review materials on the American Cancer Society website. You are included in the group that will review [materials that we have designed specifically for this study/materials provided on the American Cancer Society website]. FOR ACS GROUP: You will also be given access to the new materials when you have finished the study.

It is very important to our study that you review the website within 6 weeks, before we contact you again. It will probably take you 45 to 60 minutes to review it the information thoroughly, but you can take as much or as little time as you would like. You can review the materials in one sitting, or return as many times as you would like.

When you first log on to the website, you will be asked to provide further consent to participating in the study. When that is complete, you will be able to move on to view the materials. If you do not log to the website for whatever reason, we will send paper consents to you in the mail. You can return paper consent documents in a self-addressed stamped envelope we will provide. All women must provide their consent to be part of the study.

We do ask that you do not share the website or your log in information with other women you may know in the study.

PCC
Because you may have questions after reviewing the information on the website, may we send a letter to your primary care provider letting them know you’re participating? We would send it at the same time as we send you the $20 thank you. You can be in the study whether you say yes or no.

YES
NO

EMAIL
We would like to email you the link and login information for the website.

Let me remind you that we can’t guarantee the confidentiality of email communication. If you email us, please do not include your name or phone number in the subject of the email, or your consumer number at all. We do not need that. We will not send any health information via email and will be careful to limit the amount of personal information in messages we send. May we send you the information by email?

YES
NO    SKIP TO ADDRESS
DOES NOT HAVE EMAIL SKIP TO ADDRESS

What is your email address?

[Record and slowly read back, confirming all caps, spaces/not spaces and special characters.]

Is that correct?

ADDRESS
We will you $20 as a thank you and a hard copy of logon instructions.

Where should we send that?

RECORD ADDRESS

IF AGREES TO EMAIL
In about 6 weeks, we’ll send you an email reminder with a link to an online survey. If we need to contact you by phone, what is the best phone number to use?

NO EMAIL
In about 6 weeks we will call you to do your next survey. What phone number should we use?

COLLECT 2 PHONE # AND BEST TIMES

REFUSAL SCRIPT: IF PARTICIPANT DID NOT ALREADY GIVE A REASON
I understand you do not want to be in the study. It helps us with future studies to know the reasons people choose not to participate. Would you be willing to share your reasons?

[Record reason.]

Thank you very much for your time.

[Terminate phone call.]
Dear «Firstname» «Lastname»:

**Have you had a mammogram recently?** If so, we are inviting you to join the Engaged2 Study. Researchers at Kaiser Permanente Washington Health Research Institute (formerly Group Health Research Institute) and Georgetown University are working together to learn the best ways to tell women about their own breast density and breast cancer risk. As you’ve probably heard, Group Health is now Kaiser Permanente. That means our research institute’s name has changed, though our mission is still the same: to improve health and health care for everyone.

**Why breast density is important**

It is very common for women to have dense breast tissue. Even though having dense breasts is normal, information about breast density is important when considering breast cancer risk. Dense breast tissue can make it harder to find cancer during screening and may increase a woman’s risk for breast cancer.

**What this study is about**

For this study, we have developed a website that women and their doctors can use to learn about breast density, their personal breast cancer risk, options for screening and prevention and steps they can take to manage their risk. We are comparing this new website to a standard health information website that is already available.

Our long-term goal is to make this new website publicly available—so women everywhere can benefit from having information about their breast density and breast cancer risk. Getting input from real women, like you, will help us with this effort.

**Why we are asking you to help with this study**

We have invited you to be part of this study because your recent mammogram with Group Health (which is now Kaiser Permanente) showed that you have dense breast tissue. Having dense breast tissue, along with other risk factors (like age, family history or prior breast biopsy), means your risk of developing breast cancer is higher than the average for a woman of your age and race. But there may be steps that you can take to manage your risk.
What being in this study will involve

A research interviewer from Kaiser Permanente Washington Health Research Institute will call you within a week to tell you about the study. If you are interested, she will ask you a few questions to confirm you are eligible for the study. If eligible, you would do your first of three surveys for the study.

After the survey you will be randomly assigned to review either the newly-developed website, called the Engaged website, or the American Cancer Society website. Both sites provide information on breast density and breast cancer risk. We expect you will spend about 60 minutes reviewing the online information. You can use any device to view the website (desktop, laptop, tablet or smartphone).

We will ask you to do two more surveys, one in 6 weeks, and one in 12 months. When you complete these study activities, you will receive $60 to thank you for your time. Please read the enclosed study information sheet to learn more about what the study involves.

Are you interested in being in this study?

Please call us toll free at 1-866-458-5467 to let us know if you would like to participate or not. Leave a message with your full name and telephone number.

- If you say you are interested in being in this study, a research interviewer will call you back to and tell you more about the study.
- If you decide you don’t want to be in this study, we will not contact you again.
- If we do not hear from you, we may call you to see if you would like to participate.
- If you have questions about this study, please call Kelly Hansen at 206-287-2453.

Thank you in advance for taking time to consider helping with this study. We hope to talk with you soon.

Sincerely,

Karen J. Wernli, PhD
Lead researcher at Kaiser Permanente Washington Health Research Institute

Suzanne C. O’Neill, PhD
Lead researcher at Georgetown University
What is the goal of this study?

We are doing this study to learn the best ways to inform women about breast density and breast cancer risk. Our goal is to test a website that women and their doctors can use to get information about personal breast cancer risk. With this information, women can make more informed choices about breast cancer screening and prevention. Our ultimate goal is to make the website available to everyone.

We will randomly assign half the women in the study to review the new website, and the other half to review materials on the American Cancer Society website.

At the end of the study, everyone in the study will be given access to the study website.

Why don't more women already know about breast density?

Recent research has revealed important information about breast density and cancer risk. Based on this research, many states have laws requiring women get information about their breast density after a mammogram. Washington may be among the next states to adopt a similar law.

Doctors and scientists are now trying to understand the best ways to share breast density information so women can use it to understand their personal breast cancer risk. This study is part of that important effort.

Why are we asking you to participate?

We are looking for women who:

- Are 40-69 years old
- Recently had a normal mammogram at Group Health (now Kaiser Permanente).
- Have dense breasts based on their recent mammogram. Breast density and other risk factors for breast cancer mean that their risk of developing breast cancer is higher than average for women their age and race.

What does being in this study involve?

If you decide to be in this study, we will ask you to do four things:

1. Complete a 30 minute phone survey about breast health practices. We will send you $20 as a thank you for your help.

2. Accept a random assignment to review the study website or the American Cancer Society website. We will ask you to review the website within six weeks of the first phone survey. It will take about an hour. Website usage will be tracked so that we can understand how women use the website.

3. 6 weeks later, complete an online survey about your experience with the website and about your breast health practices. The second survey will take about 30 minutes. We will send you another $20 when you complete the survey.

4. A year later, complete an online survey about your breast health practices. This third and final survey will take about 30 minutes, and we will again send you $20 as a thank you. We will collect breast health information from your medical record so that we can know whether the study impacted your health care.

How do we protect you privacy?

Whenever you join a research study, your privacy is protected by federal law. A special committee reviews our research to make sure we follow these laws and take other steps to protect your privacy. For example, we use a secure computer system that tracks your study information using a code number instead of your name.

We will ask for permission to send a letter to your provider to let him or her know that you’re participating. You can say “no” to this and still participate.

How can you sign up or learn more?

- If you want to be in this study, please call 1-866-458-5467 (toll free) and leave your name and phone number.
- If you have questions, please call Kelly Hansen at 206-287-2453.

Women who help with this study will receive up to $60 as a thank you!