Informed Consent Form

Patient Reminders and Self-referrals Via Online Patient Portals and Text Messaging (PReVenT) to Improve Adherence to Breast Cancer Screening

NCT Number: NCT05526872

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You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 140 people who are being studied, at Emory Healthcare.

Why is this study being done?

This study is being done to answer the question: Can online patient portals and text message reminders improve adherence to recommended screening mammography care. You are being asked to be in this research study because you may fit the following eligibility criteria:

- Women aged 50-74 years;
- English-speaker;
- With an active Emory Healthcare online patient portal account ;
- With a mobile phone number listed in the Emory Healthcare electronic medical records
- With at least one primary care visit at Emory Healthcare system between 2015 and 2021
- No screening mammography performed in the last 2 years;
- No upcoming screening mammography already scheduled;
- No severe comorbidities at the time of the study (in palliative care or hospitalized at the time of the study);
- No family or personal history of: ovarian cancer, breast cancer, BRCA1 or BRCA2 genetic mutations, Li-Fraumeni syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome;
- No personal history of: Previous treatment with radiation therapy to the chest or breasts before the age of 30 years, dense breasts, Alzheimer's disease, dementia, or cognitive impairment.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate for a total of 6 months. The researchers will ask you to complete a 15-minute survey at enrollment, after which you will be assigned to one of two groups with receiving online portal and text messages on

recommended care or healthy habits. You will also be asked to complete a 10-minute survey, 6 months after enrollment. A small subset of patients will also be contacted 6 months after enrollment for a 10–15-minute phone interview.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. As a study participant you may be reminded about recommended screening mammography. The study results may be used to help others in the future.

What are the risks or discomforts you should know about before deciding?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include a very small risk of loss of privacy, or breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
There will be no costs to you for participating in this study. You will not be charged for any of the research activities. If eligible for study inclusion, you will be sent a $10 gift card after completing each of the baseline and follow-up surveys.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: **P**atient **Re**minders and Self-referrals **V**ia Online Pati**en**t Portals and **T**ext Messaging (PReVenT)

IRB #: STUDY00004618

Principal Investigator: Patricia Balthazar, MD

Funding Source: Association of University Radiologists General Electric Radiology Research Academic Fellowship (GERRAF) Award

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:
- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

What is the purpose of this study?
Lack of adherence to routine health care recommendations and healthy habits is multifactorial. The purpose of this study is to determine if online patient portals and text message reminders can improve adherence to screening mammography.

What will you be asked to do?
If you are eligible and want to be part of the study, you will participate for a total of 6 months. The researchers will ask you to do the following: You will complete a 15-minute survey at the time of enrollment and randomly assigned (like the flip of a coin) into one of the two study groups: (1) group 1 and (2) group 2. Participants in both groups will receive two potential message reminders via online patient portal and two potential text messages. You will receive the first message via online patient portal within 2 weeks of completing the baseline survey. You may receive a text message within 2 weeks of the portal message. Six months after enrollment, you will be contacted again to answer a 10-minute follow-up survey. We are expecting to enroll 140 participants in this study. We also will randomly select 8 participants from group 1 who indicate that they are willing to participate in a phone interview. The phone interview will be recorded.

Who owns your study data and samples?

If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that were already collected may still be used for this study.

What are the possible risks and discomforts?

The most common risks and discomforts expected in this study are:

- You may lose time at work or home to complete the surveys and participate in the phone interviews with our study team member.
- You will be asked sensitive or private questions which you normally do not discuss.

The less common risks and discomforts expected in this study are:

- Our research team is very careful in handling your sensitive information and we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA).

  However, there is always a small risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will you benefit from the study?

If you are in the study, you will be helping the researchers answer the study question. As a study participant you may be reminded about recommended routine health practices. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will get a $10 gift card after each of the two completed study surveys (total of $20), to compensate you for your time and effort. If you do not finish the study, we will compensate you for the surveys you have completed. At the beginning of the first survey, we will ask you a few questions to confirm if you are eligible for the study. If you are not eligible, the remaining survey questions will not be asked and there will be no financial compensation for answering those triage questions. A small subset of patients from one of the study groups willing to participate in an interview will be randomly selected and receive $40 gift card after completing the phone interview. If you participate in the interview, you will get up to $60 total.

What are your other options?

If you choose not to join this study, you can get care outside of this study. You do not have to be in this study to be treated for any condition.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Medical Record

If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory medical record you have now or any time during the study.

The results of your surveys and/or phone interview will be used only for research purposes and will *not* be placed in your medical record.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

Withdrawal from the Study
You have the right to leave a study at any time without penalty. The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:
By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment
There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Your demographics and general information including name, date of birth, gender, and address.
- Your insurance details.
- Medical information about you including your medical history and present/past medications and imaging tests.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your IIHI. These include subpoenas or court orders.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory may use and disclose your IIHI to run normal business operations.
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your IIHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at: [redacted]

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate

research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact study doctor, Patricia Balthazar, MD at: [redacted]

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [redacted].

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**