16-003707

Latinas LEarning About Density (LLEAD Study)

NCT02910986

Document Date: 07/18/2019

MAYO CLINIC

Name and Clinic Number

Approval Date: **July 18, 2019**
Not to be used after: **July 17, 2020**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Latinas Learning about Density (LLEAD Study)

IRB#: 16-003707

Principal Investigator: Dr. Celine Vachon and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep.

MAYO CLINIC

Name and Clinic Number

Approval Date: **July 18, 2019**
Not to be used after: **July 17, 2020**

CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator(s): Dr. Celine Vachon Mayo Clinic Rochester Dr. Bhavika Patel Mayo Clinic Arizona **Study Team Contact:** Edna Ramos Arizona	**Phone:** (507) 284-9977 **Phone:** (480) 301-7629 **Phone:** (480) 342-6112 **Institution Name and Address:** Mayo Clinic Rochester 200 1st St SW Rochester, MN 55906 Mayo Clinic Arizona 5777 E Mayo Blvd Mayo Clinic Building Phoenix, AZ 85054	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate (The RSA is independent of the Study Team)	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information

You can contact …	At …	If you have questions about …
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

Other Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

1. Why are you being asked to take part in this research study?

You are being asked to participate in this study because you are between the ages of 40 and 74 and are having a screening mammogram.

2,000 patients may participate in this study in collaboration with Mayo Clinic and Mountain Park Health Center.

2. Why is this research study being done?

Mammogram results now inform you of your breast density. The purpose of this study is to examine three different ways to communicate this information. This study will help determine if one way is better than the others in helping women understand their breast density results, and how much it costs to provide this information. This study will contribute new knowledge about how women understand breast density and help determine the best way to deliver this information to patients. In addition, we will use the information we collect in this study to address other questions about breast density, including how it relates to other lifestyle and clinical risk factors for breast cancer.

3. Information you should know

Who is Funding the Study?
The funding for this study will be provided by a grant from the National Institutes of Health.

4. How long will you be in this research study?

You will be asked to participate in this study for five years from the date you receive your breast density notification.

5. What will happen to you while you are in this research study?

If you are eligible for this study, you will be asked to complete three surveys. The first survey will take place upon your enrollment to the study and will take you approximately 20 minutes to complete.

The second survey will occur after you have received your mammogram results, so approximately 2 weeks after you have your mammogram. The clinical research coordinator (CRC) will contact you by telephone or mail to complete the survey.

The third and last survey will be approximately 1 year after you have received your mammogram results. The CRC will contact you by telephone or mail and ask you questions about how you are feeling about your results and your plans for getting a mammogram or additional screening for breast cancer in the future.

We may review your medical record for research. We may also ask you to allow us to collect and review medical records from other health care providers. We will only collect and review records related to your breast cancer screening or tests related to your breast health and breast density follow up appointments.

You will receive standard mammography as part of your routine clinical care, and you will receive your mammogram results whether or not you decide to be in this study. If you decide to be in this study, you may receive additional written educational information with your mammogram results or you may be contacted by phone to talk about your results with a *promotora* (a bilingual health educator) in addition to receiving your mammography results. We are studying 3 different ways to give breast density results to patients, and women in this study will be assigned to receive their mammogram results in one of the three ways. Whether or not you receive educational information about breast density or have a phone call about your mammogram results will be determined randomly (by chance):

- You have a 1 in 3 chance of getting your mammogram results as you usually do, without any additional written educational information.
- You have a 1 in 3 chance of getting your mammogram results along with additional written educational information about breast density.
- You have a 1 in 3 chance of getting your mammogram results along with additional written information and a phone call from the *promotora* to discuss the information.

For women in the third group, some of the phone calls with the *promotora* will be recorded for quality assurance purposes. These calls will also be reviewed for research purposes; for example, to better understand the questions women have about breast density. In the event you are assigned to the third group, which includes the *promotora* call, please select your response below:

I am willing to allow my phone conversation with the *promotora* to be recorded:

Please mark one box:

☐ Yes ☐ No Please initial here: _____Date: _____

6. What are the possible risks or discomforts from being in this research study?

This is a minimal risk study. There are no significant risks for completing the surveys or having your medical record reviewed. It is possible that some of the survey questions about how you are feeling or what you are thinking will seem too personal. You can skip any questions that you do not want to answer. The study surveys will not become a part of your medical record and can only be accessed by study personnel. All information and data from this study will be stored in a Mayo Clinic study database that is password-protected.

7. Are there reasons you might leave this research study early?

Taking part in this research study is your decision. You may decide to stop at any time.

8. What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:
Mayo will give medical services for treatment for any bad side effects from taking part in this study. Such services will be free if not covered by a health plan or insurance. No additional money will be offered.

9. What are the possible benefits from being in this research study?

This study is will not make your health better. The study may, however, help you understand the results of your mammogram.

10. What alternative do you have if you choose not to participate in this research study?

This study is being done to gather information. You may choose to not take part in this study.

11. What tests or procedures will you need to pay for if you take part in this research study?

You will need to pay for all tests and procedures that you would normally have as part of your regular medical care, including your mammogram.

12. Will you be paid for taking part in this research study?

You may be compensated a maximum of $75 upon completing this study.

You will be given $25 upon completion of the first survey, $25 upon completion of the second survey approximately 4 weeks later, and $25 upon completion of the third survey approximately one year after receiving your mammogram results.

13. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Your answers to our survey questions will be assigned a code that will be linked to your information in a secure database only accessible by research study staff.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Approval Date: **July 18, 2019**
Not to be used after: **July 17, 2020**

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.
- By signing this form, you provide Mountain Park Health Center express permission to provide Mayo Clinic with your health information related to this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

MAYO CLINIC

Name and Clinic Number

Approval Date: **July 18, 2019**
Not to be used after: **July 17, 2020**

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

MAYO CLINIC

Name and Clinic Number

Approval Date: **July 18, 2019**
Not to be used after: **July 17, 2020**

ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature