About the study

What is the Wisdom Study?

The Wisdom Study is designed to end the confusion about breast cancer screening. By comparing two safe and accepted screening recommendations, we can discover the best screening guidelines for ourselves, our sisters, our daughters, and future generations of women. Together, we can discover the best way forward.

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What are the benefits of participating in the Wisdom study?

By participating in this study, you will help us determine how to best screen every woman. You will have access to the latest information on breast health provided from a source you can trust. You may also have access to advanced genetic testing that is currently not routinely available. Most advances that have been made in the prevention, diagnosis and treatment of breast cancer are due to participation of women like you in studies like this. By participating you are joining a community of 100,000 women who will end the confusion for yourself, other women, and future generations of women.

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What is the purpose of the Wisdom study?

The goal of this study is to find the safest and most effective schedule for women to get screened for breast cancer. The study aims to determine how to best screen every woman and learn the best way to use mammograms to catch breast cancer while reducing the number of false alarms and biopsies for women without breast cancer. This study will compare routine annual and personalized screening.

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Why is this study needed?

There is a lot of confusion about when and how often a woman should get a mammogram. Breast cancer experts don’t all agree. The Wisdom study hopes to provide clarification on which method is safer and more effective for women: routine annual screening or personalized screening.

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Who is conducting this study?

The Athena Breast Health Network is conducting this study. Athena is a group of breast cancer experts, health care providers, researchers, and patient advocates at five University of California Medical Centers: (UC Davis, UC Irvine, UC Los Angeles, UC San Diego, UC San Francisco); and the Sanford Health System in North and South Dakota, Iowa and Minnesota. For more information on Athena visit our website at www.athenacarenetwork.org

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Who is funding the Wisdom study?

This study has been funded by the Patient-Centered Outcomes Research Institute (PCORI), the Robert Wood Johnson Foundation, and private donations.

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Is the Wisdom study part of Athena research?

Yes. The Wisdom study is a way for Athena to harness the power of the collaboration across the network and gather a large set of data which in turn will help us find the best way to screen all women for breast cancer. The goal of Athena is to take what we learn through research and integrate it with your care in a short period of time.

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Participation

How can I participate in the Wisdom study?

You can participate in the study if you are a female between 40 and 74 years old, you live in a region in which the Athena network currently operates, and you have never had a breast cancer or ductal carcinoma in situ (DCIS) diagnosis. We will confirm that you are eligible, and if you decide to join the study you will complete a few health questionnaires and possibly provide a saliva sample.

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Is there any cost or compensation for participating in the trial?

Your insurance provider will be billed and will cover all the costs of study services. If you are not covered by a participating insurer, gift funding will cover the cost of study participation, including the saliva test provided for women in the Personalized Group. There is no monetary compensation for participating in the study, and there is no cost to you to join the study.

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What can I expect once I join the Wisdom Study?

If you are in the Routine Annual Screening group:

1. You will complete a series of questionnaires, including questions about your health history.
2. We will encourage you to have an initial screening mammogram, or return for your next mammogram one year from the date of your most recent mammogram.
3. If our team believes you are at higher than average risk for breast cancer, you will receive a copy of your detailed risk report. You will have the opportunity to discuss your risk over the phone with a Breast Health Specialist, an individual who has specialized training in breast cancer risk assessment and genetics. – Your Specialist may recommend follow-up activities, such as more frequent screening, or suggest ideas about how you may lower your risk for breast cancer.
4. We will ask you to complete follow-up questionnaires every year to see if there are any changes to your family cancer history, personal history and health status.

If you are in the Personalized Screening group:

1. You will complete a series of questionnaires and provide a saliva sample to look for inherited (genetic) risk factors for breast cancer. This test will include 9 genes (including BRCA1 and BRCA2), and a collection of single nucleotide polymorphisms, or SNPS, that have been associated with risk of breast cancer.
2. You will receive a screening recommendation that is based on the results of your answers to the questionnaire, your mammographic breast density, and your genetic testing results. This screening recommendation letter indicates when you should return for your next mammogram based on whether you are at higher than average, average, or lower risk than average of developing breast cancer. You could be asked to return in 6 months, 1 year, 2 years, or wait until you turn 50 to start screening (if you are not 50 already).
3. If you are determined to be at elevated risk, you will receive a call from a Breast Health Specialist. She may recommend follow-up activities or suggest ideas about how you may reduce your risk for breast cancer.
4. We will ask you to complete follow-up questionnaires every year to see if there are any changes to your family cancer history, personal history and health status.

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How it works

How does the Wisdom Study work?

The Wisdom Study works to end the confusion about what is the best way to use the screening mammogram tool. If you are eligible to join, you will fill out some questionnaires, and then you will be randomly assigned into one of two screening groups: Routine Annual Screening group or Personalized Screening group. You will have the option to choose your study group if you do not agree to be assigned to a group. All Wisdom Study participants will receive one of the currently approved screening guidelines. You will have the peace of mind knowing that your own personal health history is being considered whatever your recommendation. As Wisdom Study participant, you will have a personal evaluation to determine your screening recommendation based on your answers to the health history questionnaire (and your mammogram report if you have had one). You will also receive information about how to prevent breast cancer and keep healthy.

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What is Routine Annual Screening?

Routine Annual (or every year) screening is the practice of having a mammogram every year starting at age 40. This is the current guideline that most doctors and patients follow. It is recommended by various medical professional groups such as the American Congress of Obstetricians and Gynecologists and the American College of Radiology.

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What is Personalized Screening?

Personalized screening is the practice of having a mammogram on a schedule that is based on a woman's personal risk factors. This is a new approach to screening that we are evaluating in the Wisdom study. The personalized screening approach expands upon the guidelines recommended by the United States Preventive Services Task Force. These guidelines recommend that women get a mammogram every other year starting at the age of 50, and that women under 50 discuss with their doctor when to start screening.

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Why should I choose to be randomized?

Scientists agree that randomization is the very best way to test two options with no built in bias to determine which option delivers the best results. The women who agree to be randomly assigned to a group will be doing the most they can do to help us generate new scientific evidence and end mammogram screening confusion. They study asks you to agree to follow a screening schedule for five years in the hopes of clarifying for everyone which method is best.

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Will my doctor know I am in the Wisdom study?

If you receive care at one of our participating facilities, all of the details of your participation with the Wisdom study will be communicated to them, including genetic test results and your screening recommendation. If you receive care at a different facility, all the information will be available to you on your secure Wisdom portal so that you can download the material and discuss it with your doctor.

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When I am due for my mammogram, will the Wisdom Study order my mammogram?

The Wisdom Study staff will not be ordering your mammogram. When you are due for your mammogram, please contact your Primary Care Doctor to put in a referral for a mammogram.

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What factors will you use to determine my breast cancer risk?

Decades of research have provided us with a better understanding of breast cancer biology and the factors that contribute to breast cancer risk. This Wisdom study will give us the opportunity to use what we now know to find the safest and most effective breast screening program for all women. We will be looking at the following to determine your breast cancer risk regardless of which group you are in (Routine Annual or Personalized):

- Your Age

- Your race/ethnicity
- Your family history of breast cancer
- Your history of benign (non-cancer) breast issues
- Your breast density (how fibrous and glandular your breast tissue is, which can be seen on your mammogram)

If you are in the Personalized Group, these additional factors will be included in your breast cancer risk assessment:

- Your genes (inherited gene mutations that have been linked to breast cancer risk)

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What if I move or change where I receive my care during the study?

We currently can follow women living anywhere in California, or the Midwestern states where Sanford Health Network operates. If you move during the study, please update your contact information on your Wisdom web portal, and contact your study coordinator if you know you will be moving out of state.

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I am not a patient of a UC Medical Center of Sanford health medical center, what if I usually get my mammograms at a different facility?

During the consent process, we ask that you sign a medical release form which allows us to request your mammogram and other follow up records.

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What happens if I find a lump or experience another breast symptom?

If you discover a breast lump or other breast symptom, please contact your Primary Care Doctor who will evaluate the area and recommend appropriate next steps. Please do not put off getting a mammogram to evaluate a symptom due to your involvement in the Wisdom Study.

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What happens if my personal/family history changes once I assigned to my study arm?

As a Wisdom participant, we ask that you complete a yearly questionnaire to keep us updated. If your risk should change based on changes in your personal health or family history, we will reassign you to the appropriate risk group.

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What if my insurance changes while I am in the study?

Changes to your insurance do not affect your participation in the trial, but please keep us informed within your participant portal.

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Genetic Testing

Who provides genetic testing?

Color Genomics will be providing the genetic testing for the Wisdom Study. They will provide you with a saliva kit to collect your saliva sample along with a return box and shipping label to mail back to the lab. Color Genomics will look for genetic clues, and return the results to the Wisdom Study team to give to you. To learn more, go to https://getcolor.com (Wisdom study will only test for genes linked to breast cancer risk. Wisdom study does not test other genes in the standard commercial Color Genomics panel).

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What genetic information are you testing?

The Wisdom Study is looking at nine genes associated with breast cancer risk. These nine genes are:

- BRCA1
- BRCA2
- ATM
- P53
- PTEN
- CHEK2
- CDH1

- PALB2
- STK11

In addition, the Wisdom Study is looking at over 100 single nucleotide polymorphisms (SNPs), which are small changes in the genes that individually do not mean much, but collectively can bump up or down a woman's breast cancer risk. In most cases, the SNP score itself will not place a woman into a higher risk category.

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Does the Annual group have access to genetic testing?

The Annual group will not receive genetic testing through the Wisdom Study. If desired, women in the annual group can purchase the genetic test outside of the study at www.color.com

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How long will it take to get my results?

Color's emphasis is on providing you with the highest quality results possible, and that means giving individual attention to every sample. The average turnaround time is currently 4-10 weeks from the day your sample is received at the laboratory, but the actual time will be subject to the data associated with each unique sample. Color will notify you via email each step of the way: when your kit has shipped, when you've successfully activated it, when your sample has arrived back at the lab, and when your results are ready.

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What type of results can I expect?

As a part of the study, a number of genes will be tested to see if you have alterations that increase cancer risk. It is possible that as new genes related to cancer risk are discovered, they may be added to this list, and we will notify you if changes to your medical care are indicated. We will provide the results of your genetic testing to you as part of the study. A Breast Health Specialist will be available to talk with you about your results and what they mean to your health and to your family members' health. In addition, Color Genomics will also look for small alterations in all your genes that might contribute to breast cancer risk. Scientists call these minor differences single nucleotide polymorphisms (SNPs). The results will not be returned but will be incorporated into

screening recommendations. Please note, only about 1-3% of women test positive for a gene alteration.

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Can I be discriminated against by insurance companies if I should test positive for a gene mutation?

No. The Genetics Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects individuals from genetic discrimination in health insurance and employment. The Act prohibits group health plans and health insurers from denying coverage to a healthy individual or charging that person higher premiums based solely on a genetic predisposition to developing a disease in the future. It also bars employers from using individuals' genetic information when making hiring, firing, job placement, or promotion decisions.

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Will my genetic test results become part of my medical record?

If you are seen at a participating health center in the Athena Breast Health Network, we are required by compliance offices at each study site to enter genetic testing results and study screening recommendations into the appropriate electronic medical record. If you have never been seen within the University of California or Sanford Heath Network, your information will be available only to you on your private Wisdom web portal, and you may share it with your primary care physician if you wish. If you are seen at a participating center, there is just no way around putting this genetic information in your medical record—participants who discover they have a positive gene mutation would need this information entered into their medical record anyways to have their insurance company pay for increased screening and prevention treatment. However, genetic testing is only completed in the Personalized Group. If you choose to be in the Annual Group, no genetic test is performed and therefore no results will need to be entered in your record. We want to have women participate in whatever way they feel comfortable!

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