

**Achieving Equity in Genomic Testing for Breast Cancer Through Partner-Led Strategies
and Policies - Informed Consent Form and Patient Survey**

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Date: June 21, 2023

Achieving Equity in Genomic Testing for Breast Cancer through Partner-Led Strategies and Policies Patient Survey

Welcome to our survey on breast cancer tumor testing! Thank you for taking the time to be part of our study in the Stanford University Department of Medicine. We are conducting this study to learn more about how patients are receiving medical treatment after being diagnosed with breast cancer. In particular, we want to know if patients are receiving tumor testing.

You may have previously indicated that you are interested in completing this survey. Before we start, we would like to ask you for your consent to use your responses to this survey.

If you have any more questions about the study, please contact the primary researcher on the project, Dr. Manali Patel at 650-736-2768 or manalip@stanford.edu.

On the next page you will find the consent form for our study. This form provides more information about the study and what it means for you to be part of this study. It also provides details about how your personal information is protected. Please read through the whole form before continuing.

STANFORD UNIVERSITY RESEARCH CONSENT FORM

Protocol Director: Manali I. Patel, MD

Protocol Title: Achieving Equity in Genomic Testing for Breast Cancer through Partner-Led Strategies and Policies

If you are participating in any other research studies, please indicate this to the researcher.

FOR QUESTIONS ABOUT THE STUDY, CONTACT:

Manali I. Patel, 3180 Porter Drive, Palo Alto, CA 94304; 650-736-2768

DESCRIPTION: You are invited to participate in a research study assessing access to precision medicine, particularly genomic testing, for breast cancer patients in California. We hope to identify barriers and facilitators to genomic testing for the socioeconomically and culturally diverse California population, with the hope of making it more accessible.

As a participant in the study, after you have read, understood, and provided your verbal or written consent, you will be asked to participate in the first phase of our study. Participation consists of a one-time survey that will ask about your experience as a breast cancer patient or caregiver, with specific focus on your understanding and experience with genomic testing as used in breast cancer care. This survey will last about 20-30 minutes. It can easily be completed online with a secured link provided upon your consent through Qualtrics (a secured Stanford-approved data collection platform), or if needed, via printed and mailed survey.

If you are a patient enrolling in the study, some information may be obtained from your medical record, including cancer diagnosis, dates of diagnosis and medical treatments, visits, or hospitalizations and other information described in “What Personal Information Will Be Obtained, Used, or Disclosed?” below.

If you are a caregiver enrolling in the study, some information may be obtained about your care recipient’s medical history, including cancer diagnosis, date of cancer diagnosis, and medical treatment types. We will not collect this information from the patient’s medical record unless they themselves are enrolled in the study.

DATA SECURITY: Any information that is obtained in connection with this study and that can identify you will remain confidential. Confidentiality will be maintained by storing all electronic records (computer files, electronic databases, etc.) on Stanford’s protected servers, Stanford-

approved Qualtrics systems (a secured web-based data collection platform), secured Stanford Medicine Box folders, or in a locked file cabinet in a locked office, in the case of paper documents. Both Stanford Medicine Box and Qualtrics are Stanford-approved, protected with dual-authentication login, and only accessible to authorized research staff. After completion, surveys will be anonymized and labelled with a unique identifier number. Only authorized research staff will have access to data, and all final data will be anonymous and untraceable. All

data will be confidential. The results of your participation in this project will be used for research purposes only.

Identifiers might be removed from identifiable private information. After such removal, the de-identified information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

RISKS AND BENEFITS: Only minimal risks, such as slight discomfort answering personal health or clinical practice questions, are expected. There are no physical, psychological, economic, or social risks associated with the research. Participants may experience a slight discomfort that is normal when discussing cancer care. Patients and caregivers who are participating may use all social work and mental health services available as part of their usual care. There are no other perceivable risks associated with participating in this study beyond discussion of cancer or breaches of confidentiality, which we take every care to avoid. If you are a patient, your decision regarding whether to participate in this study will not affect your current medical care. If you are a caregiver, your decision regarding whether to participate in this study will not affect your care recipient's medical care.

There is no guarantee or promise that you will receive any personal benefits from this study; however, the benefit which may reasonably be expected to result from this study is improved access to genomic testing for breast cancer patients, particularly those who come from underserved backgrounds. It is possible that participation may prompt additional discussion within your cancer care circles that may change cancer management within your own care, practice, organization, or jurisdiction as a result. Your decision whether or not to participate in this study will not affect your medical care.

TIME INVOLVEMENT: Your participation in this portion of our study, requiring a one-time completion of our survey, will take approximately 20-30 minutes.

PAYMENTS/REIMBURSEMENTS: You will receive a \$25 gift card for your participation in our survey. Only the first 250 participants will receive a \$25 gift card.

There are no costs to you for any of the research activities done as part of this research study. If you choose to complete a paper copy of the survey, we will provide a return envelope to mail the survey to our research staff. There will be no expenses on your part for mailing the survey.

ALTERNATIVES: The alternative is to not participate in the study. As a patient, your decision either to participate or not participate in this study will not affect your medical care.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this study, please understand your participation is voluntary, and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You also have the right to refuse to answer particular questions.

The results of this research study may be presented at scientific or professional meetings, provided to statewide policymakers, or published in scientific journals. However, your identity will not be disclosed.

FUNDING SOURCE: The California Breast Cancer Research Program (CBCRP) is providing financial support and/or material for this study.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns, or complaints about this research study, its procedures, or risks and benefits, you should ask the principal investigator, Dr. Manali I. Patel at 650-736-2768 or manalip@stanford.edu.

Injury Notification: If you feel you or have been hurt by being a part of this study, please contact the Protocol Direct, Manali I. Patel at 650-736-2768.

Independent Contact: If you are not satisfied with how this study is being conducted or if you have any concerns or general questions about the research or your rights as a participant and would like to speak to someone independent of the research team, please contact the Stanford Institutional Review Board (IRB) at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB: Stanford University 1705 El Camino Real, Palo Alto, CA 94306.

WITHDRAWAL FROM STUDY: The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES – FOR PATIENT PARTICIPANTS

Because information about you and your health is personal and private, it generally cannot be used in this research study without your authorization. If you consent to participating in this study, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before providing your consent.

If you are a caregiver, please note that we will not be collecting your own health information.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to learn about factors that obstruct or improve access to precision cancer care for breast cancer patients, particularly those who belong to historically underserved communities. In particular, we are wanting to learn about your understanding of, experience with, and perspectives on genomic testing.

After you have read and understood this form, and provided your consent, you will be invited to participate in a one-time survey to be completed through Stanford Qualtrics, our secured online data collection platform. This survey will ask questions about your breast cancer diagnosis, your experience with receiving medical care for your cancer, and your experience with genomic testing as a tool to guide breast cancer care.

The information you provide will not be shared with your clinical team or other parties. It will not affect the care you are currently receiving.

Do I have to sign this authorization form or provide my verbal consent?

You do not have to sign or consent to this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign or verbally consent, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., if it is necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to the Protocol Director,

Manali I. Patel, manalip@stanford.edu

3180 Porter Drive

Palo Alto, CA 94304.

What Personal Information Will Be Obtained, Used, or Disclosed?

Your health information related to this study that may be used or disclosed in connection with this research study includes, but is not limited to: your name, address, telephone number, and email address (if you have one) so that we can contact you or send you study materials. As a patient, we may also collect information on your cancer diagnosis, date of diagnosis, location of clinical care, health insurance type, and genomic testing records.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The protocol director: Dr. Manali I. Patel
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- California Breast Cancer Research Group

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information in this study will end on December 31, 2050 or when the research study ends, whichever is earlier.

If you consented in person, a paper copy of the form will be provided and if you consented over the phone, we will have a copy mailed to you. If you agree to participate in this research, please indicate this to the researcher now.

- I have read this form completely and agree to participate in the study
- I have read this form completely and would like to decline participating in the study
- I have read this form completely but would like further information before deciding

If you picked the choice “I have read this form completely but would like further information before deciding,” please provide your contact information and preferred times to be contacted so we can provide more information about our study.

First Name: _____

Last Name: _____

Phone Number: _____

Email: _____

Preferred times to be contacted: _____

If you have agreed to participate in the study, please continue to the next page. Mark your answers as check marks or X’s in the circles next to the answer choices. For questions that say “check all that apply,” you can check multiple circles.

Example:

Answer choice 1

Answer choice 2

Answer choice 3

1. What type of cancer do you have or recently had? (Check all that apply)

- Breast cancer
- GI cancer
- Thoracic cancer
- Gynecological cancer
- Hematological/blood cancer
- Head/neck cancer
- Other cancer
- None

2. If known to you, when you were told that you had breast cancer, what was the stage of your cancer?

- Early stage → **go to question 2a**
- Locally advanced (stage III) → **skip question 2a**
- Metastatic (stage IV) → **skip question 2a**
- I don't know → **skip question 2a**

2a. If you were told you had early stage breast cancer, which stage were you told you had?

- Stage I
- Stage II
- I don't know

3. When were you first told that you have breast cancer?

- 1 month ago or less → **skip question 3a**
- 2-3 months ago → **skip question 3a**
- 4-6 months ago → **skip question 3a**
- 7-9 months ago → **skip question 3a**
- 10-12 months ago → **skip question 3a**
- More than 12 months ago → **go to question 3a**

3a. If you were first told that you have breast cancer more than 12 months ago, did your cancer come back or worsen in the last 12 months?

- Yes
- No
- I don't know

4. Where are you receiving your cancer care? If more than one place, please list all.

- State (for example, California) _____
- City (for example, San Jose) _____
- Hospital or clinic (for example, Kaiser Permanente) _____

5. Are you currently receiving treatment (e.g. chemotherapy, radiation therapy, immunotherapy, hormone therapy, surgery)?

- Yes → **go to question 5a**
- No - I have completed treatment already → **go to question 5a**
- No - I have not received any treatment yet → **skip to question 6**
- I don't know → **skip to question 6**

5a. What treatment have you received? (Check all that apply)

- Chemotherapy
- Radiation therapy
- Hormone therapy
- Immunotherapy
- Scheduled for surgery or recently had surgery
- I don't know
- Other → **Please specify what other therapy you have received:** _____

5b. When was the date of your last cancer treatment?

- Within the last month
- 2-6 months ago
- 6-12 months ago
- More than 12 months ago

6. Which type of health insurance do you have? (Check all that apply)

- Private insurance that I get from my job or my partner's job
- Private insurance that is not provided through my job
- Medicaid
- Medicare
- Other public insurance that I get from the county or the government, such as the VA
- Uninsured
- Cash
- I do not know
- Other → **Please specify the type of health insurance you have:** _____

The following questions are about tumor testing. Please answer to the best of your ability.

7. Have you heard of tumor testing?

- Yes → **go to question 7a**
- No → **skip to question 8**
- I don't know → **skip to question 8**

7a. Where did you learn about tumor testing?

- From my doctor or nurse
- From an internet search
- From my patient navigator
- From a community health worker
- From a patient support group
- From a patient advocacy organization (for example, American Cancer Society)
- Other → **Please specify where you learned about tumor testing:** _____

8. *Tumor testing is done after eligible patients are already diagnosed with usually an early stage of breast cancer. It is also called genomic testing. In breast cancer, tumor testing is done on the patient's breast tumor to measure specific changes in the DNA only occurring in the tumor itself. Doctors look for these changes to predict how the cancer might behave and what treatments might be most helpful. Examples of this kind of tumor testing are Oncotype DX or Mammoprint.*

Tumor testing is different from genetic testing, which may be used when there is a family history of breast cancer.

Has your cancer doctor spoken to you about tumor testing?

- Yes
- No
- I don't know

9. Have you received tumor testing?

- Yes → **go to question 9a**
- No → **skip to question 13 on page 17**
- I don't know → **skip to question 15 on page 18**

9a. Did you receive tumor testing before you started any breast cancer treatment?

- Yes → **skip to question 9c**
- No → **go to question 9b**
- I don't know → **go to question 9c**

9b. When did you receive tumor testing?

- After starting a treatment
- After switching between different treatments
- I don't know

9c. How long after being told you have breast cancer did you receive tumor testing? (Check all that apply if you received tumor testing more than once)

- Within 1-2 months of being told I had breast cancer
- Within 3-6 months after being told I had breast cancer
- More than 6 months after being told I had breast cancer

9d. Did you experience any difficulties getting tumor testing (for example, financial difficulties, getting no information in your preferred language)?

- Yes → **go to question 9e**
- No → **skip to question 10**
- I don't know → **go to question 9e**

9e. What difficulties did you face? (Check all that apply)

- My insurance would not pay
- It cost too much
- There was no information in my language
- I did not know why tumor testing would be important
- There was no place near where I live to get the tumor testd
- Other → **Please explain what other difficulties you faced in getting tumor testing:**

10. Did receiving tumor testing affect your and your doctor's decisions about your breast cancer treatment?

- Yes → **go to question 10a**
- No → **skip to question 11**
- I don't know → **skip to question 11**

10a. In what way did tumor testing change your cancer treatment? (check all that apply)

- I decided to get treatment for my breast cancer
- I decided to not get any treatment for my breast cancer
- I could continue treatment for less time
- I had to continue treatment for more time
- My doctor changed my treatment (for example, I went from chemotherapy to surgery, or chemotherapy to hormone therapy, etc)
- My doctor added more treatment (for example, I was now on chemotherapy plus radiation, surgery plus chemotherapy, etc)
- Other → **Please specify how tumor testing affected your cancer treatment:**

11. Did your insurance pay for your tumor test?

- Yes, all of the costs → **skip to question 12**
- Yes, some of the cost → **go to question 11a**
- No → **go to question 11b**
- I don't know

11a. If your insurance **did** help cover the cost of tumor testing, how much did they cover?

Please provide your best guess

- Between 0 and 24%
- Between 25 and 49%
- Between 50 and 74%
- Between 75 and 100%
- I don't know

11b. If your insurance **did not** help cover the **entire** cost of tumor testing, how did you pay for it? (Check all that apply)

- I paid for it by myself
- My family helped me to pay
- A repayment plan negotiated with my clinic
- Donation or charity care from my clinic
- Other → Please specify how you paid for tumor testing:

12. How much in US dollars did you personally pay for tumor testing (amount not paid for by insurance)? If you do not know for sure, please provide your best guess.

SKIP TO QUESTION 15 ON PAGE 18***

IF YOU DID NOT RECEIVE TUMOR TESTING:

13. Was tumor testing made available as an option for you?

- Yes
- No
- I don't know

13a. Why was tumor testing not completed? (Check all that apply)

- I could not afford tumor testing
- I did not know if tumor testing was an option for me
- My doctor did not think that tumor testing would help improve my cancer care
- I did not know enough about tumor testing
- There was no information about the testing in my own language
- Other → **please specify why tumor testing was not completed:**

14. Would you have liked to have tumor testing done if it was an option available for your diagnosis?

- Yes → **skip to question 15**
- No → **go to question 14a**
- I don't know

14a. If you would **not** have liked to receive tumor testing, please specify why.

15. What do you worry about when it comes to receiving care for your breast cancer?
(Check all that apply)

- If my insurance will pay for the care that I need
- Not having health insurance
- Not being able to talk to my doctor or nurse in my own language
- Having trouble contacting my doctor or nurse when I have questions or concerns
- Having trouble understanding medical terms and details about my cancer
- Not having enough information about my cancer treatment options, including tumor testing
- Having difficulties getting cancer care because of where I live (for example, living in a rural area)
- Other → **please specify what your worries are when it comes to receiving care for your breast cancer:** _____

16. What would you want to change to improve the process of receiving tumor testing?
(Check all that apply)

- Paying less for tumor testing
- Learning more about tumor testing
- Learning more about my breast cancer
- Learning more about my tumor test results
- Having more time with my doctor or nurse to talk about my breast cancer and my treatment
- Being able to get tumor testing and cancer care closer to where I live
- Other → **please specify what you would like to change to improve the process of receiving tumor testing:** _____

The next questions are about how you receive health information related to your cancer care. Please answer to the best of your ability.

17. I understand my cancer diagnosis.

- Strongly disagree
- Disagree
- Agree
- Strongly agree
- Not applicable

18. I was able to learn about my cancer in my own language.

- Strongly disagree
- Disagree
- Agree
- Strongly agree
- Not applicable

19. I felt I had enough help to learn about my cancer and my treatment options.

- Strongly disagree
- Disagree
- Agree
- Strongly agree
- Not applicable

20. After learning that I had breast cancer, I understood the treatment options that were available to me.

- Strongly disagree
- Disagree
- Agree
- Strongly agree
- Not applicable

21. I understand my current treatment plan.

- Strongly disagree
- Disagree
- Agree
- Strongly agree
- Not applicable

22. I understand what tumor testing is.

- Strongly disagree
- Disagree
- Agree
- Strongly agree
- Not applicable

23. I understand how tumor testing can affect my cancer treatment.

- Strongly disagree
- Disagree
- Agree
- Strongly agree
- Not applicable

24. Tumor testing has been a good addition to my cancer care plan.

- Strongly disagree
- Disagree
- Agree
- Strongly agree
- Not applicable

25. If you have not received tumor testing: I would like to have access to tumor testing.

- Strongly disagree
- Disagree
- Agree
- Strongly agree
- Not applicable

These final questions help us organize your responses to our survey. We do not share your personal information with anyone.

26. What is your name?

First Name: _____

Last Name: _____

27. What is today's date? (mm/dd/yyyy, for example 05/25/2023)

28. What year were you born? (for example, 1995)

29. What sex were you assigned at birth, on your original birth certificate?

Male

Female

I don't know

Prefer not to answer

30. What is your current gender?

Male

Female

Transgender

Non-binary

Questioning or unsure

I use a different term → Please provide the term you use to describe your gender: _____

Prefer not to answer

31. Which of the following best represents how you think of yourself? (select ONE)

- Lesbian or gay
- Straight, that is, not gay or lesbian
- Bisexual
- Trans
- Queer
- Questioning or unsure
- I use a different term → **Please provide the term that best represents how you think of yourself:** _____
- Prefer not to answer

32. Do you identify with being Spanish, Hispanic, or Latino? If so, you will be asked whether you identify with a specific ethnic group.

- Spanish
- Hispanic
- Latino
- None of the above
- Prefer not to answer

33. Which of the following would you say is your race?

- White
- Black or African American
- American Indian or Alaska Native
- Asian
- Native Hawaiian or Pacific Islander
- Race not listed → **Please state how you describe your race:** _____
- Prefer not to answer

34. How would you describe your ethnicity? (For example, Guatemalan, Japanese, Kenyan, etc)

35. What is your marital status?

- Married
- Widowed
- Divorced
- Separated
- Never married
- A member of an unmarried couple
- Prefer not to answer

36. What is the highest level of school you have completed or the highest degree you have received?

- Less than high school diploma
- High school diploma
- Some college but no degree
- Associate's degree (2-year)
- Bachelor's degree (4-year)
- Master's degree
- Doctoral degree (PhD)
- Professional degree (JD, MD, etc)
- Prefer not to answer

37. What is your current job status?

- Employed full-time
- Employed part-time
- Self-employed
- Unemployed looking for work
- Unemployed not looking for work
- Retired
- Disabled
- Student
- Prefer not to answer

38. What is your annual household income?

- Less than \$35,000
- \$35,000 to \$49,999
- \$50,000 to \$99,999
- \$100,000 or more
- Prefer not to answer

39. How many people are living in your household (including yourself)?

- I live alone
- 2
- 3
- 4
- 5
- 6
- More than 6
- Prefer not to answer

40. What is the primary language you speak at home?

- English → **skip to question 41**
- Spanish → **go to question 40a**
- Other → **Please specify the primary language you speak at home and go to question 40a:** _____
- Prefer not to answer

40a. Since you speak another language other than English at home, in your own opinion, how well do you understand and speak English?

- Not well at all
- Slightly well
- Moderately well
- Very well
- Prefer not to answer

41. Were you born in the United States? This information is not shared outside of this study.

- Yes, I was born in the United States.
- No, I immigrated to the United States → **How many years have you lived in the US?** _____
- Prefer not to answer

42. Do you have access to any of the following? (Check all that apply)

- Desktop or laptop computer
- Tablet
- Internet access at home
- Home telephone (landline)
- Smartphone
- None of the above

Additional Questions about Participation in our Study

43. Would you be interested in participating in a 45-minute interview with our team to better understand your experiences with tumor testing and breast cancer?

Yes → **go to question 43a**

No → **skip to question 44**

43a. Please provide your contact information (name, phone number, and email if you have one) and preferred times for our team to contact you regarding an interview. Your information will be kept secure, and will not be shared with anyone outside of our immediate research staff.

Phone number: _____

Email: _____

Preferred times to be contacted:

44. Do you have a family member, friend, or other contact who serves as a caregiver for you? This could be a person close to you who helped you the most during this time.

Yes → **go to question 44a**

No → **skip to question 45**

44a. Would they be interested in participating in this survey?

Yes

Maybe

No

44b. Would you like to provide your caregiver's contact information now, or be contacted later to provide their contact information?

- I will provide their contact information now → **go to question 44c, skip 44d**
- Please contact me later to give their contact information → **skip to question 44d**

44c. Please provide the contact information for your caregiver (name, phone number, and email if they have one) and preferred times for our team to contact them. → **SKIP 44d**

- Name: _____
- Phone Number: _____
- Email: _____
- Preferred times to be contacted: _____

44d. Please let us know when you would like to be contacted about your caregiver's contact information.

- Your Phone Number: _____
- Your Email: _____
- Your preferred times to be contacted: _____

45. How did you hear about our survey? (Check all that apply)

- Through my doctor or nurse
- Through someone at the Bay Area Community Health Advisory Coalition (BAHAC)
- Through someone at the Chinese Community Health Resource Center (CCHRC)
- Through the Community Health Partnership, Inc.
- Through the Women's Cancer Resource Center (WCRC) in Berkeley
- Through the Cancer Resource Centers of Mendocino County
- Through social media
- Through ANCO
- Other → **Please specify how you heard about our survey.**

Thank you so much for taking our survey. We are grateful that you have shared your experiences related to breast cancer care and tumor testing.

46. We would like to send you a \$25 gift card for your time. When possible, we will send your gift card in the way that you prefer. Would you prefer email or mail?

- I prefer an emailed electronic gift card. → **go to question 46a, skip question 46b**
- I prefer a physical gift card. → **skip to question 46b**

46a. To receive your electronic gift card, please confirm your email address.

46b. If you would like to receive a physical gift card, please provide your name and the physical address where you would like to receive this gift card.

- First Name: _____
- Last Name: _____
- Number and Street Name: _____
- City: _____
- State: _____
- Zip Code: _____