utmb Health

The University of Texas Medical Branch at Galveston
Minimal Risk Consent Form

Protocol Title: **Tear Based Breast Cancer Detection**

IRB Number: **21-0026**

Sponsor: **Namida Lab**

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Why am I being asked to take part in this research study?
You are being asked to take part in this study because you are:

- Woman and has recently been diagnosed with breast cancer
- Being seen in breast health surgery clinic at UTMB.

Study Summary:

The following things you should know about this research study:

- The purpose of the study is to making a screening test for breast cancer using tears. If you chose to participate, you will be asked to provide a tear sample and we collect some information from you to help us in our study. (Note: Participants will not be given any results.) This will take approximately 20 minutes.
- Risks or discomforts from this research include conjunctivitis (which is the irritation or inflammation of the delicate membrane that covers the internal part of the eyelid and is attached to the cornea), scleral or corneal abrasion (irritation of the sclera, which is the white of the eye or of the cornea, which is the membrane that covers the pupil and iris of the eye) and loss of confidentiality.
- As a participant there is no direct benefit other than contributing to the development of the tear based test. You will receive a gift card in the amount of 25.00$ for your study participation.
- Taking part in this research study is voluntary. You do not have to participate and you can stop at any time.

Please take your time to read this entire form and ask questions before deciding if you want to take part in this research project.

DETAILED RESEARCH CONSENT

What is the purpose of this research study?
Namida Lab is making a screening test for breast cancer using tears. We need to collect tear samples to develop this test. Our goal is to increase breast screening rates and hopefully catch cancers at early stage when the survival rate is higher.
How many people will take part in this study?
About 50 people will take part in this study at UTMB.

What procedures are involved as part of this research study?
If you agree to take part, you will be asked to sign this consent form and complete the following procedures.
1. We collect some information from you (questionnaire) to help us in our study. This information includes your initials, age, sex, height, weight, race, questions about your eye health, questions about your reproductive health, questions about medications you may have taken today, information on your history and your family history of cancer.
2. We will review your medical record to collect clinical information regarding your breast density (size & shape), any diagnostic procedures for breast cancer, their results, treatments received and their outcome.
This information will not include your personal identifiers (name, date of birth, medical record number etc.) and will be stored within a locked file cabinet in a locked room (office of Dr. V. Suzanne Klimberg) that has limited access.
3. A tear sample will be collected:
a. A small strip of filter paper, called a Schirmer strip, will be used to collect your tear fluid.
b. The strip will be put inside your lower eyelid
c. You will be asked to keep your eyes closed for up to 5 minutes
d. After 5 minutes the strip will be removed, placed in the collection tube, and sent to the Namida Lab for testing.
(Note: Participants will not be given any results.)
Tear sample, study participant questionnaire and clinical info questionnaire will be shipped to Namida lab overnight.

What are the possible risks for choosing to participate in this research study?
It is unlikely you will be injured donating a tear sample
• conjunctivitis (which is the irritation or inflammation of the delicate membrane that covers the internal part of the eyelid and is attached to the cornea)
• scleral or corneal abrasion (irritation of the sclera, which is the white of the eye or of the cornea, which is the membrane that covers the pupil and iris of the eye).
The person collecting the tear sample has been trained on proper placement of the Schirmer strip to reduce discomfort.

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

What are the potential benefits for participating in this research study?
As a participant there is no direct benefit other than contributing to the development of the tear based test for breast cancer detection.
Will I be reimbursed for participating in this research study?
You will receive a gift card in the amount of 25.00$ for your study participation.

Is there an alternative treatment/procedure?
The alternative is not to participate in the study.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if:

- The sponsor cancels the research.
- The researchers believe that participation in the research is no longer safe for you.

How will my information be protected?
All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group.

Information you provide on the health history questionnaire will be stored separately from data for the exercise tests; the exercise test data will contain no personal information about you.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

How will my privacy be protected?
We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at UTMB, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

People outside of UTMB may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written

request that includes the study number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

Who can I contact with questions about this research study?
If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact V. Suzanne Klimberg, MD at (409)772-0529 or vsklimbe@utmb.edu

This study has been approved by the UTMB Institutional Review Board (IRB). If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information about the protection of human subjects in research, you may contact the IRB Office, at (409) 266-9400 or irb@utmb.edu.

Do I have to participate?
Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits to which you are otherwise entitled.

CONSENT TO PARTICIPATE:
The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study.

Signature of Subject	Date

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject.

Signature of Person Obtaining Consent	Date and Time of Consent Obtained

Printed Name of Person Obtaining Consent