Official Title: The Mathematics of Breast Cancer Overtreatment: Improving Treatment Choice Through Effective Communication of Personalized Cancer Risk

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
The Mathematics of Breast Cancer Overtreatment: Improving Treatment Choice through Effective Communication of Personalized Cancer Risk

CONCISE SUMMARY

Ductal carcinoma in situ (DCIS) is the presence of abnormal cells inside the milk ducts of the breast. We created a decision support website to help women diagnosed with DCIS make a decision about their treatment. This study will enroll healthy women volunteers to test this website.

After testing the website, participants will then fill out a survey. Participating in this study will take about 45-60 minutes total.

You will receive $25 in appreciation for your participation.

The only risk to this study is the potential loss of confidentiality.

INTRODUCTION

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. Please ask study staff to explain any words or information that you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Marc Ryser and his research team's salaries will be paid by this grant.

WHY IS THIS STUDY BEING DONE?

For women diagnosed with DCIS, there are several treatment options. This study will enroll healthy women volunteers to test a decision support website. The website was created to help women diagnosed with DCIS make a decision about their treatment.

After testing the site, participants will then fill out a survey. The feedback from this study will help us refine and validate the tool.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 200 people recruited from the Duke Mammography Clinic will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to take part, you will be asked to sign and date this consent form. The study team will email a signed copy to you. You will then receive an email with a survey link and study instructions. You will be asked to independently explore the decision support website. After exploring, you will be asked to complete a survey.

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HOW LONG WILL I BE IN THIS STUDY?
Your involvement in this study will take about 45 to 60 minutes total.

It will take about 20-30 minutes to explore the website and 20-30 minutes to complete a survey.

WHAT ARE THE RISKS OF THE STUDY?
The only risk to this study is the potential loss of confidentiality.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There are no direct benefits for being in this research study. However, the information we learn from this study may help future patients with DCIS.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study such as the Duke University Health System Institutional Review Board, representatives and affiliates of the NIH, or government agencies (for example, the FDA) for purposes such as quality control and safety. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law. This is very unlikely, but if disclosure is ever required, Duke University will take steps allowable by law to protect the privacy of personal information.

Survey data will be stored on a secure network. Only the study team approved by the Duke IRB will have access to the data.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

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You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

EXTERNAL WEBSITE
The study team developed and maintains the website used for the study, and Duke Health hosts it. As with any website that you visit, there may be potential security risks and Duke cannot guarantee that the website is free of risk.

WHAT ARE THE COSTS TO YOU?
It will not cost you anything to be in this study.

WHAT ABOUT COMPENSATION?
You will receive $25 after completing the session in appreciation for your participation.

For tax reporting purposes, you will need to provide your name, mailing address, and social security number (SSN) in order to receive compensation. Your information is saved on a Protected Data Directory, and only used for payment purposes. For Duke employees a Duke unique ID can be provided instead of a SSN.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. The investigators have the right to stop your participation at any time. This could be because you were unable to complete the study.

If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

CLINICALTRIALS.GOV
A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study, or if you have problems, concerns, questions or suggestions about the research, contact the Principal Investigator, Dr. Marc Ryser, at (919) 684-8294 during regular business hours and at (919) 699-8363 after hours and on weekends.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

(Optional)

_____	_____	_____
Signature of Principal Investigator	**Date**	**Time**