

THE OHIO STATE UNIVERSITY
AUTHORIZATION TO USE
PERSONAL HEALTH INFORMATION IN RESEARCH

Title of the Study: Variants in “High Risk” Breast Cancer Genes and Contribution to Cancer Risk
OSU Protocol Number: 2005C0066
Principal Investigator: Amanda Ewart Toland, PhD

Subject Name _____

Before researchers use or share any health information about you as part of this study, The Ohio State University is required to obtain your authorization. This helps explain to you how this information will be used or shared with others involved in the study.

- The Ohio State University and its hospitals, clinics, health-care providers and researchers are required to protect the privacy of your health information.
- You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you. Please carefully review this information. Ask if you have any questions or do not understand any parts of this notice.
- If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.
- Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at the Ohio State University. For example, this may include your medical records, x-ray or laboratory results. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

Please read the information carefully before signing this form. Please ask if you have any questions about this authorization, the University’s Notice of Privacy Practices or the study before signing this form.

Initials/Date: _____

Those Who May Use, Share And Receive Your Information As Part Of This Study

- Researchers and staff at The Ohio State University will use, share and receive your personal health information for this research study. Other Ohio State University staff not involved in the study but who may become involved in your care for study-related treatment will have access to your information.
- Those who oversee the study will have access to your information, including:
 - Members and staff of the Ohio State University’s Institutional Review Boards, including the Western Institutional Review Board
 - The Office for Responsible Research Practices
 - University data safety monitoring committees
 - The Ohio State University Research Foundation
- Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include:
 - The Food and Drug Administration
 - The Office for Human Research Protections
 - The National Institutes of Health
 - The Ohio Department of Human Services

These researchers, companies and/or organization(s) outside of The Ohio State University may also use, share and receive your health information in connection with this study:

- Health care facilities, research site(s), researchers, health care providers, or study monitors involved in this study;

Fergus Couch, MD, Mayo Clinic; Mary Beattie, MD, Jane Fridlyand, PhD, University of California, San Francisco

- Private laboratories and other persons and organizations that analyze your health information in connection with this study:

Myriad Genetic Laboratories, Inc, Salt Lake City, UT

The information that is shared with those listed above may no longer be protected by federal privacy rules.

Initials/Date _____

Authorization Period

This authorization will not expire unless you change your mind and revoke it in writing. There is no set date at which your information will be destroyed or no longer used. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Signing the Authorization

- You have the right to refuse to sign this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.-
- You will not be able to take part in this study and will not receive any study treatments if you do not sign this form.
- If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your mind, your authorization must be revoked in writing. To revoke your authorization, please write to:

Amanda Ewart Toland, PhD, 420 W. 12th Ave., 440 TMRF, Columbus, OH, 43210, or Margaret Johnson, HIPAA Privacy Manager, the Ohio State University Medical Center, 140 Doan Hall, 410 W. Tenth Avenue, Columbus, Ohio 43210

Signing this authorization also means that you will not be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

Contacts for Questions

If you have any questions relating to your privacy rights, please contact Kathleen Ojala, RN, JD, MHA, 140 Doan Hall, 410 W. Tenth Avenue, Columbus, Ohio 43210, 614.293.4477.

- If you have any questions relating to the research, please contact Amanda Ewart Toland, PhD, 420 W. 12th Ave., 440 TMRF, Columbus, OH 43210, 614-247-8185

Signature

I have read (or someone has read to me) this form and have been able to ask questions. All of my questions about this form have been answered to my satisfaction. By signing below, I permit Amanda Ewart Toland, PhD and the others listed on this form to use and share my personal health information for this study. I will be given a copy of this signed form.

Signature _____
(Subject or Legally Authorized Representative)

Name _____
(Print name above)
(If legal representative, also print relationship to subject.)

Date _____ Time _____ AM / PM