

## The Ohio State University Consent to Participate in Research

**Study Title:** Genetic modifiers of breast and ovarian cancer risk

**Principal Investigator:** Amanda Toland, PhD

**Sponsor:** The Ohio State University

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the signed form. You are being asked to consider participating in this study for the reasons explained below.

### 1. Why is this study being done?

At least one-fourth of all people with breast or ovarian cancer are at increased risk due to inherited (genetic) factors. This includes rare high risk genes and more common lower risk genetic variants. For example, women who carry a *BRCA* gene mutation have a high (50-85%) lifetime risk for breast cancer. However, this risk may be modified (increased or decreased) by other common genetic variants that a person may have.

There are also high risk breast and ovarian cancer families which are *BRCA* negative. Other, as yet unknown high risk genes are the most likely cause.

This study is being done to try to better understand how genetic variants may modify risk for people at high risk for breast and ovarian cancer. Work will also be done to find new cancer genes for breast and ovarian cancer. Results from the study may provide more information about risks for breast, ovarian and other cancers. This, in turn, may help you and your doctors make better decisions about cancer prevention options.

## 2. How many people will take part in this study?

The Ohio State University Medical Center (OSUMC) study investigators are part of an international group of researchers (CIMBA consortium). In all, over 29,000 people who have a personal or family history of breast or ovarian cancer will participate in the study from around the world. 1080 of these people will be recruited at OSU.

## 3. What will happen if I take part in this study?

You will be asked to: 1) read and sign this consent form and HIPAA authorization form; 2) sign a form releasing your medical records and/or tissue samples from previous or upcoming surgeries; 3) provide a blood, saliva, or mouth wash sample. Most participants will be asked to give a blood sample. If you cannot give a blood sample (because of a cancer diagnosis, or if you have poor veins) you will be asked to give a saliva or a mouth wash sample.

The medical records information that will be gathered in this study is your demographics, medical history, family history, cancer history, surgeries, pathology information, and any related genetic testing results (all information that is typically gathered during a genetic counseling session). You are also agreeing that the research team may review available medical records here at the OSUMC as needed for the next 5 years in order to update any information. This information will be de-identified (personal identifiers removed) and will be kept linked to your sample.

### **You are being asked to donate: (*person obtaining consent to check all that apply*)**

- Blood sample: To collect a blood sample, you will have four tubes of blood drawn (this is about 4 tablespoons worth). If you are not able to meet with us at The Ohio State University to have your blood drawn, a blood kit will be sent to you via FedEx. You will then need to have blood drawn at your doctor's office. The blood sample will need to be packaged and sent to us using a postage-paid FedEx envelope that is provided. You will not be required to pay for shipping of the sample however you may need to pay a small fee for blood drawing (usually \$10-\$20).
- Cheek cell sample: To collect a cheek cell sample, you would be asked to rinse your mouth with sterile water or a commercially available mouthwash (like Scope). These samples can be collected at home with a provided kit, and sent back to us at our expense.
- Tissue sample: If you have had cancer or any precancerous growths removed, we may request a piece of the tissue that was removed (this tissue is usually stored by the hospital after surgery). The tissue that we request will be extra tissue that is not needed for your diagnosis or treatment. If you have an upcoming surgery scheduled we may request a fresh piece of tissue from your surgery. This would also be a piece of tissue or cells that was removed but is not needed for your diagnosis or treatment.
- Stored research sample in the Human Cancer Genetics Sample Bank for use in other IRB approved studies. This sample may be used for these research studies.

**Receiving results: Your sample will be used in cancer genetics research.**

You have the option of receiving any clinically relevant cancer genetics research results that are linked to your sample. However, please note, some cancer genetics research studies may not provide results, and some studies may request anonymous samples. This means a small portion of your sample will be unlinked from your identifying information and used for cancer genetics research. Since this portion of your sample will not be linked to you, results cannot be reported to you. However, the overall results from the study may be published and may include information helpful to you and your doctors.

If clinically relevant results from this study become available, genetic counseling will be available, and you may be offered clinical genetic testing to confirm the research results (if available). These services may be at your or your insurance company's cost. You also have the option of hearing any overall results from the research study.

Choose one option and initial:

\_\_\_\_\_ You would like to be contacted if relevant research results become available.

\_\_\_\_\_ You would *not* like to be contacted with results.

**Family Member Contact:**

You will be asked to name a Family Member Contact who will receive notices concerning the storage of your samples and the results of any cancer genetics research studies performed on your samples, if you are unable to do so yourself. Unless you indicate that you do not want to name a Family Member Contact, you authorize the Family Member Contact to consent to analysis of your genetic material and to receive your cancer genetics research results if that person provides evidence satisfactory to OSUMC that you have died or are otherwise unable to consent for such testing yourself. The Family Member Contact may be a member of your family, or your physician. This person will need to 1) maintain a current address with the Clinical Cancer Genetics Program, 2) make decisions about your genetic material, 3) receive any relevant research results.

\_\_\_\_\_ I am naming the following Family Member Contact.

Initial

The name and current address of the Family Member Contact for your genetic material is:

Name: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Telephone number: \_\_\_\_\_

Relationship to me: \_\_\_\_\_

\_\_\_\_\_ I do not wish to name a Family Member Contact.

Initial

It is your responsibility, and that of your designated Family Member Contact, to maintain the accuracy of the above information. Failure to do so may result in you or your family not being notified of results or new or improved tests for your genetic condition, or in the inability of your family members to use your genetic material for clinical testing. You may change your Family Member Contact person at any time by notifying the Clinical Cancer Genetics Program in writing.

**4. How long will I be in the study?**

It will take a few minutes to read through and sign all the forms. If you have your blood drawn during your visit in Cancer Genetics or through a doctor's appointment at OSUMC, this will take only a few extra minutes of time during that appointment. Collecting saliva samples will take about 5-10 minutes. This means that it will take a total of about 20-30 minutes of your time to be in this study.

If you plan to make a special trip to your local doctor or outpatient lab to have your blood drawn, your travel time will add to the total amount of time it takes to participate in this study.

After your paperwork is completed and your blood and saliva samples are collected, you will not be required to do anything else for this study. However, your samples and information will be used for as long as this research program is active.

If the lab has leftover sample after this research is complete, your sample may be used anonymously for other cancer genetics research studies. Results will not be available from these studies. You will not be re-consented to these other studies.

**5. Can I stop being in the study?**

You may leave the study at any time. You will only need to submit a request, in writing, to study investigators. If this happens, your sample and all related information will be destroyed. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

**6. What risks, side effects or discomforts can I expect from being in the study?**

You may experience some physical discomfort when your blood is drawn. You may have some slight bruising at the site of needle insertion and there is a small chance of infection.

Some individuals have concerns regarding confidentiality of genetic testing and/or the potential for discrimination based on genetic test results. There are federal and state laws to protect you from health insurance discrimination based on genetic information. This protection extends to all group health care plans (HMP, PPO, etc), but does not include private health insurance plans. There are no protections for life insurance or disability discrimination. While discrimination related to genetic testing is possible, very few documented cases of any type of discrimination based on genetic information currently exist.

**7. What benefits can I expect from being in the study?**

This study has the potential to be very beneficial to people at risk for breast and ovarian cancer. Better understanding of genetic factors that modify risk will allow a more accurate prediction of cancer risk. This in turn will aid in making decisions about cancer prevention options.

**8. What other choices do I have if I do not take part in the study?**

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled

**9. Will my study-related information be kept private?**

Efforts will be made to keep your study-related information confidential. We will employ the same safeguards for confidentiality that we use for keeping clinical genetic testing records protected. All subject records will be stored by the Clinical Cancer Genetics Program at OSUMC in locked file cabinets. Samples from consented patients will be given a code/identification number. Coded laboratory samples will be stored in the Human Cancer Genetics Sample Bank and/or in the laboratory of the PI (Dr. Amanda Toland) at the Ohio State University. Computer files with linking sample information will be kept locked with restricted access passwords. All samples or data generated from study participants will be sent to collaborators devoid of personal identifiers. Any publications resulting from this study will not include information which could be used to identify you in any way.

However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices

As the study involves the use of your protected health information, you will be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form.

**10. What are the costs of taking part in this study?**

If you have your blood drawn somewhere other than OSU, you may have to pay for the blood draw (about \$10-20). Otherwise there will be no cost to you to participate in this study.

**11. Will I be paid for taking part in this study?**

No. You will not be paid for taking part in this study.

**12. What happens if I am injured because I took part in this study?**

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

**13. What are my rights if I take part in this study?**

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

**14. Who can answer my questions about the study?**

For questions, concerns, or complaints about the study you may contact **Kevin Sweet or Mandy Toland at 614-293-6694 or toll free at 1-888-329-1654.**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact **Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.**

**Signing the consent form**

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

_____	_____
<b>Printed name of subject</b>	<b>Signature of subject</b>
	_____
	<b>AM/PM</b>
	_____
	<b>Date and time</b>
_____	_____
<b>Printed name of person authorized to consent for subject (when applicable)</b>	<b>Signature of person authorized to consent for subject (when applicable)</b>
	_____
	_____
	<b>Date and time</b>
	_____
	<b>AM/PM</b>

**Investigator/Research Staff**

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

_____	_____
<b>Printed name of person obtaining consent</b>	<b>Signature of person obtaining consent</b>
	_____
	_____
	<b>Date and time</b>
	_____
	<b>AM/PM</b>

**Witness(es)** - *May be left blank if not required by the IRB*

_____	_____
<b>Printed name of witness</b>	<b>Signature of witness</b>
	_____
	_____
	<b>Date and time</b>
	_____
	<b>AM/PM</b>

**CONSENT**  
**Biomedical/Cancer**

**IRB Protocol Number: 2007C0012**  
**IRB Approval date: April 2, 2007**  
**Amendment: Oct. 15, 2007**  
**Version: 2.0**