

## The Ohio State University Consent to Participate in Research

**Study Title:** Variants in “High Risk” Breast Cancer Genes and Contribution to Cancer Risk

**Principal Investigator:** Amanda Ewart Toland, PhD

**Sponsor:** The Ohio State University; applied for National Cancer Institute funding

- **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?

This study is being done to try to better understand how some changes in the *BRCA1* and *BRCA2* genes influence cancer risk. When people have genetic testing for the *BRCA* genes, there are three possible results: 1) negative, meaning no mutation was found; 2) positive, meaning a mutation was found; and 3) a change in the gene called a “variant of uncertain significance” (VUS). A real mutation causes an increased risk of developing breast and ovarian cancer, but a change that is a normal variation does not. It is not known if a VUS is a real mutation in the *BRCA* gene, or just a normal variation, and so it is not known if it causes an increased risk of breast or ovarian cancer. People who have a VUS have little information to go on when trying to decide to take preventative options like taking medications or having preventive surgeries

This study will look at the DNA in the blood or saliva, and in breast or ovarian cancer tissue from people that have a true *BRCA* mutation and people that have a VUS. It will compare the patterns that are seen in the cancer tissue of these two groups of people. These studies may give some clues as to whether some VUSs are actually true mutations or normal variation.

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

This study is being done at OSU, the University of California, San Francisco (UCSF), and the Mayo Clinic. In total, 125 people who have had breast or ovarian cancer *and* have a known *BRCA* gene mutation will take part in this study. Forty of these people will be recruited at OSU. In addition, 100 people who have had breast or ovarian cancer *and* have a variant of unknown significance will take part in this study. Again, forty of them will be recruited at OSU.

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

You will be asked to: 1) sign this consent form; 2) sign a form releasing your medical records and breast or ovarian tissue samples from previous or upcoming surgeries; 4) donate a blood or saliva sample.

The medical records information that will be gathered in this study is your demographics, medical history, family history, pathology information, genetic risk assessment, and genetic testing results (all information typically gathered during a genetic counseling session).

After your surgery for breast or ovarian cancer, we will request a piece of the tumor tissue that is removed. This may include fresh frozen and paraffin embedded tumor tissue. The tissue that we request will be extra tissue that is not needed for your diagnosis or treatment. We will ask for a few pieces of tissue from your surgery that are each smaller than a pencil eraser.

For the donation of a blood sample, you will have four tubes of blood drawn (this is about 4 tablespoons worth). This can be done at your OSU doctor's appointment or at your local doctor's office or outpatient laboratory, and sent to us at our expense. To collect the saliva sample you will be asked to spit 2 milliliters (about half of a teaspoon) of saliva into a cup that will be provided as part of a saliva collection kit. This kit can be used at home and sent back to us at our cost.

If you already have previously stored research sample in the Human Genetics Sample Bank for use in other IRB approved studies, this sample may be used for these research studies in place of another blood draw.

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

It will take a few minutes to sign all the forms. If you have your blood drawn during 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 10-20 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 actively used for research for the duration of the study (which may be several years, depending on funding) and stored for another 3 years after that.

If the lab has leftover sample after this research is complete, your sample may be used anonymously for other cancer genetics research 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. 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?**

The risks of blood draw are: discomfort, pain, bleeding, bruising, infection, lightheadedness, and fainting. There are no known risks associated with collecting a saliva sample. The other risks of this study have to do with the information collected. We will be collecting and storing personal health information (PHI) and genetic information about you and your breast or ovarian cancer. If this information is accidentally seen by someone who is not authorized to see it, your insurance company or employer may learn about this information. There is a small risk of discrimination based on this information. However, in Ohio there are federal and state legislation in place to protect people from health insurance discrimination based on genetic information (private health insurance plans are not covered). In addition, there are very few documented cases of this kind of discrimination. So even in the unlikely event that someone sees your health or genetic information without authorization, the risk of discrimination based on this information is very low.

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

There may be no direct benefit to you from being in this study. You will receive no genetic testing results directly from this study. However, if you have a VUS, you may receive information learned from this study in the following manner: If results from this study indicate that a VUS is really a mutation or a normal variation, these findings will be given to clinical laboratories who will confirm this information. If they confirm that the VUS can be reclassified as a mutation or a normal variation, they may issue a new test report that will be given directly to your physician and/or genetic counselor. He/she will then contact you to discuss the meaning of this result in the context of your family history. It is important to note that it may take a long time to receive information like this, and also that this information may never become available for your particular VUS.

If you currently have a known mutation in *BRCA1* or *BRCA2*, you will get no additional information from being in this study.

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

Even if you don't participate in this study, new information may be learned about your VUS. Other laboratories, including clinical laboratories, are doing research on VUSs. More may be learned about your particular VUS from research on other families with the same VUS, or research done on your DNA sample by the clinical lab that did your original genetic testing. You may receive a new test report from the clinical lab based on this information.

You may choose not to participate in this study 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. 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;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If the study involves the use of your protected health information, you may also 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?**

There are no costs to you for being in this study, and your insurance will not be billed. The study will cover the cost of drawing your blood.

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

You will not be paid for being 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 Medical Center.

**CONSENT**

**IRB Protocol Number: 2005C0066**  
**IRB Approval date: Sept 6, 2005**  
**Continuing Review Approval: June 25, 2007**  
**Amendment Approval: Aug 14, 2007**  
**Version: 3.0**

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, MS at 614-293-6694 or toll-free 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 Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Amanda Toland, PhD at 614-293-6694 or toll free, 1-888-329-1654.

**15. Signing the consent form**

**Participant**

I have read (or someone has read to me) this document 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 consent form. I will be given a copy of this signed document.

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

**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 signed copy of this consent form has been given to the participant or his/her representative.

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

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

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

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