Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Principal Investigator:	Christine Garcia, MD University of Virginia PO Box 800712 Charlottesville, VA 22908 434-924-9924
Sponsor:	Foundation for Women's Cancer

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study is funded by a grant from the Foundation for Women's Cancer.

Why is this research being done?

The purpose of this study is to determine if a family communication aid is useful for patients undergoing genetic testing. Communication aids are tools provided to patients to help them not only understand test results or diagnosis, but also how to share that information with family members in a way that is beneficial and nonthreatening.

You are being asked to be in this study because you have a diagnosis of breast or gynecologic cancer and you are undergoing genetic testing as part of your clinical care.

Up to **50** people will be in this study at UVA.

What will happen if you are in the study?

SCREENING and STUDY PROCEDURES

If you agree to participate, you will sign this consent form before any study related procedures take place. A member of the study team will review of your medical history to make sure you are eligible for the study.
During this study, you will be asked to fill out some questionnaires. These questionnaires ask about:

- your knowledge of genetic testing
- your opinion about the communication aid
- if you used the communication aid
- how you feel about taking part in this study

Visit # 1 (will take an additional 30 minutes over your routine clinic visit):
At your clinic visit we will have you sign this consent. You will be asked to complete one questionnaire. At this visit, we will also provide you with a copy of the communication tool in the form of a letter, which we are evaluating for this research study. We will also provide you with two information handouts on genetic testing. The tool and handouts will help you communicate genetic test results with your family members. You do not have to use the tool if you do not want to.

Visit # 2 (will take an additional 15 minutes over your routine clinic visit):
When you come back to the clinic visit to get results of any genetic testing you had done for clinical purposes, you will complete another questionnaire for research purposes.

We will also collect information from your medical record on results of the genetic testing you have done.

FOLLOW UP:
In approximately 6 and 12 months from Visit #1 someone from the study team will contact you by phone, or at a clinic visit, to complete a questionnaire over the phone.

Study Schedule

	Visit 1	Visit 2	Follow-up (6 and 12 months)
Informed Consent	x		
Review study eligibility	x		
Medical History	x		
Questionnaire	x	x	x

Your participation is complete after the 12 month follow-up phone call.

What are your responsibilities in the study?

- You must be completely truthful.

How long will this study take?

Your participation in this study will require 2 study visits which will add additional time to your routine clinic visits and 2 follow up phone calls. If you do not have a follow up clinic visit (Visit #2), we may call you to complete the questionnaire by phone. You will not need to attend any additional visits for this research study.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to the study include:

There is the potential loss of confidentiality (the risk that someone might see your private information) associated with this research study. It would be rare for a breach of confidentiality to occur. Measures to protect your privacy will be used.

Risks from Completing Questionnaires

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and to the next question.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. Possible benefits include: help with communicating genetic test results to you family members. In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Not participating in this study. You would not complete the additional questionnaires and you would not use the research communication tool.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Will being in this study cost you any money?

All of the procedures in this study will be provided at no cost to you or your health insurance. You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. If you decide to stop being in the study, we will ask you to: let a member of the study team know.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your

doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Christine Garcia
P.O. Box 800712
Telephone: (434) 924-9924

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE