DUKE UNIVERSITY HEALTH SYSTEM

Patient Consent
A Prospective Randomized Trial Evaluating Streamlined Genetic Service Delivery

CONCISE SUMMARY

This is a study to examine a new model of patient education prior to genetic testing. Doctors now recommend that all patients with epithelial ovarian, fallopian tube or peritoneal cancer receive genetic testing. The traditional model for this kind of testing starts with education provided during formal meeting with a genetic counselor at a separate appointment. If you choose to participate in this study, you will be placed at random into either a group that receives education via the traditional model, or a group that receives a video-assisted form of patient education at your appointment today. By comparing these two groups, we are hoping to see if the new model is a safe and effective way to provide education prior to genetic testing.

The risks to this study are minimal. The benefits include the chance to get genetic education and testing, which is recommended for all patients with ovarian, fallopian or peritoneal cancer. The results of testing may make you eligible for different treatments. Results of testing can also help your family members: If they are also found to have a genetic mutation, they can take certain actions to decrease their future cancer risk.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you have a specific type of epithelial ovarian, fallopian tube or peritoneal cancer. 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. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

The gynecologic oncology team and hereditary cancer team will conduct the study. The primary investigator of the study is Dr. Rebecca Previs of the Duke gynecologic oncology team. This study is also being conducted at other sites. The study is partially supported by The Gray Foundation. However, the Gray Foundation is not involved in the design or execution of the study.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, your gynecologic oncologist will continue to be your doctor during this study.

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WHY IS THIS STUDY BEING DONE?
The goal of this study is to compare video-assisted education before genetic testing to the normal model of pre-test education with a genetic counselor. We hope to establish that this new form of pre-test education does not decrease care quality or increase patient distress.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 112 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form.

You will be randomly assigned (like the flip of a coin) to either the new model (streamlined) group or the traditional group. You will then fill out a short survey about your current anxiety level regarding the risk of having an inherited cancer mutation, answer some brief demographic questions, and complete a health literacy quiz.

If you are selected to be in the Traditional Group:

a. *During this appointment*

- After completion of baseline surveys, you will be referred for a pre-test meeting with a genetic counselor that will be scheduled for a date approximately 2-4 weeks after this appointment.

b. Within one week after consent

- Sometime during the next week, you will receive an email with a link to a secure website where you can enter your family history.
- A member of the genetics team will contact you to discuss the results you have entered, review common errors and clarify any questions they may have.

c. 2-4 weeks following consent

- You will meet with the genetic counselor. During this visit, you will receive approximately thirty to sixty minutes of counseling regarding genetic testing and potential results.
- After counseling, you will be given the option to undergo a genetic test either via saliva or blood sample. You will also be asked complete the regular genetic testing consent form and a consent for tumor testing of surgical specimen, as per standard practice.

d. Within one week after genetic counseling appointment

- You will be sent a post-education survey asking about your anxiety via an email link to a confidential survey.

If you are selected to be in the Streamlined Group:

a. During this appointment

- After completing the baseline surveys, you will watch a brief genetics education video.
- After watching the video, you will be given the option to undergo a genetic test either via saliva or blood sample. You will also be asked complete the regular genetic testing consent form and a consent for tumor testing of surgical specimen, as per standard practice.

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- If at this time, you would like to opt out of the study and receive formal genetic counseling prior to testing, you will be able to do so.

b. Within one week following consent

- You will be sent a post-education survey asking about your anxiety level via an email link to a confidential survey.
- Once the anxiety survey is completed, you will be sent another email with a link to a secure portal where you can enter your family history.
- A member of the genetics team will contact you to discuss the results you have entered, review common errors and clarify any questions they may have.

Both groups will undergo the same results disclosure and follow-up.

a. Results disclosure

- You will be notified of your testing results over the phone by a genetic counselor. Next steps depend on what your results are.
    - A genetic change detected – either a known mutation or an uncertain result- or high-risk family history despite negative genetic testing results: You will be scheduled for formal post-testing meeting with a genetic counselor 2-4 weeks after result return
    - No genetic change identified and low risk family history: You will not need further follow-up unless you have additional questions or concerns.

b. *Distress survey*

- You will take a satisfaction with genetic counseling survey (MICRA) after receiving results within one week after either formal consultation if needed or reception of results over the phone. The survey will be sent via email with a confidential survey link.

Your participation is voluntary, and if you refuse to participate it will not affect your care or involve any penalty of loss of benefits to which you are otherwise entitled. If you do not sign this consent form, you will continue to receive care, but not as part of this study.

HOW LONG WILL I BE IN THIS STUDY?
You will be in this study for potentially 2-3 months, including the time it takes to receive the genetic testing results if you choose to be tested, and the time to follow-up for post-test counseling with a genetic counselor if that is indicated. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. However, some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time. In addition, there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

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ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
The benefits include the option to receive genetic education testing, which is recommended for all patients with ovarian, fallopian or peritoneal cancer. The results of testing may make you eligible for different treatments. Results of testing can also help your family members. If they are also found to have a genetic mutation, they can take certain actions to decrease their future cancer risk.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Instead of being in this study, you have the following alternatives: Not to receive genetic counseling or testing at all, or to be referred for formal genetic consultation without participation in the trial. Please talk to your doctor about these and perhaps other options.

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. 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.

As part of the study, your records may be reviewed in order to meet federal or state regulations. As part of the study, results of your study-related activities will be recorded by the research team at Duke University Medical Center. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

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.

WHAT ARE THE COSTS TO YOU?
There will be no additional costs to you as a result of being in this study. However, standard laboratory cost for genetic testing will apply. Routine costs will also be incurred if you require post-results counseling. Both of these charges are standard of care and not considered experimental.

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WHAT ABOUT COMPENSATION?
You will not be compensated for this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
There is minimal risk of injury associated with this study. Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Previs at (919) 684-3765 during regular business hours and at (919) 970-1613 after hours and on weekends and holidays.

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. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study.

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. If you do decide to withdraw, we ask that you contact Dr. Previs in writing and let her know that you are withdrawing from the study. Please address this mail to: Rebecca Previs, Divison of Gynecologic Oncology, 201 Trent Drive, 203 Baker House, Durham NC 27710.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Previs at (919) 684-3765 during regular business hours and at (919) 970-1613 after hours and on weekends and holidays.

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.

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

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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."