Protocol Title: Randomized, Controlled Trial of an Electronic Decision Aid for Genetic Testing in Inherited Cancer Syndromes

DF/HCC Principal Investigator(s) / Institution(s):

DANIEL C. CHUNG, M.D. / MASSACHUSETTS GENERAL HOSPITAL

SARA BOUBERHAN, M.D./ MASS GENERAL/NORTH SHORE CANCER CENTER

LAWRENCE BLASZKOWSKY, M.D. / MASS GENERAL AT NEWTON-WELLESLEY HOSPITAL

ARUL MAHADEVAN, M.D. / MASS GENERAL AT WENTWORTH-DOUGLASS HOSPITAL

Main Consent

INTRODUCTION AND KEY INFORMATION

All research is voluntary. It is your choice whether you take part in this research or not. If you decide to participate, please sign and date at the end of this form. We will give you a copy and you can refer to this consent form at any time.

The following is a short summary of this research study to help you decide whether you would like to be a part of this study. More detailed information is provided later in this form.

For purposes of this research, you will be referred to as a "participant."

1. Why am I being invited to take part in a research study?

You are invited to take part in in this research study because you have ovarian or pancreatic cancer and your oncologist referred you for genetic testing.

2. Why is this research being done?

We are studying two (2) ways to learn about the options for genetic testing before making a decision. They are to meet with a genetic counselor or to use an electronic decision aid tool. The purpose of this research is to compare them and find out how well an electronic decision aid tool can help participants learn and make decisions about genetic testing when compared to a visit with a genetic counselor.

3. Who is supporting this research?

The National Cancer Institute (NCI) is supporting this research study by providing funding for the research.

4. What does this research study involve and how long will it last?

The study would involve completing four (4) short surveys. The study surveys will take place on two (2) different days with a total active study time of about one (1) hour (15 minutes on the first day and 45 minutes on the second day). There is an additional day when you will either have genetic counseling or use the electronic decision aid as part of your care, and you are randomly assigned to one of these two options. You will be asked to complete the surveys either way.

The research study procedures include: screening for eligibility and study questionnaires that would be performed in conjunction with either the genetic counselor visit or use of the electronic decision aid. The study questionnaires include:

- Knowledge Survey
- Shared Decision Making Process Survey
- Decisional Conflict Scale

You will be in this research study for up 2 weeks.

It is expected that about 350 people will take part in this research study.

Information about you and your health is personal and private. Generally, it cannot be obtained without your written permission. By signing this form, you are providing that permission and your information may be obtained and used in accordance with this informed consent and as required or allowed by law. This means that researchers may obtain information regarding your past medical history, as well as specimens and samples from previous health care providers such as hospitals and labs.

5. What are the risks to participating in this study?

There are risks to taking part in any research study. We want to make sure you know about a few key risks right now. More detailed information is provided in the "What are the risks or discomforts of the research study?" section

Major known risks to participating in this research study include:

- Disclosure of sensitive personal information may result in a loss of privacy
- Possible emotional distress due to personal questions

6. Will being in this study benefit me in any way?

We do not know if taking part in this study will benefit you. This study may help researchers learn information that could help people in the future.

7. What are my options?

Instead of being in this research study, you have other options which may include the following:

- Decide not to participate in this research study
- Use the electronic decision aid tool at an appointment with your oncologist outside of the study
- Meet with a genetic counselor outside of the study

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions at any time.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

In this research study, we are:

- Studying ways to help participants make decisions about genetic testing.
- Using surveys to measure the participants' knowledge and process of making decisions about genetic testing
- Comparing 2 standard methods (electronic decision aid and genetic counseling) for providing information about genetic testing.
- Aiming to learn about how well an electronic tool compares to traditional genetic counseling with a genetic counselor

B. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the research starts: After signing this consent form, you will be asked to answer some questions to find out if you can be in the research study.

- **A medical history,** which includes questions about your health and any prior genetic testing completed.
- **Data Collection:** Data including information about your personal and family history will be collected from your medical record. The data will be linked to your survey responses by a unique number to de-identify you.

Information will be shared with study staff at Boston Medical Center and Massachusetts General Hospital. The data will not be identifiable. The data will not be banked for future use.

If these tests show that you are eligible to participate in the research study, you will be eligible to participate in the research study. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

Additional research procedures to be performed at the time of screening, but not required to determine eligibility:

- **Randomization**: A study coordinator will let you know if you have been randomly selected to receive the electronic decision aid tool or see a genetic counselor.

After the screening procedures confirm that you are eligible to participate in the research study:

If you are told that you are randomized to see a genetic counselor, a scheduler will reach out to schedule you for a genetic counseling session.

If you are told that you are randomized to use the decision aid, no additional appointment will be needed, and a study coordinator will let you know at which upcoming appointment they will approach you with the decision aid tool.

Prior to using the electronic decision aid or seeing a genetic counselor, you will be emailed a short knowledge questionnaire. This questionnaire should take no more than 15 minutes to complete and can be completed any time before your appointment. If you do not have access to an email account, you will be provided with a paper copy of the survey. Your health care providers will not be made aware of your knowledge survey score.

Study Visit:

Participants using the Decision Aid:

You will arrive at your upcoming appointment as scheduled. Before you meet with your oncologist, a research coordinator will meet with you and show you how to use the decision aid tool. The coordinator will answer any questions you have about how to use the device and then you will be given time to go through the decision aid. The device can take between 10-30 minutes to get through completely. None of your personal information will be entered into the device. At

the end of the decision aid, you will be asked to select if you want to pursue genetic testing. If you choose to pursue genetic testing, you will also be asked to select from one of three gene test options.

Once you have finished using the decision aid, the coordinator will print out a summary sheet with your choices to give to your oncologist. Your oncologist will then meet with you as usual, and in that appointment will discuss genetic testing with you. At this point, they can address any questions or concerns you would have about the test before signing the consent form for genetic testing with you.

Participants Seeing a Genetic Counselor:

You will meet with a genetic counselor at your scheduled appointment time to discuss genetic testing. The appointment will last approximately 45 minutes and at the end of the appointment you will be asked if you want to pursue genetic testing. The genetic counselor will be available to address any questions or concerns you may have. If you choose to pursue genetic testing, you will be asked to select from one of three gene test options before signing the consent form with the genetic counselor.

This visit will involve the following:

- **Data Collection:** If you will be using the electronic decision aid as part of this research study, information about your use of the aid (e.g., length of time spent using the tool and number of pages viewed) will be recorded but no identifiable information will be stored in the decision aid. If you are meeting with a genetic counselor, information about the timing of your visit (e.g., length of time spent talking with the genetic counselor) will be recorded. Information will be shared with study staff at Boston Medical Center and Massachusetts General Hospital. The data will not be identifiable. The data will not be banked for future use.

After the final intervention:

We would like to see what you learned and how you feel about the genetic testing decision after you either use the electronic decision aid tool or meet with a genetic counselor. To do this, we will email you three surveys/questionnaires to complete online. If you do not have access to an email account, you will be provided with a paper copy of the surveys. These will be sent one (1) week after your session and should take a total of 30-45 minutes to complete.

The first questionnaire is a 10-question multiple choice knowledge survey that measures your current understanding of genetic testing and concepts related to genetic testing. Your healthcare providers will not be made aware of your knowledge survey score.

The second and third surveys will ask about your decision-making process, including your feelings about the decision and your understanding of the factors involved in making the decision.

Study Overview Chart

Participants Using the Decision Aid:

	Day 1	**Day 2**	**Day 3**
		Day of appointment	*1 week after Day 2*
Knowledge Survey	X		X
Shared Decision Making Survey			X
Decisional Conflict Scale			X
Use Decision Aid Tool and discuss choices with oncologist		X	

Participants Seeing a Genetic Counselor:

	Day 1	**Day 2**	**Day 3**
		Day of genetic counseling visit	*1 week after Day 2*
Knowledge Survey	X		X
Shared Decision Making Survey			X
Decisional Conflict Scale			X
See a Genetic Counselor		X	

C. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study, including the possibility of a breach of confidentiality. However, we will take steps to minimize the risk.

If you choose to participate, there is a risk that you will experience psychosocial discomfort while answering the survey questions. In the event that this occurs, you will have the option of being referred to Psychiatry Services or Social Work Departments to receive additional support. You will also have the option of withdrawing from the study at any point in time. In this case, arrangements can be made for you to learn about genetic testing outside of the research study.

During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

D. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?

You may be taken off the research study for any reason including:

- It is considered to be in your best interest
- The study intervention or procedures are found to be unsafe or ineffective
- There is any problem with following study intervention and procedures
- Your condition worsens
- A decision is made to end the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

E. WHAT ARE THE BENEFITS OF THIS RESEARCH STUDY?

Taking part in this research study may or may not benefit you. We hope the information learned from this research study will provide more information about a different way to help people make decisions about genetic testing.

F. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will be compensated $10 for completing the first survey and an additional $10 for completing the second set of surveys, for a total compensation of $20 if all surveys are completed.

G. WHAT ARE YOUR COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company.

You or your insurance company will be charged for portions of your care during this research study that are considered routine costs. Routine costs ***may*** include services to determine your eligibility, services to prevent (monitor) and diagnose disease, and services to treat side effects. Examples of research study routine costs may include the infusion of the study medicines, office visits, lab tests, procedures, and imaging. Routine costs related to this study include the cost for genetic counseling and testing.

You may be billed for co-payments, co-insurance, premiums and deductibles that are typical for your insurance coverage. Participation may result in additional ***routine costs*** because of more frequent research visits.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services are:

- Massachusetts General Hospital: (617) 726-2191
- Massachusetts General Hospital/North Shore Cancer Center: (617) 726-2191
- Mass General Cancer Center at Newton-Wellesley Hospital: (617) 726-2191
- Mass General Cancer Center at Wentworth-Douglass Hospital: (603) 742-8787
- Boston Medical Center: (617) 414-5155

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance

company is required by law to pay. This can be found at the website below or can be provided by the study team:

www.cancer.gov
or 1-800-4-CANCER (1-800-422-6237)

H. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments may be billed to you or your insurance company. You will be responsible for deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

I. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research doctor or study staff as listed below:

Massachusetts General Hospital

- Danielle Lynch: (617)-726-1355

- Daniel Chung, MD: (617) 726-8687

Mass General/North Shore Cancer Center
- Danielle Lynch: (617)-726-1355
- Sara Bouberhan, MD: (617) 726-2097

Mass General Cancer Center at Newton-Wellesley Hospital
- Danielle Lynch: (617)-726-1355
- Lawrence Blaszkowsky: (617) 219-1230

Mass General Cancer Center at Wentworth-Douglass Hospital
- Danielle Lynch: (617)-726-1355
- Arul Mahadevan: (603) 534-6824

Boston Medical Center
- Elizabeth Pottier: (617) 638-8260
- Nana Addo-Tabiri, MD: (617) 638-6428

24-hour contact: Massachusetts General Hospital: Daniel Chung, MD at (617) 726-3544.

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

J. RETURN OF RESEARCH RESULTS

Surveys done in this research study are only for research and have no clear meaning for your health care. For this reason, your study doctor will not share the results with you.

K. CLINICALTRIALS.GOV

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.

L. FUTURE USE OF DATA AND SPECIMENS

Your personal information collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

M. CONFIDENTIALITY

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do additional research.

N. FINANCIAL DISCLOSURES

It is possible that certain researchers on this study may have earned money from, or own some publicly-traded stock in, the company that makes or is developing the study decision aid. The amount of money that a researcher may earn and still take part in research is limited by the Harvard Medical School Faculty of Medicine Policy on Conflicts of Interest and Commitment. If you have further questions, please speak with a member of the study team or contact the Dana-Farber Cancer Institute Office of Research Integrity at 617-432-4557 or researchintegrity@dfci.harvard.edu.

O. CERTIFICATE OF CONFIDENTIALITY (COC)

To help protect your privacy, we have been issued a Confidentiality Certificate from the National Institutes of Health (NIH). With this Certificate, the researchers on this study cannot be forced (for example, by court subpoena) to disclose information that may identify you in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

Disclosure will be necessary upon request of a United States federal or state government agency sponsoring the project that will be used for audit or program

evaluation purposes or to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family or even the research doctor from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or employer learns about your participation, and obtains your consent to receive research information, then we cannot use the Certificate of Confidentiality to withhold this information. This means that you and your family must actively protect your own privacy.

The Certificate of Confidentiality cannot be used to prevent disclosure to state or local authorities when there is a duty to report concerns of abuse, neglect, self-harm or a danger to others.

P. GENETIC RESEARCH

This research will not involve genomic or germline testing. The research is focused on education and decisions around genetic testing.

Q. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;

- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s).
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or

necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

R. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

Signature of Participant or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant

To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

☐ *As someone who understands both English and the language used by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate