

Choices About Genetic Testing And Learning Your Risk With Smart Technology
(CATALYST)

User/Usability and Pilot Test Consent Forms

NCT06184867

June 10th, 2024

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Choices About genetic Testing And Learning Your risk with Smart Technology (CATALYST)

Principal Investigator: Anita Y. Kinney, PhD, RN

On behalf of the Rutgers Cancer Institute of New Jersey, we are excited to invite you to participate in the CATALYST Research Study. This informed consent form provides information about this research project and what will be asked of you if you choose to participate in it. If you have any questions now or during the research project, please feel free to ask them and you should expect to be given answers that you understand completely. It is your choice whether to participate and will not affect the quality of your clinical care at the Rutgers Cancer Institute of New Jersey or at University Hospital/New Jersey Medical School.

Who is conducting this study?

Dr. Anita Kinney is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: This study is sponsored by Rutgers Cancer Institute of New Jersey's Committee to Expedite Translational Initiatives (CETI).

Why is this study being done?

You are being invited to take part in a research study that aims to develop and test a patient centered **CA**ncer **R**isk **E**valuation (CARE) digital health tool to help educate and support families who may be at increased risk for inherited cancer (cancer that runs in families). You will be asked to review the prototype of this digital assistant that is designed to educate, empower, and support patients who may be at an increased risk for inherited cancer. You will be asked to provide feedback that will be used to help us improve the website platform and the CARE digital assistant.

Who may take part in this study and who may not?

Participants must meet the following eligibility criteria:

- 1) Age 18 or older
- 2) Have ever been diagnosed with breast cancer, ovarian cancer, fallopian tube cancer, peritoneal cancer, colorectal cancer, endometrial cancer, pancreatic cancer, prostate cancer or have other features suggestive of inherited cancer.
- 3) Speak/read and understand English
- 4) Capable of providing informed consent
- 5) Have Internet access (via smartphone, tablet, or computer)

Why have I been asked to take part in this study?

Protocol Title: CATALYST
Protocol Version Date: V2 10August2023
Consent Version Date: V2 10August2023

You are being asked to take part in this study because you have had one or more of the following cancers: breast, ovarian, fallopian tube, peritoneal, colorectal, endometrial, pancreatic, or prostate cancer or have any other features suggestive of inherited cancer.

What will I be asked to do if I take part in this study?

- You will be asked to review and sign a consent form with a research staff member and answer a few questions electronically or by phone. You will also be asked to review and sign the Health Insurance Portability and Accountability (HIPAA) authorization form electronically or on paper, so that the researchers can collect data from their medical records. If you choose to sign the HIPAA authorization form by paper, we will mail you a paper copy of the HIPAA authorization form with a pre-stamped envelope to email or mail back the signed HIPAA authorization form.
- If you consent to the study, you will be asked to participate in a guided interview with a HIPAA trained member of the CATALYST research team. You will be asked to review the prototype of a **C**ancer **R**isk **E**valuation (CARE) digital health tool. You will first be asked to login to a Rutgers approved webpage from your smart device (phone with internet, computer, or tablet). This interview will be hosted and recorded remotely via Rutgers' Microsoft Teams or Zoom. The interview will last about 60 to 90 minutes and will include questions about your health, demographic information, your attitudes about and experiences with cancer genetic services, and your opinions and suggestions for improving the digital health tool and other aspects of the webpage. You will answer a series of questions as you navigate through different sections of the webpage and interact with the digital health tool. Your feedback will be used to revise the webpage's quality for future research studies.

How long will the study take and how many subjects will take part?

The total number of participants is 56 participants.

The total estimated participation time for the one-time guided interview is approximately 60-90 minutes.

What are the risks of harm or discomforts I might experience if I take part in this study?

Initial discomfort/embarrassment: Some individuals may experience discomfort or distress when answering questions about or thinking and talking about cancer or other health issues. Participants will be asked questions of a sensitive or personal nature, which could potentially cause some discomfort or embarrassment while answering. If this happens, you can skip those questions or withdraw from the study altogether. If you decide to quit the study, your responses will NOT be saved.

Privacy and loss of confidentiality: Breach of confidentiality is a risk of harm, but a data security plan is in place to minimize such a risk. Nevertheless, there is still the potential for unintentional breach of confidentiality for participants. All efforts will be made to maintain privacy and confidentiality. We are aware that data will contain demographic and personal health information, and consistent measures will be employed to protect the security and confidentiality of this data. All data will be securely stored in a

study database. Participants will be assigned a study ID, and the analyses will be limited to the variables necessary for the completion of the proposed study, and results will be reported in aggregate so that individuals are not identified. Study publications or presentations resulting from this research will not identify participants by name but will present only aggregate data. Every effort will be made to protect the information you give us. The researchers are trained to protect your information and to use procedures that reduce the possibility of loss of privacy and/or confidentiality.

Psychological or Social Risks Associated with Loss of Privacy:

Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Further, patterns of genetic variation also can be used by agencies to identify a person or their blood relatives (for example, to establish relationships between parents and their children).

Economic Risks of Harm:

Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family economic distress.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that helps protect against genetic discrimination. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Are there any benefits to me if I choose to take part in this study?

There may or may not be direct benefits to you for taking part in this study. However, you may find satisfaction in contributing to research and you may learn new information about hereditary cancer and cancer risk reduction for you and your family members.

What are my alternatives if I do not want to take part in this study?

Taking part in this study is voluntary, so you can choose not to participate. There will be no penalties involved if you choose not to take part in this study, and it will not change or influence your medical care.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?

We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Will there be any cost to me to take part in this study?

There will be no cost to you to take part in this study.

Will I be paid to take part in this study?

Participants will be offered a \$75 gift card upon completion of testing the website and the guided interview.

How will information about me be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Identifiable information will not be stored with your responses. Instead, your responses will be assigned a subject number which will be stored separately from your identifiable information so others will not know which responses are yours. These study IDs will help maintain confidentiality. A study database will be hosted at Rutgers Cancer Institute in New Brunswick, NJ on secure computing servers with secure data entry and submission for all other sites. No information that can identify you will appear in any professional presentation or publication. There may be circumstances where this information must be released.

What will happen to my information (data, recordings and/or images) collected for this research after the study is over?

All information will remain confidential and de-identified and stored in password protected and encrypted databases. Your de-identified information may be shared with other investigators in future research.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part, or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to the Principal Investigator:

Anita Y. Kinney, PhD, RN
Rutgers Cancer Institute of New Jersey
195 Little Albany Street, Room 5541
New Brunswick, NJ 08901-1384

Who can I contact if I have questions?

If you have questions, concerns, or complaints about the research, wish to find out more information, or if you feel you may have suffered a research related injury, you can contact the CATALYST research team at (732) 735 – 8692 or at ekh47@cinj.rutgers.edu.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

HIPAA AUTHORIZATION FORM: PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the research and how will my information be used?

You have been asked to take part in a research study. Your participation in this study is described at the beginning of the consent form, and that information still applies. This additional form is required by the federal Health Insurance Portability and Accountability Act (HIPAA). The purpose of this form is to get your permission (authorization) to use health information about you that is created by or used in connection with this research. This form gives permission to study investigators to view your medical records to confirm medical referrals, medical information, and procedures related to this study including the dates of genetic counseling/risk assessment and genetic testing services and the results of genetic counseling/risk assessment and genetic testing. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research. If you would like to consent to this research study, you will be asked to sign the consent form and this HIPAA authorization form electronically. If you wish to sign the consent and HIPAA authorization form on paper, you will be asked to mail back a signed copy to us through email or mail (in a pre-stamped envelope that we will provide you).

What information about me will be used?

- Medical Record Number
- Name (First and Last)
- Contact Information (phone number, address, email address)
- Demographic Information (age, race, ethnicity, education)
- Cancer Diagnosis

- Medical History, Consultations or Treatment, including visit notes with clinicians/genetic counselors
- Medical Tests, Reports and Procedures (such as pathology report)
- Laboratory/diagnostic tests
- Dates of Medical/Laboratory tests
- Other relevant medical records as necessary

Who may use, share or receive my information?

The research team may use or share your de-identified information collected or created for this study with the following people and institutions:

- Rutgers University Research Staff involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The sponsor of this research study, the Rutgers CINJ CETI
- The developers of the *Alex* interactive conversational tool, BotsCrew
- The communications company for SMS/text messaging, Twilio

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision:

Anita Y. Kinney, PhD, RN
Rutgers Cancer Institute of New Jersey
195 Little Albany Street, Room 5541

New Brunswick, NJ 08901-1384

How long will my permission last?

There is no set date when your permission will end. Your health information may be studied for many years. If you decide to be in this research project, your permission to access and use your health information in this research project may not expire, unless you revoke or cancel it. Otherwise, we will use your information as long as it is needed for the research project.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent

I have read this entire consent and HIPAA authorization form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print): _____

Subject Signature: _____ Date _____

I agree to be contacted for future research opportunities: ☐ Yes ☐ No

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all the information contained in this consent and HIPAA Authorization form.

Investigator/Person Obtaining Consent Name (Printed): _____

Signature: _____ Date _____

**ADDENDUM: CONSENT TO AUDIO-/VISUALLY
RECORD OR PHOTOGRAPH SUBJECTS**

You have already agreed to take part in a research study entitled: **Choices About genetic Testing And Learning Your risk with Smart Technology (CATALYST)**, conducted by Dr. Anita Kinney. We are asking your consent to allow us to both audiotaping (sound) and videotaping you as part of the research. If you do not agree to be recorded, you may not be able to participate in the main part of the study.

The recordings will be used for quality assurance, and analysis by the research team. The recordings may include the following information that can identify you: video of you, or audio recordings of your voice. Each speaker will be given an identification number for transcription purposes. Recordings will be reviewed by the study team to verify transcription accuracy and then will be destroyed. Transcripts will not include identifiers.

The audio and video recordings and transcripts will be uploaded onto designated HIPAA (Health Insurance Portability and Assurance Act) compliant, password-protected network drive maintained and protected by a firewall and saved without identifiers or link to subjects' identity. Recordings will be destroyed once we have obtained de-identified transcripts. The de-identified transcripts will be retained indefinitely but will not include any identifiable information to you.

After information that could identify you has been removed, de-identified audio and video responses may be used by or distributed to investigators for other research without obtaining additional informed consent from you.

Your signature on this form permits the investigator named above to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than those stated in the consent form without your written consent.

AGREEMENT TO BE RECORDED

Subject Name (Print): _____

Subject Signature: _____ Date _____

Investigator/Person Obtaining Consent Name (Printed): _____

Signature: _____ Date _____

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Choices About genetic Testing And Learning Your risk with Smart Technology (CATALYST)

Principal Investigator: Anita Y. Kinney, PhD, RN

On behalf of the Rutgers Cancer Institute of New Jersey, we are excited to invite you to participate in the CATALYST Research Study. This informed consent form provides information about this research project and what will be asked of you if you choose to participate in it. If you have any questions now or during the research project, please feel free to ask them and you should expect to be given answers that you understand completely. It is your choice whether to participate and will not affect the quality of your clinical care at the Rutgers Cancer Institute of New Jersey or at University Hospital/New Jersey Medical School.

Who is conducting this study?

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Why is this study being done?

You are being invited to take part in a research project that aims to develop a patient centered **C**ancer **R**isk **E**valuation (CARE) digital health tool to help families learn about and make important health care decisions about hereditary cancer risk (cancer that runs in families). You will be asked to review the prototype of this digital assistant that is designed to educate, empower, and support patients who may be at an increased risk for inherited cancer. You will be asked to provide feedback that will be used to help us improve the website platform and the CARE digital assistant.

Who may take part in this study and who may not?

Participants must meet the following eligibility criteria:

- 1) Age 18 or older
- 2) History of breast cancer, ovarian cancer, fallopian tube cancer, peritoneal cancer, colorectal cancer, endometrial cancer, pancreatic cancer, prostate cancer, or any other features suggestive of inherited cancer.
- 3) Speak/read and understand English
- 4) Capable of providing informed consent
- 5) Have Internet access (via smartphone, tablet, or computer)

Why have I been asked to take part in this study?

You are being asked to take part in this study because you have had one or more of the following cancers: breast, ovarian, fallopian tube, peritoneal, colorectal, endometrial, pancreatic, prostate cancer or have any other features suggestive of inherited cancer.

What will I be asked to do if I take part in this study?

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How long will the study take and how many subjects will take part?

The total number of participants is 56 participants.

The total estimated participation time for the one-time guided interview is approximately 60-90 minutes.

What are the risks of harm or discomforts I might experience if I take part in this study?

Initial discomfort/embarrassment: Some individuals may experience discomfort or distress when answering questions about or thinking and talking about cancer or other health issues. Participants will be asked questions of a sensitive or personal nature, which could potentially cause some discomfort or embarrassment while answering. If this happens, you can skip those questions or withdraw from the study altogether. If you decide to quit the study, your responses will NOT be saved.

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necessary for the completion of the proposed study, and results will be reported in aggregate so that individuals are not identified. Study publications or presentations resulting from this research will not identify participants by name but will present only aggregate data. Every effort will be made to protect the information you give us. The researchers are trained to protect your information and to use procedures that reduce the possibility of loss of privacy and/or confidentiality.

Psychological or Social Risks Associated with Loss of Privacy:

Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Further, patterns of genetic variation also can be used by agencies to identify a person or their blood relatives (for example, to establish relationships between parents and their children).

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There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that helps protect against genetic discrimination. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Are there any benefits to me if I choose to take part in this study?

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Will I receive the results of the research?

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Will there be any cost to me to take part in this study?

There will be no cost to you to take part in this study.

Will I be paid to take part in this study?

Participants will be offered a \$75 gift card upon completion of testing the website and guided interview.

How will information about me be kept private or confidential?

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What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part, or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to the Principal Investigator:

Anita Y. Kinney, PhD, RN
Rutgers Cancer Institute of New Jersey
195 Little Albany Street, Room 5541
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If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

HIPAA AUTHORIZATION FORM: PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the research and how will my information be used?

You have been asked to take part in a research study. Your participation in this study is described at the beginning of the consent form and that information still applies. This additional form is required by the federal Health Insurance Portability and Accountability Act (HIPAA). The purpose of this form is to get your permission (authorization) to use health information about you that is created by or used in connection with this research. This form gives permission to study investigators to view your medical records to confirm medical referrals, medical information, and procedures related to this study including the dates of genetic counseling/risk assessment and genetic testing services and the results of genetic counseling/risk assessment and genetic testing. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research. If you would like to consent to this research study, you will be asked to sign the consent form and this HIPAA authorization form electronically. If you wish to sign the consent and HIPAA authorization form on paper, you will be asked to mail back a signed copy to us through email or mail (in a pre-stamped envelope that we will provide you).

What information about me will be used?

- Medical Record Number
- Name (First and Last)
- Contact Information (phone number, address, email address)
- Demographic Information (age, race, ethnicity, education)
- Cancer Diagnosis
- Medical History, Consultations or Treatment, including visit notes with clinicians/genetic counselors

- Medical Tests, Reports and Procedures (such as pathology report)
- Laboratory/diagnostic tests
- Dates of Medical/Laboratory tests
- Other relevant medical records as necessary

Who may use, share or receive my information?

The research team may use or share your de-identified information collected or created for this study with the following people and institutions:

- Rutgers University Research Staff involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The sponsor of this research study, the Rutgers CINJ CETI
- The developers of the *Alex* interactive conversational tool, BotsCrew
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Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

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Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision:

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How long will my permission last?

There is no set date when your permission will end. Your health information may be studied for many years. If you decide to be in this research project, your permission to access and use your health information in this research project may not expire, unless you revoke or cancel it. Otherwise, we will use your information as long as it is needed for the research project.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent

I have read this entire consent and HIPAA authorization form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print): _____

Subject Signature: _____ Date: _____

I agree to be contacted for future research opportunities: ☐ Yes ☐ No

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all the information contained in this consent and HIPAA Authorization form.

Investigator/Person Obtaining Consent Name (Printed): _____

Signature: _____ Date: _____

**ADDENDUM: CONSENT TO AUDIO-/VISUALLY
RECORD OR PHOTOGRAPH SUBJECTS**

You have already agreed to take part in a research study entitled: **Choices About genetic Testing And Learning Your risk with Smart Technology (CATALYST)**, conducted by Dr. Anita Kinney. We are asking your consent to allow us to both audiotaping (sound) and videotaping you as part of the research. If you do not agree to be recorded, you may not be able to participate in the main part of the study.

The recordings will be used for quality assurance, and analysis by the research team. The recordings may include the following information that can identify you: video of you or audio recordings of your voice. Each speaker will be given an identification number for transcription purposes. Recordings will be reviewed by the

study team to verify transcription accuracy and then will be destroyed. Transcripts will not include identifiers.

The audio and video recordings and transcripts will be uploaded onto designated HIPAA (Health Insurance Portability and Assurance Act) compliant, password-protected network drive maintained and protected by a firewall and saved without identifiers or link to subjects' identity. Recordings will be destroyed once we have obtained de-identified transcripts. The de-identified transcripts will be retained indefinitely but will not include any identifiable information to you.

After information that could identify you has been removed, de-identified audio and video responses may be used by or distributed to investigators for other research without obtaining additional informed consent from you.

Your signature on this form permits the investigator named above to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than those stated in the consent form without your written consent.

AGREEMENT TO BE RECORDED

Subject Name (Print): _____

Subject Signature: _____ Date: _____

Investigator/Person Obtaining Consent Name (Printed): _____

Signature: _____ Date: _____

CATALYST

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Choices About genetic Testing And Learning Your risk with Smart Technology (CATALYST)

Principal Investigator: Anita Y. Kinney, PhD, RN

On behalf of the Rutgers Cancer Institute, we are excited to invite you to participate in the CATALYST Research Study. This informed consent form provides information about this research project and what will be asked of you if you choose to participate in it. If you have any questions now or during the research project, please feel free to ask them and you should expect to be given answers that you understand completely. It is your choice whether to participate and will not affect the quality of your clinical care at the Rutgers Cancer Institute or at University Hospital/New Jersey Medical School.

Who is conducting this study?

Dr. Anita Kinney is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Study: This study is sponsored by the Rutgers Cancer Institute's Committee to Expedite Translational Initiatives (CETI).

Why is this study being done?

We would like to invite you to participate in a research project called **Choices About Genetic Testing And Learning Your Risk with Smart Technology, CATALYST**. The purpose of this research project is to educate, empower and support families who may be at increased risk for hereditary cancer (cancer that runs in families). The study is designed to evaluate models of health care delivery that improve awareness and access to potentially lifesaving cancer genetic services.

You are being asked to take part in this study because you have a history of one or more of the following cancers: breast, ovarian, fallopian tube, peritoneal, colorectal, endometrial, pancreatic, prostate cancer or have other features suggestive of inherited cancer.

How long will the study take and how many subjects will take part?

The total number of participants is 56.

If you decide to participate in this study, you will be asked to complete a baseline, 1-month, and 6-month survey. The surveys will take approximately 30-45 minutes each to complete. The duration of the study is six months.

CATALYST

What will I be asked to do if I take part in this study?

- You will be asked to review and sign a consent form with a research staff member and answer a few questions electronically or by phone. You will also be asked to review and sign the Health Insurance Portability and Accountability (HIPAA) authorization form electronically or on paper, so that the researchers can collect data from their medical records. If you choose to sign the HIPAA authorization form by paper, we will mail you a paper copy of the HIPAA authorization form with a pre-stamped envelope to email or mail back the signed HIPAA authorization form.
- You will be asked to complete an initial survey over the phone or online. This survey will ask you questions about several different items, including your health, your thoughts, and your feelings toward genetic risk assessment.
- Following the completion of the initial survey, you will be randomized to one of two groups described below. Randomization is a method used to ensure the research study is fair. It means that participants are assigned by chance to different study groups. This study involves two different study groups:
 - **Group 1** is the Enhanced Usual Care (EUC) group. Participants in this group receive a clinical letter containing information about you and your family's potential risk for hereditary cancer, and the next steps you could take to find out more information about your potential hereditary cancer risk and cancer genetic risk assessment services, including genetic testing.
 - If you indicate that you would like to proceed with obtaining a genetic test, a Genetic Testing Kit will be mailed to you directly.
 - **Group 2** is the Genetic **C**ancer **R**isk **E**valuation (CARE) Digital Assistant Group. Participants in this group will be asked to sign-in to a webpage and engage with a digital assistant online through a smart device (phone, computer, or tablet) to learn more information about their personal and their family's potential hereditary cancer risk and cancer genetic risk assessment services, including genetic testing.
 - If you indicate that you would like to proceed with obtaining a genetic test, a Genetic Testing Kit will be mailed to you directly.
- One month after the initial survey, you will be asked to complete another survey over the phone or online.
- Six months after the initial survey, you will be asked to complete another survey over the phone or online.

What are the risks of harm or discomforts I might experience if I take part in this study?

Initial discomfort/embarrassment: Some individuals may experience discomfort or distress when answering questions about or thinking and talking about cancer or other health issues. Participants will be asked questions of a sensitive or personal nature, which could potentially cause some discomfort or embarrassment while answering. If this happens, you can skip those questions or withdraw from the study altogether. If you decide to quit the study, your responses will NOT be saved.

CATALYST

Privacy and loss of confidentiality: Breach of confidentiality is a risk of harm, but a data security plan is in place to minimize such a risk. Nevertheless, there is still the potential for unintentional breach of confidentiality for participants. All efforts will be made to maintain privacy and confidentiality. We are aware that data will contain demographic and personal health information, and consistent measures will be employed to protect the security and confidentiality of this data. All data will be securely stored in a study database. Participants will be assigned a study ID, and the analyses will be limited to the variables necessary for the completion of the proposed study, and results will be reported in aggregate so that individuals are not identified. Study publications or presentations resulting from this research will not identify participants by name but will present only aggregate data. Every effort will be made to protect the information you give us. The researchers are trained to protect your information and to use procedures that reduce the possibility of loss of privacy and/or confidentiality.

Psychological or Social Risks Associated with Loss of Privacy:

Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Further, patterns of genetic variation also can be used by agencies to identify a person or their blood relatives (for example, to establish relationships between parents and their children).

Economic Risks of Harm:

Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family economic distress.

There is a federal law call the Genetic Information Nondiscrimination Act (GINA) that helps protect against genetic discrimination. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Are there any benefits to me if I choose to take part in this study?

There may or may not be direct benefits to you for taking part in this study. However, you may find satisfaction in contributing to research and you may learn new information relating to cancer education and clinical trial participation. Participation may help you communicate genetic test results with your family members and you may learn more about you and your family's risk for hereditary cancer.

There is compensation upon completion of study surveys and there will be additional compensation for participants who complete all surveys.

CATALYST

What are my alternatives if I do not want to take part in this study?

Taking part in this study is voluntary, so you can choose not to participate. There will be no penalties involved if you choose not to take part in this study, and it will not change or influence your medical care.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?

We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Will there be any cost to me to take part in this study?

There will be no cost to you to take part in this study.

Will I be paid to take part in this study?

If you are in the Enhanced Usual Care (EUC) group, you will receive a \$50 gift card after completion of each survey (initial, 1-Month, and 6-Month), and will receive an additional \$30 gift card if you complete all surveys for a potential compensation of \$180.

If you are in the Genetic **C**Ancer **R**isk **E**valuation (CARE) Digital Assistant Group, you will be asked to log in to the website platform at least once and you will be offered a \$50 gift card after completion of each survey (initial, 1-Month, and 6-Month), and will receive an additional \$30 gift card if you complete all surveys for a potential compensation of \$180.

How will information about me be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Identifiable information will not be stored with your responses. Instead, your responses will be assigned a subject number which will be stored separately from your identifiable information so others will not know which responses are yours. These study IDs will help maintain confidentiality. A study database will be hosted at Rutgers Cancer Institute in New Brunswick, NJ on secure computing servers with secure data entry and submission for all other sites. No information that can identify you will appear in any professional presentation or publication. There may be circumstances where this information must be released.

What will happen to my information—data, recordings and/or images— collected for this research after the study is over?

CATALYST

All information will remain confidential and de-identified and stored in password protected and encrypted databases. Your de-identified information may be shared with other investigators in future research.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part, or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to the Principal Investigator:

Anita Y. Kinney, PhD, RN
Rutgers Cancer Institute
195 Little Albany Street, Room 5541
New Brunswick, NJ 08901-1384

Who can I contact if I have questions?

If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the CATALYST research team at (732) 735 – 8545 or ekh47@cinj.rutgers.edu.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email at irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?

You have been asked to take part in a research study. Your participation in this study is described at the beginning of the consent form, and that information still applies. This additional form is required by the federal Health Insurance Portability and Accountability Act (HIPAA). The purpose of this form is to get your

CATALYST

permission (authorization) to use health information about you that is created by or used in connection with this research. This form gives permission to study investigators to view your medical records to confirm medical referrals, medical information, and procedures related to this study including the dates of genetic counseling/risk assessment and genetic testing services and the results of genetic counseling/risk assessment and genetic testing. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research. If you would like to consent to this research study, you will be asked to sign the consent form and this HIPAA authorization form electronically. If you wish to sign the consent and HIPAA authorization form on paper, you will be asked to mail back a signed copy to us through email or mail (in a pre-stamped envelope that we will provide you).

What Information About Me Will Be Used?

- Medical Record Number
- Name (First and Last)
- Contact Information (phone number, address, email address)
- Demographic Information (age, race, ethnicity, education)
- Cancer Diagnosis
- Medical History, Consultations or Treatment, including visit notes with clinicians/genetic counselors
- Medical Tests, Reports and Procedures (such as pathology report)
- Laboratory/diagnostic tests
- Dates of Medical/Laboratory tests
- Insurance Information
- Other relevant medical records as necessary

Who May Use, Share or Receive My Information?

The research team may use or share your de-identified information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the research project
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The sponsor of this research study, the Rutgers CINJ CETI
- The developers of the digital assistant, BotsCrew
- The communications company for SMS/text messaging, Twilio

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?

Protocol Title: CATALYST
Protocol Version Date: V1 21June2023
Consent Version Date: V2 10June2024

CATALYST

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision:

Anita Y. Kinney, PhD, RN
Rutgers Cancer Institute
195 Little Albany Street, Room 5541
New Brunswick, NJ 08901-1384

How Long Will My Permission Last?

There is no set date when your permission will end. Your health information may be studied for many years. If you decide to be in this research project, your permission to access and use your health information in this research project may not expire, unless you revoke or cancel it. Otherwise, we will use your information as long as it is needed for the research project.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent

I have read this entire consent and HIPAA authorization form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print): _____

Protocol Title: CATALYST
Protocol Version Date: V1 21June2023
Consent Version Date: V2 10June2024

CATALYST

Subject Signature: _____ Date: _____

I agree to be contacted for future research opportunities: ☐ Yes ☐ No

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all the information contained in this consent and HIPAA Authorization form.

Investigator/Person Obtaining Consent Name (Printed): _____

Signature: _____ Date: _____