

STANFORD UNIVERSITY Research Consent Form*IRB Use Only*Approval Date: February 08, 2021
Expiration Date: **(Does Not Expire)**

Protocol Director: Catherine Benedict

Protocol Title: Pilot Study of a Decision Aid Tool for Family-building After Cancer

FOR QUESTIONS ABOUT THE STUDY, CONTACT:

Catherine Benedict, PhD
401 Quarry Rd., room 2C29, Palo Alto, CA 94305
650-736-7659

DESCRIPTION: You are invited to participate in a research study on fertility and family-building after cancer. You will be asked to complete three surveys over a 3-month time period and to review a website that aims to provide education about fertility and family-building options after cancer and to help you make a decision about “next steps” to plan for future family-building. The purpose of this study is to test whether the website helps young female cancer survivors feel more informed about their fertility and options to have a child after cancer, less distressed, and more confident in being able to make decisions about family-building. Ultimately, we hope to develop a resource to better support patients in managing fertility care after cancer, making decisions about family-building options, and to help patients plan ahead for potential future challenges related to a chosen option for family-building. All data will be kept confidential.

The National Cancer Institute is providing financial support for this study.

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

Future use of Private Information

Research using private information is an important way to try to understand human experiences. You are being given this information because the investigators want to save private information for future research.

Your data will be stored in secure, password protected electronic drives. All data will be de-identified and generic study IDs will be used.

Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

RISKS AND BENEFITS: The risks associated with this study are minimal. You may experience some distress if you learn of new information about infertility risks associated with cancer treatment or challenges of family-building options that involve assisted reproductive technology (such as in vitro fertilization or surrogacy) or adoption. The benefits which may reasonably be expected to result from this study include education about family-building options and things you can do to prepare for potential future challenges. We hope that participation in this study will help you think about your options for having children in the future, learn about potential challenges, and feel supported in planning and preparing for the future. We cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your medical care.

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It is possible that, based on information gained from this study, the researchers may have serious concerns (relating to matters such as severe depression, physical abuse, etc.) about your health and/or safety; in such a case, the researchers may contact you and provide a referral for your care.

TIME INVOLVEMENT: Your participation in this experiment will take approximately 3 months. This will include completing 3 surveys over a 3-month time period and looking at a "decision aid and planning tool" website. First, after enrolling in the study, you will be asked to complete a baseline survey. Then we will send you the link to access the website and you will be asked to review it. One month later, you will be asked to complete the second survey, and three months later you will be asked to complete the third survey. All surveys can be completed over the internet and take about 30 minutes to complete.

PAYMENTS/REIMBURSEMENTS: You will receive \$10 as payment for your participation. Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You have the right to refuse to answer particular questions.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Cancer Institute, which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to test a “decision aid and planning tool” that was developed to educate and provide support to young female cancer survivors who are interested in having children after receiving cancer treatments known to have infertility risks. The information you provide will help us develop support resources for patients to make decisions about family-building after cancer and to prepare for the challenges of pursuing assisted reproductive technology and adoption.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Catherine Benedict, 401 Quarry Rd. room 2C29, Palo Alto CA 94305.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, your name, date

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of birth, address, telephone number, email address, medical record number, and medical information related to your cancer diagnosis such as diagnosis or procedure codes.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director (Catherine Benedict, PhD)
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff
- Study co-Investigators

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Cancer Institute

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on June 31, 2025 or when the research project ends, whichever is earlier.

Signature of Adult Participant

Date

Print Name of Adult Participant

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WITHDRAWAL FROM STUDY: The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Catherine Benedict. You may contact her now or later at 650-736-7659. You should also contact her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

The extra copy of this signed and dated consent form is for you to keep.

Signature of Adult Participant

Date

Print Name of Adult Participant