FERTILIT-*E* AIM 1

Informed Consent Form to Participate in Research
John M. Salsman, Ph.D., Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are a young adult (age 18-39) with a past diagnosis of cancer, who received treatment associated with a risk of infertility (i.e., systemic chemotherapy, pelvic radiotherapy, and/or pelvic surgery with potential impact on reproductive function), and who completed this treatment within the last five years. Your participation is voluntary. Please take your time in making your decision as to whether you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

We are conducting this study to develop and adapt a mobile Health tool (Fertilit-*e*) with content that is tailored for fertility preservation decision-making in young adults with cancer. We will ask questions to help understand the functionality and content of Fertilit-*e* prototypes. Our study results will help improve decision support aids about fertility preservation and enhance patient centered care for young adults with cancer.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Twenty-four people at this research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

To participate in this study, you will meet with a study interviewer online and complete a guided review of prototypes for Fertilit-*e*. The prototypes will focus on the following domains: personal information, values, and preferences, fertility risk and options, personal stories, financial concerns, frequently asked questions, additional resources and an overall summary. As part of this research study, you will provide feedback about ease of use, functionality, content, and design elements for Fertilit-*e*.

As part of this research study, you will be video and audiotaped. This is being done to ensure that your responses are accurately captured. You understand that you may request the recording be stopped at any time during the research study. You can also withdraw your consent to use and disclose the audiotape before it is used. You should also understand that you will not be able to

inspect, review, or approve the audiotapes or other media (including articles containing such) before they are used in this study. The audiotapes will be destroyed once the study is finished.

How Long Will I Be in the Study?

The interview will last approximately 45-60 minutes. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen because of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Are There Benefits to Taking Part in the Study?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit cancer patients and survivors in the future.

What Other Choices Are There?

This is not a treatment study. Your alternative is to not participate in this study.

What Are the Costs?

All study costs, including procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive a $25 gift card after you complete the interview as a thank you for your time.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored through pilot research funds from the Cancer Prevention and Control Program of the Wake Forest Baptist Comprehensive Cancer Center. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** general information about financial burden, body image, and fertility/future parenthood.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be deidentified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are finished.

You can tell Dr. John M. Salsman that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

John M. Salsman, Ph.D.
Department of Social Sciences & Health Policy
Division of Public Health Sciences
Medical Center Boulevard
Winston- Salem, NC 27157

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study team by phone or email.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB.

1)Please see below:
You may print a copy of this online informed consent form for your records.

Choose one:

- o I accept the consent and wish to participate in this study. This documents your permission to take part in this research.
- o I decline the consent and do not wish to participate in this study.

2) Subject Name
3) Signature
4) Date and Time of Consent