Institutional Review Board
Informed Consent Document for Research
MASTER CONSENT

Study Title: Expanding Rural Health Cancer Control Capacity: Focus on Cancer Survivorship
Version Date: 11/11/2020

Part 1 of 2: MASTER CONSENT

This informed consent applies to patients.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

What is the purpose of this study?
You are being asked to take part in this research study because you are a survivor of cancer, and were identified by your provider or their support staff as an eligible participant.

This study is researching information on how to best implement guideline-based, locally accessible survivorship care to rural cancer survivors. Our goal is to improve our understanding of the needs of cancer survivors in rural communities and optimize implementation strategies that could help rural healthcare facilities overcome challenges to delivering guideline-based survivorship care planning and delivery. We also hope to enhance our capacity to bring cancer prevention and control research education and services to rural populations.

To accomplish this goal, we plan to provide a telehealth (providing health-related services through electronic communication technologies) survivorship care plan to participants in combination with assistance from a patient navigator. A survivorship care plan is an individualized plan that gathers and organizes information about your diagnosis, treatment, and future recommendations so that you can better manage survivorship care. The survivorship care plan will be created and delivered by the REACH for Cancer Survivorship Program nurse practitioner along with a research nurse from your treating hospital. The REACH for Cancer Survivorship is a survivorship clinic offered through Vanderbilt-Ingram Cancer Center. A Patient navigator is an individual who will help you throughout this process to navigate the healthcare system and locate and utilize beneficial resources.

This study is being done by Dr. Debra Friedman at the Vanderbilt-Ingram Cancer Center.

What will happen and how long will you be in the study?
If you agree to be in this study, you will be asked to complete the following:

- A baseline survey that is expected to take about 10-20 minutes to complete.

- A telehealth visit through HIPAA-compliant software (e.g. Zoom), with the REACH for Cancer Survivorship Program nurse practitioner and a research nurse from your treating hospital.
- A post-intervention survey three months after your telehealth visit that is expected to take about 15-30 minutes to complete .
- If selected and willing, an end of study interview and/or focus group that is expected to last about 45-60 minutes and will be recorded. Up to 20 participants who complete an interview and/or focus group will be provided a $25 gift card in appreciation of their time.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record may contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
Some of the questionnaires may raise personal, sensitive issues or make you feel uncomfortable. If you are not comfortable answering any question, you can choose not to answer it and skip the question. You can refuse to answer a question for any reason.

There is a slight risk of accidental release of confidential information. The study team attempts to minimize this risk by limiting access to PHI and de-identifying all research data. All confidential records that could identify subjects will be protected, respecting the privacy and confidentiality rules in accordance with the IRB's regulatory requirements. All electronic data will be stored in a password protected secure database where only study personnel will have access. The study team will perform the study according to good clinical practices.

Risks that are not known:
If unanticipated risks become known, you will be informed of such risks so that you can decide if you would like to withdraw from the study.

Good effects that might result from this study:
The benefits to science and humankind that <u>might</u> result from this study:
- We may learn more about the needs of rural cancer survivors
- We may learn more about the effectiveness, usefulness, and feasibility of a combination of telehealth and patient navigation with survivorship care plans.

- Data obtained may inform therapy for patients in the future and surveillance and secondary prevention interventions to avoid adverse long-term outcomes for current long-term survivors.

Reasons why the study doctor may take you out of this study:
You may be taken out of the study if you request it. If you are taken out of the study for any reason, you will be told why.

What will happen if you decide to stop being in this study?
Participation in this study is fully voluntary. You can choose to stop being in this study at any time. If you decide to stop being part of the study, you should tell the study team or principle investigator. At that time, we will stop gathering information about you; however, the data that is already part of the study will be kept.