Institutional Review Board
Informed Consent Document for Research

Study Title: Enhancing Cancer Care of Rural Dwellers Through Telehealth and Engagement (ENCORE)
Version Date: 11/12/2020 NCT04758338

Part 1 of 2: MASTER CONSENT

This informed consent applies to patients.

Name of participant: _____ Age: _____

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

What is the purpose of this study?
You are being asked to take part in this research study because you have recently been diagnosed with a new cancer or a prior cancer has relapsed, and you were identified by your healthcare provider or their support staff as an eligible participant.

This study hopes to better understand how telehealth (providing health-related services through electronic communication technologies) can help improve treatment and care for patients with cancer, such as yourself, who live in rural communities. This study also hopes to better understand the benefits to patients who participate in a support intervention while receiving treatment for their cancer.

The study is being conducted by Dr. Debra L. Friedman and Dr. Tuya Pal at Vanderbilt-Ingram Cancer Center (VICC). We hope to enroll about 700 patients during the entirety of this study. We will not be collecting any biological samples.

You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights.

Procedures to be followed:
If you agree to be in this study, the following will happen:

- At the start of the study, you will be asked to complete a Baseline Survey that is expected to take about 30-45 minutes of your time.

- If your healthcare provider shared treatment recommendations with you after anonymously presenting your cancer diagnosis at the VICC HOPE Molecular Tumor Board to receive guidance from fellow oncology providers, you will be asked to complete a post-provider recommendation survey.
- At the start of the study, you will be randomly assigned to participate in one of two telehealth Patient Support Interventions that will take place over a six-week period. You will be required to participate in the telehealth Patient Support Intervention you are assigned via internet or broadband service. For this reason, a reliable video capable device (e.g., smartphone, tablet, laptop, and/or computer) with internet access will be needed. If you do not have a reliable device, one will be provided to you at no cost, with the expectation that it will be returned to the study team at the conclusion of the study. This device will be mailed to your home after enrollment. If you do not have reliable internet service, a data plan can be provided to you at no cost for the duration of the study.
- During the second and fourth week of the Support Intervention, you will be asked to complete a medication survey where you will be asked if you are taking any chemotherapy medications. If you are, you will note how much of those medications you have taken within those 2-week periods from 0-100%.
- Following the 6-week intervention, you will be asked to complete Follow-up Surveys asking about your experience throughout the patient support intervention that are expected to take about 45-60 minutes of your time. All participants who complete the Patient Support Intervention and the baseline and follow-up surveys will receive a $25 gift card in appreciation of their time.
- Some of you (up to 25-30 participants) will be asked to complete two end of study interviews, 6-week post intervention and two years post-intervention to further ask about your experience with the patient support intervention. The interview will be over the phone and recorded and is expected to take about 30-60 minutes of your time. Those who are selected and complete an interview will be provided an additional $25 gift card in appreciation of their time.

If any questions throughout the study make you feel uncomfortable, you do not have to answer those questions. This is a longitudinal study, meaning we will follow your medical experience throughout your cancer treatment over the next 2-3 years. This information can help us understand and improve care options for future patients.

You do not have to be in this research study. 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.

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Side effects and risks that you can expect if you take part in this study:
Some of the questions are personal and may make you uncomfortable. For example, questions will be asked about your physical abilities, emotions, and feelings. The study questions have been used many times by many hospitals and clinics. To the best or our knowledge, they have not caused anyone serious problems. You do not have to answer any question that you do not want to.

There is a possibility that confidential information you provide will be seen by others. However, the research staff will keep all study information in a locked file. The coded data will be kept on a secure computer, which will be protected by a password. The study team will perform the study according to good clinical practices.

Risks that are not known:
If unanticipated risks become known, we will inform you 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 might result from this study:

- We expect this study will improve care for patients with cancer living in rural areas.
- We may learn the benefits to provider collaboration and knowledge sharing after presenting your cancer diagnosis at the VICC HOPE Molecular Tumor Board by your oncologist.
- We may also learn what the benefits are to cancer patients participating in a patient support intervention while undergoing treatment.

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?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Privacy:
Any information about you may be made available to others to use for research. To protect your privacy, we will not release your name. All information collected will be de-identified. These questionnaires may help us or other researchers learn more about the risks, treatments, or how to prevent this and other health problems. 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.

Study Results:
Study results will not be shared with participants.