Research Study Informed Consent Document

Study Title for Participants: A Stepped-Care Telehealth Approach to Treat Distress in Cancer Survivors

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Protocol WF-30917CD, A Stepped-Care Telehealth Approach to Treat Distress in Cancer Survivors (TELEHEALTH) (NCT#03060096)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study of cancer survivors who have completed treatment. You are being asked to take part in this study because you have a history of cancer and distress (i.e., anxiety and/or depressive symptoms). This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

Taking part in this study is your choice.

You can choose to take part, or you can choose not to take part in this this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

The purpose of this research study is to determine the feasibility and effects of a telephone-based, stepped-care mental health intervention (which means that the level of intervention is based on the severity of symptoms) versus enhanced usual care for post-treatment cancer survivors with moderate or severe levels of emotional distress (anxiety and/or depressive symptoms).

What is the usual approach?

You are being asked to take part in this study because you have a history of cancer and distress (i.e., anxiety and/or depressive symptoms). Approaches to treating anxiety or depression may include medications and/or counseling.

What are my choices if I decide not to take part in this study?

If you decide not to take part in this study, you have other choices.

- You may choose to have the usual approaches described above.
- You may choose to take part in a different research study, if one is available.
- You may choose to do nothing.

What will happen if I decide to take part in this study?

Approximately 90 participants will be enrolled in this research study. If you are eligible for the study, you will complete a set of questionnaires and then be randomly assigned to receive either the stepped-care telehealth intervention or enhanced usual care. A computer will randomly put you in a study group—like a coin toss—to decide what group you get placed into. This means that you are put into a group by chance and you have an equal chance of being placed in either group; participation in either group will last for 12 weeks. This is done because no one knows if one study group is better, the same, or worse than the other group. Once you are put in a group, you cannot switch to the other group. The study investigators may switch you to a different group with a higher level of care if your symptoms of anxiety or depression worsen during the study. You will also complete questionnaires and telephone interviews during week 8 and weeks 13-15 of the study. In addition, you will provide information on your health history; study staff may obtain health information from your medical records as well. Individuals who are unable to afford a telephone may be provided with assistance to cover this expense. This will be determined on a case-by-case basis.

What are the study groups?

<u>Stepped-Care Telehealth Group</u>

If you are randomized to the Stepped-Care Telehealth Group, you will be placed into one of two groups for the next 12 weeks, either low-intensity or high-intensity stepped-care telehealth. The group you are placed in is based on your answers to questions on study assessments. It is possible that you might change the group of stepped-care telehealth that

you are in placed in at the beginning of the study. This change would be based on your answers to questions on study assessments during the study.

- Low-intensity stepped-care telehealth: If you are placed in this group, you will receive a workbook with lessons designed to help manage anxiety, depression and distress. Over the twelve weeks you are in the study, you will be asked to review the information in the workbook, complete the written exercises, and practice the techniques (approximately 1 hour and 45 minutes per week or 15 minutes daily). You will also receive a brief call (approximately 5-10 minutes) every two weeks from study staff to see how you are doing and offer support.

- High-intensity stepped-care telehealth: If you are placed in this group, you will receive a workbook with lessons designed to help manage anxiety depression and distress. You will also participate in 12 weekly 45 minute therapy sessions with a licensed therapist. This therapy is called cognitive behavioral therapy, which is a type of treatment that teaches people different ways to handle anxiety and/or depressive symptoms, such as by relaxing your body, changing your thoughts, and solving problems. Over the twelve weeks you are in the study, the study therapist will call to review the information in the workbook and you will be asked to practice these techniques between telephone calls (approximately 1 hour and 45 minutes per week or 15 minutes daily).

Enhanced Usual Care Group.
If you are randomized to this group, you will receive information about referrals/resources in your local area, including support groups and mental health providers. You will also be provided "Facing Forward: Life after Cancer Treatment," a book developed by the National Cancer Institute to assist with the transition from active treatment to survivorship. It addresses the topics of follow up medical care, physical changes, body changes and intimacy, feelings, and social and work relationships. Finally, you will also receive information about self-help resources for anxiety and depressive symptoms. When you finish this study you will receive a copy of the Telehealth Study Workbook.

Stepped-Care	**Enhanced Usual Care (EUC Control)**
• Self-guided CBT workbook • Low Intensity: Bi-weekly check in brief calls with research staff. • High Intensity: Weekly CBT by telephone with a trained therapist.	• Survivorship resources • Contact information for local mental health providers

As part of this research study, all bi-weekly check in calls (low intensity group) and telephone therapy sessions (high intensity group) will be audiotaped. Experts will review randomly selected sessions in order to make sure the study staff are handling all calls in the same way. You may request that the recording be stopped at any time during the

course of the research study. Please choose one of the following regarding the use and disclosure of the audiotapes used in this research study:

_____ I would like the audiotapes of me to be destroyed once their use in this study is finished.

_____ The audiotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. No identifying information will be associated with these audiotapes. I understand that I will not be able to inspect, review or approve their future use.

What exams, tests and procedures are involved in this study?

Aside from study questionnaires and telephone interviews listed above in the "What are the study groups?" section, no additional tests or procedures will be conducted.

What risks can I expect from taking part in this study?

Risks and side effects are that some individuals may find discussing their problems with others to be uncomfortable, embarrassing, and/or stressful. Every effort will be made, however, to address each participant's concerns or problems in the most supportive, empathic, and therapeutic manner. 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. A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study. Although unlikely, there also may be other side effects that we cannot predict.

The risk of harm or discomfort that may happen as a result 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. If at any time you are suicidal, we will contact your emergency contacts that you provided during this study.

There may be some risks that the study investigators do not yet know about.

What benefits can I expect from taking part in this study?

If you agree to take part in this study, there may or may not be direct benefit to you.
You may or may not experience a decrease in your anxiety and/or depressive symptoms. Further, the information we gain may benefit cancer patients in the future.

If I decide to take part in this study, can I stop later?

Yes. You will be in the study for about 13-15 weeks. You can decide to stop at any time. If you decide to stop for any reason, it is important to let study staff know as soon as possible so you can stop safely. If you are in the high-intensity stepped care group, you will no longer have access to the study therapist.

The study staff will tell you about any new information or changes in the study that could affect your health or your willingness to continue in the study.

The study investigator may take you out of the study if the study is no longer in your best interest.

What are the costs of taking part in this study?

There are no costs to you for taking part in this study. All study costs, including any study treatment or materials, 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. Your therapy sessions or check-in calls will be conducted on your personal telephone. If you are unable to continue in the study due to the inability to purchase phone minutes or the lack of a phone, please contact the study investigator or staff person _____ *(insert name of site staff)* at _____ *(insert telephone number)* to see if assistance might be available.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please tell your study investigator right away for treatment options. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs. If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance coverage, you would be responsible for any costs. Even though you are in a study, you keep all of your legal rights to receive payment for injury caused by medical errors.

Limits of Confidentiality

At any point during the study, confidentiality will be broken if a participant is 1) imminently suicidal, 2) found to be homicidal, or 3) suspected of committing child or elder abuse as defined by the statutes of the state in which you live. Further, we may contact your emergency contacts if you seem to be experiencing any significant confusion or may be medically ill.

If you ever have thoughts of wanting to be dead or harming yourself, you can call the National Suicide Prevention Hotline at 1-800-273-8255.

Who will see my medical information?

Your privacy is very important to us. The study investigators will make every effort to protect it. The study investigators have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study investigators will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor supporting the study now or in the future. This would include any organization helping the company with the study.
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- Authorized personnel as needed to conduct the study.
- Wake Forest NCORP Research Base and any representative working on its behalf.
- The Study investigator and their study staff or designees
- The NCI and the groups it works with to review research.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.

- You and your study investigator will not be told when or what type of research will be done.
- You will not get reports or other information about some research that is done using your information.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study investigator about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor (*insert name of study investigator[s]*) at (*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

My Signature Agreeing to Take Part in the Study

I have read this consent form or had it read to me. I have discussed it with the study investigator and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study.

Participant's signature: _____

Date of signature: _____
mm/dd/yyyy

Signature of person(s) conducting the informed consent discussion: _____

Date of signature: _____
mm/dd/yyyy