PROGRAMS TO SUPPORT YOU DURING CHEMOTHERAPY (PRO-YOU)

Informed Consent Form to Participate in Research

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 receiving chemotherapy for a gastrointestinal cancer. Your participation is voluntary. Please take your time in making your decision as to whether or not 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?

The purpose of this research study is to learn how two different supportive programs may help people feel better while receiving chemotherapy and in between treatments. This study will measure if one type of supportive program is more useful than the other for improving well-being. There are a few studies that suggest that similar programs may be effective for some people with cancer. However, research is needed to confirm these results during active treatment.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 44 people at 2 research sites will take part in this study, including approximately 36 people at this research site.

WHAT IS INVOLVED IN THE STUDY?

You will be randomly assigned to one of two supportive programs. These two programs will use different methods for helping you cope with chemotherapy such as gentle movements, counseling, writing, or relaxation techniques. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal/one in two chance of being placed in either group.

Once you agree to participate and are enrolled, we will ask you to complete study questionnaires. We will also ask you to complete similar questionnaires midway through the study (week 8), and two weeks after your final supportive program session (week 10) and six weeks after your last session (week 14). Questionnaires ask for basic information about you, your health, emotional functioning, and symptoms. Each questionnaire will take approximately 30 minutes to complete and will not require any additional clinic visits.

WFU School of Medicine
Institutional Review Board
IRB Number:
IRB00038321
Meeting Date Approved 9/6/2019
Version Valid Until: 2/10/2020

There will be four supportive program sessions that can be done while sitting in the chair during treatment. Also, we will ask you to complete daily practices at home throughout the study and to record how many times you do the home practices.

In addition, we will ask you to answer a brief set of questions daily by phone or internet survey and wear a monitor on your wrist for two weeks before and two weeks after the supportive programs. This will help us understand your experience in between treatments.

You may be asked to complete an interview at the end of the study either in person or by telephone to provide feedback.

As part of this research study, you will be videotaped. This is being done to ensure quality of implementation. You will not be identifiable in the video. You understand that you may request the filming or recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the videotape before it is used. You should also understand that you will not be able to inspect, review, or approve the videotapes or other media (including articles containing such) before they are used in this study.

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

_____I would like the videotapes of me to be destroyed once their use in this study is finished.

__The videotapes 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. I understand that I will not be able to inspect, review or approve their future use.

Further, we would like to collect a blood sample before and after the supportive program (two times). This sample will be obtained during your routine blood draws and will be stored until it is analyzed. You will have approximately 1 tablespoon of blood withdrawn from a vein on two occasions. In the event that you are not scheduled for a blood draw prior to chemotherapy, we will ask to draw blood for study purposes only. You always have the option to refuse this procedure. The total amount of blood withdrawn during the study will be approximately 2 tablespoons. We will analyze these samples for measures of inflammation.

We will also access your medical record to obtain information such as your diagnosis, stage of disease, treatment plan, height, weight and medications.

Is it ok for this study team to keep your information and contact you for future studies (please circle your response)?

Yes No

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 14 weeks, until 6 weeks after you have completed the supportive program.

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.

WHAT ARE THE RISKS OF THE STUDY?

Risks associated with taking part in this study are expected to be rare. Any gentle movements taught will be adapted to your ability level. Yet, it is possible that any movement may result in minor injury. You may also feel some discomfort in talking about and answering questions about your health and/or emotional well-being.

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.

As part of this study, you will be asked questions about depressive symptoms and mental health. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities."

There are also potential risks related to the blood draws. You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

Because these supportive programs are not commonly used during chemotherapy, there may be risks that we do not know about at this time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: you may find programs offered during this study useful for helping you cope with distress that you may experience during chemotherapy.

WHAT OTHER CHOICES ARE THERE?

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

WHAT ARE THE COSTS?

There is no cost to you for taking part in this study.

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.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a research study. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid up to $125 for completing all study assessments. Ten dollars for: each of the questionnaires ($40 total), each of the 4 weeks of brief daily questions ($40 total), each 2 week session of wearing a wrist monitor (2 sessions or 4 weeks total; $20 total), and $25 if asked to complete an interview. To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Center for Complementary and Integrative Health (NCCIH) and the National Center for Advancing Translational Sciences. 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 HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North

Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call the study investigator.

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**:** questionnaire information, wrist monitor data, results of inflammation analyses, as well as parts of your medical record.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

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.

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, documents, or biospecimens 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, documents, or biospecimens 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 Center For Complementary & Integrative Health of the National Institutes of Health, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. Research data will be included in your medical record.

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 including Vanderbilt University; 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.

1) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

2) Representatives from government agencies such as the Office for Human Research Protections and other similar agencies.

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 de-identified and 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 completely finished.

You can tell the study investigator 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:

Department of Social Sciences and Health Policy
Division of Public Health Sciences
Wake Forest School of Medicine
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.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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

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 discontinue the study interventions due to a change in treatment location, the investigators may contact you to complete study assessments. 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, funding agency, other government agencies and institution also have the right to stop your participation in the study at any time to ensure that you are protected. This could be because your chemotherapy changes your eligibility for the study.

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 investigator.

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.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature:_____ Date: Time: am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent: Date: Time: am pm