Wake Forest®
School of Medicine

Department of Social Sciences and Healthy Policy

MAPPING TO GUIDE SELF-MANAGEMENT IN CANCER SURVIVORS

Informed Consent Form to Participate in Research
Stephanie Sohl, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research study is to determine how easy or difficult it is for patients to complete a self-management mapping activity and how helpful the activity is in planning their future health goals. You are invited to be in this study because you have completed active treatment for colorectal cancer. Your participation in this research will involve 2 visits (either in person or by phone) and will last about 2-3 weeks.

Participation in this study will involve completing surveys, a mapping activity in-person, and an interview. All research studies involve some risks. A risk to this study that you should be aware of is the chance that you may feel some emotional discomfort since you will be thinking about and discussing your health. There is the possibility that you may benefit from participation in this study, and we hope the information we gain from this study can help us plan future studies.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Stephanie Sohl. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is: ssohl@wakehealth.edu or 336-713-5093.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at 336-716-4542 or the Research Subject Advocate at Wake Forest at 336-716-8372.

INTRODUCTION

You are invited to participate 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 have finished active treatment for colorectal 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 determine how easy or difficult it is for patients to complete a self-management mapping activity and how helpful the activity is in planning their future health goals.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

30 people will take part in this study. All participants will be recruited through this research site.

WHAT IS INVOLVED IN THE STUDY?

At your first study visit, you will complete a questionnaire. You will then meet with a member of the study team in-person to complete the study mapping activity that will last approximately 1.5-2 hours. You will be asked to use a giant piece of paper to create a picture of areas of your life that are affected by cancer and its treatment. You will also have the chance to set a goal to work on for the next 2 weeks, including action steps. Two weeks later, you will have a follow-up visit either in person or by phone to complete another questionnaire. Finally, you will be asked to participate in an interview to provide feedback on the mapping activity and any suggestions you may have for improvement.

As part of this research study, you will be audiotaped. This is being done to ensure study quality and so we can accurately capture the experiences you share with us through the mapping activity. You may request that the recording be stopped at any time during the course of the research study. You can also withdraw your consent to disclose the audio recording before it is used. You should also understand that you will not be able to inspect, review, or approve the audio recording 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 audio recording used in this research study:

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

____ The photographs/videotapes/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. I understand that I will not be able to inspect, review or approve their future use.

If it is more convenient for you, the study team can send you a copy of the map you create over email through your personal email address. Email is not considered a secure form of communication and information you disclose may be viewed, accessed or disclosed by others. You can choose your preferred method of receiving the study map. No sensitive or identifying information would be shared in email messages exchanged between you and the study team.

_____ I give permission for the study team to email me my map at this email: _____

_____ I prefer to receive a paper copy of my map mailed to my home address.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 2-3 weeks.

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 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.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There may be other risks of participating that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects and other risks.

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 your mood and behavioral 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.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

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: a personalized plan and potential increase in motivation for improving your health.

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 any 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). 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 NIH 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 of the intent to harm yourself or others.

Audio recordings will be stored on a secure server that is password protected and only accessible to study team members. Audio recordings will also be shared securely with a service

provider who will transcribe these recordings. We will retain recordings until all data analysis is complete. At that time any research information will either be destroyed or it will be deidentified and kept for an indeterminate period of time. During study activities, you may request that recordings be stopped at any time.

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.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $50 in the form of two gift cards if you complete all of the study activities. If you withdraw for any reason from the study before completion, you will be given a $25 gift card for each complete study visit. If applicable, you will be provided with parking validation for any research-related visit.

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 Clinical and Translation Science Institute at Wake Forest University Health Sciences, and the National Institutes of Health. 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 information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: demographic information, questionnaire information, and information about your health, as well as parts of your medical record.

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) or the Office of Human Research Protections (OHRP), 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 unless there are photographs or recorded media which are identifiable.

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.

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. 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 Dr. Stephanie Sohl 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:

Stephanie Jean Sohl, Ph.D.
Assistant Professor 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.

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.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of 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. This could be because you failed to follow instructions pertaining to the study activities, or because the entire study has been stopped.

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, Dr. Stephanie Sohl at 336-713-5093, or study team member , Brittany Briceno, at 336-716-3158.

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 at (336) 716-4542 or the Research Subject Advocate at (336) 716-8372.

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