SUPPORT FOR OPTIMAL RECOVERY FOLLOWING GYNECOLOGIC SURGERY STUDY (SOARING)

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 is to learn how two different supportive programs may help women feel better post-operatively. This study will assess the feasibility of a study design to measure if one type of supportive program is more useful than the other for improving well-being after surgery. There are a few studies that suggest that similar programs may be effective for some people. However, research is needed to confirm these results for those who are undergoing a gynecologic surgical procedure. You are invited to be in this study because you are undergoing gynecologic surgery at the Wake Forest Baptist Comprehensive Cancer Center. Your participation in this research will involve no additional clinic visits and last about 5 weeks.

Participation in this study will involve methods for helping you cope with the surgical experience, such as gentle movements, counseling, writing, or relaxation techniques. You will also be completing questionnaires, daily surveys, and participating in a videoconference session post-surgery. All research studies involve some risks. A potential risk to this study that you should be aware of is minor injury as a result of gentle movements. There is also a possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. Your alternative is to not participate in this study. 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 Stephanie Sohl, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information.

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

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 undergoing gynecologic surgery at the Wake Forest Baptist Comprehensive Cancer Center. 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 women feel better post-operatively. This study will assess the feasibility of a study design to measure if one type of supportive program is more useful than the other for improving well-being after surgery. There are a few studies that suggest that similar programs may be effective for some people. However, research is needed to confirm these results for those who are undergoing a gynecologic surgical procedure.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 44 people will take part in this study.

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 the surgical experience. These methods may include 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 chance of being placed in either group.

The study team member who assigns participants to the supportive programs will be made aware of your group assignment after you have provided informed consent and are enrolled in the study. Some of the study team members collecting data as part of this study will not know which group you are in, so we ask you not to discuss study procedures with your treating surgeon, medical staff, or research personnel.

Once you agree to participate and are enrolled, we will ask you to complete some study questionnaires. These questionnaires will take place at four time points: before surgery (baseline), approximately one day after surgery, two weeks after surgery, and 4 weeks after surgery. The questionnaires ask for basic information about you, your health, emotional functioning, and symptoms. Each questionnaire will take approximately 30 minutes or less to complete and will not require any additional clinic visits.

Also, we will ask you to meet with a person who will talk with you about the supportive program the day after surgery by a videoconference. We will set up the videoconference for you in your hospital room. This person will also call you before surgery to answer any questions. You will be asked to complete the daily practices we provide you 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 one week before and one week after surgery (wrist monitors record movements that can be used to estimate rest and activity patterns). You will be asked to complete the surveys (that take around 3-5 minutes) at approximately 6:00pm each evening and you will have the option to complete the survey any time before you go to sleep.

You may be provided a tablet computer to borrow for the study period (unless you already have a similar portable device that you prefer) and you will be shown how to use it for study activities.

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

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

As part of this research study, you will be audiotaped. This is being done to ensure quality of Study implementation. You may request the recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the recording before it is used. You will not be able to inspect, review, or approve the recordings 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 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. I understand that I will not be able to inspect, review or approve their future use.

The study team member leading the supportive program may interact with you one-on-one using text messaging or phone calls through your personal cell phone device. The option to use text messaging is intended to make scheduling a time to speak with the study team easier and more convenient. The study team member will provide their personal contact information to you, in the event you wish to send them a text message or call them with questions or concerns regarding your completion of the study intervention following your discharge from the hospital. Use of personal cell phone devices, such as text messaging and phone calls, are not considered secure forms of communication and information you disclose may be viewed, accessed or disclosed by others. You can choose your preferred method of contact for interacting with the study team – either by text or phone call, to a number you provide them with upon initiating conversation. No sensitive or identifying information would be shared in text messages exchanged between you and the study team.

_____ I give permission for the study team to text and/or call me at the number I provide them with.

_____ I do NOT give permission for the study team to text me; I prefer a phone call only.

Study materials are also available through a link to a website. The study team can share this link with you if it is more convenient to use your personal device. Email is also not considered a

secure form of communication. No sensitive or identifying information would be shared in emails exchanged between you and the study team.

_____ I give permission for the study team to email me a study link.

_____ I do NOT give permission for the study team to email me with a study link; I prefer to only use the study device.

We may also send you an email with a link to complete follow-up questionnaires on a secure website. Please indicate if you prefer to receive questionnaires by email or paper mail.

_____ I prefer to receive follow-up questionnaires by email.

_____ I prefer to receive follow-up questionnaires by paper mail.

If relevant, please provide preferred contact information for use by the study team:

Email: _____

Phone number: _____

How Long Will I Be in the Study?

You will be in the study for about 5 weeks, until 4 weeks after you have completed surgery.

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?

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.

Any gentle movements taught will be adapted to your ability level and can be done in a bed. You may also feel some discomfort in talking about and answering questions about your health and/or emotional well-being. There is a possibility that paying more attention to your thoughts and feelings could cause discomfort. 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.

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.

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

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: you may find programs offered during this study useful for helping you cope with distress or symptoms that you may experience from surgery.

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.

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 National Center for Complementary and Integrative Health (NCCIH) 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 [list what will be reported, such as child abuse and neglect, or 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 [restate what will be disclosed, such as including research data in the medical record].

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 de-identified and kept for an indeterminate period of time. During study activities, you may request that recordings be stopped at any time.

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 $100 at the end of the study if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be paid $10 for each questionnaire completed, $10 for completing each week of daily assessments, $10 for wearing the actigraphy watch for each week, and $10 if you complete the follow-up interview, and $10 bonus for completing all assessment time points.

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.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

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 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, interview information, 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.

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), 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.

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 Stephanie Sohl, PhD 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
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 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 new information becomes available, you had an unexpected reaction, or because the entire study has been stopped.

Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

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