ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Levine Cancer Institute /W**earable **A**ctivity **T**racker **D**evices and Cancer-Related Fatigue: A Clinical Utility Pilot Study For Patients Undergoing Anti-Cancer Treatment
Protocol Number:	**LCI-SUPP-CRF-WATD-001**
Principal Investigator: (Study Doctor)	**Dori Beeler, PhD**
Telephone:	[redacted]
Address:	[redacted]

SUMMARY

You are invited to participate in a research study. The purpose of this research is to monitor your cancer-related fatigue symptoms. By wearing an activity tracker device (WATD) on your wrist, we will be able to monitor your heart rate variability (the changes in your heart rate) as well as your sleep quality. We will also evaluate your cancer-related fatigue by having you complete a diary and surveys about your fatigue experiences. Through these results, we hope to better understand the relationship between heart rate variability and cancer-related fatigue. You are invited to be in this study because you have pancreatic or breast cancer, have planned, or are receiving treatment for your cancer at Levine Cancer Institute, and are experiencing cancer-related fatigue.

Participation in this study will involve you wearing an activity tracker device on your wrist and completing a diary and surveys about your cancer-related fatigue and use of the activity tracker device and associated application. All research studies involve some risks. A risk to this study that you should be aware of is emotional distress that some questions in the questionnaires could cause. Additional information regarding the risks associated with this research study will be included in the "WHAT ARE THE RISKS OF THE STUDY?" section below. You likely will not benefit from participation in this study.

Your participation in this study is voluntary. You may choose not to participate in this study and still receive treatment for your cancer-related fatigue as recommended by your clinician. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

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Please ask any questions you may have and take as much time as you need to make your decision.

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. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, please contact the study investigator using the contact information listed on the first page of this consent form.

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

INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you have pancreatic or breast cancer, have planned, or are receiving treatment for your cancer at Levine Cancer Institute, and are experiencing cancer-related fatigue. Cancer-related fatigue (CRF) is a common symptom patients experience that is often described as tiredness or exhaustion related to cancer and anti-cancer treatment. CRF often impacts patient's personal lives, making it difficult to maintain their normal daily routine which may lead to other symptoms, such as depression, anxiety, heart rate changes, or sleep disturbances. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Your cancer treatment will continue as planned whether or not you decide to participate in this study. Please take your time in making your decision if you would like to join. 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 study is to monitor your cancer-related fatigue symptoms. By wearing an activity tracker device (WATD) on your wrist, we will be able to monitor your heart rate variability (the changes in your heart rate) as well as your sleep quality. We will also evaluate your cancer-related fatigue by having you complete a diary and surveys about your fatigue experiences and use of the activity tracker device and associated application. Through these results, we hope to better understand the relationship between heart rate variability and cancer-related fatigue.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

You will be one of approximately forty-six participants that will be enrolled in this study.

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WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will have the opportunity to review this consent form and discuss any questions you may have with your study doctor and research team. After you sign consent, the study staff will confirm that you qualify for the study. The following is what happens at each study visit:

Screening:

- You will be given the Wearable Activity Tracking Device, instructed on how to use it and provided with a return envelope.

Baseline:

- You will provide an email address for surveys to be sent to
- Your demographic information will be collected (age, race, marital status and presence of a caregiver)
- You will be asked questions about your medical history (cancer diagnosis and current anti-cancer treatment)
- FACIT-Fatigue questionnaire completion
- PHQ-8 questionnaire completion
- You will wear the device to establish your baseline heart rate variability.

Weekly:

Day 7 -

- FACIT-Fatigue questionnaire completion
- Experiential Diary collection

Day 14-

- FACIT-Fatigue questionnaire completion
- PHQ-8 questionnaire completion
- Experiential Diary collection
- Acceptability Survey completion
- WATD return, either in person or in previously provided return envelope

Survey Details: All surveys will be completed either in person or electronically. If you are unable to complete the surveys by either of those two methods, they may be completed on paper or over the phone with a research designee.

Functional Assessment of Chronic Illness Therapy Fatigue Scale (FACIT-Fatigue) Questionnaire: This questionnaire consists of 13 questions that will measure how your fatigue is affecting your daily routine and is measured using a 5-point scale.

Personal Health Questionnaire Depression Scale (PHQ-8) Questionnaire: This questionnaire consists of 8 questions that will measure any depression you may be experiencing and is measured using a 4-point scale. Depending on the severity of your depression, you may be

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referred to a PsychoOncologist (a provider who specializes in mental health issues that are associated with cancer) for a more detailed evaluation.

Experiential Diary: This open- and closed-ended diary will consist of questions that ask about your experience of wearing the WATD, how often you wore it and transmitting to the application throughout the study.

Acceptability Survey: This open- and closed-ended survey is made up of 10 questions that ask about concerns you had with complying with the study, wearing the WATD and ease of using the WATD.

Wearable Activity Tracker Device (WATD) Details:

WATD: The WATD will be provided to you free of charge for the purposes of this study. During your screening visit, you will be instructed on how to use the WATD and also provided an instruction sheet to reference.

Your smartphone will be loaded with an application called "Elite HRV." Elite HRV will collect certain data and information from the Wearable Activity Tracking Device. Disclosures regarding Elite HRV's use of that data and information are found at this website: https://elitehrv.com/privacy, which you are encouraged to review.

You will need to have access to the internet or Wi-Fi to upload your daily HRV application measurements. You will return the device at study completion either at an office visit or in the self-addressed postage paid envelope provided.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for no more than one month.

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?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks related to participating in the study include:

Emotional Distress: Some questions in the questionnaires could create emotional distress or confusion. As part of this study, you will be asked questions about depression and fatigue. 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. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

Confidentiality and Privacy: Taking part in this research study may involve providing information that you consider confidential or private. You may be asked to submit your information using electronic systems to sign consent or complete surveys. Efforts, such as using a code instead of your name when possible, keeping paper and electronic research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. However, there is some risk of loss of confidentiality and privacy.

There also may be other risks that we cannot predict.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study to identify possible safety issues to participants and to provide advice and recommendations on possible changes to the research study for the protection of participants.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there will not be any direct benefit to you. It is possible that your cancer- related fatigue may get better, stay the same, or get worse while you are participating in this study. We hope the information learned from this study will benefit other people with cancer-related fatigue in the future.

WHAT OTHER CHOICES ARE THERE?

You may choose not to participate in this study and still receive treatment for your cancer-related fatigue as recommended by your clinician. Please ask any questions you may have and take as much time as you need to make your decision.

WHAT ARE THE COSTS?

The WATD will be provided to you free of charge for the purposes of this study. You will return the device at study completion in a self-addressed postage paid envelope provided. Costs for your regular medical care, which are not related to this study, will be your own responsibility. Some medical insurance companies will not pay for regular medical care once they become aware that a patient is participating in a research study. Since we do not know what each individual insurance company will cover, you may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

If you have any questions about the costs associated with this research study, please contact the study team using the contact information on the first page of this form or reach out to Atrium Health Customer Billing Support for assistance.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

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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 or permitted by law, or necessary to protect the safety of yourself or others.

Text Message Communication: I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

Email Communication: By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

The Study Investigator asking you to participate in this study has not received, nor will receive money or other benefits for personal use from the study sponsor. However, the funder will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the Study Investigator or study staff is associated.

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 if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue.

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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 using the contact information listed on the first page of this consent form.

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 Chair of the IRB at [redacted] or the Research Subject Advocate at [redacted]

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

AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED 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**:** all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps 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. In addition, Elite HRV may

collect certain data and information from the application on the Wearable Activity Tracker Device, as more fully explained here: https://elitehrv.com/privacy.

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; representatives of Elite HRV; 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 Atrium Health Facilities; 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, videotapes, audiotapes or other recorded media which identify you unless we have your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

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 an indeterminate period of time. This authorization does not expire.

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 Dori Beeler, 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:

Dori Beeler, PhD

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[redacted]

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 Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities 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. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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. Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

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.

Participant Name (Printed): _____

Participant Signature: _____ Date: _____
Time: _____ am pm

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the participant the nature and purpose of the above study. There has been an opportunity for the participant to ask questions about this research study. I have been available to answer any questions that the participant has about this study.

Person Obtaining Consent (Printed): _____

Person Obtaining Consent Signature: _____ Date: _____
Time: _____ am pm

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