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Wake Forest School of Medicine

DEPARTMENT OF ANESTHESIOLOGY

A PILOT FEASIBILITY STUDY OF AN AMBULATORY MULTI-VITAL SIGNS MONITOR IN PERIOPERATIVE PATIENTS

Informed Consent Form to Participate in Research
Timothy Harwood MD-Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is evaluate your vital signs, which include blood pressure, pulse rate, and SpO2 (oxygen level in your bloodstream) using a portable wrist monitoring device called a Caretaker. This device has been cleared by the FDA for use and allows us to check your vital signs in your normal setting.

Participation in this study will involve wearing this portable device at 2 different time points: 1) for approximately 24 hours after your preanesthesia visit to get baseline vital signs during your normal activity and during sleep; and 2) after your surgery up to 24 hours while you recover prior to your discharge from the hospital. All research studies involve some risks. It is not anticipated that you will receive any 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. There may be other choices available to you. Some other choices may include only having the standard hemodynamic monitoring that the usual surgical patients receive in this medical center after your surgery. 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. Timothy Harwood. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is [redacted] (research offices).

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 Research Subject Advocate at Wake Forest at [redacted].

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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 having surgery and are anticipated to have to stay in the hospital at least overnight while you recover from your surgery. 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?

We have several reasons to conduct this research study:

- To study the incidence of abnormal vital signs (low or high blood pressure, pulse and oxygen levels) in ambulatory pre-surgical patients
- To examine these abnormalities up to 24 hours after surgery.
- To see what the risk factors are that correspond with abnormal vital signs.

Measurements of vital signs in the preoperative assessment in the surgery and other preoperative assessment clinics generally check these values once. However, studies show that these vital signs can vary greatly during activities, rest, and sleep.

In particular, we are interested in the level of oxygen in your body. Pulse oximetry is the measure of oxygen concentration in your blood stream. Based on experience with pulse oximetry in patients undergoing outpatient surgery, researchers believe that they can monitor the level of oxygen in the blood very accurately. Lower than average levels of oxygen in the blood after surgery could cause harm to patients so they are monitored prior to discharge from the recovery room. If patients' oxygen levels are deemed too low, then they are admitted to the hospital for oxygen therapy. However, very little information is known about what oxygen levels are in patients after they are discharged from the recovery room. Currently some of the hospital units use a central monitoring device that collects your blood pressure, heart rate, breathing rate and oxygen saturation. For this study, we would like to evaluate your vital signs at 2 different time periods: 1) preoperatively, to get a baseline when wearing the device at home under normal living conditions, including sleeping; and 2) immediately after your surgery when you on the postoperative nursing floor recovering from your surgery.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

One hundred fifty (150) people at Wake Forest Baptist Medical Center will take part in this study. In order to identify the total number of subjects needed, we may need to screen and consent as many as 200 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

In this study, we will monitor your heart rate, blood pressure, and pulse oxygen levels using a portable and wearable device called the Caretaker. This device is FDA cleared to be used for this reason. The Caretaker is placed on your wrist with a connector that is secured to your middle finger. The sensor on the finger shines a light through your finger to measure your heart rate and blood oxygen levels. It also measures your blood pressure and pulse. Preoperative baseline measurements will be collected first, with you being trained on placing the device prior to your leaving from your preanesthesia visit appointment. You will then place the device on as instructed before you go to sleep the night after your preanesthesia appointment. The day after you wear the device you can then take the device off and bring back with you on the morning of your surgery.

You will then undergo your scheduled surgical procedure just as you would if you were not in the study. If you elect to participate in this study, the device will be placed again on your wrist and finger for measurement of the same numbers after your surgery for up to 24 hours. The device automatically stores the data that is collected. After your study participation, we can then download the information collected. We will then be able to analyze vital signs on patients that are discharged from an intensive monitoring environment to home or a much lesser monitored environment. Only patients scheduled for admission to our Day Hospital overnight will be monitored. We will collect the monitors prior to your discharge.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about a total of approximately 24-36 hours combined between the 2 monitoring times, based on the length of time you wear the monitor. 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.

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the device we are studying include:

- Annoyance while wearing the device (prior studies indicate this is a minor issue)
- Potential for light sleepers to be bothered while wearing at night

However, we use similar monitors already for many hospitalized patients on a daily basis and find few complaints.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks 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, interactions and other risks.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?
You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options: receiving only the standard hemodynamic monitoring on the postoperative unit as you would normally receive should you not be participating in this study. This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?
All study costs related to the use of the Caretaker device to be used in this 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.

WILL YOU BE PAID FOR PARTICIPATING?
If you complete both portions of this research study you will be paid $50.00 for your time and efforts by assisting us with this research study. In order to receive this payment we are asking you to wear the device at least 16 hours preoperatively as well as postoperatively. 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 Caretaker Medical. 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 information we get from your study participation and your medical record about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** vital signs collected throughout your hospital stay, medications you received, surgical procedure performed.

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. Representatives from Caretaker Medical may also review the results of your study information.

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 can tell Dr. Harwood 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:

Timothy Harwood, MD
[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.

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. 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, Dr. Harwood at [redacted] or after hours at [redacted].

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 [redacted] or the Research Subject Advocate at [redacted].

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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

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