Wake Forest®
School of Medicine

Department/Section of Anesthesiology

A Pilot Trial of Continuous Portable Postoperative Hemodynamic And Saturation Monitoring On Hospital Wards

Informed Consent/Information Sheet for Research

Dr. Ashish Khanna, Principal Investigator

INTRODUCTION

We are currently performing data collection to try to optimize the monitoring and recording of patient's vital signs on the postoperative floor. These vital signs include your blood pressure, heart rate, breathing rate, and oxygen levels. At Wake Forest Baptist Medical Center, continuous monitoring of vital signs is not yet a gold standard of care and is limited to certain units. Most patient assessments are still performed on an intermittent basis with every 4-hour vital signs checks. As an institution we are leading the way in adoption of portable monitoring technology and some units have begun to utilize a continuous portable monitoring system called ViSi over the past few years. However, the use of this technology has been incomplete and inconsistent, since there is much question as to whether it leads to improved patient outcomes. This data that we have been collecting while you were recovering from your surgery, will not be linked to your personal health information after initial data collection is completed. We hope that this data will lead to more standardized ways of monitoring patients after surgery in an effort to improve patient outcomes.

You are being given this information sheet regarding this research study, but you will not be required to sign it. Please let us know if there are any questions we can answer and if you would not be interested in your data being collected and used for research. There is contact information to reach us at the end of this form if you would *not like for us* to use your vital sign information.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Our goal is to obtain data from all patients who are having surgery and recovering postoperatively on 2 pre-designated hospital units. You are receiving this information sheet since you spent part or all of your time during the last few days on one of these two units and your vital signs data was collected, and will be used for research purposes, unless you would not like for us to do so. We used vital signs data from a portable device that you wore on your wrist or conventional vital signs data that was collected when a health care provider came into your room and collected this information.

HOW LONG WILL I BE IN THE STUDY?

You were in the study for as long as you were on the hospital ward/nursing floor.

WHAT ARE THE RISKS OF THE STUDY?

When participating as part of this research, your vital signs will be downloaded electronically from your electronic health record after you are discharged from the hospital. This information is then correlated to medical and nursing treatments of you while you were here in the hospital

recovering from your surgery. You will have blood collected to measure troponin, equivalent to one teaspoon (5 mL), on each of the first three days after surgery that you are admitted to the post-surgical floors on 10 Reynolds or 9 Ardmore East. Troponin is measured to detect heart injury. There is no charge to you for these labs. After all of this information is collected it is de-identified so that investigators do not know that this information is yours. However, there is always the risk of it being identified. 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. We will do our best to protect your confidential information. 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. Your medical record will be reviewed after you are discharged. The information we will collect for this research study includes**:** your vital signs and medical/nursing treatments that were done as a result of those vital signs. We will also monitor how often the "alarms" were triggered based on the results of your vital signs. After your discharge, you may be asked to complete an anonymous, short, satisfaction survey about the advantages and disadvantages of using the ViSi portable continuous monitoring device, if you wore one while in the hospital recovering.

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. Thus, an improvement in patient safety for hospitals all over the world will also benefit you and your loved ones should the need for future hospitalization ever arise.

WHAT OTHER CHOICES ARE THERE?
This is not a treatment or intervention study that will modify or introduce a new treatment modality to your care plan. Your alternative is not to participate. If you decide to not allow the study investigators to use your hospital information, *please contact the research staff and let them know using the contact information at the end of this form.*

WHAT ARE THE COSTS?
There are no costs to you for participating 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. We will not have collected any information that could identify you so no information about you will be disclosed.

WILL YOU BE PAID FOR PARTICIPATING?
You will not receive payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?
There is no sponsor for the conduct of this study.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we did 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 have collected for this research study includes**:** vital signs (which includes your blood pressure, heart rate, respiratory rate, and oxygen saturation levels), as well as any nursing and medical treatments performed as a result of your vital signs. 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 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 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.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor (the department of Anesthesiology at WFBH); 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. 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 that is collected from your chart after discharge about you is maintained in the research records and will be kept for an indeterminate period of time. This information will be de-identified. This authorization does not expire. 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. Khanna 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:

Ashish K. Khanna, MD

Wake Forest®
School of Medicine

Department of Anesthesiology, Janeway Tower
100 Medical Center Boulevard
Winston-Salem, NC 27157

If you take away permission to use your Protected Health Information researchers will not use the vital sign and medical treatments that is in your medical record. We will stop collecting any more information, but any information we have already collected can still be used for the purposes of the research study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Allowing us to collect and use your vital signs data and medical information as part of this study is voluntary. You may choose not to take part in this study. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. Please call the research staff if you would like to leave the study at [redacted]. If research staff is not in the office please leave a name and number and you will be contacted. You may also email research staff at [redacted]

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, contact the study investigator, Dr. Khanna at [redacted] or [redacted]. If research staff is not in the office please leave a name and number and you will be contacted. You may also email research staff if you would not like us to use your hospital information 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 WFSM Chairman of the IRB at [redacted].

You will not be asked to sign this form. Unless otherwise notified, your consent to participate is implied.