CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

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Project Number:  2002586  

Project Title: Estimation of Short-term Heart Rate Variability, Bed Posture and Changes in Blood Pressure Using a Hydraulic Bed Sensor  

INTRODUCTION  

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.  

You are being asked to participate in a research study. This research is being conducted to evaluate the potential use of a hydraulic bed sensor for the assessment of heart rate variability, bed posture and changes in blood pressure. When you are invited to participate in research, you have the right to be informed about the study procedures so that you can decide whether you want to consent to participation. This form may contain words that you do not know. Please ask the researcher to explain any words or information that you do not understand.  

You have the right to know what you will be asked to do so that you can decide whether or not to be in the study. Your participation is voluntary. You do not have to be in the study if you do not want to. You may refuse to be in the study and nothing will happen. If you do not want to continue to be in the study, you may stop at any time without penalty or loss of benefits to which you are otherwise entitled.  

This research is funded by the University of Missouri and the Center for Eldercare and Rehabilitation Technology (CERT).  

WHY IS THIS STUDY BEING DONE?  

The purpose of this research is to investigate:  

i. The agreement of the short-term Heart Rate Variability (HRV) indices computed using Electrocardiography (ECG) and HRV indices computed using Ballistocardiography (BCG) registered with a hydraulic bed sensor to evaluate the potential use of BCG as an unobtrusive replacement of ECG for short-term HRV analysis.  

ii. The relation of bed posture and changes in BCG waveforms recorded by a hydraulic bed sensor.  

iii. A non-invasive monitoring of changes in Blood Pressure (BP) using BCG and Photopletismography (PPG).  

Heart rate variability (HRV) is the variation of the beat-to-beat time in milliseconds usually measured with electrocardiography (ECG). Electrocardiography (ECG) is a commonly used, noninvasive procedure for recording electrical changes in the heart activity.
Ballistocardiography (BCG) is an unobtrusive measurement principle that reflects the mechanical vibrations of the body caused by the heartbeat. BCG can be recorded using bed sensors, chair sensors, weighting scales, etc. Blood pressure (BP) is the pressure exerted by circulating blood upon the walls of the blood vessels. It is expressed in terms of systolic pressure over diastolic pressure in millimeters of mercury (mm HG), which can be measured using an arm-cuff digital BP commercial monitor. Photoplethysmography (PPG) is a technique that measures the change in skin blood volume using a small light probe that is placed on the surface of the skin. Different sites for measuring PPG include the ear, forehead, ankle and finger.

HOW MANY PEOPLE WILL BE IN THE STUDY?

We will recruit 60 participants aged 18 to 50 years old for the short-term Heart Rate Variability and effect of bed posture study. We expect at least 20 participants for the Blood Pressure changes study, since participation in this study is optional. This study will take place at the Center for Eldercare and Rehabilitation Technology (CERT)-Engineering Building West, room EBW 332/348, Columbia, MO.

STUDY EXCLUSION CRITERIA

If you have answered YES to any of the Health Status questions shown in the Health Status Questionnaire; you will not be eligible to participate in the study.

WHAT AM I BEING ASKED TO DO?

Participation in the study will involve one visit. This visit will last about 45 minutes and include the following activities:

You will be asked to:

Heart Rate Variability study
   Experiment 1: Lie still on your back for ten minutes.

Bed Postures study
   Experiment 2: Lie on your back for one minute.
   Experiment 3: Lie on your left side for one minute.
   Experiment 4: Lie on your right side for one minute.
   Experiment 5: Lie on your stomach for one minute.

Blood Pressure Changes study (optional)
   Experiment 6: Lie down on your back and breathe normally until three BP measurements are taken using a commercial digital arm-BP monitor (with a BP cuff).
   Experiment 7: Pedal a stationary upright bicycle at a low pace and lowest level of resistance for two minutes. Increase your pace until you feel that your level of exertion has reached 11-14 in the Borg Rating of Perceived Exertion (RPE) scale.
   Experiment 8: Return to the bed and lie down on your back until the BP measurements show steady values (three to five minutes).
During all the experiments, ECG will be recorded using three leads and BCG will be recorded using a hydraulic bed sensor placed unobtrusively under the bed mattress. In addition, pulse (with two finger sensors) and respiration (with a respiratory belt transducer wrapped around your abdomen) will be recorded to refine the heart rate estimation algorithms. If the participant agrees to participate in the Blood Pressure Changes study, blood pressure will be measured using a commercial digital arm-BP monitor.

Additional information regarding height, weight, age and previous cardiac condition will also be registered in the Health Status Questionnaire.

HOW LONG WILL I BE IN THE STUDY?

This study will take 45 minutes approximately to complete. You can stop participating at any time without penalty.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

If you agree to take part in this study, there will not be direct benefit to you. You may expect to benefit from taking part in this research to the extent that you are contributing to scientific and technical knowledge.

WHAT ARE THE RISKS OF BEING IN THE STUDY?

ECG: An electrocardiogram (ECG) is a test that gives us a measure of the heart’s electrical activity. You will be asked to lie flat on a bed and three small electrode pads (like stickers) will be placed on your chest.  
**Risks from ECG:** The test may cause some redness or itching where the pads are placed.

BCG: A ballistocardiogram (BCG) is a test that gives us a measure of the heart’s mechanical activity. BCG will be recorded by lying on the bed without any cables attached to your body.

**Risks from BCG:** There are no risks associated to this measurement method.

Pulse sensing: A piezo-electric sensor will be wrapped around your fingertip detecting the pulsatile expansion and contraction of the finger circumference, due to changes in blood pressure. An infrared photoelectric sensor will be wrapped around your left ring fingertip detecting blood flow changes.

**Risks from pulse sensing:** There are no risks associated to this measurement method.

Respiration sensing: The Respiratory Belt Transducer contains a piezo-electric device that responds linearly to changes in length. It will be placed around your chest to measure changes in thoracic or abdominal circumference during respiration.

**Risk to respiration sensing:** There are no risks associated to this measurement method.

BP sensing: A digital commercial BP monitor composed of an inflatable rubber cuff will be wrapped around your arm. The cuff will inflate and then release pressure. Systolic and diastolic pressure will be measured.

**Risk to BP sensing:** There are no risks associated to this measurement method.

There should not be any added risk to your usual exercises that you are performing for participation in this study.
WHAT ARE THE COSTS OF BEING IN THE STUDY?

There is no cost to you.

WHAT OTHER OPTIONS ARE THERE?

You have the option to not participate in this research study.

CONFIDENTIALITY

Consent forms and the Health Status Questionnaires will be stored in a locked cabinet in Dr. Skubic's office. You will be identified by a code number only, and data signals collected will be stored by code number only on a secure server. The code key connecting your name to any specific information will be kept in a locked cabinet in Dr. Skubic's office. Data collected will not be given to anyone unaffiliated with the study.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

WILL I BE COMPENSATED FOR PARTICIPATING IN THE STUDY?

You will receive an individually wrapped candy or a pen for your participation in this research study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary. You do not have to participate in this study. If you decide to participate, you can change your mind and drop out of the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, the investigator of this study may decide to end your participation at any time after she/he has explained the reasons for doing so.

PLEASE NOTE: Recording of ECG, BCG and BP is only done for algorithm development purposes.

WHO DO I CONTACT IF I HAVE QUESTIONS, CONCERNS, OR COMPLAINTS?

Please contact Licet Rosales at 217-722-3852 or Dr. Marjorie Skubic at 573-882-7766 if you have questions about the research study. Additionally, you may ask questions, voice concerns or complaints to the research team.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Health Sciences Institutional Review Board (which is a group of people who review the research studies to protect participants’ rights) at (573) 882-3181 or irb@missouri.edu.
You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact Licet Rosales at 217-722-3852 or Dr. Marjorie Skubic at 573-882-7766.

A copy of this Informed Consent form will be given to you before you participate in the research.

**SIGNATURES**

I have read this consent form and my questions have been answered. My signature below means that I do want to be in the study. I know that I can remove myself from the study at any time without any problems.

________________________________________  __________________________
Subject                                      Date