



Research Consent Form

Comparing Pleth Variation Index (PVI) and Stroke Volume Variation (SVV) on Medical-Surgical Patients in GW Hospital Intensive Care Units

GW IRB Reference number: 100762

Principal Investigator: Francoise Bissai, RN-BSN

Telephone number: 703-568-2164

1) **INTRODUCTION**

You are invited to participate in a research study comparing a reading from the pulse oximeter that is attached to your finger to a reading your doctors are already looking at from the catheter in your artery. The pulse oximeter attached to the finger sensor is already being used to monitor your oxygen level. The arterial line you have is being used for, among other things, to monitor your blood pressure and draw blood. For the purpose of this study, we will connect the pulse oximeter finger sensor to a monitor that can continue to monitor your oxygen level and an additional specific reading that we will compare to your arterial line reading. You are being asked to take part in this research study because you have problems with managing fluid volume in your body and you are breathing with the help of a ventilator. You also have a normal heart rhythm. Your participation is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. You do not have to take part in this study to receive care at George Washington University Hospital. You may not receive any benefit from taking part in this study; however, the research may give us knowledge that may help people in the future.

This study is being conducted by the investigator listed above from the Department of Nursing at George Washington University Hospital. Before you decide to participate, please take as much time as you need to ask any questions and discuss this study with anyone at GWU, with family and friends, and your personal physician or other health professional.

2) **WHY IS THIS STUDY BEING DONE?**

You are being asked to take part in this study because your doctor has determined that you need a separate monitor called the FloTrac to assess and monitor your fluid volume. This monitor is connected to your arterial line in order for it to work. By engaging in the

study, we hope to learn if there is a co-relation between the pulse oximeter reading and the arterial line reading in terms of fluid volume level and your response when you are given fluid. The research will be conducted in all three Intensive care units at GW Hospital

3) HOW MANY PEOPLE WILL TAKE PART IN THE STUDY

About fifty (50) patients in the ICU at GW hospital will be consented for this study.

4) WHAT IS INVOLVED IN THIS STUDY?

If you choose to take part in this study, this is what will happen: a monitor will be connected to the pulse oximeter sensor already connected to your finger. Numbers will be displayed on the monitor; your nurse will record these numbers every hour together with the numbers on your FloTrac monitor for a total of two days. If you receive any fluid or blood products as part of your treatment, this will also be recorded. After the two days, the pulse oximeter finger sensor will be disconnected from the monitor used specially for the study and reconnected to your main monitor that sits over your bed. No blood will be drawn from you and no tests or drugs will be administered as part of this study. If you decide to take part in this research study, there is no change in the standard care that you receive and your oxygen level will continue to be monitored as usual.

5) HOW LONG WILL I BE IN THIS STUDY?

The total amount of time you will spend in connection with this study is two days. If your breathing tube is removed and you are breathing on your own or if you develop an irregular heart rhythm before the two days, you will no longer be part of the study. This will in no way change the course of your treatment.

You always can choose to stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first who may clarify any uncertainties or misunderstandings you may have.

6) WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?

There are no physical risks associated with the study; however risks associated with confidentiality of medical records are addressed in section 12 of this consent form.

7) ARE THERE POTENTIAL BENEFITS TO TAKING PART IN THIS STUDY?

There are no benefits to you for participating in this study

8) WHAT ARE MY OPTIONS?

You do not have to take part in this study if you do not want to participate. Should you decide to take part and later change your mind, you can do so at anytime. Your

participation in this study will in no way alter the course of your treatment. No changes will be made to your care as a result of this study.

9) **WILL I RECEIVE PAYMENT FOR BEING IN THIS STUDY?**

You will not be paid for taking part in this study.

10) **WHAT WILL IT COST ME IF I DECIDE TO PARTICIPATE IN THIS STUDY?**

There will be no additional costs to you as a result of taking part in this study. Routine medical care for your condition (the care you would receive whether or not you were in this study) will be charged to you or your insurance company.

If you have any questions about your insurance coverage, please call your insurance representative or you may contact financial services for information at telephone # 202-715-4000.

11) **ARE THE RESEARCHERS BEING PAID FOR THE STUDY?**

The researchers of the study are not being paid for their work in this study.

12) **WHAT ABOUT CONFIDENTIALITY?**

Your information will be kept as confidential as possible. Access to study records will be limited to those who need the information for purposes of this study, as well as your health care providers should they need access to the information. All records are kept in a secure location and access is limited to research study personnel.

Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed, unless you give the appropriate authorization.

13) **HOW WILL MY PRIVACY BE PROTECTED?**

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of health information that identifies you.

Protected health information that may be used and released (disclosed) in this study includes information such as this research consent form, your age, gender and medical diagnosis and other data created or collected during this study. By signing this form, you allow the use, sharing, copying, and release of your protected health information to carry out the study by the research team and nurses who are part of the study and other clinical staff who are not involved in the study but who may become involved in your care. You also allow the release of your health information to:

- GWU Institutional Review Board (“IRB”) or its authorized representatives,

- Representatives of the Office of Human Research Protections (OHRP) or other regulatory agencies who may review your records to ensure that your rights as a research subject are protected;
- Accrediting agencies

You may request to review or have a copy of your personal health information collected during this study and placed in your medical record. This right to review and copy your personal health information only extends to information that is placed in your medical record; it does not extend to information that is placed in your research record.

This permission does not end unless you cancel it, even if you leave the study. You can cancel this permission any time except where a healthcare provider has already used or released your health information, or relied on your permission to do something. Even if you cancel this authorization, the researchers may still use and disclose protected health information they already have obtained about you as necessary to maintain the integrity or reliability of the research. However, no new PHI or new biological specimens will be collected from you after you revoke your authorization.

To cancel your authorization, you will need to send a letter to *Francoise Bissai, RN* stating that you are canceling your authorization. This letter must be signed and dated and sent to this address: *GW Hospital, Rm. 41048 (ICU-4), 900 23rd St NW Wash DC 20037*. Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits.

Your protected health information will be treated confidentially to the extent permitted by applicable laws and regulations. Federal law may allow someone who gets your health information from this study to use or release it in some way not discussed in this section and no longer be protected by the HIPAA Privacy Rule. By signing this form you authorize the members of the research team to use and share with others (disclose) your PHI for the purpose of this study. If you do not wish to authorize the use or disclosure of your PHI, you cannot participate in this study because your PHI is necessary to conduct this study.

14) CAN I WITHDRAW FROM THE STUDY LATER?

You may withdraw from the Study at any time. Leaving the Study will not affect your current or future medical care at GWUH.

15) WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

The Office of Human Research of George Washington University, at telephone number (202) 994-2715, can provide further information about your rights as a research subject. Research related injury should be reported to the, Francoise Bissai of this study at 703-568-2164. For problems arising evenings or weekends, you may call at (703) 568-2164.

16) CONSENT DOCUMENT

After you sign this Consent Form, the research team will provide you with a copy. Please keep a copy of this document in case you want to read it again.

If you agree to participate in this study, please sign below:

DOCUMENTATION OF CONSENT

Subject's Name (printed) and Signature

Date

Name (printed) and Signature of Person Obtaining Consent

Date

Principal Investigator's Signature

Date

DO NOT SIGN AFTER THE EXPIRATION DATE OF: 5/15/2009

