

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: An observational data-collection study to evaluate the changes in cardiovascular hemodynamics using the Vigileo™ cardiac output monitor during peripheral vascular changes

PROTOCOL NO.: MIM-0810-0002-GW
WIRB® Protocol #20092282

SPONSOR: Edwards Lifesciences LLC
Irvine, California
United States

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STUDY-RELATED

PHONE NUMBER(S): Christopher D. Junker, M.D.
202-715-4710

Christina Seneff
202-715-5257
301-951-7435 (evenings and weekends)

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may have an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

General Information

We invite you to take part in an observational research study related to cardiac (heart) output. An observational study is one in which information is collected but no experimental (unapproved) treatment or medicine is given to you. Your participation in this research is entirely voluntary.

Before you sign this consent form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the study doctor or study staff if you are participating in another research study.

Source of Funding

The study is funded by Edwards Lifesciences LLC (sponsor). The sponsor will pay your study doctor or the institution for the costs of doing this study.

Background

The current best measure of cardiac output - CO (the rate of the blood flow through the heart) is done by the placement of a Pulmonary Artery Catheter - PAC (a special monitoring tube inserted into a large vein in the neck, chest or groin to measure heart function and blood pressure). This procedure, while giving trustworthy and precise measures of heart function, has some drawbacks. This includes the invasive (entering the body) nature of the catheter placement procedure.

In this research study, data about arterial pressure waves are collected so they can be analyzed using two different types of cardiac output measurements. These include Arterial Pressure-based Cardiac Output (APCO) and continuous cardiac output using a pulmonary artery catheter (PAC).

All devices used in the study are commercially available and routinely used in hospitals for patient monitoring.

Purpose of Study

The purpose of this research study is to collect cardiac output data (information on how much blood your heart is pumping) as measured by the Edwards monitor.

Study Design and Enrollment

This study will be conducted at approximately 9 hospitals: 3 in Europe, 3 in Japan and 3 in the United States. Approximately 90 subjects will be enrolled in the study. A maximum of 30 subjects will be enrolled at GWUMC.

Your participation in the study will last up to 3 days.

Study Procedures

If you agree to take part in this study, the following procedures will take place. None of the procedures are experimental.

- a) An Edwards Lifesciences FloTrac Sensor will be attached to your arterial line.
- b) The cardiac output data will be collected during your recovery as long as your arterial line is needed.
- c) Your age, gender, height and weight will also be collected.

Potential Risks and/or Discomforts

This study does not involve the use of any investigational products or devices. It is an observational and data collection study only. Participating in this study does not expose you to any greater risks than are otherwise associated with being in the hospital.

Potential Benefits

This is not a treatment study. You will not directly benefit from the study. Information obtained from this study will benefit the sponsor, Edwards Lifesciences, and may benefit patients in the future.

Costs for Participation

There will be no additional costs to you as a result of taking part in this study. If a pregnancy test is required, it will be paid for by the 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.

Payment for Participation

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

Alternative to Being in the Study

You do not have to participate in this study if you do not want to. Your care and treatment will be the same whether you choose to be in the study or not.

Authorization to Use and Disclose Information for Research Purposes

Access to your study records will be limited to those who need the information for purposes of this study, as well as your health care providers if they need access to the information. All records will be kept in a secure location and access will be 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.

Federal law requires hospitals, researchers and other healthcare providers (like physicians and labs) to protect the privacy of health information that identifies you. This kind of information is known as "protected health information" or "PHI". This section tells you your rights about your

protected health information in the study. This section also lists who you let use, release, and get your protected health information. You are free to not allow these uses and releases by not signing this form. If you do that though, you cannot participate in the study.

Protected health information that may be used and released (disclosed) in this study includes information such as:

- Your history of chronic conditions such as heart, lung, and vessel disease, or other significant conditions such as cancer or previous surgeries;
- Your vital signs, ventilator settings, and medications you are given during the study;
- Results of physical examinations related to your medical condition;
- Admissions information such as your symptoms and complaints on arrival to the hospital;
- Your blood pressure and cardiac output data collected from your heart monitor during the study.

By signing this form, you allow the use, sharing, copying, and release of your protected health information to carry out the study by:

- Your healthcare providers (like doctors and hospitals) which are not part of the study.
- The study doctor and his research team.

You also allow the study doctor and his or her research team, and other healthcare providers that are part of the study to release your health information to:

- GWU Institutional Review Board (IRB) or its authorized representatives, as well as representatives of the Office for Human Research Protections (OHRP) who may review your records to ensure that your rights as a research subject are protected;
- Western Institutional Review Board® (WIRB®)
- The sponsor of the study and any contractors or partners it may have (research monitors and auditors);
- clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to your care; and
- GWU, GWUH, or MFA workforce who are involved with the research.

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. Such cancellation will not affect information a healthcare provider has already used in reliance on your permission to do so. 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 will be collected from you after you revoke your authorization.

To cancel your authorization, you will need to send a letter to your study doctor. This letter must be signed and dated and sent to this address: Dr. Christopher Junker, 900 23rd Street, NW, Suite G-105, Washington DC, 20037. A copy of this revocation will be provided to the study doctor and his or her research team. 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 study doctor and 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.

Voluntary Participation/Withdrawal

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

The study doctor or sponsor can decide to stop your participation in this study at any time without your consent. The sponsor may stop the entire study at any time. The sponsor may also decide to stop the study doctor's involvement in this study.

Whom to Contact to Ask Questions About Your Rights as a Research Subject

Research related injury should be reported to the study doctor, Dr. Christopher Junker. Dr. Junker will be available for questions, concerns, or complaints throughout the study. His telephone number is 202-715-4710. Further information regarding this study may be obtained by contacting the study coordinator, Christina Seneff, at telephone number 202-715-5257. For problems arising evenings or weekends, you may call Christina at 301-951-7435.

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Subject's Consent to Participate

After you sign and date this consent form, the research team will provide you with a copy. Please keep a copy of this consent form in case you want to read it again.

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

DOCUMENTATION OF CONSENT

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Consent and Assent Instructions:

Consent: Subjects able to provide consent must sign on the subject line below.

Consent is provided by the Legally Authorized Representative for subjects unable to consent.

Assent: Verbal assent is required for subjects able to provide assent.

Subject's Name (printed)

Date

Subject's Signature

Name of Legally Authorized Representative (printed)

Date

Signature of Legally Authorized Representative

Date

Authority of Subject's Legally Authorized Representative or Relationship to Subject

Name (printed) and Signature of Person Conducting
Informed Consent Discussion

Date

ASSENT SIGNATURES, For Subjects with a Legally Authorized Representative:

Assent:

For subjects who have a legally authorized representative, I confirm that:

I have explained the study to the extent compatible with the subject's understanding, and the subject has agreed to be in the study.

OR

The subject is not able to assent due to lack of mental capacity.

Signature of Person Conducting Assent Discussion

Date

----- Use the following only if applicable -----

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

Signature of Impartial Witness

Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.