Santa Barbara Cottage Hospital

CONSENT TO BE A RESEARCH SUBJECT

EVALUATION OF THE ACCURACY OF A MINIMALLY-INVASIVE HEMODYNAMIC MONITORING DEVICE IN PREDICTION OF FLUID RESPONSIVENESS IN SEVERE SEPSIS AND SEPTIC SHOCK

Protocol Version 3
12/29/2016

Principal Investigator: Jeffrey C. Fried, MD

Investigator Telephone: 805-569-7460

IRB: Cottage Health System Institutional Review Board
P.O. Box 689
Santa Barbara, CA 93102

Name of Subject:_____

State of California

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1. To be told what the study is trying to find out.

2. To be told what will happen to me and whether any of the procedures, drugs or devices is different than what would be used in standard practice.

3. To be told about the frequent and/or important risks, side effects, or discomforts associated with the things that will happen to me for research purposes.

4. To be told if I can expect any benefit from participating and, if so, what the benefit might be.

5. To be told the other choices I have and how they may be better or worse than being in the study.

6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study.

7. To be told what sort of medical treatment is available if any complications arise.

8. To refuse to participate at all or to change my mind about participating after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study.

9. To receive a copy of the signed and dated consent form.

10. To be free of pressure when considering whether I wish to agree to be in the study.

If I have questions about the research study, I should ask the researcher or research assistant. In addition I may contact the Institutional Review Board (IRB), which is concerned with protection of volunteers in research projects. I can reach the IRB office by calling 805-569-7439 during normal business hours, or by writing the Cottage Health System Institutional Review Board, Santa Barbara Cottage Hospital, P.O. Box 689, Santa Barbara, CA 93102.

By signing below, I state that I have read and have had the opportunity to ask questions about the rights which all subjects in a research study have.

_____ _____

Signature of Patient or Legally Authorized Representative ***Date***

COMPARISON OF THE ACCURACY OF MONITORING DEVICES IN PREDICTION OF FLUID RESPONSIVENESS IN SEVERE SEPSIS AND SEPTIC SHOCK

Purpose of this Research Study:
You have been asked to participate in a research study because you have severe sepsis or septic shock. Dr. Jeffrey C. Fried is engaged in a study to assess the utility of a minimally-invasive monitor (FloTrac) in predicting how much intravenous fluid you should be given during your treatment.

Study Procedures:
If you agree to participate in this study, your care will be based on the standard monitoring device normally used for your condition but the data collected will be collected and analyzed. You will also receive intravenous saline fluids to test how well the monitor predicts your ability to react to fluids. This is routine for almost all patients with your condition and presents very little risk to you. If your physician doesn't feel this administration of fluids is safe, you will not be given the fluids. Some patients with your condition receive these fluids multiple times during their hospital stay based on their treating physician's clinical judgment. If you receive multiple administrations of fluids, we would like to collect the reading from the monitor at the time of fluid administration as part of this study.

Risks and Discomforts:
The possible discomforts and risks attendant to this procedure are primarily related to inadvertent disclosure of protected health information.: There is also a rare risk of you reacting poorly to the intravenous fluids. Your physician will make the determination of whether giving fluids is safe and you will not receive fluids if your physicians doesn't feel this is safe.

Potential Benefits:
This study may not have any direct benefit to you. If this monitoring device proves to be accurate, other patients with the same condition as you will benefit from receiving an appropriate amount of fluid as part of their treatment, with less risk of receiving too much or too little fluid during their treatment.

Alternatives to Participation:
If you do not participate in this study, you will receive the current standard treatment for severe sepsis and septic shock in this hospital, including assessment of fluid status with an arterial and central venous catheters and associated monitoring devices, which you have already consented to having placed.

Patient Confidentiality:
Study related records will be held in confidence. Your consent to participate in this study includes consent for the investigator and his assistants to review all of your confidential health information (medical records and other pertinent health information) as may be necessary for

purposes of this study. Your health information may also be inspected by governmental agencies such as the Food and Drug Administration and the Cottage Health System (CHS) Institutional Review Board (IRB; a committee for the protection of research participants). Representatives from these groups may inspect your health information for study monitoring and/or auditing purposes, while maintaining your health information as confidential to

the extent required by law. Additionally, parts of your health information that pertain to your participation in this study may be photocopied. Confidentiality will be maintained by using your study number and/or initials as an identifier on the photocopies. If publications result, your name will not be used and you will not be identifiable in any way. The investigator is required by law to retain your research-related data for six years.

Participation in Research is Voluntary:
You are free to decline to participate or to discontinue participation in the study at any time without any penalty or loss of benefits to which you may otherwise be entitled. The investigator is also free to terminate the study at any time.

Payment or Reimbursement:
You will not be paid to participate in this study.

Payment for Treatment of Research-Related Injury:
There are very limited risks to participating in this study. Any injury which occurs would likely be covered by your medical insurance, government program, or other responsible third party. No financial compensation other than immediate medical treatment of the injury will be provided. In the event that you believe participation in this research study has led to injury, you may contact Jeffrey C Fried, MD at (805) 569-7460 to identify the medical resources that may be available to you and to assist you in obtaining appropriate medical care. Your doctor, the investigator(s), their affiliated organizations and Cottage Health System do not have any program to provide compensation for persons who may experience injury while participating in research projects.

Additional Information:
If you would like any additional information regarding this study you may contact Jeffrey C. Fried, MD at 805-569-7460. If you would like any additional information regarding your rights as a research subject, you may contact the Institutional Review Board at (805) 569-7439.

_____ _____

Signature of Patient or Legally Authorized Representative ***Date***

Authorization for Use or Disclosure of Health Information
From A Cottage Health System Facility

COMPARISON OF THE ACCURACY OF MONITORING DEVICES IN PREDICTION OF FLUID RESPONSIVENESS IN SEVERE SEPSIS AND SEPTIC SHOCK

Completion of this document authorizes the disclosure and/or use of individually identifiable health information, as set forth below, consistent with California and Federal law concerning the privacy of such information.

A. ABOUT THE HEALTH INFORMATION:

State and Federal privacy laws protect the use and release of your health information, also known as *Protected Health Information* (PHI). Under these laws, your health care provider cannot release your PHI to the research team unless you give your permission. This form describes the different ways that the researcher, and research team may use your health information for the research study. The HIPAA Privacy Rule designates PHI uses into two categories, *required* and *optional research activities*.

- Authorization for *required activities* refers to the *PHI which is needed* as part of the investigation. **You cannot participate in the research study if you do not authorize the use of your PHI for required purposes.**
- Authorization for *optional activities* refers to the *PHI which is not needed* as part of the investigation. **You do not have to authorize the use of your PHI for the optional research activity(ies) in order to participate in the study.** An example of an optional research activity includes a request for collecting and/or banking your tissue specimen or blood sample for future research.

The specific required and optional uses of PHI for which you are being asked to provide your authorization are listed in section B.

B. HEALTH INFORMATION TO BE RELEASED:

1. REQUIRED RESEARCH ACTIVITIES

If you provide your authorization for the required research activities and sign this form, you are allowing the release and disclosure of medical information collected at a Cottage Health System Facility (Santa Barbara Cottage Hospital, Goleta Valley Cottage Hospital, Santa Ynez Valley Cottage Hospital, and/or Pacific Diagnostic Laboratories in association with the research study listed above. This includes your electronic medical record of this hospitalization, including your age and sex, diagnosis, lab results, radiologic exams, vital signs and other monitoring information collected during your intensive care unit stay, and any fluid or medications you received during the study.

2. OPTIONAL RESEARCH ACTIVITIES

This research study does not include any optional requests for the use of your PHI.

C. TO WHOM INFORMATION MAY BE GIVEN:

This information will only be used, as necessary, as part of your consented enrollment in the research study described in the informed consent section of this document. By signing this form, you are authorizing that your health information collected at the facility listed in Section B(1) above, be made available to employees and/or designees of Santa Barbara Cottage Hospital who are coordinating the study, the Cottage Health System Institutional Review Board overseeing the study, other authorized officials of Cottage Health System and of its facility(ies) engaged in the research, and other regulatory officials as needed in the task of study monitoring and/or auditing purposes.

If the recipient of your health information is not subject to the HIPAA Privacy Rule, your PHI may be subject to re-disclosure by the recipient.

D. REVOKING AUTHORIZATION

You may refer to the Cottage Health System Notice of Privacy Practices or ask the investigator regarding any special conditions regarding your right to revoke your authorization. However, if you do not provide your authorization or if you wish to revoke your authorization for the required research activities at any time, you may no longer participate in the study. A decision to participate in this research means that you agree to the use of your health information for the required research activities related to this study (conditioned authorization), and you agree not to see your research-related health information until the study is completed.

This authorization is valid until the completion of the research. If you wish to revoke your authorization, you may do so at any time, but it must be in writing.

You will be given a copy of this signed Authorization form.

E. SIGNATURE:

I give my permission to use and disclose my health information (PHI) for purposes of this research study. My signature below attests to this authorization:

_____ _____

Signature of Patient or Legally Authorized Representative ***Date***

OFFICIAL SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I have read this document (or someone has read it to me). I have been given an opportunity to ask questions concerning the details of the research. I wish to participate in this study. I shall receive a signed copy of this document, which includes the *State of California Experimental Subject's Bill of Rights, the Consent to be a Research Participant,* and *the Authorization for Use or Disclosure of Health Information*. My consent is valid for the duration of this study.

Legally Authorized Representative (LAR) Signature:

Printed Name of LAR	Reason patient is unable to sign

I hereby attest that I am the official decision maker for this patient, as I have indicated in the circled category below, and I further attest that, to the best of my knowledge, no other surrogate exists with a higher priority than me:

1. Agent named in an advanced health care directive; 2. Conservator or Guardian; 3. Spouse;
4. Domestic Partner; 5. Adult son or daughter; 6. Custodial parent; 7. Adult brother or sister;
8. Adult grandchild; 9. Other adult, not listed above: _____

Legally Authorized Representative (LAR) Signature	Date	Time

Witness name & signature (Cannot be a member of the Research Team. To be used with translated short form consent or for patients unable to read the consent form [illiterate, visually impaired])

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject or his/her legal representative and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

Investigator's Signature	Date	Time
Name & Signature of Person Obtaining Consent (if other than Investigator)	Date	Time

The patient must be given a copy of this consent form. A signed copy must be filed:

- *in the patient's medical record in the physician's/investigator's office, and*
- *in the Cottage medical chart if any portion of this study will take place at a CHS facility.*