Informed Consent Form

Title: Comparison of Different Ventilator and Vaporizer Technologies to Study Economic and Environmental Implications

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UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Low-flow Anesthesia: Cost-effectiveness of the FLOW-i Anesthesia Machine, a Comparison to Established Anesthesia Delivery Unit

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

RESEARCH TEAM
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STUDY LOCATION:
University of California, Irvine Medical Center
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STUDY SPONSOR:
MAQUET

WHY IS THIS RESEARCH STUDY BEING DONE?
During surgery you will receive a series of standard medication to place and maintain you under general anesthesia. The anesthesia machine helps to deliver anesthetic gases while at the same time breathing for you. The goal of this study is to evaluate whether using a type of anesthesia machine which uses low flow rates of anesthetic gas is more cost effective by wasting less gas.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 128 participants will take part in the research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this is not a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if you:
- Are age 18-65
- Are scheduled to undergo a surgery under general anesthesia in UCI Medical Center
- Agree to sign the consent and HIPAA forms
- Are to receive sevoflurane as an anesthetic during your procedure

Exclusion Requirements
You cannot participate in this study if you:
- Are under the age of 18
- Have Chronic Obstructive Pulmonary Disease (COPD)
- Have a Body Mass Index (BMI) > 30
- Have an ASA > 2
- Are a pregnant female
- Have a procedures less than 2 hours
- Do not agree to sign the consent and HIPAA forms

HOW LONG WILL THE STUDY GO ON?
This study includes one visit and takes place during the duration of your surgical procedure.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...
Prior to your procedure, we have reviewed your electronic medical record and determined that you are eligible to participate in this study based on the inclusion and exclusion requirements. If you do not wish to participate, any information that we may have collected from you will be discarded. No medical records or personal information will be retained for this study. No other “screening” exams, tests, or procedures are required of you to participate in this study.

During the main part of the study...
The GE anesthesia machines currently owned by the operating room will be used to serve as the comparator to the Flow-i machine. The high volume anesthesia machines do not use a low volume system. Subjects will be randomized upon surgical schedule assignment into one of two groups:

(1) MAQUET FLOW-i device
(2) GE anesthetic device

Time points for both groups include:

T_0: Time of intubation when breathing tube is placed

T_1: Time of incision, time when surgical incision begins

T_2: Time of anesthetic weaning, typically the time when patient emergence begins.

Aside from the randomization to either Group 1 or Group 2, there will be no changes in the surgical or anesthetic procedure, including the medication or treatments given to the subjects as determined by the treating physician. All subjects will receive general anesthesia in accordance to local practice.

For this study, the vaporizer(s) will be weighed on a tared scale before research procedures commence, after intubation, after time of incision, and when the gas is shut off during weaning of anesthesia in preparation for extubation to calculate the amount consumed during this time (grams/minute). In addition, the following variables will be recorded from your medical record such as (gender, Body Mass Index, type of surgery, time anesthesia is administered/begins, heart rate, etc.) will be collected and used for the analysis of the study.

This is not a physician-blinded study being that the physical characteristics of the standard delivery units are distinguishable from the MAQUET FLOW-i machine.

***After you complete the main part of the study*:**
Your participation will only take place during the duration of your surgical procedure. There is no additional intervention as well as follow-up from the study team members.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?
The risks associated with this study are the same as the risks associated with any surgical procedure and anesthetic given. Active routine monitoring and other measures will be taken to minimize any risks to you as a subject of this study. There is a risk associated with the randomization of this study. While this randomization removes the decision as to which device to use from the lead researcher, it does not alter the original strategy for anesthesia treatment. The decision of the anesthetic treatment is ultimately left to the discretion of the administering anesthesiologist.

You should talk to the research team about any side effects you experience while taking part in the study.

Risks and side effects related to the MAQUET FLOW-i anesthesia machine include:

- All risks associated with the study are the same risks associated with patient care since there are no procedures specifically related to this study. All devices, medication, treatments, and monitoring used are part of standard patient care.
- Side Effects: The expected frequency of a given side effect or harm is no different between the two study groups; both are considered standard of care.
- Breach of confidentiality: Your medical record will be accessed, but only information relevant to the study will be collected. Identifiable information will be kept separately, and solely for organization purposes. However, all identifiable subject data collected will be coded and the code key will be stored in a secure location, accessible only by study personnel for organizational purposes.
- Randomization: You will be assigned to a study group by chance (like a coin flip) rather than by a medical decision made by the researchers. All risks associated with each intervention are the same as standard of care. The treatment you receive may (or may not) prove to be less effective or to have more side effects than the other study group.

ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY?

Participant Benefits

You will not directly benefit from this study.

Benefits to Others or Society

Due to rising cost of healthcare, an accompanying rising concern is the cost of anesthesia. The low-flow system has the ability to reduce the usage of anesthetic gas in surgical procedures, therefore reducing overall hospital expenditures, and enable the hospital to provide quality patient care at lower costs.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

The only alternative is not to participate in this study, and receive the standard of care treatment in lieu of participation in this research.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

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

Compensation

You will not be compensated for your participation in this research study.

Reimbursement

You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you for participation in this study. However, you will be billed as usual for all costs related to your surgical procedure.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor, Maquet, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you elect to withdraw or are withdrawn from this FDA-regulated research study, the data collected from your participation in this study must remain in the trial database in order for the study to be scientifically valid.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data

All identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.

Personal identifiable data are retained for organizational purposes within the UCIMC study team members only. All data will be de-identified before any statistical tests or being shared with MAQUET for research purposes.

Data Storage

Research data will be maintained in paper format in a secure location at UCI for up to six years. Only authorized individuals will have access to it.

In addition, research data will be stored electronically on a password-protected server. Only study team members will have access to the data for research purposes stated in the protocol.

Data Retention

The researchers intend to keep the research data up to six years in accordance with UCI policy.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized UCI personnel, MAQUET, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be released or disclosed by these entities without your separate written consent, except as specifically required by law. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. Publications and/or presentations resulting from this study will not include identifiable information about you.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy

ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?

Investigator Financial Conflict of Interest

No one on the study team has a disclosable financial interest related to this research project.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: As the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

Subject Signature	**Date**
Printed Name of Subject	
Signature of Person Obtaining Informed Consent *(Individual must be listed on Page 1 of this consent)*	**Date**
Printed Name of Person Obtaining Informed Consent	

***A witness signature is required on this consent form only if:* (Researchers: check which one applies)**

☐Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
Witness Signature **Date**
(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

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

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.