The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: **Continuous Ward Monitoring with the GE Portrait Mobile Monitor: the COSMOS trial**

Phase 1

Sponsor: GE Healthcare

Principal Investigator: Daniel Sessler, MD
Phone number: 216-444-4900
After hours phone contact#: 216-444-2000 ask for the Anesthesiologist on call

Study Coordinator: Elyad Ekrami, MD
216-445-4289

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because you will have surgery at the Cleveland Clinic. The purpose of this study is to evaluate a new wearable monitor (GE Portrait Mobile Monitor). The monitor is an experimental device that continuously measures blood oxygen, breathing rate, and heart rate. It is not cleared by the Food and Drug Administration (FDA).

You will be asked to wear the GE Portrait Mobile Monitor for up to 72 hours. Neither you nor your doctors will see the results. You will be asked about your medical history and respond to some questions about how you feel. Your participation in the research will last about 3 days.

More detailed information can be found under the section labeled: "Information on the Research."

Why might you choose not to participate in this research study?

You might not want to wear an investigational device. You may not like the way it fits, or be worried that the device will be uncomfortable.

More detailed information about the risks of this study can be found in the section labeled "Risks."

Why might you choose to volunteer for this study?

You will not receive direct benefit from being in this study. However, taking part may help patients recovering after surgery receive better care in the future.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?

The alternative to being in this study is to not take part.

More detailed information about the alternatives to this study can be found in the section labeled "Alternatives."

Do the researchers or institution have any conflicts of interest relating to this study?

A Cleveland Clinic institutional official serves on the Board of Directors of the company sponsoring this research. For this service, the institutional receives compensation, which includes equity in the company. The institutional official may benefit financially if this research is successful. These financial interests are being managed and are within permissible limits established by the local institutional Conflict of Interest Policy. If you have any questions regarding conflict of interests, please ask your doctor or call the Cleveland Clinic Institutional Review Board at (216) 444-2924."

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

Vital signs including blood oxygen, heart rate, and breathing rate are usually measured approximately every four to eight hours after surgery. The GE Portrait Mobile Monitor is a battery-powered wearable device that measures vital signs continuously and may therefore detect problems sooner.

The purpose of this study is to collect and evaluate signals from the GE Portrait Mobile Monitor. Specifically, we will use your vital sign information to design alerts that will identify possible problems without too many "false alarms." Neither you nor your caregivers will see vital signs

from the experimental monitor. However, nurses will take routine vital signs, just as if you do not participate in our study.

The device being used is the GE Portrait Mobile Monitor which is an experimental device that is not FDA cleared.

How Many People Will Take Part in this Study?

Approximately 100 people will take part in this part of the study at Cleveland Clinic.

What is involved if you decide to take part in this research study?

You will also be asked to wear the GE Portrait Mobile Monitor for up to 72 hours to monitor your vital signs. Regardless of the study, you will have vital signs assessed by nurses every 4-8 hours as usual, and more often if needed. Your medical record will be reviewed. You will be asked about your medical history and some other questions. You can decline to answer any question that makes you uncomfortable.

How will my data be used?

Your data may be sent outside of the Cleveland Clinic for data analysis and will be shared with the sponsor, GE Healthcare. Any personal information that could identify you will be removed before data are shared.

Will I be notified of the results of the tests/studies on my samples?

The tests/studies described are for research purposes only. It is not the purpose of these tests/studies to look for or provide you with any medical information or diagnoses relating to

your present condition or any other disease or illness. Therefore, you will not receive results from these research tests/studies.

2. ALTERNATIVES
What are the alternatives to participation in the research study?

Your alternative is not to participate in this study. Whether or not you participate, nurses will measure your vital signs every 4-8 hours and more frequently if necessary.

3. RISKS
What are the risks of participating in the research study?

The GE Portrait Mobile Monitor is an experimental device that has not been cleared by the Food and Drug Administration (FDA). Wearing the device may be uncomfortable. You may have a reaction to the "stick on" pads, such as irritation, redness, or itchiness. You can easily remove the pads or the system yourself, if they are bothersome. We will record information about your medical history, hospital stay, and study results. Some of these data may be shared with the GE Company, but we will not give the company your name or identifying information. Your data will be kept confidential, but there is a potential risk of loss of confidentiality.

Confidentiality Risks
There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential through the use of the following safeguards: If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for the length of the study. After that time it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

Questionnaire/Survey Research
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Unknown Risks
There may be risks or side effects related to the GE Portrait Mobile Monitor that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

4. BENEFITS

What are possible benefits of participating in the research?

There will be no personal benefit to you by participating in this research study. The knowledge to be gained from this research may be beneficial for other patients, society, or science.

5. COSTS
Are there any costs to you if you participate in this study?

There is no cost to you to be in this research study.

6. PAYMENT
Are there any payments to you if you participate in this study?

You will receive $1 per hour for the time you wear the GE Portrait Mobile Monitor up to a maximum of 72 hours. A check will be mailed to you about 8 weeks after you are discharged from the hospital.

The IRS requires Cleveland Clinic to report payments to an individual of $600 or greater (in a calendar year) on a Form 1099-MISC. Your name, address and social security number will be collected to track the payments made to you and, if you receive $600 or greater, will be used to process a Form 1099-MISC.

7. RESEARCH RELATED INJURY
What will happen if you are injured as a result of taking part in the research?

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

In the event you suffer a research related injury as a result of being in this study, the costs for medical treatment may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research-related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland

Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY
What will happen to your information that is collected for this research?

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

Authorization to Use/Disclose Protected Health Information
Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing Daniel Sessler MD, 9500 Euclid Avenue — P77, Cleveland, OH 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

Clinical Trials

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

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact Daniel Sessler, M.D. at 216 444-4900. During non-business hours, weekends and holidays, please contact Elyad Ekrami, MD at 216-445-4289 or pager 216-444-4000 X24801 or ask for the anesthesiologist on call. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date