Optimizing Cerebral Autoregulation During Surgery

Informed Consent Form

NCT05308290

April 22, 2022

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Optimizing cerebral autoregulation during hip, knee, or lung surgery**

Application No.: **IRB00137091**

Funded By: **National Institutes of Health**

Principal Investigator: **Charles Brown MD, MPH**
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Phone: [redacted]
Fax: [redacted]

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.
- The person being asked to be in this research study may not be able to give consent to be in this study. You are therefore being asked to give permission for this person to be in the study as his/her decision maker.

2. Why is this research being done?

This research is being done to look at two different ways to manage blood pressure control during surgery for hip, knee, or lung surgery and to determine which way to manage your blood pressure is associated with the lower risk of being confused after surgery.

During surgery blood pressure is constantly measured and medications are used if needed to help keep blood pressure at a safe level. It is thought that problems with low blood flow to the brain during surgery might lead to temporary confusion after surgery.

Who can join this study?

People aged 60 years and older, who are scheduled for clinically indicated hip, knee, or lung surgery may join.

How many people will be in this study?

About 90 people are expected to take part in this study at Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Baseline Assessment:

After you agree to be part of the study you will be asked to complete several questionnaires. These questionnaires will ask you about things you do daily and how you view your quality of life. The questionnaires take about 15 minutes to answer.

We will also look at your medical record to learn about your health.

Intraoperative Monitoring:

When you are in the operating room we may use up to three devices:

1) The first device is called Near Infra-Red Cerebral Oximetry (NIRS) and measures the amount of oxygen in the blood which is traveling through your brain.
2) The second device is called a Bispectral Index Monitor (BIS) and measures how deep your anesthesia is.
3) A third device called the Clearsight monitor, which is used to measure real-time arterial blood pressure using a finger cuff.

NIRS is used in most patients undergoing cardiac surgery and the BIS and Clearsight monitors are also used commonly. All of these devices are approved by the U.S. Food and Drug Administration (FDA).

All of these devices are *non-invasive*: they allow for the information to be collected by monitors placed on your skin surface.

While the monitors are being applied, you will be randomly assigned (by chance, like flipping a coin) into 1 of 2 study groups: Control Group or Intervention Group.

- People in the **Control Group** will have their blood pressure controlled during surgery according to current standard care at Johns Hopkins Hospital. Fluid or drugs will be given to keep the average blood pressure according to usual clinical practice.

- People in the **Intervention Group** will get fluid or medicines to maintain a specific blood flow to the brain (determined by information we get from the NIRS and Clearsight monitors) rather than to maintain a specific blood pressure in the body. Information from the BIS monitor will be used to determine how asleep you are during surgery.

Follow-up:
On the first 3 days after surgery, you will be tested once a day to see how clearly you are thinking. We will ask you to answer questions in order to see how well you are remembering things and how clearly you are able to think.

After you are discharged from the hospital, at two months and six months after surgery, a research assistant will call you to ask you questions about your current physical function and to see how clearly you are thinking. This phone call should take about 15 minutes to complete. At 1 year a research assistant will interview you in person or by telephone to ask you questions about your physical function and your ability to think clearly.

How long will you be in the study?
You will be in this study for about 1 year.

4. What are the risks or discomforts of the study?

Monitors
There are no known risks of Clearsight monitor, Near Infra-Red Cerebral Oximetry (NIRS), and Bispectral Index Monitor (BIS) devices used in the study.

Because your blood pressure may be maintained at a higher level, there are theoretical risks of more bleeding and more work being done by your heart.

Interviews or questionnaires
You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Identifiable private information
There is the risk that information about you may become known to people outside this study.

5. Are there benefits to being in the study?

There may or may not be a direct benefit to you from being in this study. If you are in the Intervention Group, you may benefit from better management of your blood pressure during surgery. However, this cannot be guaranteed.

If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in the study?

You do not have to join this study. Other options include standard of care blood pressure management. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins 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.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study may be harmful.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins 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. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records ([which may include information about HIV, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory will know your identity and that you are in the research study. Other people at Johns Hopkins, including your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

How will your information be protected?
A study code identification number will be used to protect your identity. Your personal data are processed in such a manner that they can no longer be attributed to you without the use of additional information.

- Such additional information is kept separately and is subject to technical and organizational measures. Only qualified and authorized staff of the study will perform study-related monitoring activities.
- Your personal data will be processed at all times in accordance with applicable legal requirements and will be used solely for the purposes of conducting this clinical study and to aid future scientific research in patients with a similar condition.
- In general, only the study team will have direct access to your personal data.
- If you withdraw consent to participate in the study, no further personal data from you will be collected.
- Any published information including reports and articles about the study will not include your name or any information that could personally identify you.
- The study team will not store any of your coded personal data longer than the mandatory retention periods defined by the applicable laws.
- The study team will not remove from medical records any personal data after the applicable retention period has expired.

12. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

13. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Charles Brown at [redacted]. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at [redacted].

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Charles Brown at [redacted] during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call 911 or go to your local emergency department. You should also call Dr. Charles Brown at [redacted] during regular office hours, after hours and on weekends. **After the tone, enter the phone number where you can be called, press the # key, and hang up.**

d. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

15. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

Signature of Legally Authorized Representative (LAR) **FOR ADULTS UNABLE TO CONSENT**	(Print Name)	Date/Time

Relationship of LAR to Participant (Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

_____

Signature of Physician/Mid-Level Provider (Print Name) Date/Time

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time
FOR ADULTS UNABLE TO CONSENT

_____

Relationship of LAR to Participant Date/Time
(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).