

## **Written Consent to Participate in a Research Study**

**Project Title:** Evaluation of brain and peripheral metabolic and inflammatory markers in patients undergoing open-heart surgery – a pilot study.

**Principal Investigator Name:** Antoinette Burger, PhD, CCRP

**Sponsor:** Departments of Anesthesiology and Perioperative Medicine and Radiology

**IRB Assigned Project Number:** 2116027

### **Key Information About the Study**

You are being asked to participate in a pilot research study investigating postoperative cognitive decline through measuring brain and peripheral metabolic and inflammatory markers in patients undergoing open-heart surgery. The purpose of the research study is to measure metabolic markers in the brain and blood of patients undergoing open-heart surgery.

Please read this form carefully and take your time. You can discuss this study with your family, friends, or doctor if you want. Let us know if you have any questions before participating. The research team can explain words or information that you do not understand. Research is voluntary and you can choose not to participate. If you do not want to participate or choose to start then stop later, there will be no penalty or loss of benefits to which you are otherwise entitled. The study team may withdraw you from the study at any time if any study procedures are or may be harmful to you.

### **Purpose of the Research**

You are being asked to participate in this study because you are 60 years or older and will be undergoing open-heart surgery. The purpose of this study is to measure metabolic and inflammatory markers in the brain and blood of patients undergoing open-heart surgery.

### **What will happen during the study?**

If you take part in this study, you will have the following tests and procedures:

You will be screened for eligibility with two screening measures, and for magnetic resonance imaging (MRI) safety and compatibility.

If you are eligible to take part in the study, you will undergo an MRI with spectroscopy (MRS) scan of your brain at the NextGen Precision Health Imaging Suite, located in the basement of the NextGen Precision Health building within 10 days prior to undergoing surgery. The MRI scanner takes pictures of the inside of your brain using a very strong magnet. You will lay on a table that will slide into the middle of the magnet. You will have to lie still while the MRI is working. The MRI takes about 60 minutes. We will also draw blood (research only) through a vein in your arm, using aseptic techniques, during this visit to measure metabolic and inflammatory markers.

During your surgery, additional blood drawn during standard of care (SOC) blood draw (for research purposes) will be obtained to measure ketone levels and inflammatory markers. After your surgery, the study team will visit you daily and complete the same assessments we used for screening before you started the study for three days after surgery, this will take no more than 15-20 minutes per visit. Should you experience postoperative cognitive decline after surgery, we

will visit you daily, and do the same assessments used for screening, until it resolves. On the second day after your surgery, we will draw blood again (additional blood obtained for research only, during SOC blood draw) to measure ketone and inflammatory markers. Blood drawn for research purposes at each time point will consist of two tubes (maximum of 16mL (equivalent of one and a half table spoons)) for a total of 48mL (equivalent of four and a half table spoons) total.

There will be about 20 participating in this study.

**Will you share with me any results or health problems/issues that you learn about me while in the study?**

If we find any clinically relevant research results as a result of MRI/MRS scans and/or blood tests that include results about you, we will inform you as soon as possible. If the investigators identify potential health problems or issues as part of the research, you will be provided with this information and, with your permission, the investigators will share this information with your primary care physician or other healthcare provider of your choice. It is possible that you may need testing or treatment for a new or existing health condition. You and/or your health plan/insurance are responsible for the costs of this testing or treatment.

**How long will I be in the study?**

Your participation is expected to last no more than 10 days.

**Are there benefits to taking part in the study?**

You may not directly benefit as a result of your participation in the study. Information learned from the study may help other people in the future.

**What are the possible risks of participating in this study?**

Blood draws may cause pain at the needle site, and you may experience slight bruising afterwards.

MRI/MRS scanning is considered low-risk, however, participants who undergo MRI/MRS scanning may experience headache, nausea, dizziness, and body fatigue from lying in one position for an hour. Side effects from MRI/MRS scanning are rare, and treated symptomatically if it occurs. The magnet in the MRI machine is very powerful and attracts any metal objects brought into the room. People with heart pacemakers or other metal objects in their body cannot be in the study because they cannot go in the MRI room. The MRI scan is painless, but it can be uncomfortable for some people. The machine makes lots of loud beeping and hammering noises that can bother some people. You will wear earplugs or headphones during the scan to protect your ears. You may also feel something like a mild electric shock or gentle tapping on your body during the scan. This is normal and happens when the nerves in your body are stimulated by the magnets. The MRI scan may bother you if you feel uncomfortable in small spaces. You will be able to speak to us through an intercom during the scan, so you can ask us to stop the test at any time.

To help lower these possible risks, we will monitor you very closely during all procedures. Blood draws will be conducted with aseptic techniques by qualified medical practitioners.

We will tell you about any new important information we learn that may affect your decision to continue to participate in this study.

There is a small risk of loss of confidentiality, however, we take all reasonable steps to prevent that from happening. All data collected will be accessible only to investigators of the study.

**What other choices do I have if I don't want to be in this study?**

You are not required to be in this study. You can simply choose not to participate. There will be no penalty to you, should you wish not to participate.

**Will I receive compensation for taking part in this study?**

You will be compensated for taking part in this study. For your time and effort, you will receive a \$75 gift card upon completion of the imaging day and a \$75 gift card for completion of the in-hospital part (on postoperative day 3 or when postoperative cognitive decline resolves, whichever occurs first), for a total of \$150. Should you decide to withdraw from the study, you will be eligible for compensation of study sections you have completed, e.g. you may be eligible to receive the gift card for completion of the imaging day if you withdraw on/after the imaging day but will then not receive the in-hospital part gift card.

We will need your Social Security Number in order to pay you. Any payment may need to be reported as income on your tax return. If you are not a resident/citizen (non-resident alien) of the United States, you will need to work with the MU Nonresident Tax Specialist at 573-882-5509.

**Are there any costs for participating in this study?**

You and/or your health plan/insurance will be billed for everything that is considered standard of care. This includes tests and procedures you would receive without being in this study. Some health plans/insurance companies will not pay for these costs for people who are in research studies. Check with your plan/company to find out what they will pay for.

Other costs to you from being in this study may include testing or treatment for existing or new health conditions, insurance co-payments for doctor visits, transportation, parking, childcare, and/or time off work.

A social worker and financial counselor are available to discuss concerns with you. Please let the research staff know if you would like to visit with them and an appointment will be made.

You should discuss any questions about costs with the researchers before agreeing to participate.

### **Will information about me be kept private?**

The research team is committed to respecting your privacy and keeping your personal information confidential, including health information. We will make every effort to protect your information to the extent allowed by law. Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location.

When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed.

We may record your research information, including the results of tests and procedures, in your medical record if the information could be useful for future treatment.

We may share what we collected from you as part of this research, after removing your identifiers, for future research without additional informed consent from you.

### **Permission to Use your Protected Health Information:**

State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.

You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

Some identifiers about you will be obtained from your health records and are necessary for this research. The identifiers will include your name, address, dates related to you, phone numbers, medical record number, social security number, and other characteristics that could identify you.

We may share any of this information with the following:

- Authorized members and staff of the University of Missouri Institutional Review Board (IRB).
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
- Study monitors and auditors who make sure that the study is being done properly.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), and the Office for Human Research Protections (OHRP)

Any research information shared with outside entities will not contain your name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.

The people who get your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

Your permission for us to use and/or release your information will not expire unless you cancel your permission in writing.

You can cancel your permission at any time by writing to:

Investigator's Name: Dr Antoinette Burger

Institution: University of Missouri-Columbia School of Medicine

Department: Anesthesiology and Perioperative Medicine

Address: 1 Hospital Street, DC005.00, Columbia, MO, 65212

The information we have already collected may still be used for this research study, but we will not collect anymore information after we receive your letter.

You will not be allowed to access your protected health information that is obtained or created during this research project until the end of the study.

If you have not already received a copy of the University of Missouri Health Care Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you may contact the Privacy Officer at 573-882-9054.

### **Who do I contact if I have questions or concerns?**

If you have questions about this study or experience a research-related injury, you can contact Dr Antoinette Burger at 573-884-3740 or [aburger@health.missouri.edu](mailto:aburger@health.missouri.edu).

If you have questions about your rights as a research participant, or have problems or complaints, please contact the University of Missouri Institutional Review Board (IRB) at 573-882-3181 or [muresearchirb@missouri.edu](mailto:muresearchirb@missouri.edu). The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

If you want to talk privately about any concerns or issues related to your participation, you may contact the Research Participant Advocacy at 888-280-5002 (a free call) or email [muresearchrpa@missouri.edu](mailto:muresearchrpa@missouri.edu).

### **Do I get a copy of this consent?**

You will receive a copy of this consent for your records.

We appreciate your consideration to participate in this study.

**Consent to Participate - Signatures**

<b>Subject's Signature</b>	<b>Date</b>

<b>Investigator Authorized to Obtain Consent</b>	<b>Date</b>