The Ohio State University Consent to Participate in Research

Study Title:	**Preoperative dietary fat consumption and baseline inflammatory markers in older patients presenting for major non-cardiac surgery**
Principal Investigator:	Michelle L. Humeidan, MD, PhD
Sponsor:	The Ohio State University Department of Anesthesiology

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

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

Mental problems place a significant burden on patients, caregivers, and healthcare resources. Temporary disruption in mental status is one of the most common postoperative complications in older surgical patients, with increased incidence in high-risk populations. Several factors contribute to risk of this temporary mental status disruption.

The main purpose of this study is to correlate your diet's characteristics, wait circumference and health status with inflammatory substances in your body and/or postoperative mental status in patients over the age of 60.

Prior to surgery, many patients choose to receive a standard epidural or combined spinal epidural (CSE) blocks, a procedure that provides anesthesia medication to create a band of numbness around your bellybutton. The anesthesia medication is administrated using a catheter

(a small tube) that is inserted into the lower back region. This catheter is used to administer drugs which help manage the pain associated with surgery. Prior to placing the catheter in the lower back, anesthesiologists inject a numbing medication known as lidocaine into the skin to reduce any sensation while the epidural needle is inserted.

Therefore, if you decide to participate in this study, after signing the informed consent, we will collect information about your diet during the month before your surgery as well as administer a baseline mental assessment. After surgery, research staff will give 5-minute cognitive assessments twice a day during your hospital stay, as well as one 3 months post-surgery over the phone.

In addition, we will collect blood samples and spinal fluid (drops that are discarded during your epidural procedure for analgesia management) to analyze for certain inflammatory substances that may be present due to your current diet style.

1. Why is this study being done?

Mental problems with memory, language or judgement places a significant burden on surgical patients, caregivers, and healthcare resources. Temporary disruption in mental status is one of the most common postoperative complications in older surgical patients, with increased incidence in high-risk populations. Several factors contribute to risk of this temporary mental status disruption, but the increased incidence and sequalae in older patients is thought to be due to convergent pro-inflammatory responses occurring with aging, diet and perioperative exposure to stress, significant tissue trauma and physiological imbalances, and medications with pro-inflammatory characteristics like opioids.

The main purpose of this study is to correlate your diet's characteristics, wait circumference and health status with inflammatory substances in your body and/or postoperative mental status in patients over the age of 60.

You are being asked to take part in this study because you are scheduled to undergo a surgical procedure that might require hospitalization and/or epidural procedure for pain management.

2. How many people will take part in this study?

A total of 70 patients will participate in this study.

3. What will happen if I take part in this study?

If you decide to participate in this study, after providing informed consent by signing this form you will go through the following study procedures:

- Research staff will collect information about your diet during the month before your surgery using the Diet History Questionnaire and an Omega-3 checklist survey as well as administer a baseline mental assessment.

- On the day of surgery, research staff will review your medical history including demographics (gender, age, height, weight), allergies (seasonal and drug related), history of concomitant medications and drug use, and medical conditions or any other disease that could exclude you from participating in the study. In addition, research staff will collect up to a total of 32 mL of blood, with a maximum of 16 mL before surgery and 16 mL the morning after surgery and up to 1 mL of cerebrospinal fluid (CSF) before surgery.

- After surgery, research staff will administer a 5-minute mental status assessment (confusion assessment method assessment [CAM-3D]) twice a day during your hospital stay, as well as one mental status assessment (telephone-Montreal Cognitive Assessment [T-MoCA] three months post-surgery over the phone.

4. How long will I be in the study?

If you agree to be part of this study, you will need to go through the screening process that will last around 10 minutes before surgery. Consequently, we will collect information related to your diet and administer a baseline mental assessment (15 minutes). Then, we will be present during your epidural or CSE procedure (20 minutes) and intravenous catheter placement to collect blood samples and CSF fluids. Lastly, we will administer 5-minute mental assessments twice a day during your hospital stay and another mental assessment 3 months post-surgery day (5 minutes).
Therefore, a total of up to 105 minutes of your time will be dedicated to this study.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Since this research mainly involves a short memory and thinking test, the risk of taking such a test is minimal. It may include the anxiety of taking a test.

Possible side effects from blood drawing include lightheadedness, fainting, inflammation of the vein, pain, bruising or bleeding at the site of puncture. There is also a slight possibility of infection. However, we will try to collect blood samples during your standard intravenous catheter placement required for a surgical intervention.

Lastly, there always exists the potential for loss of private information; however, all efforts will be made by the study team to minimize these risks.

7. What benefits can I expect from being in the study?

There is no direct benefit to you from participating in this study, but you may be helping others in the future by collaborating with us to find better ways to identify certain inflammatory substances linked to mental status disruption.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

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.

10. Will my de-identified information (and bio-specimens) be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent.

11. What are the costs of taking part in this study?

There is no cost to you for participating in this study. There will be no additional costs for the administration of mental status assessments and blood/CSF sample collection or tests, and you will not be charged any additional fees for participating in this study.

12. Will I be paid for taking part in this study?

There is no monetary compensation provided for participating in this study.

13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;

- Information gathered for this research about:
- Diaries and questionnaires

II. Who may use and give out information about you?
Researchers and study staff.

III. Who might get this information?
· The sponsor of this research. "Sponsor" means any persons or companies that are:
· working for or with the sponsor; or
· owned by the sponsor.
· Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
· If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information may be given to:
· The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
· Governmental agencies in other countries;
· Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
· The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?
· To do the research;
· To study the results; and
· To make sure that the research was done right.

VI. When will my permission end?
There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?
Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact:

Dr. Michelle Humeidan, MD, PhD
410 W 10th Ave
N411 Doan Hall
Columbus, OH-43210-1267
Phone:(614) 293-3559
Email: Michelle.Humeidan@osumc.edu

Dr. Ruth M. Barrientos, Ph.D.
460 Medical Center Drive
Columbus, OH 43210-1257
Phone: (614) 293-6591
Email: Ruth.Barrientos@osumc.edu

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact:

HIPAA Privacy Officer
The Ohio State University Medical Center
1590 North High Street
Suite 500
Columbus, OH 43201

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of participant	**Signature of participant** **AM/PM** **Date and time**
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)** **AM/PM** **Date and time**
Relationship to the participant	

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent** **AM/PM** **Date and time**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness** **AM/PM** **Date and time**
Printed name of witness	**Signature of witness** **AM/PM** **Date and time**