Official Title: Mitochondrial function in circulating cells and muscle tissue

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CONSENT AND HIPAA FORM

STUDY TITLE:	Mitochondrial function in circulating cells and muscle tissue
PRINCIPAL INVESTIGATOR:	Elisabet Borsheim, Ph.D. 15 Children's Way, slot 314 Little Rock, AR 72202 Office Telephone: (501) 364-3053 After Hours: (409) 392-4203
CO-INVESTIGATORS:	Eugenia Carvalho, Ph.D. Richard Frye, M.D. Gohar Azhar, M.D. Sean Adams, Ph.D.
STUDY SPONSOR:	Arkansas Children's Nutrition Center (ACNC) United States Department of Agriculture (USDA)
STUDY LOCATION:	Arkansas Children's Nutrition Center; Arkansas Children's Hospital Research Institute 15 Children's Way, Little Rock, AR 72202 and University of Arkansas for Medical Sciences Reynolds Institute on Aging, Little Rock, AR 72205

The following information is provided to tell you about the research study you will be participating in should you choose to do so. Please read this form carefully. Feel free to ask any questions you may have about the study and the information below. You will be given a chance to ask questions and your questions will be answered. You will be given a signed copy of this consent form.

PURPOSE OF THE RESEARCH:

This is a research study conducted by the principal investigator Dr. Elisabet Borsheim, PhD, and her co-investigators at the Arkansas Children's Hospital Research Institute (ACHRI), the Arkansas Children's Nutrition Center (ACNC), and the Reynold's Institute on Aging, UAMS. Up to 40 women, age 25-35 years, will be recruited.

You are being invited to take part in this research study which is designed to evaluate if the function of mitochondria (small parts of the cell that creates power, i.e., the cell's powerhouse) in circulating blood cells reflects the function of mitochondria in muscle tissue. For this, we will be collecting a small muscle biopsy and will also collect one blood sample. We will study these samples in special machines to determine how much oxygen the mitochondria can take up in the process of energy production. This is a measure of how well they function.

STUDY VISIT:

If you consent to participate in the study, we will set up an appointment for you at either the Reynolds Institute on Aging, UAMS or at Arkansas Children's Nutrition Center, ACH. The visit will last approximately two to three hours, and all study-related procedures will be performed during this time.

EXPLANATION OF STUDY PROCEDURES:

- Anthropometrics/vital signs: We will measure your height, weight and waist and hip circumferences, blood pressure, pulse and temperature.

- DXA: We will measure your muscle, fat and bone using a DXA (short for Dual-energy X-ray Absorptiometry). It is like an X-ray of your body. The scan takes about 5 minutes to perform.

- Blood collection: Blood will be collected by a trained phlebotomist. A total volume of up to 50 ml (~3.5 tablespoons) will be drawn for isolation of cells (peripheral blood mononuclear cells (PBMCs) and platelets), and for analyses of insulin, glucose, lipid levels, and other analytes such as metabolites or hormones. We will provide you these test results to take to your primary care physician (PCP), who will discuss further with you in follow up visits in case of any incidental findings from these results,

- Biopsy: A small piece (biopsy) of muscle tissue will be collected from the muscle on the outside of your thigh, about 4-6 inches above the knee, by a medical doctor. The skin will first be cleansed with an antiseptic scrub solution and allowed to dry. The skin and tissue below will thereafter be injected with numbing medicine (lidocaine). A small incision about the size of this dash "—" will then be made, through which a needle about the size of the

letter "O" is gently pushed into the muscle. A small piece of the muscle is removed with the needle. The skin is then closed with Dermabond clinical glue (used routinely for closure of surgical sites), and a light dressing is applied. You will be given thorough instructions about how to care for the biopsy site.

- You will be asked to fill out a physical activity questionnaire about your physical activity level and habits.

DISCOMFORT AND RISKS:

The potential risks associated with participation in the study are as follow:

- DXA. This X-ray scan takes about 5 minutes to perform. Each scan exposes you to approximately 2 days' worth of the naturally occurring radiation you are exposed to while living in the Little Rock, AR area.

- Blood Sampling: The total amount of blood drawn for this study will be approximately 50 ml (about 3.5 tablespoons) at one time. The risks related to this blood draw include pain and bruising.
- Muscle biopsies. Risks associated with the muscle biopsy include bleeding, bruising, pain, scarring and possible infection at the site. To decrease or eliminate pain during the procedure, local anesthetic will be used. Pain or discomfort may continue for a few days after the procedure. You will be given thorough instructions about how to care for the biopsy site. Biopsy procedures will only be performed by trained physicians and the biopsy will be collected under sterile conditions.

There is also the risk of a loss of confidentiality that is inherent in all research. The study staff will do everything possible to protect your confidentiality.

In the event you are hurt by being in this research, treatment will be available. This treatment may include: first aid, emergency treatment and/or follow-up care. This treatment may be billed to you or your insurance company in the normal manner. Normally, no other form of compensation is available. **If you think you have been hurt by this research, please let the study physician or nurse know right away by calling:** Gohar Azhar, MD (501) 526-5821 (office) or Scott E. Schutzler, RN (501) 388-1025.

If you have any questions about your rights as a research subject or concerning a research-related injury, or to speak to someone not directly involved with the research, you can call the Institutional Review Board representative at phone number (501) 686-5667.

POTENTIAL BENEFITS ASSOCIATED WITH PARTICIPATION IN THIS STUDY:

You will not benefit directly from your participation in this project. However, the information from the study may help understand the underlying causes of metabolic diseases, and this may help the medical community and patients in the future. Any significant new findings discovered during the course of the research that may relate to your willingness to continue to participate in this study, will be provided to you.

ALTERNATIVE PROCEDURES:

None. You may decline to participate in the study.

TIME COMMITMENT:

You will come to UAMS or ACNC one time for a two-hour visit, if you meet the initial criteria.

PRIVACY DISCLOSURE OF PARTICIPATING IN THIS STUDY:

Any personal information collected during this study will be kept private. To protect your confidentiality, your information and specimens will be de-identified (meaning your name will not be listed on the information or specimens) and a unique code will be assigned. The data and specimens resulting from these studies will be stored at the ACNC indefinitely for potential use in future research studies that are within the scope of the current one. The results of this study may be published in a medical/scientific journal and/or presented at medical/scientific meetings, but you will not be identified by name. In the event of an official audit, representatives of the Institutional Review Board (IRB) at the UAMS, the Office for Human Research Protections (OHRP), the Arkansas Children's Hospital Research Institute (ACHRI), the Arkansas Children's Nutrition Center (ACNC), the United States Department of Agriculture (USDA), or other institutional oversight offices, may be given access to research study records and pertinent health records that may contain your name or other identifying information. By law, some of our study personnel must release certain information to the appropriate authorities if at any time during the study there is concern that abuse, and/or neglect, has possibly occurred or you disclose a desire to harm yourself or others.

COMPENSATION FOR PARTICIPATION IN THIS STUDY:

You will be reimbursed for lost time and travel in the amount of $100 upon completion of the 2-hour study visit. There will be no costs to you for any of the assessments conducted in this study, including parking. The reimbursement will be mailed to you as a check, and it may take 2-4 weeks for the check to arrive.

VOLUNTARY PARTICIPATION:

Your participation in this study is voluntary, and you may withdraw from this study at any time by notifying the principal investigator Dr. Borsheim at the phone number or address on page 1 of this form. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. Neither students' grades nor employees' status will be influenced or affected by participation in this study. You will be given a copy of the informed consent document.

REASONS YOU MAY NOT BE ABLE TO STAY IN THE STUDY:

Your participation in this research may be terminated by the investigator without regard to your consent if you are unable or unwilling to comply with the guidelines and procedures explained to you or if the study is terminated prior to your completion.

HIPAA Research Authorization:

To do this research, we need to collect health information about you. We will only collect information that is needed for the research. This may include name, address, date of birth, height and weight. Being in this research study will create new health information about your health, body composition and metabolism and questionnaires. For you to be in this research study, we need your permission to collect, create, and share this information.

We may share your health information with people at the University of Arkansas for Medical Sciences (UAMS), Arkansas Children's Hospital (ACH), and Arkansas Children's Nutrition Center (ACNC) who help with the research or things related to the research process, such as the study staff (including the investigators and research coordinators/assistants), the UAMS Institutional Review Board, and the research compliance offices at UAMS and ACH and other institutional oversight offices. Additionally, we may need to share your health information with people outside of UAMS and ACH who make sure we do the research properly, such as the Office for Human Research Protections or the Food and Drug Administration. We believe that those involved with research understand the importance of preserving the confidentiality your health information. However, some of the people outside of UAMS and ACH may share your health information with someone else. If they do, the same laws that UAMS and ACH must obey may not apply to others to protect your health information.

This authorization to collect, use, and share your health information expires at the end of the research. If you sign this form, you are giving us permission to create, collect, use and share your health information as described in this form. You do not have to sign this form. However, if you decide not to sign this form, you cannot be in the research study. If you sign this form but decide later that you no longer want us to collect or share your health information, you must send a letter to Dr. Elisabet Borsheim, whose address is on the first page of this form. The letter needs to be signed by you, should list the "Study Title" listed on this form, and should state that you have changed your mind and that you are revoking your "HIPAA Research Authorization". You will need to leave the research study if we cannot collect and share any more health information from you. However, in order to maintain the reliability of the research, we may still use and share your

information that was collected before Dr. Borsheim received your letter withdrawing the permissions granted under this authorization.

If you decide not to sign this form or change your mind later, this will not affect your current or future medical care at UAMS or ACH.

BANKING OF DATA AND SPECIMENS:

With your permission, your information and specimens (muscle biopsy and blood) will be stored indefinitely for potential use in future research studies that are within the scope of the current one. Specifically, this would mean that the information and specimens could be used for new studies studying similar topics, but which are not extensions of the current study. Biopsies and blood samples will be stored in a locked laboratory. Your information and specimens will be de-identified (meaning your name will not be listed on the information or specimens) and only the staff listed in the study protocol will have access to them. You may choose to withdraw permission for banking at any time you decide. A letter addressed to the principal investigator, Dr. Borsheim, expressing your desire to withdraw this consent would suffice.

Consent for storage of samples:

_____ **Yes**, I allow the Arkansas Children's Nutrition Center and Arkansas Children's Hospital Research Institute to store data and related blood and muscle specimens collected from me for future research.

_____ **No**, I do not allow the Arkansas Children's Nutrition Center and Arkansas Children's Hospital Research Institute to store data and related blood and muscle specimens collected from me for future research.

RIGHT TO ASK QUESTIONS:

If you have any questions during the study, you can contact Dr. Elisabet Børsheim (501) 364-3053 (office) or (409) 392-4203 (cell) on a 24-hour basis or if you cannot reach the investigator or wish to speak to someone not directly involved with the research, you can call an IRB representative at (501) 686-5667. If you have any questions about your rights as a research participant or concerning a research-related injury, you can call an IRB representative at (501) 686-5667.

You have been given the opportunity to ask any questions you may have, and all such questions or inquiries have been answered to your satisfaction. You have not waived any legal right to which you are legally entitled by signing this form.

I have read the above statement and have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I understand the purpose of the study as

well as the potential benefits and risks that are involved. I hereby give my informed and free consent to be a participant in this study

Subject Statement

The purpose and voluntary nature of this study, as well as the potential benefits and risks that are involved have been explained to me. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the study team. I understand that my health information can be collected and used by the researchers and staff for the research study described in this form and the research consent form. I have been told that I will be given a copy of this consent form.

_____
My Name (Please Print)

_____ _____
My Signature Date

_____ _____
Signature of Person Date
Obtaining Informed Consent