

Study Title: **Substrate Utilization in Pre-pubertal children during submaximal Exercise and Rest (SUPER kids)**

PI (researcher): **Elisabet Borsheim, Ph.D.**

Institution: **Arkansas Children's Nutrition Center (ACNC), Arkansas Children's Research Institute (ACRI)**

Support: **ACNC and United States Department of Agriculture (USDA)**

## **Key Information for *SUPER kids***

This first part gives you key information to help you decide if you want to join the study. We will explain things in more detail later in this form.

The word “you” means both the person taking part in the research and the person who gives permission for the research.

We are asking if you want to volunteer for a research study about how the body uses energy. By doing this study, we hope to learn how children use nutrients during rest and exercise.

Please ask the research team if you have any questions about anything in this form. If you have questions later, please contact the researcher in charge of the study. The contact information is provided later on this form.

### **What will happen if I join the study?**

If you join, your part in this research will last up to 2 months, and will include 3 study visits, and up to 2 food pick-up visits. During the study, we will:

- ✓ Ask questions about your child's health and medications.
- ✓ Ask your child to eat certain foods/drinks, ask you to record your child's diet.
- ✓ Highly encourage your child to avoid exercising too hard and avoid certain foods/drinks that give too much energy (caffeine) before a study visit.
- ✓ Collect urine from your child, and check his/her height and weight.
- ✓ Ask your child to rest, and exercise by riding a stationary bike.

### **Do I have to join this study?**

No. It is okay to say no. You will not lose any services, benefits, or rights you would normally have if you decide not to join. If you decide to take part in the study, it should be because you really want to volunteer.

### **What do I need to know to decide if I should join this study?**

People decide to join studies for many reasons. Here are some of the main things you should think about before choosing to join this study.

#### **Main reasons to join the study**

- ✓ We may find out more information about how the body uses energy.
- ✓ The results from this study may help other children in the future by providing a better understanding of how children use nutrients while resting and exercising.

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**Main reasons not to join the study**

- ✓ You and your child may not want to attend the study visits.
- ✓ You and your child may not want to do the study assessments; such as provide samples (urine).

These are just some of the reasons to help you decide if you want to join the study. We will explain more about the risks, benefits, and other options to joining the study later in this form.

Tell the study team if you decide that you do not want to be in the study. Remember, it is okay to say no. You can still get your medical care from UAMS and Arkansas Children's if you are not in the study.

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## **Informed Consent Form & HIPAA Form**

- We are asking you to be in a research study. You do not have to join the study.**
- The word “you” means both the person taking part in the research and the person who gives permission for the research.**
- You can still get your medical care from UAMS and Arkansas Children's even if you are not in the study.**
- Take as much time as you need to read this form and decide what is right for you.**

### **Why am I being asked to be in this research study?**

- We want to learn more about how children of different body types and fitness levels use energy during rest and exercise.
- By doing this study, we hope to find out more about how children use nutrients that are stored in their body while they rest, and while they exercise.
- We are asking people like you, who participated in the study MI Energy to help us.
- Up to 130 children, 8-11 years old will be part of this study.

### **What if I don't understand something?**

- This form may have words you do not understand. If you would like, research staff will read it with you.
- You are free to ask questions at any time – before, during, or after you are in the study.
- Please ask as many questions as you would like before you decide if you want to be in this study. If you decide to take part in the study, it should be because you really want to volunteer.

### **What will happen if I say yes, I want to be in this study?**

First, if during your participation in the study MI Energy, you agreed to future contact and use of your child's data in follow-up studies, and the use of your child's information and samples in future research; then, we will see if your child qualifies for this study by checking his/her test results from MI Energy and asking you some questions about his/her health.

If your child qualifies, we will send you information via mail, email, text links, or website links. We may also reach out to you by phone, emails, or video conferencing to help you understand this form and the study.

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We will ask you and your child to attend an initial study visit either virtually (e.g., phone or video) or in-person at the Arkansas Children's Nutrition Center (ACNC), and 2 additional in-person study visit(s) at ACNC. You may come to ACNC to pick up food up to 2 additional times during your participation in the study if needed. The ACNC is a Well-Child facility, so we will ask you not to come to your study visit if you and/or your child are ill. The study visit will be rescheduled if that is the case to a time when both you and your child are well and without any symptoms of illness.

During this study, we will do these things:

- Ask about your child's health, what medicines, vitamins, and dietary supplements he/she takes.
- Coach you and your child on a specific diet plan; we will ask your child to follow this plan for 3 days before the next study visit, and we will ask you to record his/her diet using an app or paper log during these 3 days. We will provide you with the food supplies your child will need to complete this diet plan; these supplies can be picked up at the ACNC. The food items we will provide contain nuts, wheat, dairy, and eggs.
- Highly encourage your child to avoid foods/drinks that have a substance called caffeine for the last 3 days before the next study visits.
- Highly encourage your child to avoid activities that make him/her breathe very hard and sweat hard for the day before the next study visits, and ask you to record his/her activities.
- Ask your child not to eat food or drink anything besides water at least 10 hours before the next study visits.

We will ask your child to come fasted to the ACNC for two in-person visits. During each visit, we will review your child's food logs to make sure your child followed the study instructions. During each in-person visit, we will do the following:

- Ask your child to provide a urine sample. We will use this to measure health markers immediately after collection, and we will then discard the remaining samples.
- Measure your child's weight and height. Your child will be wearing light clothes like a hospital gown, or shorts and t-shirt but no shoes during these measurements.
- Ask your child to lie still on a bed with his/her eyes closed for about 30 minutes under a "bubble" or wearing a so-called face tent, which is a mask that covers part of the face. We will measure what is in the air your child breathes in and out (oxygen and carbon dioxide) while they are resting in order to calculate how much energy they are using while resting. Your child should be familiar with this set-up from participating in MI Energy.
- Ask your child to cycle on a stationary bike at a set moderate intensity for about 25 minutes, after a few minutes of rest. Your child will wear a facemask that communicates with a computer. The computer will analyze the composition of the air your child breathes in and out during exercise. Your child's heart rate will be monitored while on the bike using a

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strap that goes around the chest. Your child should be familiar with the stationary bike, heart rate monitor and mask from participating in MI Energy.

If at any moment we think that your child needs to re-attempt the diet plan and/or overnight fasting, we may ask you and your child to come back on another day for a rescheduled study visit to ensure these steps are successfully completed in preparation for study visit(s).

If you agree to participate in this study, you agree also to release your child's data, including information and/or samples, from other studies into this study and/or vice-versa.

If your child has participated or will participate in any of these studies: MI Energy, Arkansas Active Kids! – Objective 3, or The ChiPP Study; then, we may use information and/or samples that have already been or will be collected from your child during participation in these studies for the purposes of this study as well and/or vice-versa.

### **How long will I be in this study?**

You will be in the study for up to 8 weeks. It will include a virtual or in-person initial study visit that will last up to 1 hour; and, 2 in-person study visit(s) at the ACNC that will last up to 2 hours each. The visits will happen at least 3 days apart each.

### **What if I say no, I do not want to be in this study?**

- Nothing bad will happen because of what you decide.
- You can still get medical care at UAMS and Arkansas Children's.

### **What happens if I say yes but change my mind later?**

- You can stop being in the study at any time.
- Nothing bad will happen if you change your mind and leave the study.
- You can still get medical care at UAMS and Arkansas Children's.
- If you decide to stop being in the study, call the study team at 501-364-3309.

### **Will it cost me anything to be in the study?**

The study will not cost you anything. You or your insurance company will be responsible for the costs of your regular medical care, as usual.

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### **Will I be paid for being in the study?**

Yes. We will give you \$25 for a complete first visit. If done virtually, this will be provided when you stop by the ACNC to pick up your child's food supplies, or at your in-person visit. We will give you \$50 for each complete in-person visit(s). You will be paid in check or gift card(s). If we need to reschedule your visit, then we will only pay you once you complete the study visit.

If you change your mind and decide not to be in the study, you will only be paid for the parts you completed. In this case, we will give you \$25 if part of the visit is completed. If we ask you to come back for a repeat visit, we will give you an additional \$25 for the repeat visit.

If you get more than \$600 in one year (January-December) from Arkansas Children's, we may send you a tax form if the law requires it.

### **Will being in this study help me in any way?**

We do not think that being in this study will help you personally. But it may help people in the future. What we learn may help in the following ways:

- We may learn more about how children use nutrients while they rest and while they exercise.

### **What are the risks of being in this study?**

The risk of joining this study are:

- The risks for this study are no more than what happens in everyday life.
- Someone could find out that your child participated in the study and learn something about him/her that you did not want others to know. We will do our best to protect you and your child's privacy.
- Your child may find some of the study procedures embarrassing.
- There is a possibility for your child to feel sick or dizzy due to fasting.
- During the exercise tests, your child may experience some discomfort associated with exercise. This is normal. However, if he/she feels she cannot continue we will stop the test at his/her request.
- After the exercise tests, your child may have sore muscles associated with the exercise performed. This is also normal. However, if soreness persists please contact Dr. Borsheim at 501-364-3053.

### **What are the alternatives to being in this study?**

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You do not have to be in this study. There are no alternatives to being in this study because it does not involve any treatment or other procedures that may help you.

### **Can I be taken out of the study even if I want to continue?**

Yes, the study doctor (or head researcher) can take you out of the study if:

- You do not follow study instructions.
- It is not in your best interest to continue.
- The study is stopped for any reason.
- We realize you no longer qualify.

### **What information will be collected about me in the study?**

During the study, we will need to learn private things about you, including:

- General contact and background information about you/your child, such as name, address, telephone number, and email address. We will also collect your child's date of birth, height, weight, and other demographic information.
- Medical information about your child, such as medical history, metabolism, diet, physical activity, and fitness.
- If you agree, we will ask your child to provide a urine sample during study visit(s).
- We and other collaborating researchers may use the information we collect from your child for future research. However, we currently have no specific plans to do so.

### **Who will see this information? How will you keep it private?**

- The local study team will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows you are part of the study.
- We will take your name off information and study samples that we collect from you during the study. We will give your information and study samples a code, so that no one can identify you.
- When we share the results of the study in presentations, poster, and publications, we will not include your name or anything else that could identify you.
- There are people who make sure the study is run the right way. These people may see information that identifies you. They are

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- ✓ United States Department of Agriculture (USDA)
- ✓ Arkansas Children's Research Institute (ACRI)
- ✓ Arkansas Children's Nutrition Center (ACNC)
- ✓ OHRP (Office for Human Research Protections), a federal agency
- ✓ UAMS Institutional Review Board
- ✓ Other institutional oversight offices
- State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else.

**Where will my information and samples be kept? For how long will it be kept?**

- Once we give your information and study samples a code, we will keep the key to this code in a secure server.
- Only the researchers and other trained research staff will be able to link it to you.
- We will not put information about you from the study in your medical record.
- After we measure health markers called ketone bodies in the urine samples we collect from you during your study visits, we will then discard these samples.
- We may keep your information indefinitely (no time limit). Only the researchers and other trained research staff will have access to the code key, which will not be destroyed while information is kept.

**If I stop being in the study, what will happen to my information and samples collected in the study?**

- If you wish to have your information taken out of the study, call Dr. Elisabet Borsheim at 501-364-3053.

**Will my information or samples from the study be used for anything else, including future research?**

Yes, being in this study may qualify your child for future follow-up studies by the same study team. We will discard the samples we collect from you during this study. However, we may use your information for future research.

- The type of future research will be metabolism, nutrition, exercise, health, or development.
- Your information may be stored on secure database and/or servers, and/or locked spaces.

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- Your information may be shared with researchers who work at the University of Arkansas for Medical Sciences, Arkansas Children's Hospital, Arkansas Children's Nutrition Center, and Arkansas Children's Research Institute.
- Your information will be labeled with a code during storage and future use.
- Your information may also be shared with other researchers, who are not part of this study. These other researchers may be from outside our institution. Those researchers will not seek your consent at that time.
- You may choose to withdraw permission for future use of information at any time you decide. Please contact Dr. Borsheim to let her know. If the information has been shared, or if publication of results has occurred, then we may not be able to remove information.

### **Will you tell me the results of the study?**

Yes, but only upon your request. If you wish to have your individual results, they will be provided once the study is completed.

### **Will you tell me anything you learn that may affect my health?**

Yes. If we learn something about you that might be important for your health, we will tell you.

### **What if new information comes up about the study?**

We will tell you if we learn anything that may change your mind about being in the study.

### **Where can I find more information about this clinical trial?**

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 this website any time.

### **What if I have questions?**

- Please call the head researcher of the study – Dr. Elisabet Borsheim 501-364-3053 – if you
  - ✓ have any questions about this study
  - ✓ feel you have been injured in any way by being in this study

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- You can also call the office at UAMS that supervises research if you have questions about your rights as a research participant or cannot reach the study team or want to speak to someone not directly involved with this study. To do so, call the UAMS Institutional Review Board at 501-686-5667 during normal work hours.

## **HIPAA Research Authorization**

- The word “you” means both the person who takes part in the research, and the person who gives permission to be in the research.
- We are asking you to take part in the research described in this consent form. To do this research, we need to collect health information that identifies you. We may collect the following information: name, address, phone number, email address, date of birth, height and weight, lab tests, and exercise testing, rest testing, physical activity and diet data. Being in this research study will create new health information about your health and your metabolism. This information will be used for the purpose to see how children of different body types and fitness levels use nutrients that are stored in their body while they rest, and while they exercise. We will only collect information that is needed for the research. For you to be included in this research, we need your permission to collect, create and share this information.
- We will, or may, share your health information with people at the University of Arkansas for Medical Sciences (UAMS), Arkansas Children's (AC), and Arkansas Children's Nutrition Center (ACNC), or United States Department of Agriculture (USDA) who help with the research or things related to the research process, such as the study staff, the UAMS Institutional Review Board and the research compliance office at UAMS and AC 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 of your health information. However, some of the people outside of UAMS/AC may share your health information with someone else. If they do, the same laws that UAMS/AC must obey may not apply to others to protect your health information.
- This authorization to collect, use and share your health information does not expire.
- 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. You need to sign this form if you want to 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, 15 Children's Way, Little Rock, AR 72202. 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. However, in order to maintain the reliability of the research, we may still use and share your information that was collected before the

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Principal Investigator 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 or benefits at UAMS or AC.

**By signing the document, I am saying:**

- I agree to be in the study.
- I know that joining this study is voluntary.
- Someone has talked with me about the information in this form and answered all of my questions.

**I know that:**

- I can stop being in the study at any time and nothing bad will happen to me.
- I can still get medical care at UAMS or Arkansas Children's no matter what I decide.
- I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- I do not give up any of my legal rights by signing this form.

**I agree to be part of this study:**

Child's Name: \_\_\_\_\_

\_\_\_\_\_  
Your name (please print)

\_\_\_\_\_  
Your signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship to Participant

\_\_\_\_\_  
Printed name (person obtaining consent)

\_\_\_\_\_  
Signature (person obtaining consent)

\_\_\_\_\_  
Date

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**My information collected in this study may be used in future research related to metabolism, nutrition, exercise, health, or development.  YES  NO**

**I agree to be contacted for future research related to studies of metabolism, nutrition, exercise, health, or development.  YES  NO**

Your name (please print) \_\_\_\_\_

Your signature \_\_\_\_\_