Informed Consent Form and Authorization to Share Personal Health Information for Research

STUDY TITLE: Bioenergetics and Metabolism in Pediatric Populations

PROTOCOL NO.: UAMS Protocol #206164

STUDY SPONSOR: ABI Discovery Acceleration Initiative and NIH Grants

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STUDY SITE: Arkansas Children's
1 Children's Way
Little Rock, AR 72202

STUDY-RELATED PHONE NUMBERS: Dr. Eugenia Carvalho
Office Hours (8 am-5 pm): (501) 364-3057

Dr. Shannon Rose
Office Hours (8 am-5 pm): (501) 364-4083

- **In this form, the word "you" refers to you or your child.**
- **We are asking your child to be in a research study.**
- **Your child does not have to be in the study.**
- **If you say yes, your child can quit the study at any time.**
- **Please take as much time as you need to make your choice.**
- **You can still get your medical care from Arkansas Children's.**
- **During the study, we will tell you if we learn any new information that might affect whether you wish for your child to continue to be in the study.**

Why is my child being asked to be in this research study?

We want to learn more about obesity, the development of insulin resistance, and Type 2 Diabetes in children. Insulin is made in your body. Insulin allows your body to use the sugar that you eat for either energy or storage for later use. Insulin helps your body maintain a normal amount of blood sugar. When the body does not produce enough insulin or doesn't respond well to insulin, the result is high blood sugar. Insulin resistance occurs when the body does not respond properly to insulin, causing the body to not absorb sugar. As a result, the body has to produce more insulin to pick up sugar in the body. Insulin resistance leads to Type 2 Diabetes. Over time, high blood sugar can cause Type 2 Diabetes. Having Type 2 Diabetes increases a person's risk for heart problems, nerve damage (tingling, numbness, burning, or pain starting in toes and fingers), kidney problems, eye damage, and other health problems. We want to learn more about the body's process of developing insulin resistance and Type 2 Diabetes.

We are looking for children who are healthy and of a normal weight, healthy and obese, obese with insulin resistance, or obese with Type 2 Diabetes or insulin resistance and prescribed metformin therapy at your normally scheduled doctor visit after enrollment to be part of a research study. We are looking for up to 175 children who are 5-9 years old or 5-17 years old with Type 2 Diabetes/insulin resistance to be part of this study. We will ask you some questions about your child's health and possibly review medical records to see if your child qualifies for the study.

What if I say yes, I want my child to be in this study?

Prior to the study visit, we will contact you and ask for any medications that the child is taking and ask about the child's health. The study visit will be rescheduled or canceled if the criteria to be in the study is not met. We may send you a copy of this form and information about the study visit before you come for the study visit. Also, kids who want to participate in the study visit will need to be fasting when they arrive for the visit meaning no food or liquid after 12 am, except for water and medications the day of the visit.

If you say yes, we will have you and your child come for a study visit and will ask you some questions about your child's date of birth, gender, race and ethnicity, grade in school, parent's occupation, health, medicines he/she takes, and allergies. We will have you complete a form showing how close your child is to puberty and may have a doctor come to examine your child. We will ask you or your child some questions about his/her exercise. We will have you help your child complete a form about the way your child might have felt or acted in the past week. We will ask you to fill out a form that asks about the food and drink that your child eats and drinks the day of and day following the visit. We will measure your child's weight, height, around your child's stomach, heart rate, and blood pressure.

We will ask if we can collect some spit from your child (less than a teaspoon) and if we can gently swab the inside of your child's cheek. This is optional. This sample will be used for future research studies involving pediatric nutrition.

We will collect some information on how much fat, muscle, and water is in your child's body. We will have your child stand on a device (Tanita Body Composition Analyzer) for about a minute. This device will not cause any pain to your child.

Also, we may collect some data while your child breathes normally into a device. We will look at how much air your child breathes in and out. We will give your child a clip to put on his/her nose and a mask to breathe into. We will have your child normally breathe into the mask. This can take as little as 10 minutes or can take longer depending on the child.

Depending on your child's weight, we will collect about 2-6 tablespoons (up to 100 ml) of blood from your child and do some tests on the blood. The tests done on your child's blood are experimental and the results of these tests will not affect your child's current health treatment. If you agree to let us use any extra blood leftover after these tests, we will store and use the leftover blood for future research studies involving pediatric nutrition.

We will have your child drink and/or eat food mixed with a marker (deuterated palmitate) in order for us to measure how the body processes fat to produce energy. Deuterated palmitate is not dangerous; it is non-toxic and not radioactive. It contains a special type (isotope) of hydrogen that is already naturally occurring in the body, but it is a little heavier than the type that is most abundant. The drink will merely raise the level of what is already there. This drink has been used in several studies. Before your child drinks or eats this, we will collect urine from your child. We will also collect urine from your child at about 2 hours, 6 hours after drinking this, and in the morning following the visit. This urine sample will be used to look at how your child's body processes fat. The urine collection will be collected at home or at another location after you leave the study visit, if you decide you do not want to stay at the research location during the entire study visit. If you decide to collect the urine sample at a location other than the research location, a specimen cup to collect the urine will be given to you and you will be instructed to collect the specimen and place it on ice or place it in the refrigerator immediately. The sample should be stored in a refrigerator until you are able to return it to study staff. If you agree to let us use any extra urine leftover after testing, we will store the urine and use it for future research studies involving pediatric nutrition.

If you agree, we will collect stool (poop) from your child. This is optional. Stool will either be collected during the study visit or at another location after the study visit (i.e. home). If you agree to collect stool, collection supplies will be given to you and you will be instructed on collecting the sample which should be stored in your freezer until you are able to return it to study staff. If you agree, leftover stool after testing for this study will be used for future research studies involving pediatric nutrition.

If any study task(s), such as the blood draw or urine sample collection, is not successfully completed, you may be asked to return and attempt the task again. If you agree to return, a return visit will be scheduled and you will return to the research location and complete the task or tasks from the previous visit that were not successfully completed.

The results from the forms you fill out or tests we perform in the lab will be entered into a database. For this study, all of the procedures described above are considered experimental. If your child is prescribed metformin therapy (a treatment for Type 2 Diabetes/insulin resistance),

this will occur at his/her regularly scheduled doctor appointment. The only study procedures that are optional for this study are the collection of spit and cheek swabs and collection of stool.

What if I don't understand something?

This form may have words you don't understand. You can ask as many questions as you like before you decide whether you want your child to be in this study. You are free to ask questions at any time before, during, or after your child is in the study.

How long will this study take?

The study visit will take up to 4 hours. This is a one-time visit for those who are healthy with a normal weight and also for healthy obese children. If your child is obese with insulin resistance, we may ask your child to participate in 2 visits—the initial visit and a second visit about 12 months after the first visit. We may ask your child to participate in 2 visits if your child has Type 2 Diabetes or insulin resistance and is prescribed metformin therapy at your child's normally scheduled doctor visit. The first visit is the initial visit and the second visit would occur at about 6 months after the first visit. Each study visit will have the same procedures. Also, if a study task is not successfully completed at the study visit, you may return to attempt the task/tasks again. This return visit would take less than 4 hours. If you decide to let us use your child's samples for future research studies, we may use your samples until they are used up.

What if I say no, I do not want my child to be in the study?

Nothing will happen. Your child can still get medical care at Arkansas Children's.

What other choices do I have if I do not want my child to participate?

The alternative is not to participate.

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

Your participation in this study is voluntary. It is up to you if you want your child to participate in this study. Your child can stop being in the study at any time without any penalty and you will still get all of the services you have the right to receive and you will not lose any benefits which you should receive.

If you decide to take part in this research study you may change your mind at any time in the future. If you decide to stop being in the study, call Dr. Carvalho at (501) 364-3057 (office hours 8am- 5pm).

If you quit, we will keep the samples (urine, stool, spit, cheek swab, blood) that we have already collected from your child and will still use the samples for experiments. We will not collect any more information from your child. If you withdraw your permission, we will not perform any additional study procedures and/or tests and your child will be released from our study center.

We may still review study data collected prior to you withdrawing. We cannot take your child's information out of studies that have already started.

Can my child be taken out of the study even if I want him/her to continue?

Yes, Dr. Carvalho can take your child out of the study if:

- Your child does not follow study instructions.
- It is not in your best interest to continue.
- The study is stopped for any reason.

Who will see the information about my child that is collected?

The only people allowed to see your child's information are the people who work on the study, people who pay for the study (study sponsor), and people who make sure our study is run the right way. They are the people at Arkansas Children's Hospital who help with the research or things related to the research process, such as the study staff, the people who fund the Arkansas Biosciences Institute (ABI) Discovery Acceleration Initiative, people who fund the National Institutes of Health (NIH) Grants, and the research compliance office at Arkansas Children's Research Institute, the Office for Human Research Protection (OHRP), Food and Drug Administration (FDA), University of Arkansas for Medical Sciences (UAMS) Institutional Review Board (IRB) and other institutional oversight offices, and other parties as required by law. In addition, the questionnaire that is completed asking about how your child felt or acted in the past week may be shared with your child's physician if the results indicate a need for assessment by his/her doctor. If your child does not have a regular doctor that he/she is seen by, then we will contact a doctor near your home for follow-up and will share the results from the questionnaire. The information we collect and a copy of this form will be locked in our files. We may put a copy of this consent form in your medical records.

State law requires we tell the authorities if we learn about possible child or adult abuse. Also, we must tell the authorities that you might hurt yourself or someone else.

When we share the results of the study at a professional meeting and/or publish the results in medical journals we will not include anything that directly identifies your child. We will do our best to make sure no one outside the study knows your child is part of the study.

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.

Will it cost me anything to be in the study?

The study will not cost you anything. You or your insurance company will not be charged for any procedure or test that is related to the study. You (or your insurance company) will only be responsible for payment of costs associated with standard medical care that your child receives, which is separate from the study.

Will my child be paid?

Yes. We will give you a total of $100.00 in gift cards after completion of each study visit. We will give you $50.00 in gift cards after we complete the tasks done at the study location: body measurements, questionnaires, blood draw, breathing activity, first urine sample, and the child drinks or eats the deuterated palmitate (marker). You will receive the other $50.00 in gift cards after the completion of each study visit and all samples are obtained. If samples are collected at another location (ex: home), then the participant will receive this $50.00 in gift cards once the samples are returned to the study staff. The study participant will receive $100.00 in gift cards for each additional study visit completed. This is to thank the study participant for your time. If you change your mind and decide not to be in the study, your child will only be paid for the parts he/she completes.

If you are asked to return to complete a study task(s) that was not successfully completed at a study visit. You will be compensated $25.00 in gift cards for returning to the study location and attempting the study task(s) again.

Will being in this study help my child in any way?

Your child will not receive any direct benefit from participating in the study. However, the information we collect will help us learn more about how obesity, Type 2 Diabetes, and how insulin resistance develops in children.

What are the risks of being in this study?

The questions could make you sad or upset. Also, someone could find out that your child was in the study and learn something about your child that you did not want others to know.

There is a small risk that an unauthorized person could find out which sample is your child's. We have procedures in place to keep your child's data private. The information we collect and a copy of this form will be locked in our files. The samples that we collect (urine, blood, stool, cheek swab, and saliva) will be in a freezer for long-term storage in the study doctor's laboratory. We will assign your child's name to a number and use that number on forms and samples. The key that assigns your name to a number will be kept secure. Only this number and the study acronym will be on the samples that we collect.

There is a risk that your child will experience mild pain, or a bruise, or soreness when we get blood. We may put some cream on where we get the blood to numb the area or may use a device to help lessen the pain while we get the blood. Rarely, swelling or infection may occur. A trained phlebotomist or nurse will take the blood using proper techniques to try to prevent this from occurring. If a bad effect occurs from drawing blood, we have doctors and nurses that will respond immediately.

Some of the future research projects could involve identifying your child's DNA and other parts of your child's blood, which could identify your child. DNA carries instructions for building and maintaining our bodies. It determines the color of our eyes and hair, our height, and personal features. Everyone's DNA is unique to them, so the government has a special law called the Genetic Information Nondiscrimination Act (GINA) which protects your child if his/her

information becomes known. GINA generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or an individual's family members. These health insurers or health plan providers are also prohibited from using such information for decisions regarding coverage, rates, or preexisting conditions. GINA also prohibits employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. Furthermore, the researchers have adopted strict privacy and confidentiality procedures for maintaining your child's genetic information as described in this consent form. You should be aware, though, that if your child's genetic information were accidentally released to the wrong source, federal law does not protect against genetic discrimination by companies that sell life insurance, disability insurance, long-term care insurance, or by adoption agencies.

If you feel you have been injured by this research, let the Principal Investigator know right away by calling Dr. Carvalho (office hours 8am-5 pm: 501-364-3057).

What if new information comes up about the study?

The researcher will let you know about anything that may change your mind about being in the study.

What if I have questions?

We encourage you to ask any/all questions and to express your concerns or complaints as they relate to this study. You may contact Dr. Rose (office hours 8am- 5pm: 501-364-4083) or Dr. Carvalho (office hours 8am-5 pm: 501-364-3057) with any questions or concerns you have about participating in this study. You may also direct your questions or express your concerns to the professionals who are helping Dr. Carvalho conduct this research study.

If you have questions concerning the protection of your child's information and/or his/her rights as a participant in this study or if you have questions, concerns, or complaints about the research, we urge you to contact the representative of the UAMS IRB at:

Institutional Review Board
University of Arkansas for Medical Sciences
4301 W. Markham St., Slot 636
Little Rock, AR 72205
Telephone: 501-686-5667
E-mail: IRB@uams.edu

The UAMS IRB is a group of people who perform independent review of research. The UAMS IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact the UAMS IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

What should I do if I want my child to be in the study?

Read the form completely. Talk to your child and decide if he/she can participate in the whole study.

Authorization to Share Personal Health Information in Research

To do this research, we need to collect health information that identifies you. We may collect information from your Arkansas Children's Hospital medical record or from other healthcare providers including information concerning medical history, date of birth, sex, weight, height, blood pressure, heart rate, measurement around stomach, race, grade in school, ethnicity, parental occupations, and allergies. This information will be used to for this research study to learn more about and determine if there is a difference in samples between individuals who are of a healthy weight, obese, obese and have insulin resistance, and obese with type 2 diabetes/insulin resistance and just started metformin therapy as prescribed by a doctor at regularly scheduled visits. We will only collect information that is needed for the research. Participating in this research will create the following new health information about your child: The results of the tests we do on the samples we collect and the other study procedures. For you to be in this research, we need your permission to collect, create and share this information.

We will, or may, share your child's health information with people at Arkansas Children's Hospital who help with the research or things related to the research process, such as the study staff, and the research compliance office at Arkansas Children's Research Institute. We may need to share your child's health information with the people who fund the ABI Discovery Acceleration Initiative and people who fund the NIH Grants. We may need to share your child's health information from the questionnaire asking about how your child felt or acted in the past week with your child's physician or with a physician referred to for follow-up if it is determined that the results require assessment by a physician. Also we may need to share your child's health information with people outside of Arkansas Children's Hospital who make sure we do the research properly such as, the Office for Human Research Protection, the Food and Drug Administration, and other parties as required by law. Some of these people may share your child's health information with someone else. If they do, the same laws that Arkansas Children's Hospital must obey may not apply; therefore, information may be re-disclosed by the recipient and is no longer protected under the Health Insurance Portability and Accountability Act (HIPAA).

This authorization does not expire. If you sign this form, we will create, collect, use, and share your child's health information forever. It is possible that we may collect some information from your child's medical records even after his/her direct participation in the research project ends up until the time that data analysis for this study is complete and results have been published. The information collected from your child's medical records even after his/her direct participation includes the same information that will be collected for the study. This information may be used to confirm the study results or data.

If you sign this form, you are giving us permission to create, collect, use and share your child's health information as described in this form. You do not have to sign this form. However, if you decide not to sign this form, your child cannot be in the research study. He/she can only participate in the study if you sign this form.

If you sign this form but decide later that you no longer want us to collect or share your child's health information, you must send a letter to the person and the address listed by "Principal Investigator" on the first page of this form. The letter needs to be signed by you. It 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". If the HIPAA authorization is revoked, your child will no longer be a part of the research study and we cannot collect or share any more health

information from the revocation date forward. However, in order to maintain the reliability of the research, we may still use and share your child's information that was collected before the 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 child's current or future medical care at Arkansas Children's Hospital.

Consent for Future Research

We would like to do some future research studies on pediatric nutrition with your child's samples and information that we collect during the study visit. The samples and information collected from the visit will be stored at Arkansas Children's Research Institute or may be shared with researchers who work at the University of Arkansas for Medical Sciences, Arkansas Children's Hospital, or Arkansas Children's Research Institute. The samples may be shared with a different group. We do not know who these other groups might be yet. If shared, Dr. Carvalho will make sure the study using the samples has procedures in place to protect your child's sample. The samples and information collected during the visit may be stored forever and tested on until used up. The samples and information collected during the study visit will only have your child's study number on it and the study acronym. If you decide you no longer want us to use your child's sample or information for future research studies, you may ask the study staff that the sample or information be removed. If the sample or information has been shared or if publication of results has occurred, then we may not be able to remove the sample. You can choose to agree to have leftover samples from this study be used for future research studies or not. This is optional. Your child can still take part in this study if you do not agree to have the optional studies done.

Please read the choices below and initial the option that reflects your decision.

_____(initials) My child's data and samples may be used for this study only.

_____ (initials) My child's data and samples may be used for this study and for other future research studies on pediatric nutrition.

Recontact for Future Research Studies

Future researchers may want to know more about your child or invite your child to participate in their studies. Would it be okay for them to contact you? Your child would not be required to participate in their projects.

Please read the choices below and initial the option that reflects your decision.

_____ **Yes**, I would like to be contacted regarding potential future research study participation.

_____ **No**, I do not want to be contacted regarding potential future research study participation.

SIGNATURE, DATE, AND IDENTITY OF PERSON SIGNING

Consent Instructions:

Consent: For subjects under 18, consent is provided by the parent. We do not plan to reconsent your child when they turn 18 to allow for the continued use of any samples that may remain. However, your child can contact us after they turn 18 to ask that any remaining samples be removed.

CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent for my child to be in this research study. *I have been told that I will be given a copy of this consent form.*

I authorize the release of my child's medical and research records for the purpose of this study. By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name (printed)

_____ _____
Signature of Parent Date

_____
Relationship to participant

_____ _____
Printed Name of Person Conducting the Informed Consent Discussion Position

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date

ASSENT SECTION:

Statement of person conducting assent discussion:

- I have explained all aspects of the research to the subject to the best of his or her ability to understand.
- I have answered all the questions of the subject relating to this research.
- The subject agrees to be in the research.
- I believe the subject's decision to enroll is voluntary.
- The study Principal Investigator and study staff agree to respect the subject's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Signature of Subjects ages 7-17:

- This research study has been explained to me and I agree to be in this study.
- No one will be mad at me if I say no or change my mind later.

_____	_____	_____
Subject's Signature for Assent	Date	Age (years)