Informed Consent Form

STUDY TITLE:	Immunometabolism in Pediatric Obesity
PROTOCOL NO.:	UAMS Protocol #228816
STUDY SPONSOR:	NIH Grants
PRINCIPAL INVESTIGATOR:	Shannon Rose, PhD, 13 Children's Way, Slot 512-41B Little Rock, AR 72202
STUDY SITE:	Arkansas Children's 1 Children's Way Little Rock, AR 72202
STUDY-RELATED PHONE NUMBERS:	Dr. Shannon Rose Office Hours (8am-5pm): (501) 364-4083

- **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.**
- **Your child can still get medical care from Arkansas Children's even if you are not in the study.**
- **During the study, we will tell you if we learn any new information that might affect whether your child wishes to stay in the study.**

Study Summary

This is a study to learn about obesity and how insulin resistance and Type 2 Diabetes develops in children.

Those who are not taking/planning to begin Metformin will complete 1 study visit. Those who are taking/planning to begin Metformin therapy will be asked to complete 2 study visits. The study visit will last up to 2 ½ hours and will involve questions about your child's health and medications, questionnaires about your child's development, exercise habits, and how your child has felt or acted in the past week, measurement of your child's height, weight, around your child's stomach and hips, heart rate, blood pressure, how much fat, muscle, and water is in your child's body, and a blood draw. We will also review your child's medical records.

There is a risk of mild pain, a bruise, soreness, and rarely swelling or infection from the blood draw.

If you are interested in learning more about this study, please continue to read below.

Why are you 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.
- This study will help us learn more about how insulin resistance and Type 2 Diabetes develops. We will consider the role of the immune system and other body processes in the development of insulin resistance and Type 2 Diabetes.
- We are asking children like you who are healthy and of a normal weight, healthy and overweight or obese, overweight or obese with insulin resistance, or overweight or obese with insulin resistance or Type 2 Diabetes and prescribed Metformin therapy at your normally scheduled doctor visit after enrollment to help us. 80 children 5-17 years old will be part of this study.

What if I don't understand something?

- This form may have words you don't understand. Research staff will read it with you, if you like.
- You may ask as many questions as you like before you decide whether you want to be in this study.
- You are free to ask questions at any time before, during, or after you are in the study.

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

We first will see if you qualify to be in the study. We will …

- Ask you some questions about your child's date of birth, gender, and race and ethnicity
- Ask you some questions about your child's health
- Ask you some questions about what medicines your child takes

If you qualify, we will schedule a visit and do these things:

- Ask about your child's grade in school, health, medicines, allergies, and parent's occupation.

- Give you forms with questions about your child's development, exercise habits, and how your child may have felt or acted in the past week.
    - ✓ We will read the questions out loud and fill out the form with you, if you like.
- Measure your child's weight, height, around your child's stomach and hips, as well as their heart rate, and blood pressure
- 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.
- Collect about 2-6 tablespoons (up to 100 ml) of blood from a vein in your child's arm or hand and do some tests on the blood. The amount collected depends on your child's weight. 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 or metabolism.
- If you agree, we will collect stool (poop) and urine from your child. This is optional. These can be collected during the study visit or at another location after the study visit (i.e., home). If you agree to collect stool and/or urine, collection supplies will be given to you and you will be instructed on collecting the sample which should be stored in your refrigerator (urine) or freezer (stool) until you are able to return it to study staff. If you agree urine and stool will be used for future research studies involving pediatric nutrition or metabolism.

If one of these tasks are not able to be completed at the visit, we may ask you to return to attempt the task(s) 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.

If your child has insulin resistance or Type 2 Diabetes and was prescribed Metformin therapy at your normally scheduled doctor visit we will ask you to return for a second visit about 6 months after your child began the Metformin therapy. At this second visit we will…

- Ask you to repeat all of the tasks you were asked to complete at the first visit
- Ask you to bring your child's Metformin medication and bottle to the visit (this will be returned to you at the end of the visit)
- Ask you to tell us how often your child has been taking their Metformin.

If your child was not prescribed Metformin therapy or did not begin taking Metformin therapy as prescribed, you will not be asked to return for a second visit.

In addition to the tasks which will be completed at the visit, we will review your child's medical records for additional information on your child's health and medicines your child takes or has taken.

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 being done for the study only and are not part of your child's regular care. 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 urine and collection of stool.

After you complete the visit(s) we will provide you with a summary of your child's body measurements (height, weight, around your child's stomach and hips), heart rate, blood pressure, how much fat and water is in your child's body, resting metabolism, and the result of the screening for depression. If your child show signs of being at risk of depression, we will provide you with a list of resources to seek help for depression in children. If you have concerns about these results, we will refer you to your child's regular doctor.

The tests on the blood sample will be done for research only; we do not plan on telling you any of these results, because we don't expect them to tell us anything about your child's health. However, if we notice something that might need follow-up, we will let you know and refer you to your child's regular doctor. If your child does not have a regular doctor, we can help you find one.

How long will this study take?

The study visit will take up to 2 ½ hours. The length of the visit may depend on the conversation about the consent, and your child's blood draw. This is a one-time visit for children who are not prescribed Metformin therapy or do not begin taking Metformin therapy as prescribed. For children, who are prescribed Metformin therapy and begin taking Metformin therapy as prescribed, we will ask you to complete 2 visits, the first visit and a second visit about 6 months after the first visit. Also, if a study task is not successfully completed at the study visit, you may return to attempt the task(s) again. The return visit will take less than 2 ½ hours. We will continue to collect information from your child's medical records even after his/her visits have been completed up until the time the study is complete and results have been published. We hope to finish study visits for all children in 2 years; however, testing samples, reviewing the information collected, and publishing results may continue forever. If you decide to let us use your child's samples (leftover blood, urine, or stool) for future research studies, we may use your samples until they are used up.

Who will see the information about me that is collected?

- We will do our best to make sure no one outside of Arkansas Children's and those listed below know you are part of the study.
- The local study team will know your name and have access to your information.
- We will take your name off of study specific information and study samples that we collect from you during the study. Your name will remain on this consent form and contact information forms, and these will be locked up.
- When we share the results of the study at a professional meeting and/or publish the results in medical journals, we will not include your child's name or anything that might directly identify your child (e.g., date of birth, contact information).
- There are people who make sure the study is run the right way. These people may see information from the study about you. They are
  - ✓ The study sponsor: the NIH (National Institutes of Health), a federal agency
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ UAMS Institutional Review Board
  - ✓ Other institutional oversight offices
- State law requires we tell the authorities if we learn
  - ✓ about possible child or adult abuse
  - ✓ that you might hurt yourself or someone else

Where and how long will my information and samples be kept?

- We will code your information and study samples and keep the code in a locked file.
- Only the head investigator and study staff will have access to the code for your information.
- We will put information about you from the study in your medical record. It will indicate your participation in the study and when you complete a visit. A copy of this consent form will be scanned into your medical records.
- You child's paper information will be kept in a secure space at Arkansas Children's or secure offsite storage facility. Your child's electronic information will be maintained on secure servers maintained by Arkansas Children's or UAMS. If information is shared with a different group for future research purposes (see below), your child's name, date of birth, and other identifying information will be removed. We will store your child's information until the time the study is complete and results have been published. Reviewing the information collected, and publishing results may continue forever.

Your child's sample will be kept in a secure space at Arkansas Children's. If the sample is shared with a different group for future research purposes, they will not know your child's name, date of birth, or other identifying information. We will store your child's samples until used up or until the time the study is complete and results have been published. Reviewing the information collected, and publishing results may continue forever.

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

- Nothing bad will happen.
- You can still get medical care at 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.
- You can still get medical care at Arkansas Children's.
- If you decide to stop being in the study, call Shannon Rose, Ph.D. at (501) 364-4083.

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.

If I stop being in the study, what will happen to any information or samples collected from me in the study?

- We will keep the samples (blood, urine, and stool) that we have already collected from your child and will still use the samples for experiments.
- We will keep the information that we have already collected from your child.
- We will not collect any more information from your child.
- We may still review study information collected prior to you withdrawing.

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

Yes, if you agree.

- We would like to do some future research studies on pediatric nutrition or metabolism 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.
- The samples and information collected during the visit may be stored forever and tested on until used up.
- If shared, Dr. Rose 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 study visit will only have your child's study number, visit number, and the study acronym on it.
- 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 used for this study only and not used for future research studies.
    - We will keep the blood sample and information collected for this study; however it will only be used for this study and will not be used for future studies.
    - We will remove samples collected for future research purposes only (urine and stool).
    - 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 or information.
- 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 future studies done.
- In addition to using the information and samples we collect for this study, future researchers may want to know more about your child or invite your child to participate in their studies. If you agree, they or we will contact you. Your child would not be required to participate in their projects, you can decide after learning about the future research.

There will be a place at the end of this form for you to say whether

- **You agree to be contacted for future research related to this study.**
- **You agree that your information and samples collected in this study may be used in future research.**

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 your regular medical care as usual.

Will I be paid?

Yes. We will give you a total of $50.00 in gift cards after completion of each study visit. You will receive the gift card(s) after we complete the tasks to be done at the study location: body measurements, questionnaires, and blood draw. This is to thank you for your time. If you change your mind and decide not to be in the study, your child will only be paid for the visit(s) he/she completes. If you child is asked to complete 2 visits, you will be given a total of $100 for completing both visits ($50 for the first and $50 for the second visit).

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.

If you receive more than $600 in one year (January-December) from Arkansas Children's we may send you a tax form if required by law.

Will being in this study help me in any way?

Being in the study may or may not help you, but may help children with obesity, insulin resistance or Type 2 Diabetes in the future.

What are the risks of being in this study?

The risks are:

- Someone could find out that you were in the study and learn something about you that you did not want others to know. We will do our best to protect your privacy.
- The questions could make you sad or upset.

- The blood draw may cause your child to experience mild pain, or a bruise or soreness. We may put some cream or spay on where we will get the blood to numb the area or we may use a vibrating device to lessen the pain while we get the blood.
- With the blood draw, 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 head researcher know right away by calling Shannon Rose, Ph.D. (office hours 8am-5 pm: 501-364-4083).

What if I get sick or hurt while I'm in this study*?*

- If you get sick or hurt when you are here for the study, we will help you get the care you need. This may include first aid, emergency care 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 payment is available.
- If you feel you have been injured by this research, let the head researcher know right away by calling Shannon Rose, Ph.D. (office hours 8am-5 pm: 501-364-4083).

What are the alternatives to being in this study?

- You do not have to be in this study.
- There are no other alternatives to being in this study.

What if new information comes up about the study?

- We want you to know about anything that may change your mind about being in the study.
- The researcher will let you know by
  - ✓ calling you,
  - ✓ sending you a letter, or
  - ✓ telling you at a follow up visit

Where can I find more information about this study?

A description of this study will be available on http://www.ClinicalTrials.gov. 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, Shannon Rose, Ph.D. at 501-364-4083, if you
  - ✓ have any questions about this study
  - ✓ have questions about your rights
  - ✓ feel you have been injured in any way by being in this study
- You can also call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if you
  - ✓ have questions about this study
  - ✓ have questions about your rights
  - ✓ can't reach the study team
  - ✓ need to speak to someone not directly involved with this study

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

Sign this form. We will give you a copy of this form to keep.

By signing the document I am saying:

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

I know that:

- I can stop any and all parts of the study at any time and nothing bad will happen to me.
- 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.
- My decision will not change my medical care at UAMS.
- I do not give up any of my rights by signing this form.

I agree to being contacted for future nutrition or metabolism research related to this study.

___ YES ___ NO

My samples and information collected in this study may be used in future nutrition or metabolism research.

___ YES ___ NO

I agree to be part of this study:

_____	_____
Participant's name (please print)	Parent/Legal Guardian's name (please print)
_____	_____
Signature of Parent/Legal Guardian	Date
_____	_____
Name of person obtaining consent (please print)	Signature of person obtaining consent
_____	
Date	

ASSENT:

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 years:

- 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)