KEY INFORMATION FOR THE RESEARCH STUDY TITLED:
Maternal Obesity and Offspring Neurodevelopment: the MOON study

Principal Investigator:
Xiawei Ou, Ph.D.
Department of Radiology, Department of Pediatrics
1 Children's Way, Slot 105, Little Rock, AR 72202
Office Telephone: 501-364-4837
After Hours: 615-525-5353

Co-Investigators:
Aline Andres, PhD
Charles Glasier, MD
Jayne Bellando, PhD
Elisabet Borsheim, Ph.D

Study Location(s):
Arkansas Children's Hospital
1 Children's Way
Little Rock, AR 72202
Arkansas Children's Nutrition Center
1 Children's Way
Little Rock, AR 72202

We are asking you to choose whether or not to volunteer for a research study about relationships between mother's weight and other health status (such as whether there is inflammation) during pregnancy and baby's brain development in the first 2 years of life. This page gives you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

We are using advanced magnetic resonance imaging (MRI) methods to study whether babies' brain development are associated with mother's body mass index and systemic inflammation (if any) during pregnancy. MRI is a safe and a regularly used medical imaging method. It has no radiation. In order to tease out the potential relationships, we will also gather information regarding your health status during pregnancy, and your babies' growth/development and health status during infancy.

By doing this study, we hope to learn whether there is a relationship between mother's weight status during pregnancy and babies' brain development; whether systemic inflammation is a reason for the relationship (if any), and whether other health status and environmental factors also play a role in this relationship (if any). Your participation in this research will last about 2.5 years, which will include two study visits during pregnancy (at ~12 and ~36 weeks) and 3 study visits after your baby is born (at ~2 weeks, ~1 year, and ~2 years of age)

WHY MIGHT I CHOOSE TO VOLUNTEER FOR THIS STUDY?

The knowledge learned from this study can help us potentially promote brain development in all children. Your participation will help us better understand whether weight status and other health parameters during pregnancy are associated with babies' brain development. If there are such associations, the study results will also let us know whether things such as inflammation are the likely reason, and whether things such as certain diet and physical activity during pregnancy can help to resolve the potential effects. For a complete description of benefits, refer to the Full Consent.

WHY MIGHT I CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may find some study procedures uncomfortable, such as blood draw; and you may be not familiar with and have concerns about other procedures, such as MRI. For a complete description of risks, refer to the full Consent.

DO I HAVE TO TAKE PART IN THE STUDY?

No. It is okay to say no. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer. If you are a student/employee, nothing about academic or employment will change no matter what you decide.

WHAT IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

You can contact the person in charge of the study, Dr. Xiawei Ou, Associate Professor of Radiology and Pediatrics at UAMS with any questions, suggestions, or concerns at 501-364-4837 or ouxiawei@uams.edu.

If you have any questions, suggestions, or concerns about your rights as a volunteer in this study, or wish to speak to someone not directly involved in the research, you can call the UAMS Institutional Review Board at 501-686-5667 during business hours.

If you want to know more about the research, let the study team know so they can give you more information.

Also tell the study team if you have decided you don't want to be in the study. It is perfectly okay to say no.

Informed Consent and HIPAA Form

- **We are asking you to be in a research study. You do not have to join the study.**
- **You can still get your medical care from UAMS/ACH even if you are not in the study.**
- **Please 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 factors during pregnancy that may influence or promote baby's brain development.
- This study will help us learn more about whether there are relationships between mothers' weight/health status and other factors during pregnancy and babies' brain development during the first 2 years of life.
- We are asking people like you who are pregnant to help us.
- 260 pregnant women (age 18 years and older) and their children will be part of this study.

What if I don't understand something?

- 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 like before you decide whether you want to be in this study.

What will happen 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 questions about your health condition. If you qualify, we will schedule your study visits. At or before each visit, we will follow up with you and your child's health to be sure that you still meet the criteria to remain in the study. There will be five study visits in total:

1st research visit at Arkansas Children's Nutrition Center (ACNC) at ~12 weeks of pregnancy, we will:

- Ask you to complete a medical history questionnaire.
- Request your medical records from your OB/GYN to obtain detailed information on your pregnancy.
- Measure your weight, height, waist and hip circumferences. Measure your body composition (fat percentage) using a methodology called air displacement plethymography (ADP). For this procedure, you will sit in a pod-like chamber for approximately 4 minutes. You will be asked to remain still while the machine measures the amount of air displaced by your body. Blood pressure and pulse will also be collected using an automatic sphygmomanometer.

- Ask for your background information such as your and the baby's father's education, income, marital status, race, ethnicity, and age by having you complete a questionnaire.
- Measure your IQ (If IQ test is not obtained at the 1st visit, the test will be scheduled at the participants convenience before the 36 week visit.)
- Evaluate if there is anxiety and/or depression using questionnaire.
- Ask you to complete a web-based diet history questionnaire. This is an online questionnaire for you to complete at home at your own convenience.
- Ask you questions regarding your sleep pattern using a sleep questionnaire.
- Get a blood sample from you, to measure inflammation markers (such as cytokines and proteins involved in inflammation). Please do not eat or drink anything but water after midnight the night before your appointment. You may take any medications you need. A trained phlebotomist (someone who specializes in drawing blood) will tie a band around your arm to bring out your veins. He/she will stick you with a hollow needle which will collect up to 35 mL of blood (about 7 teaspoons).
- Get a stool sample from you to evaluate what bacteria are in your gut. Sample can be collected using the scoop from the collection tube provided. If we are unable to collect stool while you are at the clinic, we will provide you with a collection kit for you to collect at home and returned to the center before your next visit.
- Get a saliva sample from you to evaluate inflammation markers.
- Get a urine sample from you to evaluate glucose, metabolite (such as those related with drug/alcohol use) and hormones (such as estrogen).
- Get toenail samples from you to measure alcohol and substance exposure before pregnancy. About 100mg of toenails will be collected from each of your toes.. If we are unable to collect a sample while you are at the clinic, we will provide you with a collection kit for you to collect at home and return to the center before your next visit.
- Provide you a special watch called Actigraph and ask you to wear it on your wrist for 7 days and then mail back to us (a paid envelope will be provided) or bring back to us before your next visit. If the measurement is unsuccessful, you may be asked to repeat this assessment.
- Provide you with a stool collection kit for you to collect a 36wk sample to bring in to the next visit.
- If data collection is unsuccessful a repeat visit may be scheduled.

2nd research visit at Arkansas Children's Nutrition Center (ACNC) at ~36 weeks of pregnancy, we will:

- Ask you whether there were any newly developed medical conditions associated with pregnancy.
- Measure your weight, height, waist and hip circumferences.
- Blood pressure and pulse will be collected using an automatic sphygmomanometer.
- Measure your body composition (fat percentage) using the ADP.
- Ask you to complete a web-based diet history questionnaire (you can complete at home before your next visit).
- Ask you questions regarding your sleep pattern using a sleep questionnaire.

- Evaluate if there is anxiety and/or depression using questionnaire.
- Get a blood sample from you, to measure inflammation markers. Please do not eat or drink anything but water after midnight the night before your appointment. You may take any medications you need.
- Get stool/saliva/urine samples from you. If we are unable to collect a samples while you are at the clinic, we will provide you with a collection kit for you to collect at home and return to the center before your next visit.
- Provide you an Actigraph watch and ask you to wear it on your wrist for 7 days and then mail back to us (a paid envelope will be provided) or bring back to us before your next visit. If the measurement is unsuccessful, you may be asked to repeat this assessment.
- Provide you a self-collection kit to be given to the nurse at Labor & Delivery unit. Upon delivery, you will need to call a research team member who will pick up the cord blood sample and the placenta right away.
- Provide you with a sample collection kit for you to collect 2wk samples to bring in to the next visit.
- If data collection is unsuccessful a repeat visit may be scheduled.

3rd research visit at ACNC and Arkansas Children's Hospital (ACH, a block away from ACNC) when your child is ~2 weeks of age. This visit will be split and will be at different times or days depending on your availability and radiology scheduling. At these visits we will:

- Measure the weight, height, and head circumference of your child.
- Measure your child's body composition using quantitative nuclear magnetic resonance (NMR, an equipment similar to MRI but with much weaker magnetic field).
- Get a blood sample from your child to measure inflammation markers. Heel stick will be performed.
- Collect a stool sample from your child to measure bacteria and metabolites. If we are unable to collect a stool sample while you are at the clinic, we will provide you with a collection kit for you to collect at home and return to the center before your next visit.
- Ask for your child's feeding pattern including whether you are breastfeeding, the frequency of nursing and the time of each feeding session, the type of formula. We will ask you to complete an infant feeding questionnaire. We will also ask you to provide a sample of breast milk (if breastfeeding), and weigh you child before and after feeding (for breast-feeders only). If we are unable to collect a breast milk sample while you are at the clinic, we will provide you with a collection kit for you to collect at home and return to the center before your next visit.
- Ask you to complete an infant sleep questionnaire to know more about your child's sleep pattern.
- Ask you to complete a questionnaire regarding postpartum depression and parental stress.
- Evaluate if there is anxiety and/or depression using questionnaire.
- Perform a MRI study of the brain on your child during natural sleep. MRI has no radiation at all, and is routinely used in clinical care. Your child will not be sedated in any way.
- Provide you with a sample collection kit for you to collect 1yr samples to bring in to the next visit.

- If data collection is unsuccessful (such as during MRI your child wake up and wouldn't stay still), a repeat visit may be scheduled.

4th research visit at ACNC and ACH when your child is ~1 year of age. This visit will be split and will be at different times or days depending on your availability and radiology scheduling. At these visits we will:

- Measure the weight, height, and head circumference of your child.
- Measure your child's body composition using NMR.
- Assess home environment and parenting style using questionnaires.
- Collect a stool sample from your child to measure bacteria and metabolites. A stool collection kit will be provided at your 2wk appointment for specimen collection. If we are unable to collect a stool sample while you are at the clinic, we will provide you with a collection kit for you to collect at home and return to the center before your next visit.
- Collect saliva sample from your child by cheek swab to evaluate inflammation markers.
- Ask you to complete an infant feeding questionnaire to know more about your child's diet.
- Ask you to complete an infant sleep questionnaire to know more about your child's sleep pattern.
- Ask you to complete a questionnaire regarding postpartum depression, parental stress, and stress during COVID.
- Evaluate if there is anxiety and/or depression using questionnaire.
- Perform a MRI study of the brain on your child during natural sleep. This is performed at ACH Radiology and will be at the child's bed time.
- Perform a neurodevelopmental evaluation of your child: this will include some observational and interactive assessment (such as observing how your child walk, how your child react when speak to), and some questionnaires for you to complete.
- Provide you with a sample collection kit for you to collect 2yr samples to bring in to the next visit.
- If data collection is unsuccessful (such as during MRI your child wake up and wouldn't stay still), a repeat visit may be scheduled.

5th research visit at ACNC and ACH when your child is ~2 year of age. This visit will be split and will be at different times or days depending on your availability and radiology scheduling. At these visits we will:

- Measure the weight, height, and head circumference of your child.
- Measure your child's body composition using NMR.
- Assess home environment and parenting style using questionnaires.
- Collect a stool sample from your child to measure bacteria and metabolites. A stool collection kit will be provided at your 1yr appointment for specimen collection. If we are unable to collect a stool sample while you are at the clinic, we will provide you with a collection kit for you to collect at home and return to the center.
- Collect saliva sample from your child by cheek swab to evaluate inflammation markers.
- Ask you to complete an infant feeding questionnaire to know more about your child's diet.

- Ask you to complete an infant sleep questionnaire to know more about your child's sleep pattern.
- Ask you to complete a questionnaire regarding postpartum depression, parental stress, and stress during COVID. Evaluate if there is anxiety and/or depression using questionnaire.
- Perform a MRI study of the brain on your child during natural sleep. This is performed at ACH Radiology and will be at the child's bed time.
- Perform a neurodevelopmental evaluation of your child: this will include some observational and interactive assessment (such as observing how your child walk, how your child react when speak to), and some questionnaires for you to complete.
- If data collection is unsuccessful (such as during MRI your child wake up and wouldn't stay still), a repeat visit may be scheduled.

In addition, at ~24 weeks of pregnancy, you will be contacted by phone to get an update of weight, and whether there are complications during pregnancy. At that time you will also be requested to complete a dietary intake questionnaire (same as the one administered during the first study visit) online; and you will be reminded of the next visit at ~36 weeks of pregnancy.

All procedures may be repeated if the first one is invalid, aborted, or for inter-rater reliability. Blood and biospecimen samples collected from you and your child will not be used for commercial gain. The research will not include whole genome sequencing.

How long will this study take?

- The whole study lasts ~2.5 years. You and your child will be asked to attend 5 study visits. The 3rd, 4th, and 5th visit may be split to two visits depends on scheduling.
- The first study visits is at ACNC when you are about 12 weeks pregnant, and will take about 3-4 hours in the morning.
- The second study visits is at ACNC when you are about 36 weeks pregnant, and will take about 2-3 hours in the morning.
- The third study visit is at both ACNC and ACH, when your child is about 2 weeks of age, and it will take about 2-3 hours at ACNC and 1-2 hours at ACH in later afternoon and/or early evening (while the MRI scan only takes ~45minutes for data acquisition, the availability of the MRI scanner, the scan preparation, and the repeat if your child wakes up and moves during the scan may make your total stay longer).
- The fourth study visit is at ACNC and ACH, when your child is about 1 year old, and it will take about 2.5 hours at ACNC and 1.5-3 hours at ACH, depends on how fast your child fall into sleep and let us do the MRI. It will be split to 2 visits, one to ACNC, one to ACH.
- The fifth study visit is at ACNC and ACH, when your child is about 2 year old, and it will take about 4 hours at ACNC, and 1.5-3 hours at ACH, depends on how fast your

child fall into sleep and let us do the MRI. It will be split to 2 visits, one to ACNC, one to ACH.

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 UAMS or ACH.
- No penalty of loss of benefits to which you might otherwise be entitled to.

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 UAMS and ACH.
- If you decide to stop being in the study, call the study team at 501-364-4837 or email ouxiawei@uams.edu

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 for being in the study?

Yes. You will be provided the following compensation upon the completion of each study visit including all requested samples. This is to thank you for your time.

- $50 gift card (1st visit at ~12 weeks of pregnancy)
- $50 gift card (2nd visit at ~36 weeks of pregnancy)
- $25 gift card (if provide cord blood and placenta at delivery)
- 6 months' worth of diapers for your child (3rd visit at infant age ~2 weeks)
- 6 months' worth of diapers for your child (4th visit at infant age ~ 1 year)
- 6 month's worth of diapers or pull-ups (5th visit at age ~2 years)
- Completion of the MRI at the 5th visit will receive additional $50 gift card as bonus.
- Repeat MRI visit (if the previous MRI was attempted by reasonable amount of time but did not succeed because infant wakes up during scan) will be compensated with 4 additional cases of diapers, if completed.
- Other repeat visits, that are necessary, will be compensated with a $25 gift card.
- Partially completed visits will be partially compensated (2 cases of diapers will be withheld for each uncompleted assessment or a $25 dollar gift card with be held for unreturned samples or Actigraph)
- Snacks and meals may be provided.

- Hotel accommodations may be provided by request through Arkansas Children's Hospital research staff for participants traveling over 75 miles to participate in the postnatal research visits.

We will need to collect your social security number for our IRS reporting purposes. This information will not be saved in your study records.

Will being in this study help me in any way?

Being in the study may or may not help you, but may help others in the future. What we learn may help in the following ways:

- While all of the measures in this study are not for diagnostic purpose (including the MRI), all data from you and your child will be monitored by the research team, and we will discuss with you in the rare case of incidental findings that referrals may be needed.
- The knowledge learned from this study can help us potentially promote brain development in all children. Your participation will help us better understand whether weight status or other health parameters during pregnancy are associated with babies' brain development. If there are such associations, the study results will also let us know whether things such as inflammation are the likely reason, and whether things such as certain diet and physical activity during pregnancy can help to resolve the potential effects.

What are the risks of being in this study?

For you:

- The risks for this study are no more than what happens in everyday life.
- 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.
- When getting the blood sample, there may be a slight amount of pain, the possibility of a bruise, and a remote chance of infection. Because you must fast (not eat anything) from midnight the night before your appointment until you have your blood drawn, you may feel hungry prior to your appointment. There is also a possibility for you to feel sick or dizzy before, during, or after your blood draw.
- When your body composition is being measured, you may feel claustrophobic. You will be surrounded by large windows and will be able to see out at all times. If at any point you become claustrophobic, you will be given a panic button that will allow you to stop the procedure at any time.
- As mentioned above, there is a small risk that someone outside the study team might get access to your study information or your child's study information. We will take steps to protect your information to minimize this risk.

For your baby:

- The heel stick at ~2 weeks of age may cause brief pain to your baby. It will be done by an experienced phlebotomist.

- The cheek swab at age ~1 and ~2 years may upset your baby. It is non-invasive and is not expected to induce pain.
- The MRI scan has no radiation but it makes a loud noise. We will use ear muffs and/or headsets for your child to isolate the noise, and will monitor your child during the scan. If your child wakes up or becomes uncomfortable, we will stop the scan.
- The NMR is weaker than a regular MRI, and NMR examination have no radiation as well. But the MRI and NMR may pose a risk if your child has any internal metal. We will screen your child carefully to ensure that he/she has no internal metal before doing the MRI and NMR. If there is a chance your child has internal metal that may be a safety concern, we will not do the MRI and NMR.

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

- If you get 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.
- If you are not here and get hurt or sick, and think it is because of the study, do these things:
  - ✓ call your doctor or if an emergency, call 911
  - ✓ give your doctor or ER staff
    - the name of this study: Effects of maternal obesity and inflammation on offspring brain development
    - the name of the head researcher for this study: Dr. Xiawei Ou
    - a copy of this form if you have it
  - ✓ call Dr. Charles Glasier (501-364-1175), who is a medical sub-investigator for this study.
- This treatment may be billed to you or your insurance company in the normal manner. No other form of payment is available.

What are the alternatives to being in this study?

- You do not have to be in this study.

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.
- You or your child take medications or have new medical conditions known to influence the study
- It is not in your best interest to continue.
- The whole research study is stopped for any reason.

Who will see the information collected about me and my child? 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 of information and study samples that we collect from you during the study.
- When we share the results of the study (e.g., as scientific papers), we will not include your name or anything else that may identify you (e.g., DOB, address, phone number, etc.).
- 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
    - National Institute of Child Health and Human Development, federal agency who gave us money to do this study
    - OHRP (Office for Human Research Protections), a federal agency
    - UAMS Institutional Review Board
    - Arkansas Children's Research Compliance
    - Other institutional oversight offices
- State law requires we tell the authorities if we learn about possible child or adult abuse or that you might hurt yourself or someone else

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

- You and your child's samples and health information will be coded with a special number that is not related to your personal information such as Date of Birth or Social Security Number.
- All information will be in locked, confidential files and on a secure computer file.
- All samples will be stored in freezers in locked laboratories.
- Your privacy and the confidentiality of your information are very important to us and we will try our best to protect them.
- Except for identifying information, if you agree, your child's data may be available to other investigators not listed on this protocol. However, we will not provide you/your child's information or samples to other researchers unless it is necessary for their research and unless they have obtained approval from an Institutional Review Board (IRB). Any information shared will be de-identified, and additional consent from you would not be sought at that time.
- If you choose to allow us to use your information or samples for future research, the samples and data will be stored indefinitely or until needed for analyses related to similar research questions as this study.

- If you choose to NOT allow us to use your information or samples for future research, once the study is complete in approximately 5 years, your information and samples will destroyed.
- If you wish to no longer have your samples stored, simply send a letter to Dr. Ou to the address listed on the front of this form with your name, your child's name and date of birth. You may also call Dr. Ou at 501-364-4837.

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

- If you withdraw from the study, we can keep any information or samples collected from you before you chose to quit the study. If you wish to have your information and samples taken out of the study, call Dr. Ou at 501-364-4837.

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

- Yes, with your consent. Your de-identified information and samples may be used for future studies about your health and your child's growth and development that we didn't think about when we started the study. You will be given the option to opt in or out of this future use later in this form. Neither decision will affect your ability to participate in the study.

Will you tell me anything you learn that may impact 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 want you to know about anything that may change your mind about being in the study.
- The study team will let you know by either
  - ✓ calling you
  - ✓ sending you a letter
  - ✓ telling you at a follow up visit

What if I have questions?

- Please call the head researcher of the study (Dr. Xiawei Ou, 501-364-4837; after hours: 615-525-5353) if you have any questions about this study; have questions about your rights, or feel you have been injured in any way by being in this study.
- You can also call the office at UAMS that supervises research if you can't 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.

HIPAA Research Authorization:

To do this research, we need to collect health information about you and your child. We will only

collect information that is needed for the research. We may collect the following information from your medical record: your baby's birth weight and height, delivery method, Apgar score, and complications during delivery. This is information will be collected to document your baby's size and health immediately after birth. Being in this research study will create new health information about you and your child's health, such as results from anthropometric measurements (such as height, weight, waist circumference) of you and your child, results of your child's MRI, and results of your and your child's behavioral assessments. For you and your child to be in this research study, we need your permission to collect, create, and share this information.

We may share your and your child's health information with people at the University of Arkansas for Medical Sciences (UAMS), Arkansas Children's, 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 Arkansas Children's and other institutional oversight offices. We may also share your information with agencies that pay for all or part of the research or who work with us on the research, such as the National Institute of Child Health and Human Development, the funding agency listed on the front page of this form. Additionally, we may need to share your or your child's health information with people outside of UAMS and Arkansas Children's who make sure we do the research properly, such as the Office for Human Research Protections. We believe that those involved with research understand the importance of preserving the confidentiality your and your child's health information. However, some of the people outside of UAMS and Arkansas Children's may share your and your child's health information with someone else. If they do, the same laws that UAMS and Arkansas Children's must obey may not apply to others to protect your or your child's health information.

This authorization to collect, use, and share your or your child's health information will not expire. If you agree, the researchers will be keeping your information for possible use in future studies. If you sign this form, you are giving us permission to create, collect, use and share your and 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, neither you nor your child can be in the research study.

1. If you sign this form but decide later that you no longer want us to collect or share your health information, you need to send a letter to:

   Arkansas Children's Hospital
   Health Information Management Director
   1 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".
- ✓ If you send in this letter to revoke your HIPAA Authorization, you will not be in the research study any more.
- ✓ We cannot collect or share any more health information after we get the letter from you.
- ✓ However, we may still use and share your information that was collected before we got your letter revoking your HIPAA Authorization.

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

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.
- ✓ I do not give up any of my rights by signing this form.
- ✓ My decision will not change my medical care at UAMS and ACH.

I agree for myself and my baby to participate in this study. Our health information can be used for the purposes of this study.

_____ _____
Print Name of Participant (Mother) Participant ID

_____
Print Name of Participant (Child)

_____ _____
Signature of Participant (or Parent/Guardian if applicable) Date

_____
Relationship to Participant

_____ _____
Signature of Person Obtaining Consent Date

I agree to being contacted for future ACNC research: YES ___ NO ____ Initials____

My samples and information collected in this study may be used in future research (you will still be allowed to participate if you choose to NOT allow future use of your data):

YES ___ NO ____ Initials___