KEY INFORMATION FOR

PRAGMATIC, RANDOMIZED, BLINDED TRIAL TO SHORTEN PHARMACOLOGIC TREATMENT OF NEWBORNS WITH NEONATAL OPIOID WITHDRAWAL SYNDROME (NOWS)

Parental Consent + Assent of Mother of Baby

(for use when non-emancipated minor is legal guardian of the baby)

We are asking you to choose whether or not you want to allow your child to participate in a clinical trial (research study) about babies who have neonatal opioid withdrawal syndrome (NOWS). Neonatal opioid withdrawal syndrome can cause a number of problems. These problems may include tremors, seizures, fussiness, vomiting, and poor feeding. Babies can develop NOWS if their mothers took drugs called opioids while the babies were still inside their mothers. There are many different names for opioids. Some brand names, generic names, and street names are listed on the last page of this form.

Before delivery:

Because your child's baby may have been exposed to opioids during pregnancy, your child's baby could have NOWS after he/she is born. If your child's baby does have NOWS after he/she is born, your child's baby's doctor and medical team will help your child's baby to get over it. The doctor may give your child's baby a drug (either morphine or methadone) that will help your child's baby get over NOWS.

After delivery:

Your child's baby has or may have NOWS and is currently being given a drug (either morphine or methadone) by the baby's doctor to help the baby get over NOWS.

Your child's baby will need to be weaned (slowly stop getting) from the drug so that your child's baby will get better. The question the researchers want to answer is whether or not there is a difference between a slow weaning method and a fast weaning method. As part of the study, the researchers want to ask your child some questions at the end of the study.

This page and the next 2 pages give you key information to help you decide whether you want your child to participate. We have included detailed information after the second 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?

By doing this study, we hope to learn about the best way babies can stop getting the morphine or methadone the doctors may be using to treat your child's baby's if your child's baby has NOWS symptoms.

Some of this study will occur while your child's baby is still in the hospital.If your child's baby needs medicine to help with the NOWS symptoms, while your child's baby is in the hospital, then your child's baby will be placed in one of two groups, "slow weaning" or "fast weaning. If your child's baby does not need medicine for NOWS symptoms, we will let you know and your child's baby will not stay in the study. In some hospitals, doctors use a SLOW WEANING approach, in which the baby spends more time on morphine or methadone, and in other hospitals doctors use a FAST WEANING approach, in which the baby spends less time on morphine or methadone. Nobody knows which approach is better for the baby. The question the researchers want to answer is whether one of these 2 approaches is better than the other. Details about these groups are given in the section "What will happen if I say yes, I want to be in this study?" in the main part of the consent form. During your child's baby's hospital stay, medical and research staff will complete the weaning process, collect information about what medicines are used and how much is given, The staff will also track your child's baby's health. The research team will check your child's baby's size and weight when your child's baby is ready to leave the hospital. After your child's baby leaves the hospital the research team will ask your child to answer questionnaires about how well your child and her baby are doing and will ask your child to bring her baby in for tests on how well he/she is developing. The questionnaires will include things like how your child is feeling, how your child feels when she is caring for her baby, how her baby is feeding, how her baby behaves, and about any urgent care hospital visits for the baby after the baby is home. Your child will be asked to bring her baby in for a play-based exam that will allow medical professionals to determine how well your child's baby is developing compared to other babies his/her age.

Your child's and child's baby's participation in this research will take about 4 hours over the course of about 2 years after your child's baby has been discharged from the hospital. The length of the hospital portion will depend on your child's baby's responses to the treatment, but it is likely to be less than 30 days. There will be a total of 6 contact times. The first (at discharge) and last (when your baby is 24-months old) will be in person. The other 4 times will be either phone calls, home visits, or be done electronically.

WHY MIGHT I CHOOSE TO ALLOW MY CHILD TO VOLUNTEER FOR THIS STUDY?

Your child/ your child's baby may not benefit directly from being in this study. Although there is no guarantee your child/child's baby will benefit directly, benefits could include one or more of the following:

- less exposure to morphine or methadone for the baby

For a complete description of benefits, refer to the Full Consent.

WHY MIGHT I CHOOSE NOT TO ALLOW MY CHILD TO VOLUNTEER FOR THIS STUDY?

The reason(s) you may not want your child to volunteer for this study include:

- Your child might be uncomfortable sharing private health information with the research team.
- Fast weaning (versus slow weaning) could increase signs of NOWS for your child's baby.
- It is possible that slow weaning could result in receiving more days of morphine or methadone than with fast weaning for your child's baby.

For a complete description of risks, refer to the Full Consent.

If you chose not to let your child be part of this study, your child's baby's treatment will be the hospital's usual care, which will be treatment with either morphine or methadone and changes in dose will be made by your child's baby's medical team. For a complete description of alternate treatment/procedures, refer to the Full Consent and/or ask your child's doctor.

DO I HAVE TO ALLOW MY CHILD TO TAKE PART IN THE STUDY?

No. It is okay to say no. If you decide to let your child take part in .the study it should be because you really want to allow her to volunteer for this study. Your child will not lose any services, benefits, or rights your child would normally have if you choose not to allow your child volunteer.

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.

<Insert local institution name>

Informed Consent Form

- **We are asking you to allow your child to be in a clinical trial (research study). Your child does not have to join the study.**
- **Your child will still get medical care from [insert local context here] even if your child is not in the study.**
- **Please take as much time as you need to read this form and decide what is right for your child.**

Why am I being asked to allow my child to be in this clinical trial (research study)?

- We want to learn more about how to help babies born with Neonatal Opioid Withdrawal Syndrome (NOWS). Babies who, while growing inside their mothers, have been exposed to opioids can have NOWS. There are many names for opioids. Some of the brand names, generic names, and street names are listed on the last page of this form. The signs of NOWS are different in different babies. Signs can include tremors, seizures, fussiness, vomiting, poor feeding, as well as many other symptoms.
- This study may help us learn more about which method(s) might work better than others for treating NOWS. Specifically, the research team is testing whether it may be better to wean babies fast or slow from the methadone or morphine that is being used to treat babies' NOWS symptoms.
- We are asking people like your child, who may have a baby with NOWS, to help us.
- Approximately 502 babies who are being treated with methadone or morphine for NOWS will be in this study. The babies' parent/legal guardian (i.e., people like your child) will also be in the study, if they want to be.
- This clinical trial (research study) is sponsored by the National Institutes of Health and is being conducted at about 24 hospitals across the United States.

What if I don't understand something?

- This form may have words you don't understand. If you'd like, research staff will read and explain it with you.
- You are free to ask questions at any time - before, during, or after your child is in the study.

- Please ask as many questions as you like before you decide whether you want to allow your child to be in this study.

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

We first will see if your child/your child's baby qualifies to be in the study. We will make sure that your child's baby

- Was inside his/her mother for at least 36 weeks.
- Is at risk for having NOWS or is receiving morphine or methadone to treat NOWS but weaning has not started.
- Can receive medicines by mouth or by nasogastric tube.
- Is being fed by mouth.

Your child's baby can not be part of this study if he or she has (or had) certain medical problems. The person who is going over this consent with you can list these problems if you want to know what they are.

If you want your child to be in the study, and your child wants her baby to be in the study, we will do these things:

- Ask you and your child to sign this consent/assent form.
- We will monitor your child's baby for signs of NOWS to see if your child's baby qualifies to be in the study.
- If the doctors have started giving your child's baby morphine or methadone to treat NOWS, we will make sure he/she is on a stable amount. We will also make sure the doctors have not started lowering the amount yet.
- If your child's baby does not qualify to be in the study, we will let you and your child know.
- The amount (dose) of morphine or methadone your child's baby will receive will be lowered in steps. If your child's baby is showing signs that he/she is having problems with the lowered amount, the amount will be raised to help your child's baby.
- Tell you/your child that your child's baby will be placed in 1 of 2 different groups. Your child's baby will continue to receive the medication that her or his doctor is currently prescribing (morphine or methadone). However, the step used to decrease the dose in group 1 will be different than the steps used to decrease the dose in group 2. One group will have medication decreased faster than the other group. The chances your child's baby will be in either group is the same as flipping a coin and getting either heads or tails. You will not know if your child's baby was put in the fast weaning or slow weaning group. Your child's baby's doctor and nurses will not know if your child's baby was put in the fast weaning or slow weaning group. However, we can find out which group your child's baby is in if we need to in an emergency.

- Babies in both groups will go through 8 steps of study drug. Babies in the slow weaning group will have the dose of the drug decreased in 8 steps. Babies in the fast weaning group will have the dose decreased in 5 steps, and then they will receive a placebo (no medicine, like salt water) for 3 steps. The steps will be changed based on how your child's baby is doing and his or her needs. The amount of time your child's baby is in the hospital will be the same no matter which group the baby is assigned to.
- Your child's baby will continue to get morphine or methadone until he or she is stable without either morphine or methadone.
- The length of time your child and her baby is in this study will depend on how the baby responds to the lowering of the amount of morphine or methadone.
- We will assess your child's baby's and family's well-being using questionnaires. Questionnaires will be done electronically, over the phone, or in person. Your child does not have to answer any questions she does not want to answer. The description and schedule for these questionnaires are listed in the "Contact Times" below.
- We will assess your child's baby's behavior and development. This will be done on your child's baby 24 to 48 hours after your child's baby has stopped getting methadone or morphine. This will help the medical team evaluate your child's baby's behavior. The assessment, includes determining how calm or excitable the baby is, how well she or he takes to being handled, and how easily he or she can be made more comfortable. This is a physical exam. It involves moving your child's baby's arms and legs and watching the baby closely.
- Your child's baby will be watched in the hospital for 48 to 72 hours after he/she stops getting study drug. The medical team will watch closely for any signs of NOWS. If your child's baby needs the study drug, it can be restarted.
- During your child's baby's hospital stay, your child and her baby will receive the hospital's usual care except for the following:
  - ✓ Your child's baby's medical team will not decide how fast or slow your child's baby is weaned from methadone or morphine. Instead, your child's baby will be randomly put into either the "fast weaning group" or the "slow weaning group." The chance of your child's baby being in either group is like the chance of getting heads or tails when you flip a coin. The chance your child's baby will be into the fast weaning group is exactly the same as the chance your child's baby will be put into the slow weaning group.
  - ✓ Your child's baby will be assessed for nervous system, behavioral, and motor development.
  - ✓ Collection of information about your child's baby when your child's baby is discharged from the hospital. This information will be from the hospital records of your child and your child's baby and will include things like your child's baby's size and weight and medication(s) used.

Description of Post-Discharge Assessments

- Your child will be asked questions about how she is doing. The questions will be about things like feeling anxious, depressed, distressed or upset. This series of questions will take about 10 minutes to answer.
- Your child will be asked questions about how she and her baby are doing together. This series of questions will take about 5 minutes.
- Your child will be asked questions about how her baby is feeding, and about any urgent care/emergency room visits or hospitalizations after her baby is home. This series of questions will take about 5 minutes.
- Your child will be asked to bring he baby in so a medical professional can:
  - ✓ Check her baby's size and weight
  - ✓ Complete a series of play-based tests that allow medical professional to determine how well her child is developing compared to other babies his/her age
  - ✓ Ask questions in-person about your child's baby's feelings and behaviors. This series of question will take about 10 minutes.

Contact Times (Discharge and Post-discharge)

- Contact 1 – at hospital discharge (of your child's baby)
  - ✓ Ask your child to allow the medical staff to obtain your child's baby's weight, length, and head circumference from your child's baby's medical record.
  - ✓ Ask your child to provide/verify her contact information
- Contact 2 – by phone, home visit, or electronically at 1 month after your child's baby is discharged from the hospital
  - ✓ Ask your child questions about how she is doing. The questions will be about things like feeling anxious, depressed, distressed or upset. This series of questions will take about 10 minutes to answer.
  - ✓ Ask your child questions about how she and her baby are doing together. This series of questions will take about 5 minutes.
  - ✓ Ask your child questions about how her baby is feeding, and about any urgent care/emergency room visits or hospitalizations after her baby is home. This series of questions will take about 5 minutes.
  - ✓ Ask your child to provide or verify contact information

- Contact 3 – by phone, home visit, or electronically when your child's baby is 6 months old
  - ✓ Ask your child questions about how her baby is feeding, and about any urgent care/emergency room visits or hospitalizations after her baby is home. This series of questions will take about 5 minutes.
  - ✓ Ask your child to provide or verify contact information
- Contact 4 – by phone, home visit, or electronically when your child's baby is 12 months old
  - ✓ Ask your child questions about how her baby is feeding, and about any urgent care/emergency room visits or hospitalizations after her baby is home. This series of questions will take about 5 minutes.
  - ✓ Ask your child to provide or verify contact information
- Contact 5 – by phone, home visit, or electronically when your child's baby is 18 months old
  - ✓ Ask your child questions about how her baby is feeding, and about any urgent care/emergency room visits or hospitalizations after her baby is home. This series of questions will take about 5 minutes.
  - ✓ Ask your child to provide or verify contact information
- Contact 6 - when your child's baby is 24 months old
  - ✓ Ask your child to bring in her baby to:
    - get his/her weight, length and head circumference
    - complete a series of play-based tests that allow medical professional to determine how well her child is developing compared to other babies his/her age.
    - ask her child questions in-person about her child's feelings and behavior. This series of question will take about 10 minutes.
    - ask her child questions about how she is doing. The questions will be about things like feeling anxious, depressed, distressed or upset. This series of questions will take about 10 minutes to answer.
    - ask her child questions about how her baby is feeding, and about any urgent care/emergency room visits or hospitalizations after her baby is home. This series of questions will take about 5 minutes.

How long will this clinical trial (study) take?

- The in-hospital portion of the study will take about 1 month. The length of the hospital stay will depend on your child's baby's responses to treatment. Your child's /her baby's post-hospital participation in this research will take about 4 hours over the course of 2 years. There will be a total of 6 contact times. The first (at discharge) and last (when your baby is 24-months old) will be in person. The other 4 times will be either phone calls, home visits, or be done electronically. The time needed to complete these calls, home visits, or electronic sessions will range from about 10 minutes to about 35 minutes.

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

- Nothing bad will happen.
- Your child's baby can still get treatment with either morphine or methadone. Your child's baby's medical team will decide when the dose is changed at [*insert local context here*].

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

- Your child can stop being in the study at any time.
- Nothing bad will happen.
- Your child and her baby can still get medical care at [insert local context here].
- If you decide to stop allowing your child to be in the study, call (*insert head researcher name*) at (*insert phone #*).

Will it cost me/my child anything to be in the study?

The study will not cost you/your child anything. You or your child's insurance company will be responsible for your child's regular medical care, as usual, including the costs of the medicines and treatments used to care for your child's baby's NOWS symptoms.

Will I/my child be paid for being in the study?

Yes. We will give you/your child $50 for each of the following contact times: 1 month post-discharge and when her baby is 6, 12, and 18 month old. You/your child will be paid $100 for the 24-month visit. If your child and her baby remain in the study for the entire 2 years, the payment total will be $300. These payments will be provided at the contact time or shortly thereafter. This is to thank you/your child for your/your child's time. We will *(LOCAL CONTEXT - insert time and method of payment)*. If you change your mind and decide not to allow your child to be in the study, you/your child will only be paid for the parts that your child has completed.

If you/your child receive more than $600 in one year (January-December) from *(insert local context/institution)* we may send you/your child a tax form if required by law.

Will being in this study help my child or her baby in any way?

Being in the study may or may not help your child or her baby. If faster weaning is successful, infants in the faster wean group will receive less morphine or methadone. The information gathered may help babies with NOWS in the future in the following ways:

- Shorten treatment time with methadone or morphine.
- Shorten hospital stays for babies.
- Decrease symptoms.
- Lower chance of return of NOWS symptoms.

What are the risks of being in this study?

The risks are:

- 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. We will do our best to protect your child's privacy.
- The questions we ask may make you child sad or upset.
- Your child's baby's NOWS symptoms may return in both groups, but possibly more frequently in the fast weaning group.
- Your child's baby may have a harder time getting used to being home. This may be more likely if your child's baby is part of the fast weaning group.
- Problems among babies being treated for NOWS are not common. These problems include:
  - seizures
  - diarrhea
  - breathing problems
  - feeding problems
- Participation in this study does not change any need to report a newborn baby was exposed to opioid(s). Local reporting requirements for neonatal opioid exposure will be followed. These requirements are <insert local reporting requirements here>.
- There may also be risks that are not known at this time. You will be given more information if other risks are found.

What if my child gets sick or hurt while in this study*?*

If your child gets hurt when he or she is in the hospital for the study, we will help him/her get the care she needs. This may include first aid, emergency care, and/or follow-up care.

- If your child is home and get hurt or sick, and think it is because of the study, do these things:
  - ✓ call your child's doctor or if an emergency, call 911
  - ✓ give your child's doctor or ER staff
    - the name of this study *Pragmatic, Randomized, Blinded Trial to Shorten Pharmacologic Treatment of Newborns with Neonatal Opioid Withdrawal Syndrome (NOWS)*, or "Weaning" for short.
    - the name of the head researcher for this study *(insert researcher name)*
    - a copy of this form if you have it
  - ✓ call the head of the study *(insert researcher name and 24 hour phone #)*
- This treatment may be billed to you or your child's insurance company in the normal manner. No other form of payment is available.

What are the alternatives to being in this study?

Your child does not have to be in this study for your child's baby to receive treatment for his/her condition.

If you do not want to allow your child to be in this study, you can choose to receive the hospital's usual care for your child/your child's baby. For the baby, the hospital's usual care is treatment with either morphine or methadone and your child's baby's medical team will decide when the dose is changed.

Can my child be taken out of the study even if my child wants to continue?

Yes, the study doctor (or head researcher) can take your child (and her baby) out of the study if:

- It is not in your child's/your child's baby's best interest to continue.
- Your child's baby has a side effect or complication related to NOWS which is considered serious and may prolong the stay in the hospital (seizure, unable to take medication by mouth either due to increased stools, breathing or feeding difficulties).
- The study is stopped for any reason.

What information will be collected about my child in the study?

During the study, we will need to learn private things about your child (and her baby's) medical condition, including information about:

- Your child's (and child's baby's) background and how to contact your child. Information to be collected includes your child's name, address, telephone number, and

other similar types of information. Your child may be contacted by text, phone, mail, home visit, or email.

- ✓ If we cannot contact your child from the information that you provide, we may access your child's/your child's baby's medical record to obtain contact information from your child/your child's baby's medical record. Information available in the public domain may also be used to make contact.

- Your child's pregnancy, including physical and mental health conditions, smoking, and whether your child took medications or other substances during pregnancy.
- Your child's baby's delivery.
- Your child's baby's height, weight and related measurements and information.
- Your child's and child's baby's drug-test results.
- Your child's baby's study treatment and responses to the study treatment.
- Your child's baby's length of time in the hospital.
- Your child's responses to questionnaires, including responses to questions about her emotional well-being and her relationship with her baby.
- How your child's baby was treated in the hospital.

The person who is going over this consent with you can tell you exactly what information will be collected if you want to know.

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

- The local study team at <insert local institution name> will know your child's name and have access to your child's information.
- We will do our best to make sure no one outside the study knows your child is part of the study.

  To help us stay in contact with you/your child during the study, we may ask you/your child if you/your child is willing to provide name(s) and contact information of back-up contact(s). It is completely up to you/your child to decide if you want to give us additional contact information.

  - ✓ If you/your child decide(s) to give us information for back-up contacts, you/your child are giving us permission to contact those person(s). If we contact one of your back-ups, that person will likely find out that your child is part of this study. You/your child may also choose to provide or share other ways for us to stay in contact with you/your child. If you/your child agree to do provide this information, you/your child are giving us permission to use these ways to contact you/your child. Someone outside of the study team may then find out that your child is part of this study.

- We will take your child's name off of information that we collect from your child during the study.
  - ✓ We may share your child's information – with your child's name removed - with colleagues at the IDeA States Pediatric Clinical Trial Network Coordinating and Operations Center at University of Arkansas for Medical Sciences, the Duke Clinical Research Institute Coordinating Center, and RTI International in North Carolina.
- When we share the results of the study in meetings or medical journals, we will not include your child's name or anything else that identifies your child or your child's baby.
- There are people who make sure the study is run the right way. These people may see information, including information that identified your child/your child's baby, from the study about your child/your child's baby. They are:
  - ✓ NIH (National Institutes of Health), the study sponsor
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ University of Arkansas for Medical Sciences (UAMS) Institutional Review Board
  - ✓ Other institutional oversight offices
  - ✓ Investigators from other sites in the study
  - ✓ RTI International
  - ✓ FDA (Food and Drug Administration)
  - ✓ IDeA States Pediatric Clinical Trial Network Data Coordinating and Operations Center at the University of Arkansas for Medical Sciences
  - ✓ Duke Clinical Research Institute Coordinating Center
- Insert local state law requirements.

  For example, state law requires that we report to the Arkansas Department of Health cases of certain diseases that a sick person could give to someone else. If we learn your child or child's baby has such a disease, we will share your child's/child's baby's name and contact information with the health department. State law requires we tell the authorities if we learn about possible child or adult abuse or that your child might hurt herself or someone else.

Where and how long will my child's information be kept?

- We will code your child's (and child's baby's) information and keep the key to the code in a locked file or other secure location at <insert local institution name>.
- Your child's and her baby's study information will also be stored, without their names, at the IDeA States Pediatric Clinical Trial Network at University of Arkansas for Medical Sciences in Arkansas and at RTI International in North Carolina."

- Your child's and child's baby's information will be stored indefinitely.
- Only *(insert local context, name/roles of persons)* will be able to link your child's information to your child.
- Your child's (and your child's baby's) medical record will indicate that your child (and your child's baby) are participants in the study. [Statement may be change if local context requires]
- We will put a copy of this consent form in your child's medical record.

If my child stops being in the study, what will happen to any information collected from my child in the study?

- We will not be able to take your child's information out of the study after it has started.

Will my child's information from the study be used for anything else, including future research?

- Yes. If your child participates in this study, we will keep information from this research study. The information will be de-identified (for example, a code number will be used instead of your child's or child's baby's names) so that it cannot be linked to your child (or your child's baby). The information will be placed into an appropriate NIH-approved information repository. In the future other researchers who were not part of this study may ask to use this information. Any information released to other researchers will not identify your child (or child's baby) or his/her participation in this research study.

Will you tell me the results of the study?

- We will not notify you directly, but the results of the study will be available on a website (http://www.ClinicalTrials.gov, see below) and in medical journals. You may contact us at any time during or after the study if you have questions about the results.

Will you tell me anything you learn that may impact my child's health?

- Yes. If we learn something about your child that might be important for your child's health, we will tell you/your child.

What if new information comes up about the study?

- We want you to know about anything that may change your mind about allowing your child to be in the study.
- The study team will let you know either by calling you or sending you a letter.

Where can I find more information about this study?

A description of this study 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. The Clinical Trials (https://clinicaltrials.gov/) identifier number is NCT04214834.

What if I have questions?

- Please call the head researcher of the study *(insert researcher name and phone #),* if you
  - ✓ have any questions about this study
  - ✓ feel your child has 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 (IRB) at 501-686-5667.
  - ✓ You may call the UAMS IRB if you have questions about your child's rights as a research participant
- *[insert local context if other than researcher named above]*

By signing the document, I am saying:

- ✓ I understand that joining this study is voluntary.
- ✓ I agree to allow my child to be in the study.
- ✓ Someone talked with me about the information in this document and answered all my questions.
- ✓ I have been asked if I wish to talk directly to the study doctor.

I know that:

- ✓ I can stop allowing my child to be in any and all parts of the study at any time and nothing bad will happen to my child or child's baby.
- ✓ 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 child's rights.
- ✓ I do not give up any of my child's rights by signing this form.
- ✓ My decision will not change my child's (or child's baby's) medical care at [insert local context/site name].

I agree to allow my non-emancipated child to be part of this study:

Printed Name of Parent/Legal Guardian of Mother of Baby

Signature of Parent/Legal Guardian of Mother of Baby | Date (mm/dd/yyyy)

I agree to allow my non-emancipated child to be contacted for future research related to this study.

___ YES ___ NO

Printed Name of Parent/Legal Guardian of Mother of Baby

Signature of Parent/Legal Guardian of Mother of Baby | Date (mm/dd/yyyy)

Assent of non-emancipated minor (mother who is legal guardian of baby with NOWS).

Printed Name of Participant Giving Assent

Signature of Participant Giving Assent | Date (mm/dd/yyyy)

Name/Signature of person obtaining consent and assent:

It is the opinion of the person obtaining consent and assent that this study was explained to the non-emancipated minor in language that was understandable to her. The non-emancipated minor was told that (1) participation is voluntary, (2) she can end her participation at any time without anything bad happening to her or her baby.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent | Date (mm/dd/yyyy)

List of Common Opioids

- **Brand Names (generic names):**
  - Demerol (meperidine)
  - Dilaudid (hydromorphone)
  - Lortab (hydrocodone)
  - MS Contin (morphine)
  - Norco (hydrocodone)
  - Opana (oxymorphone)
  - Oxycet (oxycodone)
  - Percocet (oxycodone)
  - Zohodro ER (hydrocodone)
- **Generic Names:**
  - Buprenorphine
  - Fentanyl
  - Heroin
  - Hydrocodone
  - Methadone
- **Street Names (generic names):**
  - Buse, Oranges, Subs (buprenorphine)
  - Apache, China Girl, Dance Fever, Friend (fentanyl)
  - China White, Dope, H. Horse, Junk, Smack (heroin)
  - Watson 387 (hydrocodone)
  - Amidone, Fizzies, Chocolate Chip Cookies (methadone)
  - M. Miss Emma, Monkey, White Stuff (morphine)
  - Hillbilly Heroin, O.C. Oxycet, Oxy (oxycodone)