Eating, Sleeping, Consoling for Neonatal Withdrawal (ESC-NOW): a Function-Based Assessment and Management Approach ((ESC-NOW))

NCT04057820

Parental Consent and Assent of Non-emancipated Minor Mother of Baby

March 9, 2020

KEY INFORMATION FOR

EATING, SLEEPING, CONSOLING FOR NEONATAL OPIOID WITHDRAWAL (ESC-NOW): A FUNCTION-BASED ASSESSMENT AND MANAGEMENT APPROACH

Parental Consent + Assent of Non-emancipated Minor 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 your child to be part of a clinical trial (research study) about babies who have neonatal opioid withdrawal syndrome (NOWS). Neonatal opioid withdrawal syndrome (NOWS) 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.

Your child's baby received care for NOWS during his/her hospital stay. We are asking to collect information about your child including information about your child's baby's growth and development. We also want to collect information about your child's family's environment after your child's baby leaves the hospital.

This page and the next page give you key information to help you decide whether to allow your child to be part of this study. We have included detailed information after these pages. If you have questions after reading these key information pages, please ask the research team. If you have questions later, the contact information for the research investigator in charge of the study at your child's hospital is below.

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

By doing this study, we hope to learn more about how different treatment methods for NOWS affect the growth and development of babies after they have been discharged from the hospital. We also hope to learn more about how these treatment methods may help babies and their caregivers once they are home. Your child's participation in this research will take about 6 hours of your child's time over the course of 2 years.

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

Your child may not benefit directly from being in this study. Benefits could include one or more of the following:

- Learning more about your child's well-being by responding to questionnaires that your child will be asked to answer after discharge from the hospital.

- Learning more about your child's baby's development by responding to questionnaires that your child will be asked to answer after discharge from the hospital.
- For a complete description of benefits, refer to the Full Consent.

WHY MIGHT I CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

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

- Someone could find out that your child was in the study. They could learn something about your child that you did not want others to know. We will do our best to protect your child's privacy.
- Some of the questions asked may make your child feel sad or upset.

For a complete description of risks, see 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 want to volunteer for your child. Your child will not lose any services, benefits, or rights your child would normally have if you choose not to volunteer

WHAT IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

You can contact the person in charge of the study, [TO BE INSERTED *PI Name and affiliation*, with any questions, suggestions, or concerns at TO BE INSERTED *contact information*.

If you have any questions, suggestions, or concerns about your child's rights as a volunteer in this study, or wish to speak to someone not directly involved in the research, you can call the University of Arkansas for Medical Sciences (UAMS) Institutional Review Board at 501-686-5667 during business hours. An institutional review board is a group of people who review research to protect the rights and well-being of research participants.

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 site information>

Informed Consent Form

- **We are asking to allow your child to be in a 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)?

- Neonatal opioid withdrawal syndrome (NOWS) is something that affects a lot of babies and their families. We are trying to learn as much as we can about the best way to care for babies born with 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.
- This study may help us learn more about which method(s) might work better than others for treating NOWS. Specifically, the research team is looking to see how different treatment methods for NOWS affect the growth and development of babies after they go home from the hospital. The research team is also looking at how these treatment methods may help babies and their caregivers once they are home.
- We are asking people like your child, who has a baby with NOWS, to help us.
- Up to 3,000 babies and their parents or legal guardians will be in this study.
- This research study is sponsored by the National Institutes of Health. It 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 your child to be in this study.

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

First, we will see if your child and your child's baby qualify to be in the study. We will make sure that all of the following are true:

- Your child's baby was inside his/her mother for at least 36 weeks.
- Your child's baby has been managed for NOWS.
- There is either a maternal history of opioid use, or a positive maternal toxicology screen for opioid use, or a positive infant toxicology screen for opioids during your child's baby's initial hospital stay.

Your child can not be in this study if your child's baby 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 your child and her baby qualify, we will do these things:

- Ask you to sign this consent form and ask your child to sign the assent portion of this form.
- 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 you/your child do not want to answer. The description and schedule for these questionnaires are listed in the "Contact Times" below.
- Ask your child to bring her baby in so a medical professional can
  - ✓ check her baby's size and weight.
  - ✓ complete an assessment using a series of play-based tests and questions that allow medical professionals to determine how well your child's baby is developing compared to other babies his/her age.
- We will periodically ask you/your child to update contact information.

Contact Times:

- Contact 1 - at hospital discharge:
  - Your child will be asked:
    - questions about how she is doing. The questions will be about things like feeling anxious, depressed, distressed or upset.

- questions about how your child and her baby are doing together.
- questions about how much your child enjoys being a parent and if she thinks she is good at it.

- You/your child will be asked to provide or verify contact information.
- The total time needed to complete these questions will be about 25 minutes.

- Contact 2 - by phone or electronically at 1 month after your child's baby is discharged from the hospital:
  - Your child will be asked:
    - questions about how her baby is feeding, and about any urgent care/ER visits or hospitalizations after her baby is home.
  - You/your child will be asked to provide or verify contact information.
  - The total time needed to complete these questions will be about 10 minutes.

- Contact 3 – by phone or electronically when your child's baby is 3 months old:
  - Your child will be asked:
    - questions about how her baby acts with her and with others.
    - questions about how her baby is feeding, and about any urgent care/ER visits or hospitalizations that occurred after her baby went home.
    - questions about how her baby is sleeping at home. The questions will be about where, when and how her baby is sleeping.
    - questions about how her family is doing. The questions will be about her family environment.
  - You/your child will be asked to provide or verify contact information
  - The total time needed to complete these questions will be about 35 minutes

- Contact 4 – by phone or electronically when your child's baby is 6 months old:
  - Your child will be asked
    - questions about how her baby is feeding, and about any urgent care/ER visits or hospitalizations that occurred after her baby went home.
    - questions about how she is doing. The questions will be about things like feeling anxious, depressed, distressed or upset.
    - questions about how she and her baby are doing together.
    - questions about how much she enjoys being a parent and if she thinks she is good at it.

- You /your child will be asked to provide or verify contact information
- The total time needed to complete these questions will be about 30 minutes.

- Contact 5 - by phone or electronically when your child's baby is 9 months old:
  - You/your child will be asked to provide or verify contact information

- Contact 6 – by phone or electronically when your child's baby is 12 months old:
  - Your child will be asked:
    - questions about how her baby acts with her and with others.
    - questions about how her baby is feeding, and about any urgent care/ER visits or hospitalizations that occurred after her baby went home.
    - questions about how her baby is sleeping at home. The questions will be about where, when and how her baby is sleeping.
  - You/your child will be asked to provide or verify contact information.
  - The total time needed to complete these questions will be about 25 minutes.

- Contact 7 – by phone or electronically when your child's baby is 18 months old:
  - You/your child will be asked to provide or verify contact information.

- Contact 8 –when your child's baby is 24 months old:
  - Your child will be asked
    - to bring in her baby to
      - get his/her weight, length, and head circumference
      - have her baby assessed using a series of play-based tests and questions that allow medical professionals to determine how well her baby is developing compared to other babies his/her age. The team will be checking your child's baby's physical, social and mental development,
    - questions about how your child's baby is feeding, and about any urgent care/ER visits or hospitalizations that occurred after your child's baby went home.
    - questions about how she (your child) is doing. The questions will be about things like feeling anxious, depressed, distressed or upset.
    - questions about whether she had certain bad experiences in her own childhood.
  - The total time needed to complete these questions and to have your child's baby checked by a medical professional will be about 2 to 3 hours.

How long will this clinical trial (study) take?

- The study will take about 24 months (2 years) to complete.
- Your child will be asked to answer questions 6 different times. The first 2 times will be when your child's baby is discharged from the hospital, and 1 month after your child's baby has been discharged from the hospital. The other times will be when your child's baby is 3 months old, 6 months old, and 12 months old, and 24 months old. The time needed to complete these calls or electronic sessions will range from about 10 minutes to about 35 minutes.
- You will be asked to confirm your contact information a total of 8 times. These times are when you sign the consent (during hospital stay), at hospital discharge, 1 month post-discharge, and when your child's baby is 3, 6, 9, 12, and 18 months old.
- When your child's baby is 24 months old, we will ask her to bring her baby to the clinic, medical office, or hospital for an assessment. The study team will check your child's baby's growth and physical, social and mental development. This check-up will include a play-based exam as well as questions. This assessment itself will take about 2 hours.
- The total amount time your child will spend doing this study is about 5 to 6 hours.

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

- Nothing bad will happen.
- Your child can still get medical care at [insert local context here].
- You/your child may be asked a few questions about why you/your child don't want to be in this study. You/your child do not have to answer any of these questions if you/your child don't want to.

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 can still get medical care at [insert local context here].
- If you/your child decide to stop being in the study, call (*insert head researcher name*) at (*insert phone #*).

Will it cost me anything to be in the study?

The study will not cost you/your child anything. You or your insurance company will be responsible for your child's regular medical care, as usual.

Will I be paid for being in the study?

Yes. We will give your child $50.00 for each contact time that she participates in. that only involves answering questionnaires. There are 5 of these contact times ((hospital discharge, 1 month post discharge, and when your child's baby is 3, 6, and 12 months old) that only involve answering questionnaires. Your child will receive $100 if she brings her baby back for a final in-person visit when her baby is 24 months old. If your child participates in all 5 of the "questionnaire-only' contact times - plus the in-person visit - she will be paid a total of $350.00. This is to thank her for her time. We will *(LOCAL CONTEXT - insert time and method of payment)*. If you/your child change your mind and decide not to be in the study, she will only be paid for the contact times for which she answered questionnaires or came for an in-person visit. Your child will receive payment at – or near – the contact time your child participates in.

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

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

Your child may not benefit directly from being in this study. Benefits could include one or more of the following:

- Feeling like you/your child may help improve the care of other NOWS babies in the future.
- Learning more about your child and her baby's well-being by responding to questionnaires that she will be asked to answer after discharge from the hospital.
- Learning more about your child's baby's development by responding to questionnaires that she will be asked to answer after discharge from the hospital.
- Learning more about your child's baby's mental and physical growth and development by getting results from the assessment done when your child's baby is 24 months old.
- Learning more about your child's family's well-being by responding to questionnaires that she will be asked to answer after discharge from the hospital.
- Depending on how you answer questions, your child's doctor or the study team may decide your child needs extra help or care to deal with issues or problems she is having. Your child's doctor or study team member may refer your child to national helpline(s) or other service(s) that he/she believes will be able to help her.
- Being in the study may or may not help your child, but the information gathered may help babies with NOWS in the future.

What are the risks of being in this study?

The risks are:

- The risks for this study are no more than what happens in everyday life for babies with NOWS.
- 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 your child feel sad or upset.
- LOCAL CONTEXT AS APPROPRIATE: Your doctor or study team member [insert local context as appropriate – 'may' vs 'are required to'] report suspected child abuse or neglect to appropriate authorities.

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

- If your child gets hurt when she is here for the study, we will help you get the care she needs. This may include first aid, emergency care, and/or follow-up care.
- If your child is not here and gets 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
    - o the name of this study *(insert name of study).*
    - o the name of the head researcher for this study *(insert researcher name).*
    - o 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 insurance company in the normal manner. No other form of payment is available.
- INSERT ADDITIONAL LOCAL CONTEXT AS NEEDED WITH REGARD TO BILLING.

What are the alternatives to being in this study?

You do not have to allow your child to be in this study.

If you do not want to be to allow your child to be in this study, she will be treated the exact same way she would be cared for by INSERT LOCAL CONTEXT (i.e., site/medical team) if she were not asked to be in this study.

Can your child be taken out of the study even if you/she want to continue?

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

- It is not in your child's best interest to continue.
- The study is stopped for any reason.

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

- General contact and background information about your child, such as name, address, telephone number, and date of birth,
  - ✓ If we cannot contact you/your child from the information that you/your child provide, we may access your child's medical records to obtain contact information from your child's medical record.
- Information needed to complete the questionnaires.
- Information about your child's baby's growth and physical and mental development.

The person who is going over this consent with you can give you details about 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 will know your child's name and have access to your child's information as needed for the trial.
- 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 decides 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.

- 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 her or her baby.
- There are people who make sure the study is run the right way. These people may see information from the study about your child. 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
  - ✓ Researchers from other sites in the study
  - ✓ Research Triangle Institute (RTI)
  - ✓ 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
  - ✓ *LOCAL CONTEXT: Insert any other applicable group that may access the records or provide oversight, including the FDA (Food and Drug Administration)*

LOCAL CONTEXT: 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 you have such a disease, we will share your name and contact information with the health department.

INCLUDE IF PART OF STATE LAW: 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 child's information be kept?

- We will code the study information and keep the key to the code in a locked file or other secure location.
- Only *(insert appropriate parties)* will be able to link your child's information to her.
- We LOCAL CONTEXT: *will/will not* put information about your child from the study in your child's medical record(s). *(IF yes, include state what information will be put in the participant's medical record.)*

If my child stops being in the study, what will happen to any information collected from her 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 you allow your child to participate in this study, we will keep information from this research study at the Data Coordinating Center, RTI International. The information may be shared for future research as stated in the NIH (National Institutes of Health) Public Access Policy. This policy makes sure that the public has access to published results of NIH-funded research. The study will also comply with the NIH Data Sharing Policy, Policy on the Dissemination of NIH-Funded Clinical Trial Information, and the Clinical Trials Registration and Results Information Submission rule. .

Information released under this policy will not identify your child or her baby or his/her participation in this research study. Other researchers who may see the data may include people who were not part of this 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/your child may contact us at any time during or after the study if you/your child 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 or your child's baby that might be important for her or her baby's health, we will tell you/your child.
- If the examiner finds an issue with your child's baby when the examiner does the assessment when your child's baby is 24 months old, your child will be referred to her primary care provider for follow-up. The study team will talk directly to her primary care provider if she would like the study team to do this.

What if new information comes up about the study?

- We want you/your child to know about anything that may change your/your child's mind about being in the study.

  The study team will let you/your child know either by calling you/your child or sending you/your child 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 ClinicaTrials.gov identifier number is NCT04057820.

What if I have questions?

- Please call the head researcher of the study *(insert researcher name and phone #),* if you/your child
  - ✓ 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 at 501-686-5667.
  - ✓ You may call the UAMS IRB if you have any 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 participate in the study.
- ✓ Someone talked with me/my child about the information in this document and answered all my/my child's 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 me or my child.
- ✓ 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/my child's rights.
- ✓ I do not give up any of my/my child's rights by signing this form.
- ✓ My decision will not change my child'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)

Name/Signature of person obtaining consent:

Printed Name of Person Obtaining Consent

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

Assent of non-emanicipated 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 assent:

It is the opinion of the person obtaining 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 and (2) she can end her participation at any time and nothing bad will happen if she does.

Printed Name of Person Obtaining Assent

Signature of Person Obtaining Assent | 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)