Protocol Title: Methadone Demonstration Project

NCT03134703

Methadone group- Maternal consent

Date: 11.09.2016

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

MATERNAL Consent-METHADONE Group

Protocol Title: Methadone Demonstration Project

Application No.: IRB00107690

Sponsor: Florida Department of Health

Principal Investigator: Sandra Brooks, MD, MPH
Johns Hopkins All Children's Hospital
Department of Neonatology
501 6th Avenue South,
St. Petersburg, FL 33701
Telephone: 727-767-4313
Fax: 727-767-4391

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This study is being done to compare the treatment of infants receiving methadone for treatment of Neonatal Abstinence Syndrome (NAS) to those infants who are treated with another narcotic. We would like to compare maternal bonding and depression symptoms of mothers whose infants are receiving methadone (Methadone treatment group) to mothers whose infants are treated with a narcotic other than methadone (Control group). You are eligible for this study because you have been identified by Operation PAR as being compliant with your methadone treatment. You and your infant are being asked to participate in the Methadone treatment group of this study.

How many people will be in this study?

Twenty five (25) mothers will be enrolled in the methadone treatment group of the study. We will also enroll 25 mothers in the control group.

3. What will happen if you join this study?

This consent form describes your participation in this study. A separate consent form will be given to you that describes your infant's participation in this study.

You will be asked to fill out questionnaires about your relationship with your infant that measures postpartum bonding. You will also complete a questionnaire to assess postpartum depression. These may include questions about your mental health and health behavior, stress, and your relationship with your infant. Some of these questions may be sensitive. If your answers to questions as part of this research make us concerned about your mental health or safety, we will tell you this and give you resources where you could get help.

How long will you be in the study?

You will be in this study until the last questionnaires are completed, when your infant is 6 to 8 weeks old.

4. What are the risks or discomforts of the study?

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

5. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. Participation in this study will not help you or improve your health in any way but will help us to better understand maternal-infant bonding in infants treated at home with methadone.

We expect that information learned from this study will benefit children in the future.

6. What are your options if you do not want to be in the study?

Your participation is required in order for your infant to be enrolled in the study. You and your infant do not have to join this study. If you do not join, your infant's care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

It will not cost you anything to participate in this study.

8. Will you be paid if you join this study?

You will not be paid for completing the questionnaires.

9. Can you leave the study early?

You can withdraw consent for yourself and your infant at any time. Please talk with your study doctor before withdrawing consent so that this can be done safely for your infant.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.
- If you are taken out of the study early, JHACH may use or give out your information that it already has if the information is needed for this study or any follow-up activities.

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records ([which may include information about HIV, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study. If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing.

If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 727-767-4275. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Sandra Brooks at 727-767-4313. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 727-767-4275.

13. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

Protocol Title: Methadone Demonstration Project

NCT03134703

Methadone group- Infant consent

Date: 04.12.2017

Patient I.D. Plate

PARENT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

INFANT Consent-METHADONE Group

Protocol Title: Methadone Demonstration Project

Application No.: IRB00107690

Sponsor: Florida Department of Health

Principal Investigator: Sandra Brooks, MD, MPH
Johns Hopkins All Children's Hospital
Department of Neonatology
501 6th Avenue South
St. Petersburg, FL 33701
Telephone: 727-767-4313
Fax: 727-767-4391

1. What you should know about this study:

- You are being asked to allow your infant to join a research study. This consent form explains the research study and your infant's part in the study.
- Please read it carefully and take as much time as you need.
- Ask your study doctor or the study team to explain any words or information that you do not understand.
- Joining this study is voluntary. If you allow your infant to join the study, you can change your mind later. You can decide not to allow your infant to take part at any time. There will be no penalty or loss of benefits if you decide not to allow your infant to continue the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to allow your infant to participate in the study.
- If we think your infant's participation in this study may affect your infant's clinical care, information about your infant's study participation will be included in your infant's medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your infant's doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital,

Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and Johns Hopkins All Children's Hospital.

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- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

Neonatal abstinence syndrome is a problem that can happen in infants who are exposed to certain drugs while they are in their mother's womb. Neonatal abstinence syndrome is also called NAS. Infants exposed to narcotics before they are born can have a lot of problems due to NAS after they are born. Narcotics are drugs with names such as oxycodone, morphine, methadone, subutex, suboxone and heroin.

Infants exposed to narcotics may be irritable, difficult to console, eat poorly and have shakiness and tremors. The nurses will monitor infants closely and give them a score to describe the severity of their withdrawal that we call the Finnegan scores. If the scores become high, infants need to be put on medication, usually a narcotic, to help them feel better and prevent life threatening complications of withdrawal.

NAS can increase the length of time infants stay in the hospital and increase the length of time they are separated from their mothers. We are trying to find better and safer ways of treating infants with NAS so that they can spend less time in the hospital.

NAS in infants is usually treated with a narcotic. The 2 most common narcotics used in infants are morphine and methadone. Morphine can only be used in the hospital and infants have to come off morphine before they can be discharged home. Our practice at Johns Hopkins All Children's Hospital (JHACH) NICU has been to treat infants with morphine and keep them in the hospital until the morphine is stopped.

Methadone is often used during pregnancy for mothers who are dependent on narcotics. The Food and Drug Administration (FDA) has approved methadone to treat narcotic dependence and withdrawal in adults. Methadone has been recommended for use by the American Academy of Pediatrics (AAP) to treat withdrawal in newborn infants. Methadone can be given to infants in the hospital and at home. At home treatment is usually offered to stable infants who are doing well on methadone at the hospital. The home of those infants is usually safe. Their mothers are reliable and very involved in their care.

This research is being done to find out if infants who are treated with the narcotic methadone can be safely discharged home early while still on methadone (Methadone treatment group). Your infant is at risk for developing NAS and is likely to need treatment. You have been identified by Operation PAR as being compliant with your methadone treatment. Because of this, with your permission, your infant can take part in the methadone treatment group of the study.

We will also enroll infants who are treated for NAS with other narcotics so we can compare them to infants who receive methadone (Control group).

How many infants will be in this study?

Twenty five (25) infants will be enrolled in the methadone treatment group of the study. We will also enroll 25 infants in the control group.

3. What will happen if you allow your infant to join this study?

This consent form describes your infant's participation in this study. A separate consent form will be given to you that describes your participation in this study.

If you agree to allow your infant to be in this study, we will ask you to allow your infant to do the following things:

Some of your infant's regular medical care will be a part of this study:

- Your infant's regular medical care will include:
  - Your infant will be on a monitor. The nurses will continuously watch your infant's heart rate, breathing, and oxygen level.
  - Using the Finnegan Neonatal Abstinence Score to watch for signs of withdrawal from drug exposure before being born. The Finnegan Neonatal Abstinence Score is a list of signs and symptoms of drug withdrawal. This list is used with infants to help the doctors and nurses know if and when infants need medication for withdrawal symptoms.
  - Routine feedings
  - Other standard newborn care as directed by your infant's doctor.
  - The nursing staff and volunteers will provide comfort measures.

Infants who need medication to treat their NAS receive morphine as part of their regular care for NAS and stay in the hospital until the morphine can be stopped.

- Your infant's care will be different:
  - Your infant will get the study drug, methadone, instead of morphine to treat NAS.
  - We will slowly increase the dose of methadone until your infant has a low score for NAS signs.
  - We will follow a strict protocol that will help us decide when it is safe to start decreasing the dose.
  - We will help you stay at your infant's bedside as much as possible.
  - We will teach you about NAS and how to recognize it.
  - We will teach you the Finnegan scoring.
  - The breastfeeding team will help you breastfeed your infant if so you wish.
  - You will meet our psychologist Dr. Lacy Chavis, who will counsel you and have you answer 2 questionnaires on bonding and postpartum depression while your infant is still at the hospital.
  - You will meet our social worker who will make sure that your home is safe for your infant to be discharged to.
  - When your infant has done well and you are ready, he/she will be cleared for discharge home:
    - Your infant will be discharged home while still on methadone given every 12 hours.
    - When you leave, you will take with you a mamaRoo swing and 3 HALO sleep sacks.
  - A nurse will be visiting you twice a day to assess your infant, do the Finnegan scoring and give your infant the medication.
  - You will get in touch with the nurse by phone every 3 hours when she is not visiting.
  - You will be talking to the nurse using an electronic tablet provided to you.
  - You will give the nurse an update on your infant. You will have to answer specific questions about your infant. You will also do the Finnegan scoring while the nurse is watching and guiding you.

- The methadone will be decreased every day if the scores are low.
- You will be visiting the JHACH pediatrician you would have met before you left the hospital 1 to 2 days after going home and regularly once a week as long as your infant is on methadone.
- You will also take your infant to see the same doctor once a week until 4 weeks after the methadone is taken off. After that, you can go back to your regular pediatrician.
- You will be given gas money for those visits.
- You will answer the same 2 questionnaires on bonding and postpartum depression when you are at home and when your infant is 6 to 8 weeks old.
- You will also be sent a questionnaire when your infant is 4 months, 8 months and 12 months old. It will tell us if your infant is developing normally. It will be an easy questionnaire that you will answer and send us back.

Sometimes during treatment, infants may have a set back and the Finnegan scores go up again. This is normal. Infants are comforted and the medication dose is increased – as part of routine care.

- In the case of your infant, if your infant needs the dose to be increased more than 2 times while at home, your infant will be brought back to the JHACH NICU to be monitored closely.
- If your infant is re-admitted to the hospital, your infant can not be sent home again until the methadone has been weaned off.

Sometimes, infants require a lot of medication to control their withdrawal. And sometimes they reach the maximum dose of narcotic that we can safely give them, In this case, a second medication is added to help your infant – as part of routine care.

- In the case of your infant, if at any time, your infant needs a second medication, your infant will be started on phenobarbital. Your infant will have to stay in the hospital and will not be discharged home until the methadone has been taken off.

You will be offered a mamaRoo swing and 3 HALO sleep sacks when your infant goes home on methadone.

You will be offered an electronic tablet to use until 48 hours after the methadone is stopped at home.

How long will your infant be in the study?

- Your infant will be in this study until the methadone has been stopped for one month.
- We would like you to visit our JHACH pediatrician once a week for 4 weeks after the methadone is stopped.
- You will also have to fill questionnaires at 4, 8 and 12 months of your infant's age.

4. What are the risks or discomforts of the study?

Your infant may have side effects while in the study. These side effects are the same that any infant can have being treated for NAS with a narcotic such as morphine or methadone. *The side effects may happen even if your infant is not in the study*. All infants taking part in the study will be watched carefully for any side effects. However, doctors do not know all side effects that may happen. Possible side effects include:

- Decreased breathing rate along with a lowering of the heart rate or oxygen level. This can happen because methadone, like morphine, is a narcotic. It may also happen if your infant was exposed to narcotics before your infant was born.

It is less likely to happen because your infant was already exposed to narcotics before to being born. Also, because of the way methadone works in the body and brain, it may be less likely than morphine to cause these problems.

- Increased withdrawal symptoms if the methadone is stopped too quickly. After your infant's NAS scores are low for 48 hours, we will slowly decrease the dose of methadone. The dose will be decreased very slowly.
  We will continue to watch your infant for withdrawal symptoms and can increase the dose again, if needed. *If you are breastfeeding, it is very important that you do not stop suddenly.*
- Rashes. Skin rashes can happen with any drug, but usually do not happen in infants.

There may be side effects and discomforts that are not yet known.

5. Are there benefits to your infant from being in the study?

- Your infant may or may not benefit from taking part in this study.
- Your infant may get discharged home sooner and if so, would get to spend more time at home with you.
- By taking part in this demonstration project, your infant may help us understand how to treat other infants with NAS in the future.

6. What are your options if you do not want your infant to be in the study?

Your infant's other choice includes getting standard care for NAS. Standard care includes:

- Using a monitor to watch your infant's heart rate, breathing, and oxygen level.
- Checking your infant's blood pressure at least two times every 24 hours.
- Using the Finnegan Neonatal Abstinence Score to watch for signs of withdrawal from drug exposure before being born.
- The doctors caring for your infant may order some laboratory tests.
- Comfort measures will be provided by the nursing staff and volunteers.
- Treatment of symptoms with morphine, a liquid drug given by mouth.
- Morphine may not take care of all of your infant's symptoms. Clonidine may also be given. Clonidine is another drug given by mouth.
- Routine feedings.
- Your infant will stay in the hospital until morphine and/or clonidine have been stopped and your infant is stable.
- If morphine and clonidine do not control withdrawal, phenobarbital will be started and infant will be discharged home on phenobarbital.

You do not have to allow your infant to join this study. If your infant does not take part in the study, your infant's care at Johns Hopkins All Children's Hospital will not be affected

7. Will it cost you anything to allow your infant to be in this study?

There is no cost to participate in this study. However, you or your insurance company will be responsible for the regular care that your infant gets while in the hospital.

8. Will you or your infant be paid if you allow your infant to join this study?

You will be given $10 in gas money for each of the study required JHACH pediatrician visits that will happen 1 to 2 days after discharge and then weekly until methadone has been stopped for one month.

9. Can your infant leave the study early?

You can agree to allow your infant to be in the study now and change your mind later.

- If you wish to end your infant's participation, please tell us right away.
- Leaving this study early will not stop your infant from getting regular medical care.
- If your infant leaves the study early, JHACH may use or give out your infant's health information that it already has if the information is needed for this study or any follow-up activities.

10. Why might we take your infant out of the study early?

Your infant may be taken out of the study if:

- Staying in the study would be harmful.
- Your infant needs treatment not allowed in the study.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take your infant out of the study that we do not know at this time.
- If your infant is taken out of the study early, JHACH may use or give out your infant's health information that it already has if the information is needed for this study or any follow-up activities.

11. How will your infant's privacy be protected?

We have rules to protect information about your infant. Federal and state laws and the federal medical Privacy Rule also protect your infant's privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about your infant. This includes things learned from the procedures described in this consent form. They may also collect other information including your infant's name, address, date of birth, and information from your infant's medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your infant's identity and that your infant is in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your infant's information. We make this information available to your infant's doctors for your infant's safety.

People outside of Johns Hopkins may need to see or receive your infant's information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your infant's information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your infant's information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your infant's information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your infant's information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your infant's information has no time limit. You may revoke (cancel) your permission to use and disclose your infant's information at any time by notifying the Principal Investigator of this study by phone or in writing.

If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your infant's information, your infant's part in this study will end and no further information about your infant will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What treatment costs will be paid if your infant is injured in this study?

Johns Hopkins and the State of Florida Department of Health do not have programs to pay you if your infant is hurt or has other bad results from being in the study. However, medical care at Johns Hopkins is open to your infant as it is to all sick or injured people.

The costs for any treatment or hospital care your infant receives as a result of a study-related injury that is not covered by a health insurer will be billed to you.

By signing this form you and your infant will not give up any rights you have to seek compensation for injury.

13. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your infant's rights as a participant or if you think you or your infant have not been treated fairly. The IRB office number is 727-767-4275. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Sandra Brooks at 727-767-4313. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 727-767-4275.

c. What should you do if your infant is injured or ill as a result of being in this study?

If you think your infant is injured or ill because of this study, and your infant is receiving methadone *at the hospital*, call Dr. Sandra Brooks at 727-767-4313 during regular office hours.

If you think your infant is injured or ill because of this study, and your infant is receiving methadone *at home*, call Dr. Rachel Dawkins or Dr. Melissa Brinn at 727-767-8917 during regular office hours.

If your infant has an urgent medical problem related to taking part in this study, call Kids Home Care at 727-767-8240 during regular office hours and after hours and on weekends.

d. What happens to Data that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you allow your infant to join this study, you should understand that you/your infant will not own your infant's data, and should researchers use them to create a new product or idea, you/your infant will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your infant's information with our research sponsors and partners.

14. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to allow your infant to join the study
- You and your infant will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Parent	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

Protocol Title: Methadone Demonstration Project

NCT03134703

Comparison group- Maternal consent

Date: 11.09.2016

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

MATERNAL Consent-CONTROL Group

Protocol Title: Methadone Demonstration Project

Application No.: IRB00107690

Sponsor: Florida Department of Health

Principal Investigator: Sandra Brooks, MD, MPH
All Children's Hospital, Department of Neonatology
501 6th Avenue South
St. Petersburg, FL 33701
Telephone: 727-767-4313
Fax: 727-767-4391

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- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This study is being done to compare the treatment of infants receiving methadone for treatment of Neonatal Abstinence Syndrome (NAS) to those infants who are treated with another narcotic. We would like to compare maternal bonding and depression symptoms of mothers whose infants are receiving methadone (Methadone treatment group) to mothers whose infants are treated with a narcotic other than methadone (Control group). You and your infant are being asked to participate in the control group of this study.

How many people will be in this study?

Twenty five mothers will participate in the control group. We will also enroll 25 mothers in the methadone treatment group).

3. What will happen if you join this study?

This consent form describes your participation in this study. A separate consent form will be given to you that describes your infant's participation in this study.

You will be asked to fill out questionnaires about your relationship with your infant that measures postpartum bonding. You will also complete a questionnaire to assess postpartum depression. These may include questions about your mental health and health behavior, stress, and your relationship with your infant. Some of these questions may be sensitive. If your answers to questions as part of this research make us concerned about your mental health or safety, we will tell you this and give you resources where you could get help.

How long will you be in the study?

You will be in this study until the last questionnaires are completed, when your infant is 6 to 8 weeks old.

4. What are the risks or discomforts of the study?

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

5. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. Participation in this study will not help you or improve your health in any way but will help us to better understand maternal-infant bonding in infants treated at home with a narcotic other than methadone.

We expect that information learned from this study will benefit children in the future.

6. What are your options if you do not want to be in the study?

Your participation is required in order for your infant to be enrolled in the study. You and your infant do not have to join this study. If you do not join, your infant's care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

It will not cost you anything to participate in this study.

8. Will you be paid if you join this study?

You will not be paid for completing the questionnaires.

9. Can you leave the study early?

You can withdraw consent for yourself and your infant at any time.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.
- If you are taken out of the study early, JHACH may use or give out your information that it already has if the information is needed for this study or any follow-up activities.

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records ([which may include information about HIV, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study. If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing.

If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected.
Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 727-767-4275. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Sandra Brooks at 727-767-4313. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 727-767-4275.

13. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

Protocol Title: Methadone Demonstration Project

NCT03134703

Comparison group- Infant consent

Date: 11.09.2016

Patient I.D. Plate

PARENT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

INFANT Consent-CONTROL Group

Protocol Title: Methadone Demonstration Project

Application No.: IRB00107690

Sponsor: Florida Department of Health

Principal Investigator: Sandra Brooks, MD, MPH
Johns Hopkins All Children's Hospital
Department of Neonatology
501 6th Avenue South
St. Petersburg, FL 33701
Telephone: 727-767-4313
Fax: 727-767-4391

1. What you should know about this study:

- You are being asked to allow your infant to join a research study. This consent form explains the research study and your infant's part in the study.
- Please read it carefully and take as much time as you need.
- Ask your study doctor or the study team to explain any words or information that you do not understand.
- Joining this study is voluntary. If you allow your infant to join the study, you can change your mind later. You can decide not to allow your infant to take part at any time. There will be no penalty or loss of benefits if you decide not to allow your infant to continue the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to allow your infant to participate in the study.
- If we think your infant's participation in this study may affect your infant's clinical care, information about your infant's study participation will be included in your infant's medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your infant's doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital,

Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and Johns Hopkins All Children's Hospital.

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

Neonatal abstinence syndrome is a problem that can happen in infants who are exposed to certain drugs while they are in their mother's womb. Neonatal abstinence syndrome is also called NAS. Infants exposed to narcotics before they are born can have a lot of problems due to NAS after they are born. Narcotics are drugs with names such as oxycodone, morphine, methadone, subutex, suboxone and heroin.

Infants exposed to narcotics may be irritable, difficult to console, eat poorly and have shakiness and tremors. The nurses will monitor infants closely and give them a score to describe the severity of their withdrawal that we call the Finnegan scores. If the scores become high, infants need to be put on medication, usually a narcotic, to help them feel better and prevent life threatening complications of withdrawal.

NAS can increase the length of time infants stay in the hospital and increase the length of time they are separated from their mothers. We are trying to find better and safer ways of treating infants with NAS so that they can spend less time in the hospital.

NAS in infants is usually treated with a narcotic. The 2 most common narcotics used in infants are morphine and methadone. Morphine can only be used in the hospital and infants have to come off morphine before they can be discharged home. Our practice at Johns Hopkins All Children's Hospital (JHACH) NICU has been to treat infants with morphine and keep them in the hospital until the morphine is stopped.

We are doing a study where some infants are given methadone instead of morphine. These infants have been pre-selected to take part of the study before they were born.

Your infant is eligible to take part in the control group of this study because your infant has developed NAS and is receiving treatment with morphine. This study will compare the length of your infant's hospitalization to those of infants who receive methadone. You will also be asked to fill a maternal-infant bonding questionnaire and a postpartum depression questionnaire and those results will be compared to the questionnaires that are answered by the mothers of infants who receive methadone. All the information about you and your infant will be confidential.

How many infants will be in this study?

Twenty five (25) infants will be enrolled in the control group. We will also enroll 25 infants in the methadone treatment group of the study.

3. What will happen if you allow your infant to join this study?

This consent form describes your infant's participation in this study. A separate consent form will be given to you that describes your participation in this study.

The purpose of this study is to collect information from your infant's medical record related to their NAS. The information we will collect about your infant will mainly be information that is part of their medical record. This may include information such as the results of laboratory testing and radiological imaging and their treatment that they have done as part of their regular care. This study does not influence the treatment your infant receives.

How long will your infant be in the study?
Your infant will be in this study until discharge from the hospital.

4. What are the risks or discomforts of the study?

There are no anticipated risks to your infant by taking part in this study.

5. Are there benefits to your infant from being in the study?

- Your infant will not directly benefit from taking part in this study.
- By taking part in this demonstration project, your infant may help us understand how to treat other infants with NAS in the future.

6. What are your options if you do not want your infant to be in the study?

You do not have to allow your infant to join this study. If your infant does not take part in the study, your infant's care at Johns Hopkins All Children's Hospital will not be affected

7. Will it cost you anything to allow your infant to be in this study?

No. You or your insurance company will be responsible for the regular care that your infant gets while in the hospital.

8. Will you or your infant be paid if you allow your infant to join this study?

No.

9. Can your infant leave the study early?

You can agree to allow your infant to be in the study now and change your mind later.

- If you wish to end your infant's participation, please tell us right away.
- Leaving this study early will not stop your infant from getting regular medical care.
- If your infant leaves the study early, JHACH may use or give out your infant's health information that it already has if the information is needed for this study or any follow-up activities.

10. Why might we take your infant out of the study early?

Your infant may be taken out of the study if:

- The study is cancelled.
- There may be other reasons to take your infant out of the study that we do not know at this time.
- If your infant is taken out of the study early, JHACH may use or give out your infant's health information that it already has if the information is needed for this study or any follow-up activities.

11. How will your infant's privacy be protected?

We have rules to protect information about your infant. Federal and state laws and the federal medical Privacy Rule also protect your infant's privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about your infant. This includes things learned from the procedures described in this consent form. They may also collect other information including your infant's name, address, date of birth, and information from your infant's medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your infant's identity and that your infant is in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your infant's information. We make this information available to your infant's doctors for your infant's safety.

People outside of Johns Hopkins may need to see or receive your infant's information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your infant's information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your infant's information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your infant's information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your infant's information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your infant's information has no time limit. You may revoke (cancel) your permission to use and disclose your infant's information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your infant's information, your infant's part in this study will end and no further information about your infant will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

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- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your infant's rights as a participant or if you think you or your infant have not been treated fairly.

The IRB office number is 727-767-4275. You may also call this number for other questions, concerns or complaints about the research.

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b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Sandra Brooks at 727-767-4313. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 727-767-4275.

c. What happens to Data that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you allow your infant to join this study, you should understand that you/your infant will not own your infant's data, and should researchers use them to create a new product or idea, you/your infant will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your infant's information with our research sponsors and partners.

13. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to allow your infant to join the study
- You and your infant will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Parent	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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