NIDA CTN Protocol 0080: Medication Treatment for Opioid Use Disorder in Expectant Mothers (MOMs): a Pragmatic Randomized Trial Comparing Extended-release and Daily Buprenorphine Formulations: Conceptual Model Assessments (CMA) Sub-study

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UNIVERSITY OF CINCINNATI MEDICAL
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: CTN-0080: Medication treatment for Opioid use disorder in expectant Mothers (MOMs): a pragmatic randomized trial comparing extended-release and daily buprenorphine formulations - Conceptual Model Assessment (CMA) Sub-study

UC IRB Study #: 2019-0429 **Sponsor Name:** NIDA
Marshall IRB Study#: 1839138

Local Site Name: Marshall University's Division of Addiction Sciences

Investigator Information:

Zachary Hansen, MD	304-691-6404
Principal Investigator Name	Telephone Number 24 hr Emergency Contact

Subject Name: _____ Date of Birth: _____/_____/____

KEY INFORMATION

Purpose of the Study:	The purpose of this study is to help us understand why the medications in the main CTN-0080 study may have different effects on pregnant women and their as-yet-unborn infants.
Length of the Study:	You would be in this study from point-of-consent through delivery.
Risks:	The risks you encounter would be the risks normally associated with a blood draw. The risks from the fetal assessment would not be any more than those associated with the procedure outside of research. See section titled "What are the Risks and Discomforts of the Research Study?" For more information.
Benefits of the Study:	The researcher and sponsor of this study do not promise that you will receive any benefits from this study.
Alternative procedures:	The alternative is to simply not participate. Your participation in this research study is entirely voluntary.

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INTRODUCTION:

A biomedical or health-related research study is performed to answer specific questions about a disease.

Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts, and precautions of the research. You should also be told what alternative procedures are available to you if you do not participate in the research study. The informed consent document is a written summary of this information. Be sure to ask questions while you read this consent document and ask questions if there is anything that you do not understand.

Your participation in this research study is entirely voluntary.

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The researcher and sponsor of this study do not promise that you will receive any benefits from this study.

WHY IS THIS RESEARCH BEING DONE?

This study is an extra, optional sub-study related to the CTN-0080 MOMs study. It is called the Conceptual Model Assessment (CMA) sub-study. The main CTN-0080-MOMs study is being done to compare two treatments for pregnant women with opioid use disorder. This CMA sub-study is being done to help us see why the treatments may have different effects on pregnant women and their as-yet-unborn infants.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you are participating in the CTN-0080-MOMs study.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research sub-study from the point of signing this consent point through delivery.

The researcher may decide to remove you from this research study at any time. Reasons for discontinuation may include:

- If it becomes no longer safe for you or your unborn infant to continue participation
- If study funding is stopped

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first so that stopping can be done safely. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

You may be contacted in the future by representatives of the University of Cincinnati who are interested in asking you survey questions about your participation in this research study. If you choose to participate in the survey, your responses will be used for quality assurance purposes only.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is sponsored and directed nationally by T. Winhusen, Ph.D., a researcher at The University of Cincinnati, and supported by the National Institute of Drug Abuse (NIDA).

Locally, the study is directed by Zachary Hansen, the researcher at the Joan C. Edwards School of Medicine at Marshall University through the Division of Addiction Sciences and Department of Family and Community Health (Marshall).

Medical supervision for the study is provided locally by Zachary Hansen.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 25 people may take part in this study at **Marshall University's Division of Addiction Sciences.** A total of about 200 people may take part across the country.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

When possible, procedures for this study will take place at the same time as the research procedures for the CTN-0080-MOMs study. Ideally, blood draws for this sub-study will occur at the clinic or associated lab; delivery samples will be drawn at the delivery hospital. The Estimated Gestational Age Week 36 fetal assessment may occur at the clinic or through an associated provider. CMA procedures may also occur at other locations to accommodate participant and provider needs and preferences. This may include your home or other appropriate locations within the community. If a blood draw occurs outside of the clinic, hospital, or laboratory, it will still meet all regulations for safety and handling of blood specimens.

VISITS AT WEEK 3, WEEK 5, AND ESTIMATED GESTATIONAL AGE (EGA) ~36 Weeks

At the weeks listed above, you will be asked to give a blood sample at the time when your buprenorphine blood level is expected to be at its lowest. For CAM2038, this is immediately before getting a dose of CAM2038. For sublingual buprenorphine, this is before the first daily

dose of sublingual buprenorphine. Providing each blood sample will take about 10 minutes to complete.

ESTIMATED GESTATIONAL AGE (EGA) ~36 Weeks –Blood sample + Fetal Assessment

At about 36 weeks into your pregnancy, you will be asked to attend an additional visit at the time when your buprenorphine blood level is expected to be at its highest. For CAM2038, this is about 24 hours after getting a dose of CAM2038. For sublingual buprenorphine, this is about 2.5 hours after a dose of sublingual buprenorphine. This visit may need to be performed at an OB/GYN clinic different from the one you typically attend. At this visit, you will be asked to give a blood sample and to have a fetal assessment done. The fetal assessment includes an ultrasound exam and a measurement of fetal heart rate. These procedures will take about 80 minutes.

DELIVERY
If your delivery hospital is participating in this sub-study, we will obtain a cord plasma sample. This will happen after the umbilical cord has been detached from you and your infant. If you plan to store cord blood in a family bank, then that collection will be done first. We still will collect cord blood for research purposes if there is enough remaining after your donation to a family bank. We will also obtain a blood sample from you. Both the cord blood and your blood sample are being collected to measure buprenorphine and buprenorphine-related levels.

ADDITIONAL DATA
If you become a prisoner, we would still like to find out how you are doing. Being a prisoner includes being in jail or prison, being on probation or parole, or being under house arrest or electronic monitoring. If needed, we will try to collect follow-up data from you over the phone or in person. Please note that your continued participation would have no effect on your criminal case, or release or parole from jail or prison, or probation case.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

Risks of a blood draw may include:

- momentary discomfort at the draw site
- bruising
- redness and/or swelling around the site
- bleeding at the site
- feeling of lightheadedness when the blood is drawn

Rarely:

- infection at the site of the blood draw

While the fetal assessment has no foreseen risks, you may experience discomfort during its administration.

There are no foreseen risks for either you or your infant when drawing blood from a detached umbilical cord.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there will not be a direct medical benefit to you. We hope the information learned from this research study will benefit other pregnant patients with opioid use disorder, and their infants, in the future. Potential benefits to you may include the fetal assessment provided to you at no cost.

WHAT OTHER CHOICES FOR CARE ARE THERE?

If you do not wish to participate in this portion of the CTN-0080 MOMs study, you may simply elect to not participate. Electing to not participate in this portion of the study will not impact your participation in the CTN-0080 MOMs study, nor will it affect your quality of care you or your as-yet-unborn infant already receive at **Marshall Division of Addiction Sciences**.

WHAT IS THE CLINICAL TRIALS REGISTRY?

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 results. You can search this Web site at any time.

Data-share Website

Data from this study will be available to researchers on another website, https://datashare.nida.nih.gov/ after the study is complete and the data has been analyzed. This website will NOT include information that can identify you. You can view this website at any time.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy and the privacy of your as-yet-unborn infant, this study is covered by a Certificate of Confidentiality from the Department of Health and Human Services (HHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you or your as-yet-unborn infant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of HHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a infant or elderly person or that you intend to harm yourself or someone else, about certain communicable diseases, or about any other information that requires reporting according to

state and local laws, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent form.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

You will be responsible for all costs associated with prenatal care, delivery, neonatal care, and hospital stay. Insurance may cover some of these costs. Any procedures, visits, or tests performed solely for the purpose of research will be provided at no cost to you.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be paid for your time and travel for this study. Payments will be made in the form of Clincard according to the following schedule:

Visit	Amount
Week 3	$25
Week 5	$25
36 Weeks EGA - Blood sample visit	$25
36 Weeks EGA – Second blood sample	$25
36 Weeks EGA – Fetal Assessment	$85
Total	$185

The reimbursement amounts listed in the table above will be reduced by $10 if you do not travel to attend the visit.

If you receive payments for being a part of this research study, you may be asked to complete an Internal Revenue Service (IRS) form. The amount you receive may count as income and may affect your income taxes. Your social security number will be required to complete the IRS form.

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

In the event that you become ill or injured from participating in this research study, emergency medical care will be provided to you. **Marshall University's Division of Addiction Sciences**

will decide on a case-by-case basis whether to reimburse you for your out-of-pocket health care expenses.

If you think that you have been hurt by taking part in this research contact Dr. Zachary Hansen at 304-691-6404 as soon as possible. If needed, emergency medical care will be provided. If the injury is a direct result of a study-related procedure or because you are taking either sublingual buprenorphine or CAM2038, the cost of the emergency medical care will be paid by **Marshall University's Division of Addiction Sciences** only if it is not paid by your health insurance, a government program, or other third party. The Sponsor has no plans to pay for medical care for any other injury whether or not it might be related to taking part in this research.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you may have, nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Every effort will be made to maintain the confidentiality of your and your infant's medical and research records related to this study. Agents of the United States Food and Drug Administration (FDA), the University of Cincinnati, Marshall University's Division of Addiction Sciences and the sponsor, NIDA or its designees, study monitors, auditors, the Institutional Review Board (IRB), and other regulatory authorities will be granted direct access to your original medical and research records for verification of clinical trial (research study) procedures or study data without violating your confidentiality or that of your as-yet-unborn infant, to the extent permitted by the applicable laws and regulations. By signing this consent form, you or your legally authorized representative are authorizing such access. The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is required by law.

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 results. You can search this Web site at any time. Data from this study will be available to researchers on another website, https://datashare.nida.nih.gov/ after the study is complete and the data has been analyzed. This website will not include information that can identify you. You can view this website at any time. Biological samples (e.g. blood and urine samples) obtained as part of study procedures will be destroyed once the study has completed; samples will not be stored or distributed to be used for future research studies. No genetic information will be extracted, stored or sequenced from these samples.

Authorization to Use and Disclose Health Information

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your and your infant's health information. Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you or your infant. You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you.

If you sign this informed consent form, you are giving permission for the use and disclosure of your and your infant's health information for purposes of this research study to the parties listed in this document. You do not have to give this permission. Your health care and the health care of your infant outside of the study, payment for your health care and health care of your infant, your health care benefits, and the health care benefits of your infant will not be affected if you choose not to sign this form. However, if you do not sign this form, you will not be able to participate in the study.

The State of West Virginia requires direct consent for use of information from patients with behavioral health disorders, including substance use disorder unless waived by an IRB under 45 CFR part 46. By signing this consent document, you are consenting to allow research staff to review your private health information only for use in the study as described.

Who Will Use and Disclose My Health Information? The study doctor and research staff (the study team) may use your health information and the health information about your infant to conduct, review, and determine the results of the study. The study team may also use your information and the information of your infant to prepare reports or publications about the study. However, neither your name nor the name of your infant will appear in any report or publication without your permission.

Additionally, data collected from this research study will be combined into the primary CTN-0080 MOMs database, which you have already consented to participate in.

What Health Information will be Used and Disclosed? The study team will record your medical history, the treatment you receive, and the results of examinations and tests done during the study on study forms and record the same for your infant. The study team will send

the completed study forms to the study sponsor. Representatives from the groups identified below may need to look at your medical records and your infant's medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Your medical records and your infant's medical records may include other health information about you and your infant and may include documents that directly identify you and your infant. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

Who Will Receive My Health Information? Your and your infant's study information or medical records (as described above) or both may be shared with the following people or groups:

- The study sponsor or its representatives, including companies it hires to provide study-related services
- Researchers who are conducting this study at other study centers, including monitors and project management personnel from University of Cincinnati
- UC Institutional Review Board and any other committees responsible for overseeing the research
- Staff of the UC Human Research Protection Program
- Staff of the Marshall IRB
- Marshall Health and Cabell-Huntington Hospital employees providing service or care to you
- Federal and State agencies, such as the U.S. Food and Drug Administration (FDA), Department of Health and Human Services (HHS), the National Institutes of Health (NIH), and other US and non-US government bodies that oversee or review research

Information gathered from this study will be incorporated into the main study database.

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others? Marshall and Mountain Health Network are required by the Privacy Rule to protect your health information and the health information of your infant. After your information and your infant's information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information and/or your infant's information only for research or regulatory purposes or to prepare research publications. Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative, if this might be a possibility. The goal of any such research would be to learn more about drugs, devices or diseases or to help design better studies in the future. When using your or your infant's information in these ways, the sponsor may share it with regulatory authorities, other researchers, its business partners, or companies it hires to provide research-related services.

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What Happens if I Leave the Study Early? If you stop participating in the study early for any reason, the study team will tell the sponsor why. If the study team asks you to come to any more study visits and you agree, the study team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

Will My Authorization Ever Expire? This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over and a review of your medical records may also take place after the study is over.

May I Take Back My Authorization? You have the right to take back (revoke) your Authorization at any time by writing to the person in charge of this research study whose information is listed on the front of this form. If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

May I Look At My Study Information? You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns, complaints and/or suggestions about this research study or to report a research-related injury, please contact the research team or Dr. Hansen by calling 304-691-6404.

Please call the University of Cincinnati Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm eastern time zone) if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research.
- Cannot reach the research team or you want to talk to someone else.

You may also contact the Marshall University Office of Research Integrity or the Institutional Review Board at Marshall University at 304-696-4303.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

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Comprehension Tool

1.	My participation in this sub-study is entirely voluntary.	T	F
2.	My participation includes getting my blood drawn.	T	F
3.	Two of my study visits will occur in the same timeframe - when I am at approximately 36 weeks in my pregnancy.	T	F
4.	I have to be in this sub-study to participate in the CTN-0080 MOMs study.	T	F
5.	My participation in this sub-study will last from the time I sign this consent through delivery.	T	F

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UNIVERSITY OF CINCINNATI - Medical
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

CTN-0080: Medication treatment for Opioid use disorder in expectant Mothers (MOMs): a pragmatic randomized trial comparing extended-release and daily buprenorphine formulations - Conceptual Model Assessment (CMA) Sub-study

UC IRB Study #: 2019-0429 **Sponsor Name:** NIDA
Local Site Name: Marshall Division of Addiction Sciences
Investigator Information:

Zachary Hansen, MD	304-691-6404
Principal Investigator Name	Telephone Number 24 hr Emergency Contact

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated form for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.
I give my consent to participate, and for my as-yet-unborn infant to participate.

I authorize the release of information concerning treatment relating to…

- alcohol use
- drug abuse
- My as-yet-unborn infant

…to the parties listed in the authorization section of this consent for the purposes described above.

_____

Participant Date Time

PERSON OBTAINING CONSENT
I have read this form to the participant and/or the participant has read this form. An explanation of the research was given and questions from the participant were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

_____
Printed name of Person obtaining Consent

_____

Signature and Title of Person Obtaining Consent and Identification of Role in the Study Date

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

____I **want** the researcher to inform my primary care physician/specialist of my participation in this study.
___ I **do not want** the researcher to inform my primary care physician/specialist of my participation in this study.
___I do not have a primary care physician/specialist.
___The researcher is my primary care physician/specialist.

_____
Participant
Date