Study Title: NIDA CTN Protocol 0150: Personally-Tailored Opioid-overdose and Medication for opioid use disorder (MOUD) Education (TOME) for pregnant and postpartum persons in MOUD: A pilot randomized trial (TOME trial)

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: **NIDA CTN Protocol 0150: Personally-Tailored Opioid-overdose and Medication for opioid use disorder (MOUD) Education (TOME) for pregnant and postpartum persons in MOUD: A pilot randomized trial (TOME trial)**	
PERFORMANCE SITE: **Gateway Community Services**	**PROTOCOL PRINCIPAL INVESTIGATOR:** **T. John Winhusen, PhD.**
SITE PRINCIPAL INVESTIGATOR NAME: *Dr. Candace Hodgkins, PhD, LMHC*	**PHONE NUMBER (24-hour Emergency Contact)** *904-387-4661*
PARTICIPANT NAME:	**DATE OF BIRTH:**

KEY INFORMATION

Purpose of the Study:	This study is research. Your participation is voluntary. The main purpose of this study is to evaluate the ability of a personally-tailored education intervention (TOME) to increase knowledge about opioid-overdose and medication for opioid use disorder (MOUD). The TOME intervention will be compared to standard informational materials.
Length of the Study:	The study is expected to take place over about 6 months. Your participation would last for approximately three (3) weeks.
Risks:	Risks associated with study participation include the possibility that confidentiality may be breached (as with any research study), and emotional discomfort (from answering questions of a personal nature). See section titled "What are the Risks and Discomforts of the Research Study?" for more details and additional risks related to the study.

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Benefits of the Study:	There may not be a direct medical benefit to you. We hope the information learned from this research study will benefit other pregnant and postpartum people in the future. You may directly benefit from study participation in that you will receive information about risks for overdose, the signs of overdose, how to respond to an overdose, and factors that can reduce the risk of an overdose. You will also receive information about MOUD that you may find helpful. You may also benefit from receiving a naloxone nasal spray kit.
Alternative procedures:	You may simply choose not to participate in this study. Choosing not to participate will not result in any penalty or loss of benefits to you, nor will it affect your quality of care.

INTRODUCTION:

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. Your participation in this study is entirely voluntary. If you decide to participate, you may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you. Be sure to ask questions while you read this consent document and ask questions if there is anything that you do not understand.

WHY IS THIS RESEARCH BEING DONE?

The main purpose of this research study is to determine the ability of Personally-Tailored Opioid-overdose and Medication for opioid use disorder (MOUD) Education (TOME) to increase Medication for opioid use disorder (MOUD) and opioid-overdose knowledge in pregnant and post-partum (PP) persons. The TOME intervention will be compared to standard information products.

The FDA approved the first over-the-counter naloxone nasal spray in March 2023 to help reduce drug overdose deaths. Naloxone is a lifesaving emergency treatment that reverses opioid overdose. It is a medicine with no abuse potential, and it is not a controlled substance.

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 at least 18 years old, are either currently pregnant or within 12 months postpartum and are enrolled in MOUD at this location.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately 3 weeks. The study will run for approximately 6 months overall.

The researcher may decide to take you off this research study at any time. Reasons for withdrawal may include study funding being stopped or you failing to follow important instructions given by the investigator.

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. One reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care 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 by the National Institute on Drug Abuse (NIDA).

The study is directed by T. John Winhusen, PhD. the researcher at the University of Cincinnati.

The local investigator for the study at Gateway Community Services is Dr. Candace Hodgkins, PhD, LMHC. This investigator is responsible for supervising all elements of the study at this site.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 20 people will take part in this study at Gateway Community Services. A total of about 120 people will take part across the country.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

SCREENING/BASELINE

If you decide to volunteer and sign this consent form, you will start screening procedures that help us to see whether or not this study is suitable for you. Screening procedures will take approximately 1.5-2 hours to complete. The things that will happen during screening are done only for this research study and are not part of any other routine healthcare you may receive. For screening, you will be asked to:

- Answer questions about: your past alcohol and drug use, things that can increase the risk of overdose, your mental health, treatment status, pregnancy status, and your thoughts about your MOUD treatment;
- Complete a survey to assess your knowledge of opioid-overdose and medication for opioid use disorder (MOUD);
- Answer basic questions about your gender, race, and ethnicity;
- Provide contact information for yourself and people who can help us locate you in the future and sign a release of information for them

RANDOMIZATION
If you are eligible and agree to take part in the study, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group completely by chance. It is like flipping a coin.

TOME
If you are randomized to the TOME intervention, you will:

- Receive a personalized feedback report based on your answers to the survey assessing your opioid-overdose and MOUD knowledge;
- Be offered a free naloxone nasal spray kit.

CONTROL
If you are randomized to the control group, you will be offered three handouts (physical or electronic), published by the Substance Abuse and Mental Health Services Administration (SAMHSA) that educate about opioid-overdose, opioid use disorder, and MOUD. You will also be offered a free naloxone nasal spray kit.

FOLLOW-UP
Approximately 3 weeks after randomization, you will be asked to return to the site to complete follow-up visit. You will complete the same surveys you took at the screening/baseline visit to assess your knowledge of opioid-overdose and MOUD, your thoughts about your MOUD treatment, as well as check up on how you have been since the randomization visit.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

Breach of confidentiality: As with any study, there is a potential risk of loss of confidentiality. To maintain confidentiality, all study records and data will be secured, and information collected by the study will not be shared with your healthcare provider(s). Additionally, as described below, a Certificate of Confidentiality has been obtained for the study.

Emotional Discomfort: You may also experience some emotional discomfort from answering sensitive and/or personal questions. You may experience embarrassment in answering questions about your knowledge of MOUD and opioid overdose. You can choose to not answer questions that you find to be too uncomfortable, or you may choose to withdraw from the study if you find participation too stressful. There may be unknown or unforeseen risks associated with study participation.

Side Effects of Naloxone Nasal Spray: Naloxone nasal spray is an FDA-approved medication indicated for the emergency treatment of known or suspected opioid overdose. The primary side effect of naloxone is sudden opioid withdrawal symptoms. In someone who has been using opioids regularly, opioid withdrawal symptoms can happen suddenly after receiving naloxone nasal spray and may include the following:

Body aches
Fever
Goose bumps
Nausea or vomiting
Shivering or trembling
Increased blood pressure
Diarrhea
Runny nose
Sweating
Nervousness
Stomach cramping
Increased heart rate
Sneezing
Yawning
Restlessness or Irritability
Weakness

WHAT ARE THE REPRODUCTION RISKS?

Naloxone can cause withdrawal symptoms in fetus as well as mother. Potential benefits may warrant use of the drug in pregnant women despite potential risks.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there may not be a direct medical benefit to you. We hope the information learned from this research study will benefit other pregnant and postpartum people in the future. You may directly benefit from study participation in that you will receive information about risks for overdose, the signs of overdose, how to respond to an overdose, and factors that can reduce the risk of an overdose. You will also receive information about MOUD that you may find helpful. You may also benefit from receiving a naloxone nasal spray kit.

WHAT OTHER CHOICES FOR CARE ARE THERE?

You may choose not to participate in this study. Choosing not to participate will not result in any penalty or loss of benefits to you, nor will it affect your quality of care.

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 Website will not include information that can identify you. At most, the Website will include a summary of results. You can search this Website at any time.

DATA-SHARE WEB SITE

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, the researchers have been issued a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not

disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS 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 child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, 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 not be charged for assessments related to this study. However, you and/or your third party payer (insurance, Medicaid, etc.) will still be responsible for costs related to substance use treatment and other healthcare costs not directly associated with this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be paid up to $75 for your time and travel costs related to taking part in this study.

Visit	Payment
Screening/Baseline	$45
Week 3	$30

Participants will receive cash payment at the conclusion of each visit.

If you receive payments for being a part of this research study, you will 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 ARE YOUR RIGHTS AS A PARTICIPANT?

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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 medical and research records related to this study. Agents of the University of Cincinnati, and the sponsoring agency, the National Institute on Drug Abuse (NIDA), the monitor, the auditor, the Institutional Review Board (IRB), and other regulatory authority(ies*)* 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, 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.

Authorization to Use and Disclose Health Information

A federal regulation known as the Privacy Rule requires that the researchers get your written permission to use your health care information in this research study. If you sign this form, you are giving your authorization for the use and disclosure of your health information for research purposes. You do not have to give this authorization. If you do not give your authorization you cannot be in the research study. However, if you are being treated as a patient here, you will still be able to receive care.

Who Will Use and Disclose My Health Information? The researchers will use your health information to conduct, review, and determine the results of the study. The researchers may also use your information to prepare reports or publications about the study. Your name will not appear in any report or publication without your permission.

Who Will Receive My Health Information? The following people or groups may receive your health information:

- Researchers who are conducting this study at other study centers
- The study sponsor or its representatives, including companies it hires to provide study-related services
- University of Cincinnati Institutional Review Board (IRB) or an outside external IRB reviewing the study
- Other compliance committees responsible for overseeing the research
- UC Health and UC hospital or clinic employees providing service or care to you
- Outside entities engaged with and contracted by UC Health and UC to facilitate clinical research workflow
- Federal and State agencies, such as the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), and other US and non-US government bodies that oversee or review research

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others? If the groups above share your health information with others, it will no longer be protected by the Privacy Rule.

Will My Authorization Ever Expire? Your authorization will not expire.

May I Take Back My Authorization? You may take back your authorization at any time by writing to the Site Principal Investigator, Dr. Candace Hodgkins, PhD, LMHC. If you take back your authorization, you will not be able to stay in this study. If you take back your authorization, the study team will not collect any new health information about you. Information that has already been collected may still be used and given to others. If you withdraw your authorization, no new health information will be collected unless you have a side effect related to the study.

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May I Look at My Study Information? You may be able to look at and make copies of your health information collected for this study when the study is completed.

WILL YOUR DATA BE USED FOR FUTURE RESEARCH STUDIES?

Information that could identify you will be removed from the study data. After removal, the study data could be used for future research studies. The study data could also be given to another researcher for future research studies. This may be done without getting additional permission from you.

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 please contact the Site Principal Investigator Dr. Candace Hodgkins, PhD, LMHC at 904-387-4661 or the Principal Investigator Dr. Winhusen at 513-310-0442.

Please call the University of Cincinnati Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) 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.

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 study is completely voluntary.	T	F
2. My participation in this study would last about 3 weeks.	T	F
3. I will be asked to return for a follow-up visit about 3 weeks after the randomization/baseline visit.	T	F
4. If I am deemed eligible for this study, I will be able to choose which arm I will be put into.	T	F
5. If I receive the TOME intervention, I will receive feedback based on my knowledge of opioid-overdose and MOUD.	T	F

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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SITE PRINCIPAL INVESTIGATOR NAME: *Dr. Candace Hodgkins, PhD, LMHC*	**PHONE NUMBER (24-hour Emergency Contact)** *904-387-4661*
PARTICIPANT NAME:	**DATE OF BIRTH:**

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.
I authorize the release of information concerning treatment relating to…

- psychiatric condition(s)
- alcoholism
- drug abuse

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

Participant Date

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___Oral presentation of the consent was given to the participant, who was not able to read the written consent. By signing, I certify that the oral presentation was consistent with this written document.

_____

Impartial Witness Signature (oral presentation only) Date

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.

_____

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

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PERMISSION TO CONTACT YOU ABOUT FUTURE RESEARCH

We are asking your permission to contact you about future research studies conducted by the CTN-0150 TOME investigators.

If you agree, you might be contacted about other research studies in the future. At that time, you can decide whether or not you are interested in hearing more about the study.

Your permission to allow us to contact you about future research studies would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your care or participation in the CTN-0150 TOME study. Please understand that giving your permission to do this is only to help us identify individuals who may qualify for one of our future research studies. It does not mean that you must join in any study.

Please initial your choice below.

_____ I agree to be contacted by the CTN-0150 TOME investigators about future research studies

_____ I do not agree to be contacted by the CTN-0150 TOME investigators about future research studies