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: Infant Neurodevelopmental Outcomes Sub-study (MOMs-INO)

NCT03911739

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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; Infant Neurodevelopmental Outcomes Sub-study

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

Local Site Name: The Medical University of South Carolina

Investigator Information:

Constance Guille	843-792-2123 and ask operator to page Dr. Guille
Principal Investigator Name	Telephone Number 24 hr Emergency Contact

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

Relation to Infant: _____

KEY INFORMATION

Purpose of the Study:	Your participation in this research study is entirely voluntary, as is the participation of the infant in your care. By signing this consent form, you are also consenting on behalf of the infant in your care for this study and authorizing parties listed in "HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?" detailed later in this consent document, to access his/her medical health records. The primary purpose of this study is to evaluate the impact of CAM2038, relative to sublingual buprenorphine, on infant neurodevelopment.
Length of the Study:	You and the infant in your care would be in this study for about 1 year, with approximately 2 total visits at 12 and 24 months after delivery.
Risks:	There are no foreseeable risks to you or the infant in your care.
Benefits of the Study:	There may not be a direct medical benefit to you or the infant in your care. It may be beneficial to the infant in your care if developmental delays are found early so that early intervention efforts may be sought.
Alternative procedures:	You may elect to simply not participate in this portion of the CTN-0080 clinical trial.

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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 or to have the infant in your care participate, 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, and may choose whether to have your infant take part in this 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 or your infant.

The researcher and sponsor of this study do not promise that you or your infant 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 Infant Neurodevelopmental Outcomes (INO) sub-study. The main CTN-0080-MOMs study is being done to compare two treatments for pregnant women with opioid use disorder. One of the treatments is injectable, extended-release buprenorphine (CAM2038). The other treatment is buprenorphine placed under the tongue (sublingual). This INO sub-study is being done to see if there are differences in the development of infants exposed to these two treatments in the womb. The FDA has given us permission to conduct this study. This study is being performed under an Investigational New Drug application (IND#: 140724).

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 and/or the infant in your care is involved with the main CTN-0080 MOMs research study.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You and the infant in your care will be in the research study for approximately 1 year.

The researcher may decide to take you or the infant in your care off this research study at any time. Reasons for discontinuation may include:

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

You may withdraw and/or withdraw the infant in your care from the study at any time.

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 research study is sponsored and directed nationally by T. Winhusen, Ph.D., a researcher at the University of Cincinnati, with support provided by The National Institute on Drug Abuse.

The local principal investigator for this study is Constance Guille, at The Medical University of South Carolina. Medical monitoring for the study is provided locally by Drs. Guille, Aujla and Smith.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 25 caregivers and their infants may take part in this sub-study at The Medical University of South Carolina. A total of about 200 caregivers and their infants may take part in this sub-study across the country.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

If you consent to take part in this research study, you will be asked to attend two visits to answer a series of questions and have your infant assessed by qualified research staff. No biological samples (e.g. blood or urine) will be taken in this research study and no treatment or medication will be given. This is a sub-study of the main CTN-0080 MOMs study. There are two study visits. One visit is at about 12 months after the infant was born. The other visit is at about 24 months after the infant was born. INO procedures may also occur at other locations to accommodate participant and provider needs and preferences. These may include your home or other appropriate locations within the community.

MONTH 12
About 12 months after delivery, you will be asked to go to The Medical University of South Carolina and/or another location based on the provider's needs and preferences for a research visit, which will take about two hours. As the infant’s caregiver, you will be asked to:

- Complete this informed consent form
- Provide basic demographic information
- Complete a locator form

- Allow qualified study staff to conduct an assessment of your infant's thought, language, and motor development while you are present.

MONTH 24
About 24 months after delivery, we will ask you to go to The Medical University of South Carolina and/or another location based on the provider's needs and preferences for a research visit which will take about two hours and ten-fifteen minutes. As the infant's caregiver, you will be asked to:

- If a new caregiver, provide basic demographic information.
- Answer questions related to the behavioral, emotional and social development of your infant
- Allow qualified study staff to conduct an assessment of your infant's thought, language, and motor development while you are present.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

There are no foreseeable medical risks to you or your infant for your participation in this research study beyond what you would encounter in everyday life. Possible risks may include physical discomfort while completing the assessments.

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 or the infant in your care. We hope the information learned from this research study will benefit children of mothers with opioid use disorder in the future. You may be informed of any developmental delays in the infant in your care from this research study.

WHAT OTHER CHOICES FOR CARE ARE THERE?

The only alternative is to simply not participate in this research study. Choosing to not participate in this research study or to not have the infant in your care participate will not result in any loss in the quality of care you already receive with your provider or your infant's provider, nor will you or your infant be otherwise penalized.

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 or your infant. 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 or your infant. You can view this website at any time.

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WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy and that of your 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 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, the infant in your care, or your infant's 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, your willingness to keep your infant in this study or your own willingness to stay in this study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

There are no foreseeable costs to you for your participation in this research study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be paid up to $250 total for your time and travel costs related to taking part in this study. Compensation will be made to you in the form of a ClinCard, which is a pre-paid debit card. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule below. Details of the debit card system are explained on an additional sheet.

Visit	Payment
12-Month	$100
24-Month	$150
Total	$250

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

Payments that you receive from The Medical University of South Carolina (MUSC) for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study, and to choose whether to have the infant in your care take part. If you decide to take part and to have your infant take part, you may decide to leave the study or withdraw your infant from the study at any time. Leaving the study will not result in any penalty or loss of benefits to you or to the infant in your care.

The investigators will tell you about new information that may affect your or your infant's health, welfare, willingness to keep your infant in the study or your own 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 or your infant 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, The Medical University of South Carolina, and the sponsor, NIDA or its designees, in addition to study monitors, auditors, the UC Institutional Review Board (IRB), and other regulatory authorities will be granted direct access to you and your infant's original medical and research records for verification of clinical trial (research study) procedures or study data without violating your confidentiality or that of the infant to the extent permitted by the applicable laws and regulations. By signing this consent form, you (and the infant's legally authorized representative, if applicable) are authorizing such access. The data from the study may be published; however, you and your infant will not be identified by name. Your identity and that of your infant 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. All study information will be de-identified prior to entry, and 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. After identifiers are removed from your and your infant's identifiable private information, the information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent. Such 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 or your infant. You can view this website at any time.

The study team will make every effort to protect your privacy; however, since South Carolina, in which you are receiving treatment, has specific mandatory reporting requirements around substance use in pregnant and postpartum women, there is a possibility that if you provide information about your current substance use to research staff, they will be required to report that to clinical staff for purposes of complying with your state's mandatory reporting laws. If you are or become pregnant and test positive for illegal drugs, it is a law that the South Carolina Department of Social Services (DSS) must be notified. You and your family will be evaluated by the agency. You could be ordered to mandatory drug treatment, lose custody of your children, or be jailed.

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.

Who Will Use and Disclose My Infant's Health Information? The study doctor and research staff (the study team) may use your infant's health information 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.

What Health Information will be Used and Disclosed? The study team will record the results of your infant's medical 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. 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 Infant's Health Information? Your and your infant's study information, 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
- Dr. T. Winhusen, the study Sponsor and Lead Investigator, and his research team at the University of Cincinnati
- Researchers who are conducting this study at other study centers, including monitors and project management personnel from The Medical University of South Carolina
- UC Institutional Review Board and any other committees responsible for overseeing the research
- Staff of the UC Human Research Protection Program
- Staff of the Medical University of South Carolina Institutional Review Board
- The Medical University of South Carolina employees providing service or care to you
- Braeburn Pharmaceuticals, Inc. (the manufacturer of CAM2038)
- 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

Will My and My Infant's Information be Protected by the Privacy Rule After it is Disclosed to Others?

The Medical University of South Carolina 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. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information and/or your infant's information with information from other studies for research purposes not directly related to this study. 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 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.

What Happens if I Leave the Study Early or Withdraw My Infant Early? If you stop participating in the study early or withdraw your infant from 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 or your infant. 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 or My Infant's Study Information? You have a right to see and make copies of your records, and those of your infant. However, to ensure the reliability of the study, you will need to wait to see your study records and those of your infant until the study is completed.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

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 researcher Constance Guille by calling the paging operator at 843-792-2123 and asking them to page Dr. Guille.

You may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

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.

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.

PERMISSION TO CONTACT YOU ABOUT FUTURE RESEARCH

I authorize the principal investigator and his or her co-investigators to contact me about future research provided that this future research is approved by the original IRB of record and that the principal investigator and co-investigator are affiliated with the research protocol.

If I agree, then someone from The Medical University of South Carolina's research staff might contact me in the future and he or she will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

_____ I agree to be contacted by the Principal Investigator or Co-Investigators of the research study titled: CTN-0080 MOMs Infant Neurodevelopmental Outcomes Sub-study

_____ I do not agree to be contacted by the Principal Investigator or Co-Investigators of the research study titled: CTN-0080 MOMs Infant Neurodevelopmental Outcomes Sub-study

Your permission to allow us to contact you about future research 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 at any of the facilities. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for one of our future research studies. It does not mean that you must join in any study.

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COMPREHENSION QUIZ

1. My participation in this sub- study is voluntary. T F

2. I would be expected to bring the infant in my care to study visits. T F

3. There are two study visits; one at 12 months after the infant was born and one at 24 months after the infant was born. T F

4. This sub-study guarantees the improved health of the infant in my care. T F

5. As part of this study, the infant in my care will be administered some assessments in order to check on their mental growth. T F

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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; Infant Neurodevelopmental Outcomes Sub-study

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

Local Site Name: The Medical University of South Carolina

Investigator Information:

Constance Guille	843-792-2123 and ask operator to page Dr. Guille
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, do not have my infant participate or if I discontinue my or my infant's 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 and my infant's health information for this research study.

I give my consent to participate.
If you wish to participate, you should sign below.

_____
Signature of Adult Participant 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.

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NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION (PHI)

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, MUSC Physicians Primary Care, MUSC Health Partners, MUSC Health Alliance, MUSC Strategic Ventures, LLC, and MUSC Strategic Ventures (MSV) Health, Inc.) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect, receive, or share this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

OUR PLEDGE REGARDING YOUR HEALTH INFORMATION

MUSC is committed to protecting the privacy of health information we create and obtain about you. This Notice tells you about the ways in which we may use and disclose health information about you. It also describes your rights and certain obligations we have regarding the use and disclosure of your health information. We are required by law to: (i) make sure your health information is protected; (ii) give you this Notice describing our legal duties and privacy practices with respect to your health information; and (iii) follow the terms of the Notice that is currently in effect.

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI) –

A. The following uses do NOT require your authorization, except where required by SC law:

1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
4. Business Associates. Your medical information could be disclosed to people or companies outside our Health System who provide services. These companies typically are required to sign special confidentiality agreements before accessing your information. They are also subject to fines by the federal government if they use/disclosure your information in a way that is not allowed by law.
5. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
6. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
7. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
8. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.
9. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement or for continuum of care when in the custody of law enforcement.
10. Military and Veterans. If you are a member of the U.S. or foreign armed forces, we may release your medical information as required by military command authorities.
11. Uses and disclosures about patients who have died. We may provide medical information to coroners, medical examiners and funeral directors so they may carry out their duties.
12. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
13. Research. We may use and disclosure your medical information for research purposes. Most research projects are subject to Institutional Review Board (IRB) approval. The law allows some research to be done using your medical information without requiring your written approval.
14. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.
15. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.
16. Marketing. We may send you information on the latest treatment, support groups, reunions, and other resources affecting your health.
17. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
18. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.
19. Disaster Relief Efforts. We may disclose your medical information to an entity assisting in disaster relief efforts so that your family can be notified about your condition.
Note: incidental uses and disclosures of PHI sometimes occur and are not considered to be a violation of your rights. Incidental uses or disclosures

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2. Information shared with family, friends or others. Unless you tell us not to, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:
You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation.
1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Mental Health Records unless permitted under an exception in section A.
3. Substance Use Disorder Treatment records unless permitted under an exception in section A.
4. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:
A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date.
B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI and/or appointment reminders in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.
C. The Right to See and Get Copies of Your PHI. You have the right to inspect and/or receive a copy (an electronic or paper copy) of your medical and billing records or any other of our records used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a cost-based fee. MUSC will act on a request for access or provide a copy usually within 30 days of receipt of the request. We may deny your request in limited circumstances. If you are denied access to your records, you may request that the denial be reviewed by a licensed health care professional. Additionally, we may use and disclose information through our secure patient portal which may allow you to view and communicate with certain health care providers in a secure manner. For more information see our https://mychart.musc.edu/mychart/
D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.
E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record. Notification will be provided within 60 days.
F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 349 / Charleston, SC 29425. The phone number is (843) 792-3881.
G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.
H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers, belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the U.S. Dept. of Health and Human Services, Office for Civil Rights. The address will be provided at your request or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. The changes will apply to all existing PHI we have about you.. This Notice will always contain the effective date and may be reviewed at http://academicdepartments.musc.edu/musc/about/compliance/privacy.html

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003 and was last revised on August 2018.