Remote Methadone Ingestion Surveillance Trial (RMIST)

NCT05259501

IRB Approved Date: 12/04/2024

Title of Study: NIDA-CTN-0120 – Remote Methadone Ingestion Trial: A Novel and Practical Opioid Use Disorder Treatment Approach (RMIST)

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center
The University of New Mexico Hospital (UNMH) Addiction and Substance Abuse Program (ASAP)

Key Information About this Study

The purpose of this study is to understand experiences with a novel technology-based platform designed to improve the experience of those on methadone maintenance treatment (MMT) in opioid treatment programs (OTP). This study will monitor your MMT over a 14-day period using a remote methadone monitoring platform. This study will not measure how your medication is working for you, it only monitors how regularly you are taking your medication. The platform is being tested because technologies like this may have the potential to improve the experience of those on MMT and increase access to and retention in MMT.

As a participant in this study, you will attend two visits at a local OTP clinic on two consecutive days. You will then use the remote monitoring platform at home for 14 days. During these 14 days, you will have take-home doses of your methadone. The in-clinic visits will last about 30 to 60 minutes depending on how quickly you are able to learn how to use the technology and demonstrate your understanding of the platform. You will be asked to fill out surveys about your substance use, withdrawal symptoms, and your attitude toward MMT and the platform we are studying. Your participation in the study is important as it will help the study team understand if technology-based remote monitoring methods can help improve the experience of MMT and improve access to and retention in MMT programs. The study team will work with you to help make sure you complete all your study related activities.

There are minimal risks in taking part in this study, but the study does involve the small risk of confidentiality loss. The study team has put in safeguards to keep that risk as low as possible. You may not receive any benefit from participation in the study but, we hope the information learned from this study will benefit other people with similar conditions in the future.

If you are interested in learning more about this study, please continue to read below.

Information About this Form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Your doctor or OTP provider is a research investigator in this study. They are interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Voluntary Participation – You do not have to participate if you do not want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the staff or doctors at your local OTP or the University of New Mexico Hospital (UNMH) staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the OTP or UNMH, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety, and welfare as a participant in the research. The Lead PI for this study is Madhukar H. Trivedi, MD, Department of Psychiatry at the University of Texas Southwestern Medical Center. Snehal Bhatt, MD, Chief and Fellowship Director and Associate Professor at The University of New Mexico (UNMH) is the local researcher conducting the study at the University of New Mexico (UNMH) Addiction and Substance Abuse Program (ASAP).

Funding

The National Institute on Drug Abuse (NIDA), a federal agency that promotes scientific research, is funding this study. This organization is providing money to UTSW so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

The purpose of this study is to understand experiences with a novel technology-based platform designed to improve the experience of those on methadone maintenance treatment (MMT) in opioid treatment programs (OTP). This study will monitor your MMT over a 14-day period using a remote methadone monitoring platform. This study will not measure how your medication is working for you, it only monitors how regularly you are taking your medication. The platform is being tested because technologies like this may have the potential to improve the experience of those on MMT and increase access to and retention in MMT.

The researchers hope to learn how this remote monitoring method can help improve experiences with MMT. This method uses a self-recorded, automated, video capture to monitor your take-home methadone doses. For this study, single-use methadone bottles will be made tamper-evident using a QR-code security label. You will use the platform to proceed through a guided experience of recording the process of taking your methadone outside the OTP clinic.

This study involves the use of remote monitoring technology. This technology does not affect the human body, and therefore, does not require US Food and Drug Administration (FDA) safety testing. The software is secure, Health Insurance Portability and Accountability Act (HIPAA) compliant.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Information About Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are currently receiving MMT through an OTP. This makes you the best person to help the researchers understand if platforms like these are beneficial.

How many people are expected to take part in this study?

This study will enroll approximately 15 study participants.

Information About Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately five visits with the researchers or study staff.

It is necessary for you to return to the clinic according to your agreement with your OTP. The only time you will come to the clinic outside of your agreement with the OTP is for study visits (Screening, Baseline, Training Phase, and Study Exit Visit).

If you agree to be in this study, the following study procedures will happen:

Screening (up to seven days) – After you sign this consent to participate, assessments and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. None of the procedures will change your "**standard care**" and will not affect your normal MMT or accessibility to your OTP. You will be told which procedures are for "**research only.**"

Screening Procedures

- Prisoner status assessment – We will ask you to answer questions to confirm that you do not meet the definition of a prisoner.
- Demographics – We will ask you questions to obtain basic information about you.

The screening procedures will add approximately one hour to your standard appointment.

Enrollment / Baseline (Day 0) – The results of the screening assessments and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you and will discuss other possible treatment options. Not being able to participate in this study will not affect your medical care. If it is determined that you are eligible for this study and you agree to participate, you will be enrolled as a study participant. The remote monitoring technology is used as an app on a smartphone. If you do not have a smartphone, one will be provided to you for the duration of the study.

After enrollment into the study, you will be asked to complete questionnaires during the Baseline Phase and attend two consecutive days of training on the monitoring platform in the OTP clinic where you normally get your MMT.

Training Phase (Days 0 and 1) – After you have been enrolled in the study as a participant and you have completed all Baseline Phase procedures, you will be asked to complete an in-person training at the OTP clinic where you normally get your MMT. During these visits, you will be asked to complete more questionnaires before and after completing the training on the platform. The study staff will provide training on how to set up, log in, and use the platform to record your take-home MMT doses. The first day of training may be the same day you complete the Baseline Phase.

By using the platform, you are agreeing to the platform developer's (Sonara) Terms of Service and Privacy Policy. During account creation, the platform will prompt you to complete a short survey. The survey is not related to this research study and is collected by Sonara to better understand who is using the platform to help support equitable and increased access. If you have questions about their Terms of Service, Privacy Policy, or survey, the study team can assist you with contacting Sonara.

Utilization Phase (Days 2 to 15) – During this phase, you will use the platform to record your take-home methadone doses. You will take your methadone as usual, however, you will record your doses through the platform during the next 14 days. Designated staff at the OTP clinic will confirm that you have taken your medication. If the designated staff does not see that you have taken your medication through the platform, they will contact you to remind you and make sure that there were no issues with the platform. If there are any medical issues or problems with your medication, the designated staff will let the medical staff at the OTP clinic know and they will follow up with you.

Study Exit Visit (Day 15)– At the end of the Utilization Phase, you will complete a Study Exit Visit on Day 15 (with a 5-day window after Day 15). IF you end your study participation early, the researchers will ask you to have a Study Exit Visit. You will be asked about your substance use, lifestyle, and well-being. You will also be asked about your satisfaction with the platform and your experience in the study. If you received a smartphone to use during the study, you will return it at this visit.

Staying in Touch During the Study

The study staff will use several methods of contact to keep in touch with you. We will ask you to provide us with your phone number, email address, and any other contact information. We will also ask you to provide contact information

for family and friends who may know how to get in touch with you if we are unable to contact you. You will be asked if your contact information has changed during your visits.

Phase	Procedures	Description of Procedures	Frequency
Screening Phase	Written Informed Consent	Review of this document and signatures from you and the person completing the informed consent must be completed prior to beginning any other study assessments. *Note: It is possible that changes could be made to the existing Informed Consent Form that you are signing now. If changes are made, you will be asked to sign the new Informed Consent Form after reviewing it with study staff.*	Once, prior to any other study assessments. *Repeat signing if Informed Consent Form is updated during your participation.*
	Questionnaires	You will be asked questions about yourself. It is important to complete these questions truthfully and as instructed by researchers.	Once
Enrollment / Baseline Phase	Self-Report Questionnaires	You will be asked to complete various questionnaires about things like methadone dosing experiences, attitudes towards take-home dosing, and opioid withdrawal symptoms you may have experienced. It is important to complete these questions truthfully and as instructed by researchers.	Once
Training Phase	Self-Report Questionnaires	You will be asked to complete various questionnaires about things regarding your methadone dosing. It is important to complete these questions truthfully and as instructed by researchers.	Once
	Monitoring Platform Training	You will be asked to learn how to set up, log in, and use the monitoring platform to take your take-home MMT.	Each day during training
Utilization Phase	MMT Monitoring	You will be asked to use the monitoring platform to take your take-home MMT dose.	Every take-home MMT dose across 14 days
Study Exit Visit	Self-Report Questionnaires	You will be asked to complete various questionnaires about things regarding your methadone dosing experiences in the clinic and with the take home dosing and your attitudes toward using the platform for dose monitoring. It is important to complete these questions truthfully and as instructed by researchers.	Once
	Study Exit Questionnaires	You will be asked to complete this questionnaire about things like your satisfaction with the monitoring platform and your experience in the study.	Once

Could your participation end early?
There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

The researchers will discuss your options for medical care when your participation in this study ends.

Risks – "What are the risks of participation in the research?"

Risks from the Research
The researchers have designed this study to learn how well this new method of monitoring your MMT compares to how your MMT is administered currently. We do not expect the monitoring technology to make your condition worse.

Risk of Psychological Stress
Some of the questions that we will ask you as a part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break, or stop your participation in this study at any time.

Risk of Loss of Confidentiality
Any time information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks from the Specific Research Procedures
There are minimal risks to taking part in this research study. The use of the platform does not add any risk to your ongoing MMT. Everyone taking part in the study will be watched carefully for any unknown side effects that may occur as the researchers do not know all the side effects that may happen. Be sure to tell your doctor or study staff immediately about any side effects or feelings that are different from taking your MMT prior to starting the study while taking part in this study. You should talk to your doctor or study staff about any side effects or other problems that you have while taking part in the study.

For more information about the risks or side effects, ask your study doctor or study staff.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Are there risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes completing questionnaires about your experience in the study. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
For medical emergencies, call 911. All forms of medical (or mental health) diagnosis and treatment – whether routine or experimental – involve some risk of injury. Researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them.

If you sustain any injury during the course of the research or experience, please contact the Principal Investigator Dr. Snehal Bhatt at the following telephone number (505) 994-7990. If such complications arise, the treatment team will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury-related costs. No other compensation will be offered by the Sponsor, the University of New Mexico (UNMH) – Addiction and Substance Abuse Program (ASAP). In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you have an injury or illness from the study device, taking the study drug, or the procedures required for this study, medical care will be provided. Depending on the circumstances, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

Neither the University of Texas Southwestern Medical Center, affiliates, nor the University of New Mexico have a program to pay you if you are hurt or have other bad results from being in the study. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

There are other options available to you. Your other choices include continuing your current MMT plan as you have been or pursuing other opioid treatment options such as buprenorphine.

Payments – "Will there be any payments for participation?"

In return for your time and effort, you will be paid up to $235 for participation in this study. If you do not complete the study, you will receive payment for each completed visit / assessment as described below.

Phase / Visit	Compensation Amount
Screening Phase	$25 Payments will be made in the form of a merchandise card (*this may be broken up into more than one payment during the Screening Phase)*
Enrollment / Baseline Phase	$25 Payments will be made in the form of a merchandise card
Training Phase	$30 Payments will be made in the form of a merchandise card (*$15 per training visit)*
Utilization Phase	$10 per dose monitored by the platform *(up to $100)* Payments will be made in the form of a merchandise card
Study Exit Visit	$25 Payments will be made in the form of a merchandise card
Return of Device or Data Plan	$30 Payments will be made in the form of a merchandise card (*at study completion)*

You will be issued a University of New Mexico Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of each study visit or procedure. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. Your social security number is needed to process your payments. Study payments are considered taxable income and are reportable to the IRS. Should you decide not to provide your social security number, or your

social security number does not match the name on file with the IRS, your study participation payment will be decreased in accordance with the current IRS tax rate. All information will be stored in a secure fashion.

Costs – "Will taking part in this study cost anything?"

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as the cost of your medication and your clinic visits. It is important to understand that some insurance companies do not cover some costs (for example, approved drugs used in a way different from the package instructions). If your insurance company does not cover these treatments or procedures, you will be required to pay for them. Ask the researchers if you have any questions about what it will cost you to take part in this study (for example bills, fees, or other costs related to the research).

The sponsor will provide the platform at no cost during this study. If you do not have a smartphone, you will be provided with one to use during your study participation. At the end of your participation, you must return the smartphone to the study staff.

Confidentiality – "How will your records be kept confidential?"

The information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board (IRB) and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Data sharing could change over time and may continue after the study ends.
The use and sharing of your data are required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

As part of this research study, we will put your information (i.e., de-identified data) in a large database for broad sharing with the research community. Your individual information will be labeled with a code and not with your name or other information that could be used to easily identify you. Only qualified researchers will be able to access your information from the database. These researchers must receive prior approval from individuals or committees with authority to determine whether these researchers can access this information.

Certificate of Confidentiality:
To help us further protect your information, the investigators will obtain a Certificate of Confidentiality from the US Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected, or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health and Human Services or any other federal government agency.

Your personal information collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

Research policies require that private information about you be protected, and this is especially true for your health information. However, the law sometimes allows or requires others to see your information.
The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out who it belongs to. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- Your medical history
- Information we get from your medical record
- Information contained in your underlying medical records related to your medical history and treatments prior to the study
- Information that is created or collected during your participation in the study included medical and treatment history
- Information you give us during your participation in the study such as during interviews or from questionnaires
- Demographic information like your age, marital status, the type of work you do, and the years of education you have completed

We will get this information by asking you, asking your doctors, or by looking at your chart at the OTP clinic.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the Sponsor, Dr. Madhukar H. Trivedi at the University of Texas Southwestern Medical Center and the Funder, the National Institute on Drug Abuse (NIDA). The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- the company, Sonara Health, that developed the platform
- the following collaborators at other institutions that are involved with the study: The University of New Mexico Hospital (UNMH) Addiction and Substance Abuse Program (ASAP).
- the members of the local research team
- the Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- the Research offices at the University of Texas Southwestern Medical Center.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above to collect, use, and share your health information. If you choose not to let these groups collect, use, and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location, or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
To protect your privacy, the study staff will use code numbers, instead of your name, to identify your health information. Some information directly relating to your MMT will still be associated with your PHI. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the OTP clinic for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. Snehal Bhatt
University of New Mexico (UNMH)
Addiction and Substance Abuse Program (ASAP)
2600 Yale Blvd SE
Albuquerque, New Mexico 87106
(505) 994-7999

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

You will only have access to your PHI until the end of the trial.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends, and all required study monitoring is over.

Contact Information – "Who can you contact if you have questions, concerns, comments, or complaints?"
If you have questions now, feel free to ask us. If you have additional questions, concerns, comments, or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Snehal Bhatt, MD can be reached at 505-994-7999.

If primary is not available, contact
Cade Arnink and Evangelina Moralez-Norris, Research Team Members, can be reached at 505-225-6931.

If you have any questions about your rights as a research participant or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the UNM Institutional Review Board (IRB) at 505-925-7414 or HRPO-IRB@salud.unm.edu.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments, or complaints you may wish to offer. You can contact the UTSW HRPP by calling the office at 214-648-3060.

Title of Study: NIDA-CTN-0120 – Remote Methadone Ingestion Trial: A Novel and Practical Opioid Use Disorder Treatment Approach (RMIST)

CTN-0120 RMIST – Comprehension Questions

Participant Name: _____

Date: _____

1.	My participation in this study is completely voluntary.	☐ True	☐ False
2.	I will be asked to attend two visits at my normal OTP clinic on two consecutive days and then use the remote monitoring platform for 12 to 14 days.	☐ True	☐ False
3.	I will be in the study for six months after signing the informed consent.	☐ True	☐ False
4.	There are no risks or discomforts associated with my participation in this research study.	☐ True	☐ False
5.	If I do not participate in this study, there are other possible treatment options for me.	☐ True	☐ False
6.	I have the right to withdraw from the study at any time.	☐ True	☐ False
7.	I will receive compensation for my participation in the study.	☐ True	☐ False
8.	The researchers may end my participation in this study to protect my health and safety, even if I would like to continue.	☐ True	☐ False

Title of Study: NIDA-CTN-0120 – Remote Methadone Ingestion Trial: A Novel and Practical Opioid Use Disorder Treatment Approach (RMIST)

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research, or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Witness / Interpreter Signature Section

Interpreter/witness (Interpreter signature required per hospital policies when physically present.)

I attest that I have interpreted the information in this consent form and it was explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of Interpreter	Signature of Interpreter	Date	Time AM PM

Witness Signature (required when interpreter is not physically present-e.g., Language Line is used):

By signing below:

I attest that the information in the consent form was accurately explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of witness	Signature of witness	Date	Time AM PM

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:

By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

			AM PM
Printed Name of Witness	Signature of Witness	Date	Time