UNIVERSITY OF MICHIGAN HEALTH-WEST
MICHIGAN MEDICINE

Research Subject Consent Form & HIPAA Authorization for Release of Health Information for Research Purposes

Title:

Sponsor:

Investigator:

Phone Number:

Address:

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

This form is for use in a research study in which only participants who have the capacity to consent can take part in the study. The pronouns "you" and "your" should be read as referring to the participant.

KEY INFORMATION

Purpose of the Study:	The purpose of this research study is to ... This research is important to future patients, as this knowledge may help doctors do a better job of ...
Study Participation:	If you choose to participate in this study, you will be ...
Study Length:	You will be in the research study for up to ...
Risks:	The most common risks with the medications used in this study ... A complete list of potential risks is included in the RISKS AND DISCOMFORTS.
Benefits of the Study:	Your participation in the study may help the study doctors better understand the effectiveness and safety of XXX.

Alternative procedures:	The alternative to participating in this study is to not participate. If you choose not to participate in the research study, you will receive standard medical care.

INTRODUCTION AND SUMMARY OF THE STUDY
You are being asked to participate in this research study because you ...

PURPOSE
The main purpose of this study is to see whether ...

Approximately xxx medical centers in the United States are part of this study. The plan is to include xxx people in the study. We are looking for xxx people to be part of the study at this center. Each person would participate in the study for up to xxx months/years.

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You/your family member may withdraw from the study at any time and for any reason, and neither you/your family member's decision to participate in the study, nor any decision on your/their part to withdraw, will have any effect on your/your family member's performance appraisal or employment at this clinical research center. You/your family member may refuse to participate, or you/your family member may withdraw from the study at any time without penalty or anyone blaming you.

HOW THE STUDY WILL WORK
You have been given this form to read because the study doctor has determined that you qualify for the study. Signing and dating this form means you consent to be a participant in this study.

If you agree to participate in the study, the study coordinator will ask you about your medical history and the medications you take. You will also see a study medical provider.

If randomizing include: You will be randomly assigned (like drawing straws) to one of xxx study treatments. Approximately xxx of study participants will be assigned to each study treatment.

RISKS AND DISCOMFORTS
As with any medical treatment and tests there are risks and discomforts that you need to know.

Blood Draws:
If a research blood draw include: The most common risks associated with blood draws for the laboratory tests are mild pain and/or bruising where the needle is pushed into the skin.

Study Medication: Include if study Medication

Unforeseen risks: Include or remove

Privacy Risks:
A potential risk from taking part in this study is that the confidentiality of your personal health information may be lost or compromised

Pregnancy Risks:

BENEFITS
Your participation in the study may help the study doctors better understand the effectiveness and safety of the study medications when used to prevent/treat XXX in patients with XXX.
No direct benefit to you from joining this study can be guaranteed or define the benefit

ALTERNATIVES TO PARTICIPATION IN THIS STUDY
The alternative to participating in this study is to not participate. If you choose not to participate in the research study, you will likely be ...

CONFIDENTIALITY
Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor – remove if not sponsored research
- People who work with the research sponsor - remove if not sponsored research
- Government agencies, such as the Food and Drug Administration
- Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. Every effort will be taken to preserve the confidentiality of your personal identity and personal health information. We cannot promise complete secrecy.

Data collected in this research will be deidentified (not connected to your name or personal identity) may be used for future research or distributed to another investigator for future research without your consent.

HIPAA AUTHORIZATION FOR RELEASE OF HEALTH INFORMATION FOR RESEARCH PURPOSES
The Health Insurance Portability and Accountability Act (HIPAA) allow a hospital or doctor's office to use or releasePHI for the purposes of treatment, payment or health care operations (TPO). Health care operations activities include such things as audits, quality assurance initiatives, audits from insurance companies, treating physicians, legal advisors, insurers, and data storage companies.

Since research does not fall under any of the TPO categories, we must have you sign this HIPAA authorization. This HIPAA authorization gives us permission from you to use or release your PHI for research purposes. A HIPAA authorization is in addition to your consent to participate in this research study.

WHAT WILL BE DONE WITH MY PROTECTED HEALTH INFORMATION?
Your health information will be collected and entered in a database along with the information from other people taking part in this study.

WHY AM I BEING ASKED TO RELEASE IT?
Your health information following your procedure, will be used to help evaluate whether the use of …during the procedure is beneficial or not.

WHAT IS BEING COLLECTED?
To complete this research study, we will need to collect information about you. This information may include:

- Your date of birth, name, contact information, and medical record number
- Existing medical records and medical history.
- New health information collected for purposes of this study.
- … ANY OTHER ADDITIONAL DATA

HOW LONG WILL THIS AUTHROIZATION LAST?
This authorization has no expiration date.

CAN I STOP MY PRTECTED HEALTH INFORMATION FROM BEING USED?
You can withdraw (cancel) this authorization at any time. Once you cancel your authorization, we will stop collecting your health information. Any information that was collected *before* you stopped your authorization will still be used as described above.

If you want us to stop, you must tell us in writing to: irb@umhwest.org.

WHAT HAPPENS IF I DO NOT WANT YOU TO COLLECT AND RELEASE MY INFORMATION?
If you decide not to authorize release of your health information as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot participate in this research study if you do not authorize the use or release of your PHI.

COMPENSATION AND COSTS
You will be compensated with a $XX gift card for your time and travel
OR
You will not be paid for joining in this study.

The study xxx, all scheduled follow-up visits that are performed as part of the study, will be paid for by the study. You may also receive xxx and certain xxx medications at no cost to you.

You and/or your insurance company will be responsible for the costs of xxx that are not provided by the study as well as xxx and xxx that are considered necessary as part of your regular care.

COMPENSATION FOR INJURY

If you are injured as a result of this research, medical care will be available. However, no funds have been set aside for the costs of this care. You and/or your insurance company will be responsible for these costs. If you believe you have been injured by this research, you should contact the study doctor at the telephone number on the first page of this consent form.

By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

YOUR RIGHTS AS A STUDY PARTICIPANT

Your signature and date on this consent form means you have read this information and want to join the study.

You will be given a copy of this signed and dated form to keep. You are not giving up any of your rights by signing and dating this form**.** Even after you have signed and dated this form you can change your mind at any time and stop being part of the study. Let the study staff know right away if you want to do that.

The study doctor may decide that you need to stop study provided treatments. For example, if you have a serious reaction to study medications. The entire study could also be stopped on the recommendations of a safety committee that will monitor this study or by the sponsors of the study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact them at (616) 252-5026, or irb@umhwest.org if:

- Your questions, concerns, or complaints are not being answered by the investigator or research team.
- You cannot reach the investigator or a member of the research team.
- You want to talk to someone other than the investigator or the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

NEW FINDINGS

If new things are learned during this study that might be important to you we will tell you right away.

VOLUNTARY PARTICIPATION / WITHDRAWAL

You do not have to be in this study. You can also stop at any time if you start the study and do not want to continue. There will be no change in your relationship with your personal doctors if you stop being in the study. A copy of this consent form will be placed in your medical record. You will be given a copy of this consent form.

If you decide to stop being in the study, please tell the study doctor, at the telephone number on the first page of this consent form.

STATEMENT OF CONSENT

I have read this consent form and have been given the chance to ask questions about it. I am signing and dating this form because I want to join this study.

I give my consent to participate.

_____
Name of Participant (PRINT)

_____ _____
Signature of Participant Date

Person Obtaining Consent:

I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent document, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____
Name of Person Obtaining Consent (PRINT)

_____ _____
Signature of Person Obtaining Consent Date