Date of Consent: Approval Period 1/31/2024-11/19/2024; Stamped effective January 31, 2024

Official Title of Study: Transdermal Buprenorphine for the Treatment of Radiation-Induced Mucositis Pain in Head and Neck Cancer Patients: A Pilot Study

NCT04752384

EFFECTIVE

January 31st, 2024

MCW IRB

Medical College of Wisconsin
INTRODUCTION TO THE INFORMED CONSENT

IIT-SHREENIVAS-BUPRENORPHINE: Transdermal buprenorphine for the treatment of radiation induced mucositis pain in head & neck cancer patients: A pilot study

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414-805-6700

Definitions

Performance Status – an assessment of your overall health

Oral Mucositis (OM) Pain App – a mobile app to record the amount of oral mucositis pain you experience during radiation therapy

Purpose

This project is being done to investigate the efficacy of using FDA approved doses of a Buprenorphine patch in combination with oral Tramadol to provide adequate pain control in radiation induced mucositis.

Length

You will be in this research project for about 3 months or 12 weeks after starting radiation therapy for your cancer. This study does not require any follow up after this time frame.

Procedures

All subjects who participate in this study will receive both Buprenorphine and Tramadol. You will continue to take the study drugs until your pain from radiation induced mucositis has resolved.

List of visits:

- Screening Visit(s)
  - Total Number: approx. 1-2
  - Total Time: approx. 6-10 hours
- Radiation Therapy Treatment Visits
  - Total Number: approx. 7-10
  - Total Time: approx. 2-4 hours each
- Follow-up Visits
  - Total Number: approx. 5-7
  - Total Time: approx. 2-4 hours each

Procedures that will occur at various visits:

Invasive Procedures

- Blood collection for routine laboratory tests

Non-invasive Procedures

- Weight
- Urine collection for opioid pain medication testing
- Heart monitoring by Electrocardiogram (EKG)
- Performance Status
- Quality of Life questionnaires
- Oral exam
- Oral Mucositis (OM) Pain App
- Record of calorie intake and intravenous (IV) fluids

Risks

This is a brief list of the most commonly seen side effects. The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Buprenorphine risks:

- Nausea
- Dizziness
- Spinning sensation (vertigo)
- Weakness
- Tired feeling
- Sweating
- Numbness or tingly feeling
- Headache
- Depression
- Low blood pressure (hypotension)
- Nausea
- Vomiting
- Constipation
- Blurred vision
- Double vision
- Shallow breathing

Tramadol risks:

- Agitation
- Nervousness
- Anxiety
- Seizures (convulsions)
- Skin rash
- Dizziness
- Spinning sensation
- Hallucinations
- Fever
- Fast heart rate
- Overactive reflexes
- Nausea
- Vomiting

Benefits

We don't know if this project will help you. Your condition may get better but it could stay the same or even get worse.

My Other Options

You do not have to join this project. Your other options may include:

1. Joining a different project
2. Routine care for this condition
3. Getting no treatment for this condition

If you have more questions about this project at any time, you can call Stuart Wong, MD at 414-805-6700.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you have Stage II-IV head and neck squamous cell carcinoma (HNSCC) and are a candidate for curative intent or adjuvant radiation therapy.

A total of about 20 people are expected to participate in this research at the Medical College of Wisconsin/Froedtert Hospital.

The Director of the project is Stuart Wong, MD in the Department of Medicine. A research team works with Dr. Wong. You can ask who these people are.

This project is funded by a pilot grant awarded by the National Cancer Institute (NCI) Community Oncology Research Program (NCORP).

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you do not agree to join, or if you leave, you will not be penalized or lose any benefits that you had before starting the research project. Even if you join this project, you do not have to stay in it. You may stop at any time. Take as much time as you need to make your choice.

A research project is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the research procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS PROJECT BEING DONE?

Mucositis-related pain is a common side effect of radiation treatment of head and neck squamous cell carcinoma (HNSCC). The purpose of this project is to investigate the efficacy of using FDA approved doses of transdermal Buprenorphine in combination with oral Tramadol to provide adequate pain control in radiation-induced mucositis. Buprenorphine in other studies has shown to have a better side effect profile and less habit-forming properties than other opioid medications used to treat moderate to severe radiation-induced mucositis pain.

We don’t know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope the information from this study will help us develop a better treatment for oral mucositis in the future.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

STUDY DRUGS

Buprenorphine will be administered daily as a transdermal patch that will be stuck to the skin. Tramadol will be administered as an oral pill. You will take Buprenorphine and Tramadol for pain relief during your radiation therapy and for up to 4 weeks after your radiation therapy is completed. If your pain is well controlled, the doses of both drugs will begin to be gradually reduced.

Buprenorphine and Tramadol are in the opioid class of pain medication, but they are safer to use than other drugs in its class. Please tell the study doctor if you have a history of abuse or dependency on Buprenorphine, Tramadol, or any other opioid pain medication. Your use of the study drugs will be monitored during the study, as is standard policy for all patients prescribed opioid pain medication.

STUDY GROUPS

All subjects who participate in this study will receive both Buprenorphine and Tramadol.

STUDY VISITS

Screening
If you agree to participate in the study, you will sign this consent form before screening assessments are performed to see if you are eligible. Your study doctor or a member of the study team will let you know if you are eligible to participate in the study. If you are unable to participate in the study, the study doctor will discuss other treatment options with you.

Study Drug Regimen (treatment weeks 1-7 from the start of radiation therapy)
If you are eligible to participate, you will take the study drugs once your pain from radiation-induced mucositis requires medication. You will visit the doctor weekly during this period. Assessments to track your pain status and to monitor you for side effects will occur during these weekly visits.

Follow-up (weeks 8-12)
During the follow up phase you will return to the clinic twice (week 9 and 12) for a visit with the doctor. Weeks 8, 10 and 11 you will have a phone call from the research coordinator or study staff member.

STUDY ASSESSMENTS

Screening
You will need to have all or some of the following exams, tests, or procedures to find out if you can be in the study. Most of them are routine and may be done even if you do not join the study. If some of the tests were completed recently, they may not have to be repeated.

- Informed consent: Prior to any study-related procedures being performed, you will be required to voluntarily sign and date this consent form.
- Medical history: You will be asked about your health status, including previous treatments for your cancer
- Weight: You will be weighed
- Performance status: An assessment of your overall health and ability to perform daily tasks
- Oral exam: Your mouth will be examined, and pictures of your mouth will be taken
- Electrocardiogram (EKG): EKG will be performed to check the activity of your heart

- Urine test: A urine sample will be collected confirm you are not currently taking any other opioid pain medication. This is standard policy before prescribing any new opioid pain medications.
- Blood tests: Blood samples will be collected for
    - Blood cell counts, blood chemistry and clotting ability
    - Pregnancy, if you are able to have become pregnant
- Quality of Life questionnaires: Questions about daily activities and mental, physical, and emotional symptoms, etc.
- Record of calorie intake: The study team will ask you about the food and drink you are consuming and whether it is solid or liquid

Study Drug Regimen (Treatment)
You will be allowed to enroll to the study if the results of screening assessments show that you are eligible. The following assessments will be performed weekly once you start the study drug regimen:

- Adverse events: You will be asked about if you experienced any changes in your health
- Medications: You will be asked about opioids, laxatives, medications to reduce nausea and vomiting, and medications to relieve minor mouth pain that you take
- Weight: You will be weighed weekly
- Performance status: An assessment of your overall health and ability to perform daily tasks will be done at Week 7
- Oral exam and image collection: Your mouth will be examined at each visit, and pictures of your mouth will be taken at Week 4
- Electrocardiogram (EKG): EKG will be performed to check the activity of your heart at Week 7 of radiation therapy
- Blood tests: Blood samples will be collected weekly for
    - Blood cell counts, blood chemistry and clotting ability
- Quality of Life questionnaires: Questions about daily activities and mental, physical, and emotional symptoms, etc. These questionnaires will be completed at your study visits during the radiation therapy treatment period.
- Record of calorie intake: The study team will ask you about the food and drink you are consuming and whether it is solid or liquid
- Report of intravenous (IV) fluids: The study team will ask if you received any fluids by IV infusion at each visit
- Oral Mucositis (OM) Pain App: You will record the amount of oral mucositis pain you experience during radiation therapy using an app you can download on your mobile device. If you do not have a mobile device, a device with the OM pain app installed on it will be given to you. Answers you provide on the OM Pain App will be de-identified so

that they do not contain your personal details. You may use the OM Pain App before the radiation therapy treatment period begins to become familiar with it.

Follow-up
The following assessments will be performed Weeks 8-12:

- Adverse events: You will be asked about if you experienced any changes in your health at Week 9 and Week 12 from the start of radiation therapy
- Medications: You will be asked about opioids, laxatives, medications to reduce nausea and vomiting, and medications to relieve minor mouth pain that you take at Week 9 and Week 12 from the start of radiation therapy
- Weight: You will be weighed at Week 9 and Week 12 from the start of radiation therapy
- Performance status: An assessment of your overall health and ability to perform daily tasks will be done at Week 9 and Week 12 from the start of radiation therapy
- Oral exam and image collection: Your mouth will be examined at Week 9 and Week 12 from the start of radiation therapy, and pictures of your mouth will be taken at Week 9 and Week 12
- Electrocardiogram (EKG): EKG will be performed to check the activity of your heart at Week 12 from the start of radiation therapy
- Blood tests: Blood samples will be collected at Week 9 and Week 12 after the start of radiation therapy for
    - Blood cell counts, blood chemistry and clotting ability
- Quality of Life questionnaires: Questions about daily activities and mental, physical, and emotional symptoms, etc. These questionnaires will be completed weekly. Questionnaires will be completed by telephone call Week 8, Week 10 and Week 11 with the study team or on your mobile device during the follow-up period.
- Record of calorie intake: The study team will ask you about the food and drink you are consuming and whether it is solid or liquid at Week 9 and Week 12 from the start of radiation therapy
- Report of intravenous (IV) fluids: The study team will ask if you received any fluids by IV infusion at Week 9 and Week 12 from the start of radiation therapy
- Oral Mucositis (OM) Pain App: You will record the amount of oral mucositis pain you experience during radiation therapy using an app you can download on your mobile device. If you do not have a mobile device, a device with the OM pain app installed on it will be given to you. Answers you provide on the OM Pain App will be de-identified so that they do not contain your personal details.

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this research study for up to 3 months or 12 weeks after starting radiation therapy.

B3. CAN I STOP BEING IN THE PROJECT?

You are free to withdraw from the project at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the research doctor.

You may stop at any time. If you decide to leave the project, please let the research team know.

The research doctor may stop your participation in the project at any time for any reason without your consent. He/she will tell you if this happens.

The research doctor may take you out of this project at any time. This would happen if:

- They think it is in your best interest.
- You do not follow the project rules.
- The whole project is stopped.

If this happens, the research doctor will tell you.

B4. ARE THERE ANY SPECIAL INSTRUCTIONS WHILE I AM IN THE PROJECT?

You should tell the study doctor of any changes in your current medications, including over-the-counter medications, vitamins, and herbal supplements. Some medications are not allowed during the study. Your study doctor will advise about which medications these are.

You should bring the mobile device containing the OM Pain App with you to all study visits.

You should not make any software updates to the OM Pain App yourself. The study team will perform any software updates for you during study visits.

You should not breastfeed a baby while receiving Buprenorphine and/or Tramadol.

It is possible that the Buprenorphine patch will not stick properly to your skin. If this occurs, you may use a small piece of tape on the edges to help the patch consistently stick without falling off your skin. If you have any questions regarding adhering the patch, please contact the study doctor.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

There are risks to taking part in any research project. There is a risk that you may get drugs that do not help your condition or may make it worse. There also may be problems (side effects) we do not know about yet, from the drugs themselves, or how they combine with other drugs you are taking. If we learn about new important side effects, we will tell you.

We watch everyone in the project for problems (side effects). **You need to tell the research doctor or a member of the research team immediately if you experience any problems, side effects, or changes in your health.** In an emergency, call 911.

C2. RISKS OF STUDY DRUGS

The research drugs themselves may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away.

Buprenorphine

Side effects of Buprenorphine include:

- Nausea
- Dizziness
- Spinning sensation (vertigo)
- Weakness
- Tired feeling
- Sweating
- Numbness or tingly feeling
- Headache
- Depression
- Low blood pressure (hypotension)
- Nausea
- Vomiting
- Constipation
- Blurred vision
- Double vision
- Shallow breathing

Tell your doctor if you have serious side effects of Buprenorphine including:

- Weak or shallow breathing
- Lightheadedness
- Fainting
- Blue lips or fingernails
- Confusion
- Feelings of extreme happiness
- Fast or slow heart rate
- Urinating less than usual or not at all

Tramadol

Side effects of Tramadol include:

- Agitation
- Nervousness

- Anxiety
- Seizures (convulsions)
- Skin rash
- Dizziness
- Spinning sensation
- Hallucinations
- Fever
- Fast heart rate
- Overactive reflexes
- Nausea
- Vomiting
- Upset stomach
- Diarrhea
- Constipation
- Loss of coordination
- Headache
- Drowsiness
- Fainting

C3. OTHER RISKS OF THIS RESEARCH PROJECT

Other procedures that are part of the research also involve some risks:

Blood Draws
The side effects that you might experience as a consequence of a blood draw for this project include possible discomfort and bruising at the needle entry site. Rare complications of any venipuncture (drawing blood from a vein) include fainting, arterial puncture, peripheral nerve injury, local infection, and local blood clot. It is likely that you may have a port-a-cath which may mitigate some of these problems. There may be other unanticipated risks, but every precaution will be taken to assure your personal safety and to minimize discomfort. The person drawing your blood will observe you for side effects, but please inform him or her if you experience any discomfort or feel faint.

Electrocardiogram (ECG)
An ECG procedure requires you to lie still for a few minutes while electrodes are attached to your chest, wrists, and ankles to record the activity of your heart. The ECG leads placed on your skin may cause slight discomfort during their placement and removal.

Questions on Your Well-Being
The answers that you give are confidential, but there is always a risk that your answers will be read by people who should not read your personal information. You may also feel uncomfortable answering some of the questions.

Privacy and Confidentiality
Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

C4. REPRODUCTIVE RISKS

Risks to subjects who could become pregnant
We know the drugs in this project affect babies, so we do not want anyone who might be pregnant to enter the project.

You should not become pregnant or nurse a baby while in this project. You must tell the research doctor right away if you think you are pregnant. You will be asked to have a pregnancy test to be sure you are not pregnant at the start of the project.

You may not donate eggs during your participation in the project or for 3 months after stopping the drugs.

Risks to a subject who could father a child and the subject's partner(s)
If you and your partner(s) are able to become pregnant, one or both of you must use some form of effective birth control, because we know that the drugs affect babies. You must tell the research doctor right away if you think your partner is pregnant.

You may not donate sperm during your participation in the project or for 3 months after stopping drugs.

Birth control methods for all subjects
Check with the research doctor about the birth control methods needed for this project and how long to use them. Some methods might not be good enough for this project. If you are having sex that could lead to pregnancy, you should use two forms of birth control while you are in this project.

This may include:

- Not having vaginal sex (abstinence)
- Taking birth control pills orally
- Having birth control shots or patches such as Depo-Provera
- Surgical sterilization (hysterectomy/tubal ligation or vasectomy)
- Limiting sexual activity to a partner who has undergone surgical sterilization
- Use of an intrauterine device (IUD)
- Use of diaphragm with contraceptive jelly
- Use of condoms with contraceptive foam
- Use of diaphragm with condoms ("double barrier")

You should continue using birth control for 3 months after stopping the study drugs.

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

We don't know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope the information from this study will help us develop better treatments for oral mucositis.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

Most of the medical care that you will receive in this project is considered routine care for your condition and would be recommended whether or not you join the project. Costs for routine care will be billed to you or your insurance carrier. For routine clinical care, you will be responsible for paying any copayment, coinsurance, or deductible that is required by your insurance carrier.

Activities that are part of the project will not be billed to you or your insurance company. These are:

- Quality of Life questionnaires
- Oral Mucositis (OM) Pain App
- Record of calorie intake
- Record of intravenous (IV) fluids

Some insurers will not pay for drugs, tests or hospitalization that are part of research, so check with your insurer before you join this project. If you have questions regarding costs, please contact Dr. Wong.

If you participate in this research, the costs of any necessary emergency medical treatment in the event of a research-related injury will be billed to you or your health insurance.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will be paid five times during the study for your participation. A $70 stipend will be given: at the following times: first at the time you are found eligible for the study and study medications are prescribed, then on any two subsequent clinic visits during treatment with radiation therapy at least 1 week apart, and then during two follow up visits after completing radiation therapy on Week 9 and Week 12. This will come to a maximum of $350. After the screening visit, if we find out you are not eligible for participation in the study, we will not be able to pay you. We will provide you with the lab results that you can share with your doctor. This is being done to offset treatment related costs associated with management of radiation induced mucositis pain.

Sponsor, other researchers, or research companies may patent or sell products, discoveries and data or information that result from this research. Neither Sponsor nor Dr. Wong will pay you if this happens. You will not receive any payment or commercial rights for products, data, discoveries, or materials gained or produced from your health information.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no. If you do not join this project, your research doctor can discuss other healthcare choices with you.

Your other choices may include:

- Routine care for this condition or symptoms.
- Joining a different research project
- The procedure or drug offered to you may also be available without being in any research project.

The research doctor can explain both the possible benefits and the risks of other options that are available to you.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

If we learn any important new information about the drugs that might change your mind about being in the project, we will tell you about it right away. You can then decide if you want to stay in the project.

When research data are collected and analyzed , there is the chance of finding something clinically relevant. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

In this study, you will be informed of any findings of possible clinical significance that may be discovered during review of results from your research data. The results of your research data will be placed in your medical record.

The results from the data we collect in this research study are not the same quality as what you would receive as part of your health care. The data will be reviewed by a physician who normally reads such results. We will provide you with this information so that you may discuss it with your primary care physician.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: Stuart Wong, MD, 414-805-6700

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

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Stuart Wong, MD at 414-805-6700.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); Versiti, Inc.; Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate- Froedtert Hospital (FH), Inc.; Froedtert Menomonee Falls Hospital; Froedtert West Bend Hospital; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information to be collected and used for this project is:

- Past and present medical records
- Records about your study visits and results of tests done during the study
- Records about phone calls made as part of this research
- Data entered in the Pain App, data collected from quality-of-life questionnaires
- Research records

E2. Who will see the health information collected for this project?

The only MCW/Froedtert Hospital. employees allowed to handle your health information are those on the research team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

The research team may share your information with people who don't work at MCW/Froedtert Hospital. because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here:

- Florence Healthcare, Inc.

- The funder of this study, National Cancer Institute (NCI) Community Oncology Research Program (NCORP);
- Government agencies in the U.S., such as the Food and Drug Administration (FDA), National Cancer Institute (NCI), and National Institutes of Health (NIH);
- Other federal and state agencies, such as the Office of Human Research Protections, (OHRP);
- Others required by law

Because this project involves the use of drugs and/or devices, the FDA also has the right to inspect all project records.

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information and/or biospecimens, the information and/or biospecimens may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information without any end-date in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Stuart Wong, MD at

Department of Medicine
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we will decide that you cannot continue to be part of the project. We may still use the information we have already collected.

E6. Access to records

You may not be able to see, or copy, your project-related health information until after the project has been completed; otherwise, it could affect the study.

F1. FOR MORE INFORMATION ABOUT THE PROJECT

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

You can look up this project by referring to the ClinicalTrials.gov number (NCT04752384) or by asking the research team for a printed copy.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**
Name of Witness, if applicable *please print*	**Signature of Witness**	**Date**
Rationale for Use of Witness ☐ Subject has limited/no literacy ☐ Subject has limited English proficiency ☐ Subject has limited/no vision	☐ Sponsor requirement ☐ Other _____	
*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**

** A member of the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. The Principal Investigator is responsible and accountable for the research project.*