**PRODUCT:** Lofexidine hydrochloride (HCl) tablets

**INFORMED CONSENT FORM**

**PROTOCOL NUMBER / AMENDMENT:** USWM-LX1-2010 / 1

**SPONSOR:**
USWM, LLC (dba US WorldMeds)
4441 Springdale Rd
Louisville, KY 40241

**TITLE:**
A Randomized, Double-blind, Placebo-controlled Pilot Study to Evaluate the Safety and Effectiveness of LUCEMYRA in the Treatment of Opioid Withdrawal During an Opioid Taper in Subjects with Chronic Non-cancer Pain

**DOCUMENT DATE:** Jul 3, 2019
**IND NUMBER:** 047857
**NCT NUMBER:** NCT04070157

**INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

| | |
|---|---|
| **Sponsor / Study Title:** | **US WorldMeds, LLC / "A Randomized, Double-blind, Placebo-controlled Pilot Study to Evaluate the Safety and Effectiveness of LUCEMYRA in the Treatment of Opioid Withdrawal During an Opioid Taper in Subjects with Chronic Non-cancer Pain"** |
| **Protocol Number:** | **USWM-LX1-2010** |
| **Principal Investigator: (Study Doctor)** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Address:** | **«PiLocations»** |

**INTRODUCTION**

You are invited to take part in a research study. This research study is studying LUCEMYRA as a possible treatment for symptoms that may occur when you reduce over time your opioid pain medicine. Another name for these symptoms is opioid withdrawal symptoms. US WorldMeds, LLC is sponsoring this research study.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

**BACKGROUND AND PURPOSE**

You are being asked to participate in this research study because you take opioid medications for chronic non-cancer pain and you want to stop taking your opioid pain medications. Your reasons to stop taking your opioid pain medications may be because your opioid pain medication has caused problems which you can no longer put up with, such as anxiety, difficulty sleeping, constipation (having a hard time going to the bathroom), depression (unhappiness), foggy thinking, and issues at work or home. Having these problems with opioids is NOT a sign of addiction.

Stopping prescription opioid pain medications can be difficult due to withdrawal symptoms. Sometimes the fear of withdrawal symptoms can make you want to continue taking opioid pain medications, especially if you have tried but failed to stop or reduce your opioid dose (taper).

The purpose of this research study is to study LUCEMYRA use in subjects who are tapering off their opioid prescription over a 2- to 3-week period. This study will:

- test the safety and effectiveness of the study drug, LUCEMYRA.
- test if LUCEMYRA helps reduce withdrawal symptoms.
- test if LUCEMYRA helps more people reduce their opioid dose compared to placebo.

LUCEMYRA is currently approved by the United States Food and Drug Administration (FDA) for the mitigation (lessening) of opioid withdrawal symptoms in patients stopping their opioid medication without a taper (meaning reduction over time). The taper used by some pain management physicians includes a much more gradual taper than what will be required in this study. This may result in more severe withdrawal symptoms and may require more non-opioid pain treatment than would be experienced with a slower taper. The use of LUCEMYRA in this study is investigational. An investigational use is one that is not approved by the United States FDA. The reason it is investigational is because LUCEMYRA has not been studied in subjects who are gradually tapering off their opioid medication. In this research study, LUCEMYRA will be compared to placebo. A placebo is designed to look like the study drug, but it contains no actual medicine. Neither you or the study center will know whether you are receiving LUCEMYRA or placebo.

**WHAT WILL HAPPEN DURING THE STUDY**

Your participation in this study (excluding the time spent for screening) will last about 51 days and will include about 6 study visits to the study center and about 4 phone calls with the study doctor or study staff. You will also receive reminders from time to time, either by a phone call, text, or email. There will also be a phone interview near the time of your End of Study Visit.

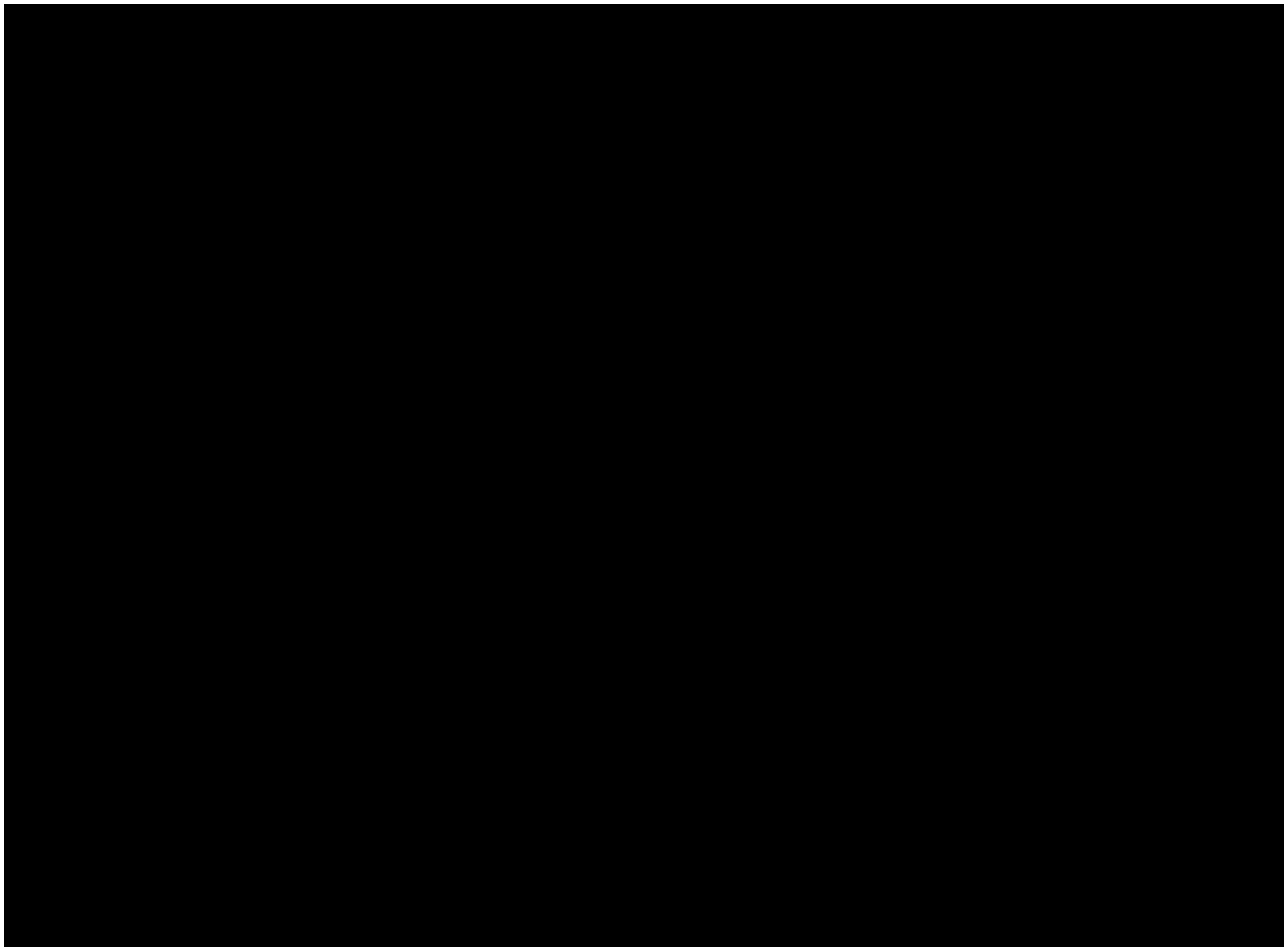
During the study, you will take the study drug, and the study doctor will have you gradually reduce your dose of opioids over a 2- to 3-week period. The study doctor will work with you on managing any pain symptoms you may have during your opioid dose reduction. If you are having trouble reducing your opioids, the study doctor may have you pause your reduction or go back to your previous opioid dose. If this happens, you will be in the study for an extra week.

**Screening:**
Before any study-related tests and procedures are performed, you will be asked to read, sign and date this form. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- The study doctor may be someone different than your physician who prescribed your opioids. You will need to inform your pain physician of your plans to participate in this study. The study doctor will require a form signed by your pain physician confirming that they will resume your care after the study.
- You and the study doctor will develop a plan for managing your pain and for reducing your opioid pain medications prior to you starting in the study.
- You will be asked about your demographic information, medical history, current medications you are taking, current pain condition, and history of opioid pain medication use and withdrawal. You will have a short psychiatric evaluation to determine whether you are depressed or have suicidal thoughts.
- You will have a complete physical examination, and your height and weight will be measured.
- If you are a female, you will have a urine pregnancy test.
- You will provide a urine sample, of approximately 2 tablespoons, to be used for routine safety laboratory tests. In addition, your urine will be tested to confirm you are taking the opioids you are prescribed, and it will check for other drugs such as marijuana or other illegal drugs and alcohol.
- You will have approximately 1 tablespoon of blood drawn for routine safety laboratory tests.
- Your vital signs will be measured, including blood pressure and pulse rate.
- You will have an electrocardiogram. An electrocardiogram will measure the electrical activity of your heart.
- You will be asked about any medications that you are currently taking.
- You will complete a list of questions about your pain, current symptoms, and mental well-being on the computer or tablet.
- You will receive instruction on how to complete an electronic medication diary to record information about your opioid medications, other medications, and the study drug while at home.
- You will be trained on how to report your pain and withdrawal symptoms, take and record your vital signs, complete questions, and complete your electronic diary.

**Opioid Reduction (Taper) Plan:**
The study doctor will ask you questions to find out how much of your opioid medications you take each day. This will allow the study doctor to determine your taper plan. You will reduce your daily dose of opioids as close to 50% as possible during Week 1. During Week 2, your daily dose will be cut in half again. During Week 3, you will not be taking any opioids.

The study doctor may need to write you new opioid prescriptions, change the number of times in a day you take your opioid, or even prescribe a different opioid in order to taper. The sponsor will cover the cost of your opioid prescriptions while you are in the study. The study doctor will tell you when to fill your prescription, if needed, and when to start tapering your opioid. You must take only the pain medications prescribed by the study doctor while in the study. The clinic will give you a schedule, so you will know the exact date when you are to taper your opioid medications and when phone calls and clinic visits will occur. Here is an example of what your schedule will look like.



Up to 60 subjects will participate in this study at approximately 10 study centers. This study will use competitive enrollment. This means that when a target number of subjects begins the study, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of subjects has already begun the study.

If you qualify to take part in this study and go on to receive study drug, then the following will happen:

Study Drug:
LUCEMYRA is a peach-colored tablet that contains 0.18 mg of lofexidine hydrochloride.

You will be randomly assigned by chance (like the flip of a coin) to receive either LUCEMYRA or placebo (inactive substance that looks like LUCEMYRA). You will have a 50% (1 in 2) chance of receiving LUCEMYRA and a 50% (1 in 2) chance of receiving placebo. This is a double-blind

study, which means neither you nor the study doctor will know if you are taking LUCEMYRA or placebo. In case of an emergency, however, the study doctor can get this information.
You will begin taking study drug after your dose of opioid pain medication has been reduced. You will be contacted to remind you how to decrease your dose of opioids.

Your first dose of study drug will take place in the clinic. You will start by taking 1 tablet, by mouth, every 5 to 6 hours, up to 4 times each day. On the second day, you will take 2 tablets 4 times each day, if you tolerated the previous dose. The study doctor will contact you on the second day to discuss adjusting your dose and to check on your well-being. The study doctor may increase or decrease your dose, depending on your symptoms. The maximum dose of study drug is 4 tablets, 4 times each day. At the end of the study, you will slowly reduce your dose of study drug, over 4 days, until you are no longer taking it.

You will have the following study visits, reminder contacts, and phone calls, and undergo the following procedures.

**Visits 1, 2, 3, 4, 5, and End of Study**
The day before your first visit to the clinic, and your first dose of study drug, you will be contacted and instructed to reduce your last opioid dose of the day. The study doctor will instruct you on what dose to take. The next day, at Visit 1, you will take your first dose of study drug in the clinic. At Visit 1 and all other clinic visits, you will undergo the following tests or procedures unless otherwise indicated:

- Brief physical examination
- Short psychiatric exam, including any suicidal tendencies
- Weight (End of Study Visit only)
- Urine pregnancy test (End of Study Visit only)
- Urine test for opioids, marijuana, other illegal drugs, and alcohol
- Measurement of vital signs
- Electrocardiogram
- Medication diary review
- Questionnaires about your symptoms and pain
- Questions about how you are feeling and any changes with your medications
- You will have approximately 0.5 tablespoons of blood drawn for routine safety laboratory tests (Visit 4 and End of Study Visit only). Although not noted as a risk in the label of LUCEMYRA, a small increase in laboratory tests that look at how your liver is working was seen in a few more patients that took LUCEMYRA over those who took placebo. This means that during the study, laboratory tests that show how your liver is working will be performed at Visit 4 and end of study. If any of your laboratory tests increase, your study doctor may require at least one additional blood draw to monitor your liver including a test for hepatitis. Please inform your study doctor if you have been exposed to a hepatitis virus in the past. A positive hepatitis result from this test

will be reported to the local health department as required by state law. The results from this test are confidential, and the results will not be shared outside of this study except as required by state law. Your study doctor will keep you informed of your laboratory test results.

If you are having suicidal thoughts call the study doctor at the telephone number listed on the first page of this form. If you feel in crisis, you can call 911 and/or a Nationwide Suicide Hotline that is answered 24 hours a day with a skilled, trained counselor. One example is the National Suicide Prevention Lifeline at 1-800-273-TALK (8255).

Also, at Visit 1, the study center will train you on how to measure your vital signs. They will also provide you with a vital sign monitor and cuff for use in the study. At the end of the study, you will return the monitor. You may dispose of the cuff.

If you have to pause your opioid dose reduction, you will have an extra study visit.

**Reminder Contacts**
The day before each scheduled opioid dose reduction, you will be contacted by phone, text, or other electronic message to remind you to reduce your opioid dose. You will also be contacted in the same way to remind you to begin tapering your dose of study drug.

**Phone Calls 1, 2, 3, and Follow-up**
While you are taking the study drug, you will have several phone calls with the study doctor or study staff to make sure that you are doing okay with your opioid dose reduction, to check on your overall well-being, and that you are tolerating the study drug. During these phone calls, you will be asked to do the following:

- Measure your vital signs
- Answer questions about how you are feeling

If you have to pause your opioid dose reduction, you will have 1 extra phone call.

There will be a follow-up phone call 30 days after your End of Study Visit.

During the study, you are encouraged to contact the study doctor and the study center anytime questions or issues arise.

**Study Interview by phone**
During your End of Study Visit, the clinic staff will schedule a phone interview between you and a person hired by the sponsor (interviewer) to interview all study subjects in this study. This interview may occur at your End of Study Visit if it is convenient for you and the interviewer. The interview could take up to 1 hour of your time. If the interview cannot be scheduled during

your End of Study Visit, it will be arranged to occur within 5 days of your End of Study Visit. You will be given a phone number to call for the interview. You will only be identified by your study identification number. The interviewer will not know anything about you. They will not even know your name. The interview will be recorded and the interviewer will ask about your experience in the study. This information may be useful in planning future research studies with LUCEMYRA.

**Daily At-home Procedures**

As part of this study, you will be required to keep a study diary and record your answers to the questionnaires daily. You will also need to record when you take your doses of study drug and any other treatments you use during the study. For most of the study, the study doctor will record your vital signs taken during phone calls; however, during the time that you are tapering the study drug, you will need to record your vital signs in your study diary. While you are at home, you will need to complete the following in your study diary:

- Answer questionnaires before bedtime; this will take no more than 10 minutes
- Record study drug and other treatment use
- Measure, and record in diary, vital signs twice a day (once in the morning and once in the evening) during reduction of study drug and through the end of the study

**<u>After Study Treatment</u>**

Because this is a research study, the study drug and your reduced opioid medications will be given to you only during this study and not after the study is over.

**EXPECTATIONS**

If you participate in this study, you will be expected to:

- Attend each study visit
- Complete all phone calls
- Take the study drug as instructed
- Taper your opioids as instructed
- Manage your pain as discussed with the study doctor
- Complete study diaries and questionnaires
- Abstain from alcohol and other illicit substances
- Bring with you at each visit your unused opioid medication and study drug.
- Return the blood pressure monitor, unused opioid medication and study drug. You and the site staff will dispose of any unused opioid medication you have discontinued during that visit.

**RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS**

**For *LUCEMYRA*:**

**Likely**

- Insomnia (difficulty sleeping)
- Orthostatic hypotension (low blood pressure upon standing up or sitting down)
- Bradycardia (low heart rate)
- Hypotension (low blood pressure)
- Dizziness
- Somnolence (drowsiness)
- Sedation
- Dry mouth

Because of the risk of low blood pressure or slow heart rate, the study doctor will frequently monitor your vital signs, and you will be instructed to contact the clinic if you experience any signs or symptoms of low blood pressure or a slow heart rate. The study doctor will explain these signs and symptoms to you, show you how to measure your vital signs at home, how to recognize symptoms, and when to call the study center.

**Frequent**

- Syncope (fainting)
- Tinnitus (ringing in the ears)

**Rare**

- Lethargy (sluggishness)
- Constipation
- Dysgeusia (distorted sense of taste)
- Gastroesophageal reflux disease (flow of stomach acid up into the passageway between the mouth and the stomach)
- Flatulence (gas)
- Fatigue (tiredness)
- Chest pain
- Hypoacusis (hearing impairment)
- Vertigo (dizziness)
- Thoughts of suicide
- Dry eye
- Blurry vision
- Decreased appetite
- Fall
- Hypersensitivity (allergic reaction)

**RISKS OF STUDY PROCEDURES**

- Opioid dose reduction and discontinuation:
    - Opioid withdrawal: Sometimes when people reduce their dose of opioid medications, or stop taking them, they may experience opioid withdrawal. Possible symptoms of opioid withdrawal include nausea, vomiting, diarrhea, muscle pain/spasms/twitching, abdominal discomfort, sweating, runny nose, watery eyes, restlessness, tremors, chills, increased heart rate and blood pressure, and agitation.
    - Uncontrolled pain: Because you have been taking your opioid medications for your pain condition, as you decrease your dose or stop taking your opioids, your pain levels may change. You and the study doctor will develop a plan for managing pain prior to you starting in the study.
    - Reducing your opioids may also cause you to have mood changes such as sadness, anxiety or generalized feelings of stress. Please contact your study doctor if you are having a difficult time mentally with reducing your dose or handling symptoms of opioid withdrawal or pain.

- Opioid use: After you complete this study, you will probably be more sensitive to the effects of opioids. Any opioid, even at doses you have taken in the past, could cause an overdose, severe medical problems, or even death.
- Central nervous system depressants: Taking central nervous system depressants with LUCEMYRA may increase the risk of low blood pressure, fainting, and slow pulse. You should be cautious when driving or operating heavy machinery, until you know how you will react to LUCEMYRA.
- Blood samples: Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection. You will have a total of approximately 2 tablespoons of blood drawn during this study.
- Electrocardiogram: Skin irritation is rare but could occur during an electrocardiogram from the electrodes or gel that is used.
- Questionnaires: The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.

If you are taking medicines which affect your central nervous system you must be on a stable dose for 30 days before starting the study, you must maintain that dose for the entire study. These medications include muscle relaxants, benzodiazepines (tranquilizers), hypnotics (medicines for sleep), soporifics (medicines for sleep), certain antidepressants, and selective serotonin reuptake inhibitors (a type of anti-depressant). Your study doctor will review your medications and tell you if you are taking any of these or other medications which must not be changed before or during the study.

During the study, you may develop new symptoms, unrelated to your opioid taper. Immediately report all new symptoms to your study doctor, even if they are symptoms you have had in the past but are now worse.

If you receive placebo (the inactive substance) as part of this study, your symptoms of opioid withdrawal syndrome, may not improve or may get worse. It is important to let the study doctor know how you are feeling.

**UNFORESEEN RISKS**
Since the use of the study drug is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant.

**BIRTH CONTROL RESTRICTIONS**
Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby), or nursing infant. Therefore, if you are pregnant, planning to become pregnant, planning to father a child, or are breastfeeding a child, you cannot participate in this study.

Females:
In order to reduce the risk of pregnancy, you should use an effective method of birth control while you are participating in this study and for 90 days after your last dose of the study drug. Acceptable methods of birth control for use in this study are oral contraceptives (birth control pills), patch, barrier method (diaphragm, sponge, or condom) with spermicide, intrauterine contraceptive systems (IUDs), levonorgestrel implant (Norplant™, Jadelle®, and others), medroxyprogesterone acetate contraceptive injection (Depo-Provera® and others), hormonal vaginal contraceptive ring, surgical sterilization of yourself or your partner, or complete abstinence from sexual intercourse. The study doctor or study staff will discuss this with you.

If you become pregnant while you are participating in this study or within 30 days after you have stopped taking the study drug, tell your study doctor or study staff immediately. The study drug will be stopped and your participation in this study will be ended. You will be asked to provide information about your pregnancy and the outcome.

Males:
In order to reduce the risk of pregnancy, you should use an effective method of birth control while you are participating in this study and for 90 days after your last dose of the study drug. Acceptable methods of birth control for use in this study are barrier method (diaphragm, sponge, or condom) with spermicide, surgical sterilization of yourself or your partner, or complete abstinence from sexual intercourse. The study doctor or study staff will discuss this with you.

If your female partner becomes pregnant while you are participating in this study or within 30 days after you have stopped taking the study drug, tell your study doctor or study staff immediately.

**ALTERNATIVES TO PARTICIPATION**
This study is for research purposes only. The only alternative is to not participate in this study.

**NEW FINDINGS**
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

**BENEFITS**
You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

Ask the study doctor for your estimated recovery time from the study treatment or procedures done during your participation in this study. The effects of the study drug may be noticeable for a few days after you stop taking it which is one reason the study doctor would like to see you one week after you stop taking study drug. They will also call you 30 days after your last dose of study drug to check on you.

**COMPENSATION FOR PARTICIPATION**

If you have any questions regarding your compensation for participation, please contact the study staff.

**CONFIDENTIALITY**

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this form. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the FDA and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

**COMPENSATION FOR INJURY**

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured, they will help you get the care you need.

If you are injured as a result of taking the study drug or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. You will not lose any of your legal rights or release the sponsor, the study doctor, the study staff, or study center from liability for mistakes by signing and dating this form.

To pay medical expenses, related to your participation in the study, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier. This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

**COSTS**

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company. You will also be provided a pharmacy card to purchase your opioid prescription in the event your study doctor needs to prescribe a different opioid dose or opioid for your taper. Your study doctor will also tell you where you need to get your opioid prescription filled.

**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 form. 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 subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

[redacted]

[redacted].

**VOLUNTARY PARTICIPATION / WITHDRAWAL**

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason, at any time, without penalty or loss of benefits to which you are otherwise entitled, and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

If you decide to stop participating, you will need to taper the study drug for 4 days, until you are no longer taking it, to avoid side effects. Stopping the study drug right away can cause severe side effects.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you
- If you fail to follow directions for participating in the study
- If it is discovered that you do not meet the study requirements
- If the study is canceled
- For administrative reasons

You will have some assessments done for safety at your last clinic visit. In addition, you will receive a follow-up phone call 30 days after your last dose of study drug.

If you leave the study for any reason, the study doctor may ask you to have some end of study tests for your safety. If the study doctor is not your regular pain physician, your regular pain physician will be notified that you are finished being in the study and the study doctor will help you set up an appointment to occur as soon as possible. If necessary, the study doctor will provide care for any residual pain you may have until your regular pain physician resumes your care. Other information from the study may be shared so your regular pain physician can resume your care.

**PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION**

I consent to having my family doctor or primary health care provider notified by the study center of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒**YES** (If yes, please complete the information below)

❒**NO**

| | |
|---|---|
| Name and address of family doctor or primary health care provider: | Name:<br>Address: |
| Telephone and Fax Number: | Tel:<br>Fax: |

**CONSENT**

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

## AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

- Your name
- Address
- Phone number
- Date of birth
- Medical history
- Information from your study visits, including all test results

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

- Representatives of US WorldMeds which includes any person or company who is supporting US WorldMeds with this study
- Representatives of [redacted] (an Institutional Review Board that reviews this study)
- The FDA and other US federal and state agencies
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported
- Governmental agencies of other countries
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study
- Other research doctors and medical centers participating in this research, if applicable
- A data safety monitoring board which oversees this research, if applicable

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe
- To compare the study drug to other drugs
- For other research activities related to the study drug

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

**STATEMENT OF AUTHORIZATION**

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use, and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

_____

Printed Name of the Person Obtaining the Authorization

_____ _____

Signature of the Person Obtaining the Authorization Date