

## Informed Consent Form Cover Page

**Study Official Title:** A Phase 1a Randomized, Double-blind, Placebo-controlled, Single Site, Single Ascending Dose Study of the Safety, Tolerability, and Pharmacokinetics of Kindolor Tosylate in Healthy Adults

**NCT #:** NCT06243835

**Document Date:** June 03, 2024

**UNIVERSITY OF CALIFORNIA, SAN DIEGO**  
**CONSENT TO PARTICIPATE IN RESEARCH**

**1. Study Title and Number**

Title: A Phase 1a Randomized, Double-blind, Placebo-controlled, Single Site, Single Ascending Dose Study of the Safety, Tolerability, and Pharmacokinetics of Kindolor Tosylate in Healthy Adults

Study [REDACTED]

**2. Principal Investigator**

Mark Wallace, MD, Professor, Anesthesiology, University of California, San Diego

**3. Principal Investigator Phone Number, Research Team Number, and Emergency Contact Number**

[REDACTED]

**4. Study Sponsor**

The NIH National Institute of Drug Abuse and Lohocla Research Corporation, the study sponsor, is paying UC San Diego to conduct this research study.

**5. Study Overview**

This research study is being conducted to find out more about the safety and tolerability of the new study medication, Kindolor. Kindolor is a new medication being developed to treat pain.

We are inviting you to participate in a research study as a healthy volunteer. This is a Phase 1 study which means that this is the first time Kindolor has been given to humans.

This form explains the research so that you may make an informed decision about participating.

- Research is voluntary - whether or not you participate is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes, but change your mind later.
- If you say no, we will not hold your decision against you.
- You can say no even if the person inviting you is part of your healthcare team.
- Your decision will not affect your health care or other benefits you may be entitled to.
- Please ask the study doctor or study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.
- You may consult with friends, family, a personal doctor, or anyone else before deciding whether or not to be in the study.
- You will be given a copy of this consent form and the Participant's Bill of Rights.

The purpose of this research study is to compare a study medicine, Kindolor, with a placebo to find out if the safety and tolerability of Kindolor is different from placebo.

A placebo looks like the study medicine but does not contain any medication (active ingredient). Researchers use a placebo to see if a study medicine is safer than not taking anything at all.

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There are 5 sessions to this study:

- Screening, where staff will determine if you eligible to participate in this trial.
- Intake and treatment which includes a 3-day admission to the site where you will receive one dose of study medication or placebo and be observed for 48 hours. You will have many tests done and blood samples taken during this time which is described in detail below.
- Discharge after you complete the treatment and 48-hour observation
- Follow Up 7 days later, or early termination, where study staff will perform additional tests to ensure your safety.
- A final telephone contact to ensure that you continued to use acceptable contraceptives, did not donate sperm (males) or are breastfeeding or have donated ova (females) during this period.

The most common risks or discomforts of this study are related to multiple blood draws, including pain, bruising, or bleeding at the site of puncture.

The risks of the study drug are not yet fully known in humans, but the most serious risks may include breakage in the tissue lining the stomach and damage to the tubule cells of the kidney (tubules are tiny ducts in the kidneys that help filter blood when it passes through the kidneys). To minimize these risks, a Kindolor Tosylate tablet has been developed that does not dissolve in solutions that mimic gastric fluid, but does dissolve in solutions that mimic the intestinal environment. Kindolor dissolving in the intestines instead of the stomach is important because this may help prevent stomach ulcers and kidney damage.

Kindolor is a non-opioid medication. Nonclinical studies in animal models to evaluate dependency showed no evidence of dependency while positive control opioid drugs in these animal studies did.

A complete listing of possible risks and discomforts associated with this study can be found in Section 9 of this document.

There are no benefits to you from participating in this research. However, the knowledge gained by your taking part in this study may be useful in the development of this new treatment for other people.

The alternative to being in this study is not to participate.

***More detailed information about this research study is provided below.***

### **6. Whom can I talk to if I have questions?**

If during your participation in the study you have questions or concerns, or if you think the research has hurt you, contact the research team at the numbers listed in Section 3 on the first page of this form. You should not agree to participate in this study until the research team has answered any questions you have about the study, including information contained in this form.

If before or during your participation in the study you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:

- UC San Diego Office of IRB Administration at 858-246-4777 or [irb@ucsd.edu](mailto:irb@ucsd.edu)

### **7. How many people will take part?**

We plan to study approximately 32 people here.

### **8. What happens if I take part in the research?**

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Throughout this form the words, “drug” and “treatment” are used, often these terms refer to experimental drugs and treatments. As you read this form, ask questions if something is not clear.

Kindolor is an investigational drug that has not yet been approved by the Food and Drug Administration (FDA). The safety of Kindolor is being tested.

Here is what will happen to you if you agree to be in this study:

If you agree to participate in this trial, you will receive Kindolor or placebo.  
You will take 1 dose of study medication or placebo at your second visit.

There are 5 sessions to this study:

### Screening Session

If you provide your consent to participate by signing the consent page within this participant information and informed consent form, the following screening procedures will take place to see if you qualify to take part in this study.

- Information will be recorded about you, including date of birth, gender, race, and ethnicity (demographic data).
- You will be asked questions about your past and present health including clinically significant family history (a medical history).
- You will be asked about any medicines you are currently taking or have taken recently, which will include any non-prescription medicines, food supplements, and natural remedies.
- You will have a complete physical examination, including measurement of your weight and height.
- You will be asked questions about your tobacco or nicotine product use, recent alcohol drinking, and cannabis use (including CBD products).
- You will have a urine drug test for some prescription or illegal drugs.
- Your blood pressure, your heart rate while sitting, and your temperature will be measured.
- About 20 mL (4 teaspoons) of blood will be collected from you to check your general health and to test for hepatitis A, B and C, and human immunodeficiency virus (HIV). You cannot take part in this study if you have any of these infections. If you test positive for hepatitis A, B and C, and/or HIV, your test results will be reported to the local health authority.
- If you are female and are able to bear children, a pregnancy test will be done on your urine. The result must be negative for you to be in the study.
- If male, you must agree to use an acceptable method of birth control during the study and for 90 days after receiving study medication and agree to not donate sperm for the duration of the study.
- If female, you must agree to use an acceptable method of birth control during the study and for 28 days after receiving study medication and agree to not donate ova or breastfeed an infant for the duration of the study.
- You will have an electrocardiogram (ECG) - an electrical recording that shows how well your heart is working, also known as an ECG. For this, patches connected by wires to a machine will be placed on your chest and legs.
- You will be tested for SARS-CoV-2 antigen. If you test positive for COVID-19 your test results will be reported to the local health authority.
- You will be given instructions and a kit to collect a stool sample at home and mail it back. You will be asked to avoid certain foods and medications before you collect your stool sample. A list will be provided by the study staff.

When all the test results are available, the study doctor will review everything to see if you qualify to come to the intake session.

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### Clinic Intake (Day -1)

If you are eligible for the study, you will be scheduled to return to the research clinic within 30 days for a final eligibility check and if still eligible, for clinic intake.

- Your medical history will be updated if anything has changed since the screening visit.
- You will be asked about any medicines you are currently taking or have taken recently, which will include any non-prescription medicines, food supplements, and natural remedies.
- You may have a brief physical examination in case there have been any changes based on recent problems.
- Your weight will be measured.
- Your blood pressure, your heart rate while sitting, and your temperature will be measured.
- About 20 mL (4 teaspoons) of blood will be collected from you to check your general health
- A urine sample will be collected to check your health and check for the presence of drugs of abuse.
- If you are female and are able to bear children, a pregnancy test will be done on your urine. The result must be negative for you to be in the study.
- You will be asked about your birth control methods (both men and women).
- You will have an ECG.
- A stool sample will be collected.
- You will complete a questionnaire about your stool consistency.
- A blood sample will be collected for a genetic test to see how your body may metabolize (breakdown and secrete the drug from your system).
- You will not be served food after the evening meal until after the treatment session the next day so that you have fasted for at least 8 hours.

### Clinic Treatments and Testing Sessions (Days 1 to 3)

When all the test results are available, the study doctor will review everything to see if you qualify for the treatment session and confinement over 3-days. During this time, no strenuous activity will be permitted.

- An intravenous line will be placed in one of your arm veins to collect multiple blood samples to minimize the number of needle sticks (Day 1).
- You will receive one oral dose of study medication or placebo with 1 cup of water (no other water is allowed for one hour before and after dosing) (Day 1).
- Your dose will be a randomly assigned kindolor tosylate or placebo in 100 mg (1 tablet), 300 mg (1 tablet), 900 mg (3 x 300 mg tablets), or 1800 mg (6 x 300 mg tablets). Dosage depends upon which study cohort to which you are assigned.
- No food will be allowed until 4 hours after dosing when you will be served set meals and may not consume red meat, grapefruit or caffeine (Day 1).
- You will have electrocardiograms. This will be done before and at 2, 6, 12, 24 and 48 hours after dosing.
- Multiple blood samples will be taken from your indwelling intravenous line at the following times: before dosing and at 0.25, 0.5, 1, 1.5, 2, 4, 8, 12, 24 and 48 hours after dosing. Approximately 20 ml (4 teaspoons) will be drawn each time for a total of 34 teaspoons. These samples will be used to measure the amount of study drug in your blood.
- Your blood pressure and heart rate while sitting will be measured at 0.25, 0.5, 1, 1.5, 2, 4, 6, 12, 24, and 48 hours after dosing. Your temperature will be taken pre-dose, 24, and 48 hours post dose.
- You will be asked questions about how you are feeling in general and if you are having any stomach problems (every day).
- A stool sample will be collected on Day 1 and Day 3 prior to clinic discharge.
- A blood and urine sample will be collected at clinic discharge to check your general health.
- You will have a physical examination at clinic discharge.

### Follow-Up Session

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You will return to the clinic about 7 days after the treatment session. You will have some or all of the following procedures performed at these visits.

- You will have a complete physical examination, including measurement of your weight.
- You will be asked about any medicines you are currently taking or have taken recently, which will include any non-prescription medicines, food supplements, and natural remedies.
- Your blood pressure, your heart rate while standing and while laying down, and your temperature will be measured.
- About 20 mL (4 teaspoons) of blood and a urine specimen will be collected from you to check your health.
- You will have an ECG.
- A stool sample will be collected.
- You will be asked questions about how you are feeling in general and if you are having any stomach problems.
- If you are female and are able to bear children, a pregnancy test will be done on your urine.
- If you are a male or female, you will be reminded to continue to utilize an effective method of birth control.

#### Telephone Contact

At about 90 days for males and 28 days for females after receiving the study medication, you will be called and asked about continued use of effective birth control methods and have not donated sperm (males) or ova (females), become pregnant or are breastfeeding an infant.

You will have completed the study once you have finished your last visit in this stage.

#### Endoscopy

If the study doctor suspects that the drug may be causing stomach problems (called gastritis), then a procedure called an endoscopy will be performed to view your stomach tissue. This procedure can take between 15 minutes and 1 hour to complete. You may be given an anesthetic throat spray or a light sedative injection to make the examination more comfortable.

#### Early Termination (ET) Visit

If you discontinue from the study early, the following assessments will be completed.

- Your blood pressure, your heart rate while standing and while laying down, and your temperature will be measured
- Your weight will be measured.
- About 20 mL (4 teaspoons) of blood and a urine specimen will be collected from you to check your health.
- You will have an ECG.
- If you are female and are able to bear children, a pregnancy test will be done on your urine.
- You will be asked questions about how you are feeling in general and if you are having any stomach problems.
- You will be asked about any medicines you are currently taking or have taken recently, which will include any non-prescription medicines, food supplements, and natural remedies.

In case of an abnormal result at any of the visits, the vital signs and/or lab tests and/or ECG may be repeated as the investigator's discretion.

#### What will happen to your blood, urine, and tissue samples?

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The study involves collection of biological samples, such as your blood and urine.

Throughout the course of the study, the total amount of blood taken will be approximately 260 mL (52 teaspoons). For comparison, a standard blood donation at a blood collection center is about 475 mL of blood (about 96 teaspoons/2 cups). Part of the samples for the study will be sent to the medical center laboratory for analysis, part will be shipped to the Mayo Clinic Laboratories for DNA analysis and part will be shipped to the University of Colorado for analysis of blood levels of kindolor. Your blood and urine samples will be destroyed once all the required laboratory tests have been completed.

This research involves genetic testing to see if your body may process the drug (called metabolism) in a different way than other people. The blood sample that is taken will only be used for this purpose and you sample will be destroyed after testing is completed.

If you withdraw from the study, you can ask your study doctor for your samples to be destroyed at any time. However, data already obtained from your samples will continue to be kept and used for the purpose described in this participant information and informed consent form.

You will be "randomized" into one of two study groups: the group taking the study medication, or a group that will take a placebo.

Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers choose which group you will be in. You will have a 50% chance of being placed in a specific group if you are one of the first two subjects enrolled in the cohort. For all subjects enrolled after the first two subjects, your odds of receiving the placebo is one out of six.

Neither you nor the researchers will know which group you are in.

A placebo is (in this case) a pill that looks like the study drug but has no real medicine in it. A placebo is often used in research studies so that the doctor and you do not know your study group. The study is done this way because knowing whether you are getting the study drug or placebo can change the results of the study. In case of an emergency, we can find out if you are getting the placebo or the medication.

The drugs in this study may affect a baby, before or after the baby is born. As a result, those able to become pregnant should not be in this study if they are:

- pregnant,
- breast-feeding, or
- trying to become pregnant.

If you are able to become pregnant, you should use birth control for the entire time you are in the study and for 28 days afterwards. Acceptable methods of birth control for use in this study are:

- Abstinence
- Vasectomized partner
- Nonhormonal intrauterine device
- Double barrier methods (diaphragm with spermicide; condoms with spermicide)

If you are able to cause a pregnancy, you should not have unprotected sex with someone who is able to become pregnant while on this study. If your partner(s) is/are able to become pregnant, you and your partner(s) should use birth control for the entire time you are in the study and for 90 days afterwards.

If you become pregnant or think you might be pregnant during study treatment or within 4 weeks after completing study treatment, you must inform the Study Doctor immediately. Information about your

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pregnancy and its outcome will be collected and used to learn more about the effects of the study medicine on pregnancy. If your female partner becomes pregnant while you are participating in this study, or within 90 days after taking the study medicine, you should tell the study doctor promptly. If your partner provides consent, the Sponsor will collect information about the pregnancy and the outcome

You should not donate sperm/ova during study treatment or within the study duration.

### 9. What are the risks and possible discomforts?

Participation in this study may involve risks or discomforts:

#### For Kindolor:

- Stomach ulceration (symptoms include stomach discomfort or pain, feeling full fast, bloating, or burning sensation)
- Increased risk of bleeding (symptoms include bruising easily, bleeding gums or nose, heavy bleeding from cuts, heavy menstrual bleeding)
- Kidney tubule injury (symptoms include swelling, nausea, vomiting, decreased urine output or no urine output)

Also, a study of mouse cells grown in a Petrie dish suggested that kindolor might cause sensitivity to sunlight that at worst case could result in rash, fever, fatigue, joint pain.

#### Placebo Risk:

- Since the placebo will be inactive, it is unlikely to experience any adverse effects.

#### Risks from Study Procedures:

Risks and discomforts that you may experience from the study procedures include:

- **Blood Samples:** Possible adverse effects from drawing blood include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection. If you feel faint, tell the study staff right away.
- **Fasting:** Fasting could cause dizziness, headache, stomach discomfort, or fainting. If you feel faint, you should tell the study doctor or study staff at once.
- **ECG:** Skin irritation, such as redness or itching, is rare, but could occur during an ECG from the electrodes or gel that is used.
- **COVID Test:** This test requires inserting a small swab inside your nose which may cause some discomfort and irritation. Nose bleeding is rare.
- **Endoscopy:** Complications that may occur but are rare include:
  - Bleeding: Endoscopy can cause bleeding, particularly if a biopsy is taken or a polyp is removed during the procedure. However, significant bleeding is rare.
  - Perforation: In rare cases, the endoscope may cause a perforation (tear) in the lining of the digestive tract, which may require surgical repair.
  - Infection: Although endoscopy equipment is typically sterile, there is a small risk of infection, particularly if tissue samples are collected during the procedure.
  - If sedation is used during the procedure, there is a risk of adverse reactions, such as respiratory depression or allergic reactions to the medications used.
  - If the doctor finds a mass or other abnormal appearing tissue, a biopsy (tissue sample) will be collected for microscopic examination.
  - Any medical issues uncovered during the endoscopy will be discussed with you by the study doctor.

#### Risks of Genetic Testing:

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This research will involve studying your biology and the likelihood that a particular biological feature (including genes) may increase the chance of developing a disease. Genes are pieces of DNA, or deoxyribonucleic acid that give instructions for building the proteins that make our bodies work. These instructions are stored in the form of a code. You inherit this code from your parents. We might use your specimens for whole genome testing. This means making a list of the entire order, or sequence, of your DNA.

Federal and State laws generally protect your genetic information in the following ways: a) Health insurance companies and group health plans may not request your genetic information from this research. b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. c) Employers with 5 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that these laws **do not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

We will minimize the possibility of results from this research being linked to you, but there is always the remote possibility that information from the research may be disclosed. If your genetic risk for certain diseases is accidentally divulged to the wrong source, you might be discriminated against in obtaining life or health insurance, or employment.

### **Risks of Loss of Confidential Information:**

There is also a risk that information about you could be released to an unauthorized party. To minimize this risk, we will use a code on any specimens and/or information we collect and we will keep a link between the code and your identity in a different location.

### **Risks Associated with Reproduction, Pregnancy:**

You should not become pregnant or cause a pregnancy while in this research. Methods of birth control required for this study are described in Section 8 above. If you are breastfeeding, you should not breastfeed a baby while taking part in the study as the study drug could harm the baby.

### **Possible Unknown Risks:**

In addition, there might be risks that we cannot predict at this time. These unknown risks may be temporary, mild, and last only while you are actively participating in the research, or they may be serious, long-lasting, and may even cause death. You will be informed of any new findings that might affect your health or welfare, or might affect your willingness to continue in the research. The study doctor will inform you in a timely manner about any new important information that is discovered during the study and discuss with you if you want to continue in the study. You may be asked to sign an updated participant information and informed consent form to confirm you agree to continue in the research study.

All medicines have the potential risk of an allergic reaction, which if not treated promptly, could become life-threatening. You should seek medical help right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing, or swelling of the face, mouth, lips, gums, tongue, or neck. Other symptoms of an allergic reaction may include rash, hives, or blisters. You will be closely monitored while in the clinic for these symptoms.

It is important that you tell the study doctor about any bad changes in your health as soon as they occur, whether or not you think they are caused by the study medicine.

We will closely monitor you during the study and will treat any discomforts or side effects that you have the best we can. If your side effects are severe we may stop giving you the study drug or placebo.

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### 10. How will information about me be protected?

While we cannot guarantee complete confidentiality, we will limit access to information about you. Only people who have a need to review your information, documents, or specimens will have access. These people might include:

- Members of the research team and other staff or representatives of UCSD whose work is related to the research or to protecting your rights and safety.
- Representatives of the study sponsor or product manufacturer
- Representatives of Federal and other regulatory agencies who make sure the study is done properly and that your rights and safety are protected, The Food and Drug Administration (FDA) may inspect research records and learn your identity.

This consent form and some details of your study participation will be noted in your UC San Diego Health record. If you do not currently have a UC San Diego Health record, one will be developed for you. People involved with your medical care and insurance may become aware of these details. UC San Diego also participates in Health Information Exchange (HIE) with multiple other health systems. Sharing your electronic Health Record (EHR) with other health systems is only allowed when they are involved in your medical care. Study details included in your EHR would also be shared. For more information about HIE, including how you can opt out of sharing, ask the study team.

Federal and state privacy laws give patients the right to access information about their care and treatment contained in their EHR. During this study, you may not be able to access certain information related to this study in your UC San Diego Health record until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

The results of this study may be published once the study is completed. However, we will keep your name and other identifying information confidential.

You will be asked to sign separate UC Health Insurance Portability and Accountability Act (HIPAA) Research Authorization form to use and disclose (share) your health information that identifies you for the purposes of this research study (see the separate authorization form for more information). Your permission as described in this informed consent and authorization form does not have an automatic expiration date.

*Your specimens and Information about you are protected by a federal Certificate of Confidentiality. This means that we cannot be forced to release your specimens or information about you for any legal proceeding, even if a court of law asks.*

The Certificate allows us to use *your specimens and* information about you for purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect *specimens and* information we share with them.

There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
- You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).
- A federal agency audits or evaluates research that it funds.
- Researchers are required to report possible intent to harm yourself or others, child abuse, elder abuse, or infectious disease cases.

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- The Food & Drug Administration requires information as part of overseeing drugs, devices or other products.

### 11. Will I need to pay to participate in the research?

There will be no cost to you for participating in this study. The Sponsor, Lohocla Research Corporation, who has initiated the study and the National Institute of Health is providing financial support and material for this study. The sponsor is paying for this research study.

All tests, procedures and visits required by the study are provided at no cost to you free of charge. Kindolor and/or placebo will be supplied at no cost while you take part in this study.

### 12. What if I agree to participate, but change my mind later?

You can stop participating at any time for any reason, and it will not be held against you. Your choice will not affect any treatment relationship you have with healthcare providers at UC San Diego Health or any services you receive from them. No matter what you decide, there will be no penalty to you. You will not lose medical care or any legal rights.

If you stop early, please contact us immediately. We will ask you to come back to the study site to have some procedures done so that you can leave the study safely. This is called the Early Termination (ET) Visit.

you stop participating, we may not be able to remove the information we have already collected about you or specimens we have already collected from you.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

In addition, the study doctor or sponsor may stop the study or take you out of the study at any time, even if you would like to continue. This may occur if:

- Your study doctor does not consider it to be in your best interest to continue.
- You develop an illness and need special care outside the study requirements.
- You do not comply with the study requirements and are not able to follow the instruction from the study staff.
- You become pregnant.
- Your study doctor has received new information about the safety of the study medicine that would cause you to no longer be able to participate.
- The study is stopped by the study site, the Sponsor, an IRB (Institutional Review Board) or a health authority (such as the FDA).

### 13. What will happen to information and/or biospecimens collected from me?

The study involves collection of biological samples, such as your blood and urine.

Throughout the course of the study, the total amount of blood taken will be approximately 260 mL (52 teaspoons). For comparison, a standard blood donation at a blood collection center is about 475 mL of blood (about 96 teaspoons/2 cups). Part of the samples for the study will be sent to the medical center laboratory for analysis, part will be shipped to the Mayo Clinic Laboratories for DNA analysis and part will be shipped to the University of Colorado for analysis of blood levels of kindolor. Your blood and urine samples will be destroyed once all the required laboratory tests have been completed.

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This research involves genetic testing to see if your body may process the drug (called metabolism) in a different way than other people. The blood sample that is taken will only be used for this purpose and you sample will be destroyed after testing is completed.

If you withdraw from the study, you can ask your study doctor for your samples to be destroyed at any time. However, data already obtained from your samples will continue to be kept and used for the purpose described in this participant information and informed consent form.

### 14. What are my responsibilities if I take part in this research?

If you take part in this research, you will:

- Be provided with an emergency contact card (containing a telephone number) to be used by health professionals to obtain advice, if study-related medical questions or problems arise during the study. You should carry this card with you at all times and show it to any health professionals you have to see.
- Provide accurate and complete information about your medical history and your present conditions and health.
- Attend the study site for all planned appointments. Inform the study staff in advance if you cannot attend an appointment.
- Stay in the clinical site facility for 4 days (2 half-days) and 3 nights, receive meals and beverages prepared by the site staff.
- Tell the study staff about all prescribed and non-prescribed medicines, including any food supplements and natural remedies, you are using before you enter the study and while you are participating on the study.
- Not take part in another study using another study medicine while you are taking part in this study.

### 15. Will I be compensated for participating in the research?

Subjects will be paid [REDACTED] for the screening visit, [REDACTED] for the dosing visit and [REDACTED] for each of the follow up visits (up to a total of [REDACTED] for the entire study) for participation in this study. Subjects will receive [REDACTED] for every additional visit to repeat labs and [REDACTED] to repeat ECG and labs. Subjects will be paid at the end of each visit.

If you receive compensation in excess of [REDACTED] per calendar year, your name and Social Security number will be collected and released to the UC San Diego Office of Accounting to process the Form 1099-Misc for Internal Revenue Service (IRS) tax-reporting purposes.

### 16. What else is important for me to know?

You will not be provided any clinically relevant information that may pertain to your health. You will not be provided a summary of the research findings. A description of this study 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.

If you are injured as a result of being in this study, UC San Diego will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor Lohocla Research Corporation, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the sponsor do not normally provide any other form of compensation for injury. For more information about this, you may contact the UC San Diego Office of IRB Administration at 858-246-4777 or [irb@ucsd.edu](mailto:irb@ucsd.edu)

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### **CONSENT TO PARTICIPATE IN RESEARCH**

If you receive Medicare benefits, the sponsor, Lohocla Research Corporation is required by law to report payments made to you for treatment, complications, and injuries that arise from this study. Information will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose. UC San Diego will provide the Sponsor with your name, date of event and health identification number (if not available, then Social Security number) only for Medicare beneficiaries that have had a study related injury for which the sponsor has issued reimbursement to the University.

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CONSENT TO PARTICIPATE IN RESEARCH

[Delete if there will be no adults who can consent for themselves]

Signature Block for Adults Able to Provide Consent

Participant	
<i>I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I agree to participate in the research described in this form.</i>	
<hr/>	
Printed Name of Participant	
<hr/>	
Signature of Participant	Date
<hr/>	
Person Obtaining Consent	
<i>I document that:</i>	
<ul style="list-style-type: none"><li><i>I (or another member of the research team) have fully explained this research to the participant.</i></li><li><i>I have personally evaluated the participant's understanding of the research and obtained their voluntary agreement.</i></li></ul>	
<hr/>	
Printed Name of Person Obtaining Consent	
<hr/>	
Signature of Person Obtaining Consent	Date
<hr/>	
Witness (if applicable)	
<i>I document that the information in this form (and any other written information) was accurately explained to the participant. The participant appears to have understood and freely given consent to join the research.</i>	
<hr/>	
Printed Name of Witness	
<hr/>	
Signature of Witness	Date
<hr/>	

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## CONSENT TO PARTICIPATE IN RESEARCH

### Experimental Participant's Bill of Rights

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.
2. Provided an explanation of the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.
5. Informed about of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. Told of the types of medical treatment, if any, available if complications should arise.
7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.
9. Provided a copy of the signed and dated written consent form and a copy of this form.
10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

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If you have any concerns or questions regarding the research study contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

- UC San Diego Office of IRB Administration at [irb@ucsd.edu](mailto:irb@ucsd.edu) or 858-246-4777