SUBJECT INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: A Multicenter, Open-Label Trial to Evaluate the Overall Performance of the Zalviso System (sufentanil sublingual tablet system) 15 mcg

PROTOCOL #: IAP312
WIRB® Protocol #20152518

SPONSOR: AcelRx Pharmaceuticals, Inc.

INVESTIGATOR: Name
Address
City, State Zip
Country

STUDY-RELATED PHONE NUMBER(S): Name
Number (24-hour number required)

PURPOSE OF THIS SUBJECT INFORMED CONSENT FORM

This Subject Informed Consent Form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or procedures that you do not clearly understand.

You have been asked to take part in this research study because you have elected to have surgery (for example, hip or knee replacement, or abdominal surgery). Before you decide to take part, it is important for you to know why the research study is being done and what it will involve.

The purpose of this form is to give you information about the research study. If you decide that you would like to take part in the study, you will be asked to sign this form. By signing this form, you are giving your permission to take part in the study (if you qualify) and become a study subject (or participant). This form describes the purpose, procedures, benefits, risks, discomforts and precautions of the research study. Take time to read the following information carefully and discuss it if you wish with a friend, with relatives and/or with your personal doctor (that is, general practitioner or primary care physician). You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction.

INTRODUCTION

This study is evaluating an experimental delivery system, the Zalviso System (sufentanil sublingual tablet system), that is available at your bedside to allow you to deliver a very small tablet of study drug (sufentanil, an opioid pain reliever) for the potential treatment of post-operative pain when you need it. Most doctors treat patients with post-operative pain using opioid pain medications (such as morphine) given intravenously (IV) on an "as needed" basis, or by using an IV patient-controlled analgesia (pain relief) device (machine) to deliver on-demand patient-controlled pain relief called an IV PCA.

The goal of the Zalviso is to decrease the amount of pain that you may experience as a result of your surgery with a non-invasive way to give pain medication.

The drug being evaluated in this study, sufentanil, has already been approved by the U.S. Food and Drug Administration (FDA) for IV anaesthetic and analgesic use during operative procedures. It has not yet been approved for sublingual (under the tongue) use, and its use in this study is "experimental."

This study is open-label, which means you and the study doctor know that you are taking study drug (sufentanil) during the entire study. All subjects in this study will receive medication to treat their post-operative pain.

AcelRx Pharmaceuticals, the sponsor, is paying the study doctor and the study site for conducting this study.

THE PURPOSE OF THE STUDY

The purpose of this study is to measure the safety and effectiveness of the Zalviso System and how satisfied patients are with the Zalviso System for treatment of moderate-to-severe acute post-operative pain.

DURATION OF THE STUDY

Approximately [13]315 subjects will be enrolled in this study at approximately 10 different hospitals in the United States. Your time in this study will include one screening visit up to 30 days before your surgery and then participation for at least 24 hours, and up to 72 hours, from the time that you begin taking the study drug.

In the sections below, information is presented on how subjects will be chosen to enter this study, how the study will be performed, what the potential risks and benefits of taking part in the study may be, and other information about this research study.

SELECTION OF SUBJECTS

To take part in the study, you must:

- Be at least 18 years of age.
- Be scheduled to undergo surgery (for example upper or lower abdominal surgery, hip or knee replacement).
- Have a negative pregnancy test if you are a female of childbearing potential.

- Be using an effective method of birth control from the screening visit through the end of the study if you are a female subject of childbearing potential. Acceptable methods of birth control include oral or transdermal contraceptives, condom, spermicidal foam, intrauterine device (IUD), progestin implant or injection, abstinence, vaginal ring, or sterilization of partner. If you use a hormonal form of birth control, you must also use a barrier method, from the time of your screening visit through 30 days after your participation in the study ends.
- Be willing and able to understand the study procedures, be able to use the Zalviso System, be able to use the pain scales and record your pain scores, and talk with the study personnel. You will be shown the Zalviso System and be allowed to handle it during your screening visit.

The study doctor or medical staff will discuss the other requirements that you must meet in order to be able to enroll into the study and can answer any questions you may have related to these criteria.

Even if you meet all of the requirements at screening, due to safety concerns you may not get the study drug if any of the following occur after your operation:

- Your breathing rate is less than 8 breaths per minute or greater than 24 breaths per minute.
- The oxygen level in your blood that cannot be maintained at 95% or greater with or without the use of supplemental oxygen.
- You are not able to answer questions and follow instructions.
- You have vomiting that is not responding to treatment.

STUDY PROCEDURES

Overview

As part of this study, you will receive study drug for at least 24 hours, and up to 72 hours, following your surgery. All subjects will receive study drug (sufentanil) to treat their pain. Additional IV morphine administered by a nurse is available if you have pain when you try to get up and walk or when you start other therapy after your operation. As a subject in this study, you will complete a screening visit before your scheduled surgery, and have a minimum of 24 hours in the study dosing period. You may choose to continue to take the study drug for another 48 hours for a total of 72 hours.

Screening Visit

The screening visit will be completed within 30 days prior to your scheduled surgery. You will be told why you are being asked to take part and what you will need to do to be in the study. You will be able to have the screening tests done after the study has been discussed with you in detail. During your screening visit, the following procedures will be done:

- Review, sign and date this consent form (this must be done before any other study-related procedures)

- Evaluation for study entry criteria
- Medical history and physical exam
- A urine sample will be obtained for drugs of abuse screening, and a pregnancy test for women of childbearing potential. A blood sample may be used for the pregnancy test.
- Training on the Zalviso System

Inpatient Admission (Study Day 1)

After the screening visit, if you qualify to take part in the study, you will be eligible for the treatment phase of the study.

While you are in the pre-operative area, the study staff will also re-instruct you on the definitions associated with a 0-10 pain scale and how to use the Zalviso System.

If you are a woman of childbearing potential, you will provide urine for a pregnancy test.

After your operation, you will be taken to the PACU (Post-Anesthesia Care Unit), where you will begin to recover from the surgery and anaesthesia. You must be awake and able to respond to questions and instructions to continue on the study.

You may receive morphine, fentanyl, or hydromorphone as your IV opioid pain medication to control your pain immediately after surgery in the PACU. During your stay in the PACU, your pain must be adequately treated with these IV medications in order to continue on the study. You will begin the study drug once you have left the PACU or are ready to leave the PACU.

You will self-administer study drug by using the Zalviso System.

To self-administer a tablet of study drug under your tongue, you will take the cap off the Zalviso System, place the dispenser tip under your tongue, press the dose button, and wait for the dosing sounds to stop before removing the dispenser tip from your mouth.

You will need to let the tablet dissolve under your tongue and not crush, chew or swallow the tablet. You also will not be able to eat or drink anything for 10 minutes after you have placed the tablet under your tongue. You should also minimize talking for 10 minutes after taking a tablet. These directions apply for all the study drug tablets you take.

You will self-record on paper your pain intensity score prior to administering the first dose, and then self-record pain intensity and pain relief scores at the following times after you get the first dose: 15 minutes, 30 minutes, 45 minutes, 60 minutes, 120 minutes, and then every 2 hours through the first 12-hour study period, and every 4 hours from 12 to 72 hours. The study staff may wake you up if you are asleep when it is time to record your pain and pain relief scores. Within the first 30 minutes after you receive the first dose of the study drug, you will be allowed to receive a dose of IV pain medication (2 mg morphine) if needed to keep you comfortable.

You will be able to self-administer study drug each time you need it, but you will need to wait at least 20 minutes in between doses when using the Zalviso System. This is because the Zalviso System is factory programmed to only deliver a tablet every 20 minutes to make sure you do not take too much study drug.

If you feel after the first dose of study drug that you are not satisfied with your level of pain relief, or at any time during the study if you are having pain due to walking or the start of therapy for your operation, you may request additional IV pain medication (morphine 2 mg). If your pain is unmanageable or you are too uncomfortable, you may withdraw from the study and receive other pain treatment that will be decided by your doctor.

You will be able to receive Tylenol® during the study period if you have a headache or fever during the study. You will be able to receive other non-opioid medications for pain control that your doctor prescribes for you.

Your vital signs (heart rate, blood pressure, breathing rate and oxygen saturation [amount of oxygen in the blood]) will be measured at the start of the study period. Heart rate and blood pressure will be measured after the first dose of sufentanil on the following schedule: every 15 minutes for an hour, then 120 minutes after first dose, then every 2 hours through first 12 hours, then every 4 hours throughout the rest of the study).

Your breathing rate may be checked at additional times as needed per the judgment of the study staff, but at least every 30 minutes through the first 24 hours, then every 2 hours through the rest of the study. Oxygen saturation will be measured continuously by an instrument that fits over your finger, which is called pulse oximetry. If your breathing rate is too low, or there is not enough oxygen in your blood, or you are too sedated, these symptoms will be managed, and you may be withdrawn from the study.

You will be asked to report any side effects that you may experience during the study.

End of Study/Early Withdraw

At the end of the study, whether you complete the 24-hour study period, the 72-hour study period, or come off of the study early, you will be asked to give a global assessment of the study drug's effectiveness on a 4-point scale where 1 = poor, 2 = fair, 3 = good, and 4 = excellent. You will also be asked to answer a short questionnaire on the use of the Zalviso System.

POSSIBLE RISKS, INCONVENIENCES AND DISCOMFORTS

The most common side effects related to the study medication reported by patients in previous AcelRx studies were nausea, vomiting, oxygen saturation decreased (low level of oxygen in your blood), pruritus (feeling itchy), dizziness, constipation, headache, insomnia

(unable to sleep or stay asleep), hypotension (low blood pressure), and confusional state (feeling confused).

Due to the possible severe side effect of low level of oxygen in your blood due to a decrease in your breathing rate, your blood oxygen levels are monitored continuously in this study and your breathing rate is measured ^{02}at least every 30 minutes for the first 24 hours^{13}, then every 2 hours through the rest of the study.

Per the package insert for the sufentanil, adverse events (AEs) in clinical trials that were considered to be probably related to sufentanil and that occurred in more than 1 in 100 patients (1%):

- Cardiovascular: slow heart rate*, elevated blood pressure*, low blood pressure*
- Musculoskeletal: stiffening of the chest wall (difficulty taking a deep breath)*
- Central Nervous System (CNS): feeling sleepy*
- Dermatological: feeling itchy (25%)
- Gastrointestinal: nausea*, vomiting*

  (* = reported incidence of 3% to 9%)

Side effects considered to be probably related to sufentanil and occurring in less than or equal to 1 out of 100 patients (1%) were:

- Body as a whole: severe allergic reaction. Severe allergic reactions can be life-threatening.
- Cardiovascular: fast or irregular heart beat*, heartbeat stopping
- CNS: chills*
- Dermatological: redness of the skin*
- Musculoskeletal: stiffening of the neck or arms or leg muscles
- Respiratory: stopping of breathing*, wheezing*, slowed breathing*
- Miscellaneous: intraoperative muscle movement*

  (* = reported incidence of 3 in 1000 to 1 in 100 patients; italics indicate that the side effect was reported in postmarketing surveillance, but not seen in clinical trials).

Opioids can interact with certain medicines that increase the effects of serotonin, a chemical in the brain. The medicines include antidepressants and migraine medicines, and the interaction causes a serious central nervous system reaction called serotonin syndrome. If you are taking an opioid along with a serotonergic medicine, you should seek medical attention immediately if you develop symptoms such as agitation; hallucinations; rapid heart rate; fever; excessive sweating; shivering or shaking; muscle twitching or stiffness; trouble with coordination; and/or nausea, vomiting, or diarrhea. Symptoms generally start within several hours to a few days of taking an opioid with another medicine that increases the effects of serotonin in the brain, but symptoms may occur later, particularly after a dose increase.

Taking opioids may lead to a rare, but serious condition called adrenal insufficiency in which the adrenal glands do not produce adequate amounts of the steroid hormone, cortisol, particularly during stressful conditions. Seek medical attention if you experience symptoms of adrenal

insufficiency such as nausea, vomiting, loss of appetite, fatigue, weakness, dizziness, or low blood pressure.

Interaction with other medications

The effects of the study drug may change when taken with other drugs, so it is very important to tell the study staff about any drugs (prescribed by a doctor or over the counter) that you take.

While not reported during any AcelRx studies of sublingual sufentanil tablets, recently, it has been determined that opioids combined with drugs that increase brain serotonin concentrations (such as certain antidepressants and migraine medications), on occasion, can produce serotonin syndrome (with symptoms that include agitation, hallucinations, rapid heart rate, fever, muscle twitching and incoordination, nausea, vomiting and/or diarrhea).

Other risks

Answering questionnaires frequently throughout your stay in the hospital may interfere with your rest or sleep.

By taking part in this study, you may not be able to take part in other research studies for a period of 30 days.

There may be other risks that are currently not known.

REPRODUCTION (PREGNANCY) RISKS

Women who are pregnant or breastfeeding cannot be in this study; therefore, a pregnancy test will be done on admission to the hospital. If the pregnancy test is positive, you cannot be in this study.

Women of childbearing potential must use a medically acceptable method of birth control. Acceptable methods include: oral or transdermal contraceptives, condoms, spermicidal foam, IUD, progestin implants or injections, abstinence, vaginal ring, or sterilization of partner. If you use a hormonal form of birth control, you must also use a barrier method. These methods must be used during this study and for 30 days after the last dose of the study drug. The Zalviso System has not been tested during pregnancy and may pose risks to an unborn child that are currently unforeseeable. You should not become pregnant until 30 days after your last dose of study drug.

NEW INFORMATION

During the course of the study, you will be informed of any new findings that may affect your willingness to continue taking part in this study. You may contact the study doctor at any time after your taking part ends to find out if any new information about this study has become available.

POTENTIAL BENEFITS

If the study drug is effective, you may benefit by having a reduction in your post-operative pain level following surgery. It is possible that you may not personally benefit from taking part in this study. However, by taking part in this study, you may contribute new information that may benefit patients in the future.

PAYMENT FOR TAKING PART

There is no payment for taking part in this study.

[OR] For your taking part in this study, you will be paid $[Amount] for each completed visit.

COST FOR TAKING PART IN THIS STUDY

There will be no cost to you for study drug, clinic visits, examinations or laboratory and test procedures that are part of this study. Medical costs of other treatment outside this study are your responsibility and will be charged to you or your health insurance company or local health agency.

ALTERNATIVE TREATMENTS

You do not have to be in this study to receive pain treatment. If you decide not to take part in this study, you have other treatment choices that will be described to you by your doctor, such as other opioids such as fentanyl, morphine, or hydromorphone, given on demand through an IV. You are urged to discuss these treatments with your primary physician to learn if these drugs might benefit you.

CONFIDENTIALITY

The personal medical information collected from you during this study will be kept confidential (private) to the extent required by law. If you agree to take part in the study, your medical information will be collected and recorded by the study doctor and study staff. You will be identified by a subject number, assigned to you as part of the study, on data collection forms and laboratory results. Your name or any other data that may identify you will not be used in any reports or publications resulting from this study. Because of the research goals of this study, however, your medical information cannot be kept completely confidential. By consenting to take part, your medical records, including personal information that may identify you, may be reviewed and/or copied by:

- the study doctor and his/her staff;
- staff of the hospital or clinic where you are being treated;
- staff or agents/designees of the study sponsor, AcelRx Pharmaceuticals, Inc.;
- the FDA (the U.S. drug agency), State Regulatory Agencies, and/or other medicine control agencies in other countries; and
- the Institutional Review Board that reviewed this protocol

The above listed parties will be able to review and/or copy your medical information only in connection with carrying out obligations relating to this study, to ensure that the study is being carried out correctly, to review the results of the study, or for regulatory

purposes, or research purposes. Because of the need to disclose information to these parties, absolute confidentiality cannot be guaranteed.

Your personal identifiers (for example, name, address, health insurance carrier) will be kept by your study doctor in a secure place with access to the information restricted.

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 will have the right to withdraw your consent to take part in the study at any time. If you withdraw from the study, no new information will be collected from you and added to the existing data or database. However, the study sponsor may still use information about you that was shared with the study sponsor before you withdrew your consent. **If you withdraw your consent, you cannot continue to take part in the study, but there will be no penalty or loss of benefits to which you are otherwise entitled.**

COMPENSATION FOR INJURIES

If you become injured during this study and your injury is a direct result of the study drug given to you in this study according to the study directions, treatment for the injury will be made available through the study doctor and the clinic or hospital. The sponsor, AcelRx Pharmaceuticals, Inc., will pay the costs of this treatment to the extent that such treatment is not paid by your medical insurance or by third-party or governmental programs. For this to happen, the injury, in the opinion of the study doctor and AcelRx Pharmaceuticals, Inc., must be confirmed to have been directly caused by the proper use of the study drug in accordance with the study directions. No other financial compensation will be provided from the sponsor. If you would like further information about compensation for research-related injuries, please ask your study doctor.

LEGAL RIGHTS

Your taking part in this study does not affect your right to seek legal assistance for any injury alleged to have been suffered as a direct result of administration of the study drug. By signing this consent form, you have not waived any of your legal rights.

VOLUNTARY WITHDRAWAL FROM THE STUDY

Your decision to take part in this research study is completely voluntary. Your medical care will not be affected if you decide not to take part. There will not be any penalty or loss of benefits to you if you decide not to take part.

In addition, you may withdraw from the study at any time. If you decide to withdraw from the research study, there will be no penalty or loss of benefits to you. Before withdrawing from this study, notify your study doctor that you wish to withdraw. This notice will allow your study doctor to inform you if there are any potential medical risks of withdrawal. Information collected from you prior to withdrawal will be used in the

study. The study doctor will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

INVOLUNTARY WITHDRAWAL FROM THE STUDY

The U.S. Food and Drug Administration (FDA), the study doctor, the Institutional Review Board, or the sponsor, AcelRx Pharmaceuticals, Inc., may stop your taking part in this study with or without your consent at any time. The reasons for study termination may include, but not be limited to:

- You fail to follow the study procedures outlined above;
- You experience a serious side effect which requires your discontinuation from the study for safety reasons;
- The study doctor or sponsor decides that continuing the study would be harmful to you;
- You have a change in your condition which requires medications/procedures not allowed in this study;
- You have a positive pregnancy or drugs of abuse (that is inconsistent with your medical history) test; and/or
- The study is terminated by the FDA, the Institutional Review Board, or the sponsor.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

For questions, concerns or complaints concerning the research, or if you feel you are developing side effects from the study dosing, contact:

Principal Investigator Name: [Name]

Daytime telephone number(s): [Number]

24-hour contact number(s): [Number]

If for any reason you suffer a serious event that requires hospitalization or requires that you take additional medication, you should inform the doctor treating you that you are taking part in a research study and give the study doctor's telephone number.

If you have any questions about your rights as a research subject, concerns or complaints about the research, or want to discuss a problem, get information or offer input, you may contact the Western Institutional Review Board at 1019 39th Avenue SE Suite 120, Puyallup, Washington 98374-2115, 1-800-562-4789 (toll free) or 360-252-2500, E-mail: Help@wirb.com. An Institutional Review Board is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's rights and welfare in mind. If you have study-related comments, complaints or concerns, you should first contact the study investigator. Please call the Institutional Review Board if you want to talk to someone other than the study investigator or have difficulty reaching the study investigator.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

SUBJECT'S STATEMENT OF CONSENT

A Multicenter, Open-Label Trial to Evaluate the Overall Performance of the Zalviso System (sufentanil sublingual tablet system) 15 mcg

I voluntarily give my informed consent to take part in this research study (IAP312). I may decide not to take part or to withdraw from the study at any time without penalty or loss of benefits or treatment to which I am entitled. If I choose to leave the study before the end of the study period, I will notify the study doctor and he/she will explain the best way for me to discontinue.

I have been given sufficient opportunity to consider the information related to the Zalviso System and the study, as well as to discuss my participation in the study with others and to decide whether or not to take part in this study. I have read this information, which is printed in English. This is a language that I read and understand. I have been told that my information will be uniquely numbered to prevent direct identification and that this information will be processed in line with the requirements of the regulatory authorities. The site staff has explained the information and procedures involved in the study and I have had the opportunity to ask questions, which have been answered to my satisfaction. I have been told that I do not give up any of my legal rights by signing this form. My signature certifies that I agree to take part in this study and I agree to the use and disclosure of my medical information as stated in this consent form. I will receive a signed and dated copy of this consent form to keep for my own information throughout the study.

_____

Printed Name of Subject

_____ _____

Signature of Subject **Date**

I certify that the information provided was given in a language that was understandable to the subject.

_____

Printed Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion Date

_____

[Printed Name of Witness

_____ _____

Signature of Witness **Date]**

[FOR VA SITES ONLY**]**

HIPAA AUTHORIZATION

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

As part of the above referenced study, medical information about you will be collected and analyzed. This medical information may include (but is not limited to):

- Information obtained from procedures performed to determine whether you can take part in the study, including a medical history, physical examination, urine drug test and urine pregnancy test.
- Information that is created or collected from you during the study, including all tests performed during the study.
- Information contained in your medical records related to your medical history and treatment.

By signing this document, you authorize the study doctor and staff to use this information in conducting the study, and to provide access to and copies of this information to the study sponsor or to others working with the sponsor to monitor the progress of the study, analyze the study data, and for regulatory and research purposes. Access to this information is necessary for the sponsor to check that the study is being done correctly, and to collect and analyze data about the safety and effectiveness of the study drug. Regulatory authorities, such as the U.S. Food and Drug Administration (FDA) and the Institutional Review Board may also review or copy your information to make sure that the study is done properly, to review the results of the study, to decide whether to approve the use of the Zalviso System, or for other purposes required by law. By signing this form, you are agreeing to these uses of your medical information identified in this form.

This Authorization to use or disclose the information as described above does not end when the study ends. In signing this form, you agree to the use and disclosure of this information for the purposes described above at any time in the future.

You agree that, while the study is still in progress, you may not be given access to medical information about you that is related to the study. While a request for access to medical information can be denied, the study doctor and staff will not automatically deny a request, but will consider whether it is medically appropriate under the circumstances to allow access. Your agreement that you may be denied access to your study-related medical information during the study will not be used to deny you access to that information after the study is completed at all locations and study results are analyzed.

If at any time before, during or after the study, you have any questions about the use or disclosure of your study-related information, we ask that you contact the study doctor at the phone numbers listed on the first page of this document.

You may choose to withdraw this Authorization at any time, but you must notify the study doctor in writing. Send your written withdrawal notice to the following address:

[Contact name and address]

If you withdraw from the study and withdraw your approval to share your medical information, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the sponsor and may continue to be reviewed and/or copied by the parties listed in this Authorization.

You should know that once information is disclosed under this Authorization to someone who is not a health care provider, the information is no longer protected by the federal privacy rules called the “HIPAA privacy regulations,” and could be disclosed to others by the recipient.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. [***will expire December 31, 2050, unless you withdraw it in writing before then. (FOR WA SITES, DE, IL, IN, CA, WI)***] Your study doctor will keep this Authorization for at least 6 years.

You may decide not to sign this document, or you may change your mind and decide to withdraw your approval to share your medical information in writing at any time. However, you can only take part in the study if you authorize the use and disclosure of the information as described above. If you decide not to sign this document, you will not be enrolled in the study. If you sign this document and decide later to change your mind and withdraw your approval to share your medical information, you will be withdrawn from the study at that time. Information collected up to the time you withdraw your

approval will continue to be used as study data if it is scientifically appropriate to do so. Your decision to withdraw your Authorization or not to take part will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

AUTHORIZATION

I authorize the release of my medical records and personal health information related to this study to the sponsor and its representatives, the Institutional Review Board, the FDA, and other regulatory agencies as described above. I have been told that I will receive a signed and dated copy of this Authorization for my records.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

_____

Printed Name of Person Obtaining Authorization

_____ _____

Signature of Person Obtaining Authorization Date