Digital Health Feedback System (DHFS) for Anti-Retroviral Therapy Medication Adherence and Transitions of Care Support During Hospital Admissions for Persons Living with HIV

Informed Consent Form, Version 4 – February 8, 2022

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UNIVERSITY OF CALIFORNIA - SAN DIEGO
CONSENT TO ACT AS A RESEARCH PARTICIPANT

Digital Health Feedback System (DHFS) for Anti-Retroviral Therapy Medication Adherence and Transitions of Care Support during Hospital Admissions for HIV Infected Participants.

INTRODUCTION

Dr. Sara Browne and her associates are conducting a research study sponsored by The National Institute of Health to determine whether the use of new technologies to measure a person's ability to consistently take prescribed medications to treat Human Immunodeficiency Virus (HIV) infection will be acceptable to participants and will accurately monitor and support medication taking behavior. The rest of the form provides additional details.

Research is voluntary - whether or not you join 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.
- Your decision will not affect your health care or any other benefits you may be entitled to.
- You can say no even if the person inviting you is part of your healthcare team.
- Please ask questions or mention concerns before, during or after the research.

KEY INFORMATION ABOUT THIS STUDY

We are asking if you want to participate in a research study. This document contains information that will help you decide whether to take part in a research study. We encourage you to read the entire document. All the information is important, but here are some important things you should know about this study:

- This is a research study. In this research study, we will use an ingestion sensor (a tiny sensor swallowed with your medication) and a wearable sensor (worn as a patch on the skin) to collect information on how you take your anti-HIV medication.
- This research study is for adults who are HIV-positive.
- You are being approached because you may qualify for this study.
- To take part, you must be willing to accept to take you HIV medication with the ingestion sensor and wear a sensor on your body. You will also have assessments and answer several questions about your experience.

If you decide to participate in this study, the following things will happen:

- During the first part of the study you will have an initial screening visit either in hospital or at the AVRC and then four visits within a two-week period, either in hospital or at the AVRC or the Owen clinic after discharge from hospital. This part of the study is designed to confirm that the DHFS is working correctly and to understand what you think about using the DHFS.
- If all goes well and you want to and are eligible to continue, you will then be on the second part of the study that will last for 14 weeks, during which you will continue to use the DHFS. During this time you will be asked to attend study visits (either in hospital or at the AVRC) once every 4 weeks for a total of 4 additional visits and you may receive text messages, calls or be offered additional in person support to maintain optimal anti-retroviral medication taking.
- After stopping use of DHFS, you will be invited to follow up for 3 more additional visits over the remaining year. If you are unable to attend these follow up visits, with your permission, we will contact you and your primary care provider by phone for any additional information.
    - The most commonly expected risks of the study are nausea, stomach cramps, constipation, and skin rash.
    - The most serious risks of the study may include asthma attack, chest pain. Serious complications can occur when other medications, including over-the-counter herbal medications, are taken with study drugs.
    - All of the risks are outlined below in this consent form. Please take as much time as you need to read this section carefully and ask any questions.
    - There may be no direct medical benefit to you. Alternatives to this study are to not participate and seek standard treatment from your doctor for HIV.
    - You do not have to participate in this research study. It is **your choice** whether to participate. You can choose to stop **at any time.**

ABOUT THIS STUDY

This study uses an ingestion sensor (a tiny sensor swallowed with your medication) and a wearable sensor (worn as a patch on the skin), which are new technologies approved by the FDA, to collect information about patients' medication taking behavior or adherence, in this case for HIV treatment. The purpose of this study is to find out if using this new system, started in hospital, works to support a person taking their HIV medications.

PURPOSE OF THIS STUDY

You have been asked to participate in this study because you have HIV infection, are currently in hospital and are starting or restarting HIV medications.

This study will look at the ability of DHFS to measure when you take the HIV medications, and what you think about using the DHFS. Additional aims of this study include:

- **Telemedicine**: We will explore if you find using a telemedicine platform for evaluations, assessments, and treatment support acceptable and useful. Telemedicine involves the use of electronic communications and software to provide clinical services remotely to patients or study participants via secure video and audio connections. This study uses secure software application downloaded onto the mobile device or tablet that you will use for the duration of the 16-week study intervention. The software is HIPAA compliant, which means it will protect your privacy and security.
- **Participant Needs Assessment**: As a study participant you will have needs assessment screening by research staff and you may be offered individualized navigation services by 211 San Diego as needed. 211 San Diego is a local non-profit organization, offering resource navigation to several health and community resources, on health and wellness, food assistance, housing and utilities and assistance with enrollment services for such resources. These navigation services may include a home visit where appropriate.
- **Psychosocial Evaluation**: All study participants will have psychosocial assessment and evaluations by Specialist Physicians either via the Telemedicine platform or in person. Specialist team assessment and management recommendations will be shared with your UCSD inpatient HIV consultation team, the transition of care team and your outpatient primary care provider to support your care.

DURATION OF THE STUDY

Researchers at the UCSD Antiviral Research Center (AVRC), together with the UCSD Medical Center (Hillcrest and Jacobs) inpatient HIV consultation team, healthcare providers from the UCSD Owen HIV Clinic and FHCSD HIV clinics and Community Physicians are doing this study. We plan to enroll about 30 people over a one year period in the study.

Your participation in this study will last up to 48 weeks (almost 1 year). During the first part of the study you will have an initial screening visit while in hospital and then four visits within a two-week period, either in hospital or at the AVRC or the Owen clinic after discharge from hospital. This part of the study is designed to confirm that the DHFS is working correctly and to understand what you think about using the DHFS.

If all goes well and you want to and are eligible to continue, you will then be on the second part of the study that will last for 14 weeks, during which you will continue to use the DHFS. During this time you will be asked to attend study visits (either in hospital or at the AVRC) once every 4 weeks for a total of 4 additional visits and you may receive text messages, calls or be offered additional in person support to maintain optimal anti-retroviral medication taking. The second part of the study is designed to evaluate longer term acceptability, accuracy and efficacy of the DHFS. After stopping use of DHFS, you will be invited to follow up for 3 more additional visits over the

remaining year. If you are unable to attend these follow up visits, with your permission, we will contact you and your primary care provider by phone for any additional information.

PROCEDURES
If you agree to participate in this study, the following will happen:

Screening Visit
To see if it is okay for you to participate in this study, while in hospital or at the Anti Viral Research Center clinic within 14 days of being discharged form hospital, you will first attend a study visit known as a "screening" visit. At the screening visit, this consent form will be reviewed with you and you will be asked to sign it.

Once you sign this form and agree to participate, we will confirm your HIV status by reviewing your medical records, determine whether you are currently on HIV medications or have been in the past and collect physical exam information from your inpatient chart. You will be asked to sign release of information forms giving the study team your permission to obtain information from your medical records, with this release to continue for the duration of the study.

The study coordinator will ask you questions about your background (e.g., your age, employment, education) and your medical/medication history and will review information from inpatient records and other medical records including laboratory test results such as blood count, chemistry values, liver and kidney function. At the screening visit, approximately 2-3 tablespoons of blood may be drawn and held for laboratory tests (including blood count, HIV viral load, CD4 T cell count, chemistry values, liver and kidney function tests, if these test results are not already available from your HIV provider or inpatient records), or future viral analysis such as resistance testing, if these results are not available from your HIV provider or inpatient records. A urine sample will also be collected for urine drug test and pregnancy test (as appropriate).

Since study personnel are working closely with your inpatient HIV consultation team, we will discuss some of the information you provide with your HIV provider to decide together if you are able to take part in this study.

Your screening visit will take 1 to 1.5 hours.

Entry Visit
The information gathered at your screening visit will determine if you are able to take part in this study. At the entry visit, we will ask for any updates about your health or any other medications or supplements you may be taking, and do a brief physical exam.

At the entry visit, we will show you in detail how the digital health feedback system (DHFS) and the telemedicine platform work.

Ingestion Sensor
The ingestible sensor is very small, about the size of a sesame seed, and is contained within a small pill, which will be put into a medication capsule along with your HIV medications. The sensor is made of minerals and metals that are commonly found in food, and contains no battery or no antenna. After you swallow the capsule containing the sensor and the HIV medication, the fluids in your stomach start to break down the capsule. The ingestible sensor activates as it comes in contact with your body's stomach fluids and it sends a unique number to the wearable sensor, including the date and time it was swallowed. The sensor will communicate this information for about 5 minutes, and you will not notice when this process starts or stops. Just like a sesame seed, the tiny ingestion sensor then passes through your digestive system, and is later passed with the stool.

Wearable Sensor
The wearable sensor is a small device with an adhesive backing like a bandage, and is worn on the skin of your torso (chest, back or abdomen) like a patch or bandage. The wearable sensor receives the information communicated by the ingestion sensor when it is in your stomach, and then transmits that information to a paired mobile device, which then uploads it to the study computer. At the entry visit, the study coordinator will show you how to place the patch on your torso.

You will use a wearable sensor to record the information about taking your HIV medications for the entire 16 weeks of the study. During the time you are using a wearable sensor it will be worn continuously and be changed weekly or earlier if needed. Throughout the 16-week study intervention, the study coordinator will be checking that the DHFS is working correctly and recording your HIV medication daily. If the DHFS is not providing this information on any business day, the study coordinator will contact you by phone call or text to confirm that you are using the wearable sensor, have taken your daily HIV medication and to help resolve any difficulties or technical issues that you may be having with the DHFS.

The wearable sensor does not cause any health problems for most people who wear it, but a few people experience minor skin irritation. When your wearable sensor is changed, it can be placed each time on a different part of the torso to try to prevent this from happening. You may be asked to photograph any rashes you experience using the camera on the mobile device given to you as part of this study. The study team will review the photos at your study visits.

At the entry visit, the study coordinator will also give you information about a few things to be cautious about when you are using a wearable sensor on your skin; for example, physical activities that might result in forceful contact with the wearable sensor (e.g., boxing or karate) should be avoided. You should remove the wearable sensor having an MRI scan or test.

Study Medication
At the entry visit, you will take one to two sensor pills to check that the system is functional. You will then take your capsule(s) of HIV medication. These will be one to two study capsules

(depending on the HIV medications your provider chose for you). This capsule(s) contain(s) your HIV medication, which is a standard brand name medication your HIV provider chose for you and the tiny ingestible sensor contained within a small pill.

Your entry visit will take about 1 hour.

Study Visits:

Week 0-2 Visits
For the first part of the study, for a two-week period, you will have 3 study visits either in hospital or at the AVRC. At all 3 visits you will take your capsule(s) of HIV medication.

At two of the visits, the study coordinator will observe you changing the wearable sensor patch, to make sure that you know how to place it correctly on your torso.

At the end of the second week, you will be asked questions about what you think about using the DHFS system. At the Day 2-5 visit, you will be asked to complete some questionnaires about your beliefs and attitudes, life style and sleep patterns, mood, and alcohol and substance use behaviors. The study coordinator will administer some of these questionnaires and others will be self-report completed via your study tablet.

During this initial 2 week period all study participants will have needs assessment screening, psychosocial assessment and evaluation by Specialist Physicians via the Telemedicine platform or in person, as needed, and may be linked to 211 San Diego navigation services as needed.

After the entry visit, the Day 2-5 and Week 16 visits will take 1.5 to 2 hours and all other in person visits will take about 30 minutes.

Week 3-16 Visits
If you choose to continue in the study you will continue to have your HIV medication use recorded by use of the DHFS. The second part of the study will last 14 weeks.
At the start of the second part of the study, the study coordinator will make sure you know how to change the wearable sensor and how to use the mobile computerized device that will be provided to you during the study. This device will wirelessly transmit information from the wearable sensor to the secure study computer. It will also tell you if your patch is on properly and if the system is working correctly. After this visit, you will be taking your medications at home or in hospital until you are discharged home. We will ask for any updates about your health or any symptoms you are having, any new medications or supplements you are taking, and do a brief physical exam. A urine sample will be collected for urine drug test at all study visits. We will also ask you to complete some questionnaires about your beliefs and attitudes, life style and sleep patterns, mood, and alcohol and substance use behaviors, as well as reporting all the HIV medications that you have been taking.

The additional study visits either in hospital or at the AVRC or the Owen clinic during the second part of the study will take place during Week 4, Week 8, Week 12 and Week 16. At these visits, the study coordinator will observe you taking your HIV medication and we will ask for any updates about your health or any symptoms you are having, any new medications or supplements you are taking, and do a brief physical exam. The study coordinator will check your study mobile computerized device and your wearable sensor and will discuss with you how this is going. At some study visits you will be asked questions addressing what you think about using the DHFS system. At some study visits, we will also ask you to complete some questionnaires about your beliefs and attitudes, life style and sleep patterns, mood, and alcohol and substance use behaviors, as well as reporting all the HIV medications that you have been taking. You may be able to continue to access the telemedicine platform for study team assessments and treatment support.

During the second part of the study should your antiretroviral medication taking decrease below what is recommended, you may receive text messages, calls or be offered additional in person support to maintain optimal anti-retroviral medication taking. At some visits a random dried blood spot test or plasma drug level may be to determine the concentration (amount) of HIV medication in your body. Dried blood spot testing (DBS) is a test where blood samples obtained from pricking the finger are blotted and dried on filter paper. The dried samples are then analyzed to measure the level of HIV medication in your blood.

We will be tracking your HIV viral loads and CD4 T cell count during and after the study and we would like to see you back at week 24, 36 and 48. If these test results are not available from your HIV provider approximately 10 ml of blood (1 tablespoons) may be drawn at some visits, including the three follow up visits, to measure your HIV viral load and CD4 T cell count. If you are unable to attend these visits, with your permission, we will contact you by phone and will obtain these results from your Primary Care Provider.

An additional 1-2 tablespoons of blood (~20ml) may be drawn and stored at some visits, including the three follow up visits at Weeks 24, 36 and 48, for random plasma drug levels or for use in future studies to understand how the virus changes over time.

RISKS/DISCOMFORTS

Participation in this study may involve some added risks or discomforts. These include:

Ingestion Sensor Risks: Although quite unlikely, you may experience possible side effects from the ingestion sensor, which include but are not limited to nausea or vomiting, mild anxiety, constipation, abdominal cramping, asthma attack, chest pain, and a bitter taste in the mouth. The ingestion sensor is made from minerals and metals that naturally occur in small amounts in food; there is an extremely small chance that consuming these materials could cause injury, although the amounts in the ingestion sensors that you will swallow with your medication are below the acceptable daily intake limits.

As described above, the ingestion sensor will communicate information to the wearable sensor through your body's tissues for a few minutes, and you will not feel or notice this, and this process has not caused any harm or injury during any previous testing. There is an extremely small risk that the ingestion sensor could damage the inside of your digestive system or get stuck somewhere inside your gut, although this has not happened in any previous testing. If the sensor did get stuck, your digestive system could become inflamed or blocked. Medical and possibly surgical treatment would be needed to correct this problem.

Wearable Sensor Risks: You may experience possible side effects from the wearable sensor, which include but are not limited to a rash or minor skin irritation, redness or discoloration of the skin, swelling, discomfort, warmth, breaks in or tearing of the skin, or slight bleeding. This is similar to what can happen with any adhesive patch or bandage worn on the skin for an extended period of time. If any of these problems occur, you may remove the wearable sensor or move it to another location on your torso. Because the wearable sensor has an adhesive material that sticks to your skin, if you know that you have an allergy to adhesive tape, you should not participate in this study. You may be asked to photograph the rash using the camera on the mobile device given to you as part of this study. You will not be identified in the photograph.

There is also an extremely small chance that the wearable sensor could cause an electric shock to your body, resulting in discomfort and/or injury. The wearable sensor has been designed and tested to meet safety standards in order to avoid this potential problem, and electric shock has not happened during any previous testing of the wearable sensor.

Other Side Effects or Risks: A small number of people in this study may have one or more of the risks or side effects listed above or other side effects may be unknown. That is one reason that your study coordinator will continue to ask for any updates about your health or any symptoms you are having, at each of your study visits while in hospital or at the AVRC or the Owen clinic. Any side effect will be carefully evaluated by the study doctor or nurse and managed according to standard of care guidelines and may require discontinuation of the study drug.

There may be risks of serious and/or life-threatening side effects when other medications including over-the-counter herbal medications are taken with study drugs. For your safety, you must tell the study doctor, nurse, or coordinator about all medications or supplements you are taking besides the study drugs before you start the study, and also before starting any new medications while on the study. In addition, you must tell the study doctor, nurse, or coordinator before enrolling in any other clinical trials while on this study.

Pregnancy and Breastfeeding: The DHFS has not been studied in pregnant or breastfeeding women. If you are a woman of childbearing potential you must have a negative pregnancy test before starting any study medications, and you must agree to use an effective means of contraception for the duration of your participation in the study. If at any time during the study you think you might be pregnant, you must immediately tell the study staff. Women who become pregnant will not be able to continue on the study. You will be advised to seek best available

medical care for the pregnancy according to U.S. HIV treatment guidelines. With your permission the study coordinator will follow up with your primary care provider to inquire how you are doing and the outcome of the pregnancy.

Risks of Drawing Blood: You may experience temporary discomfort from the blood draws. Taking blood may cause some discomfort, bleeding, or bruising where the needle enters the body, lightheadedness, and in rare cases, fainting or infection.

Loss of Confidentiality: A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality. Their plans for keeping your information private are described in the "Confidentiality" section below.

The University has policies and procedures to ensure your confidentiality. We will use our best efforts to ensure that your identity and test results will not become known outside the research program.

Unknown Risks: This is a research study, and there may be risks that are unforeseeable. The study staff will inform you of any new risks that arise during the study.

STORED SAMPLES

During the study at some study visit 1-2 tablespoons of blood (~20mL) may be drawn and stored for use in future studies to understand how the virus changes over time. You will not be identified by name in any testing and your confidentiality will be maintained. Specimens will be identified by an identification number only (your name will not be listed on the sample). All of the individuals receiving these specimens will be scientific partners in this study. Your blood may also be used in additional research to be conducted by the University of California personnel collaborating in the research. This blood and its derivatives may have significant therapeutic or commercial value.

If you decide later that you do not want the data from the specimens collected from you to be used for future research, you may tell this to Dr. Browne, who will use her best efforts to stop any additional studies. However, in some cases, such as if the data from your samples are found to be generally useful, it may be difficult or impossible, to stop such future research once the information has been widely shared with other researchers. You may reach Dr. Browne at 619-543-8080 or tell her in person.

DATA SHARING

Coded data that have been stripped of your personal identifying information may be used for additional future research. Our goal is to better understand if the services provided to you during this study, such as enhanced navigation and the use of the DHFS for treatment support, have been

beneficial by comparing your de-identified data to that of other persons living with HIV who have also been admitted to the UCSD Medical centers (Hillcrest and/or Jacobs).

The investigators will maintain the codebook in order to access identifiers to link data sets outside of the research team.

BENEFITS

There may not be any benefit to participation. You will continue your treatment for HIV as part of this study. We know that taking HIV medications every day will provide you excellent health benefits. Participation in this study may help you take your medications better and will give you additional exposure to health professionals and researchers if you have any side effects or other issues while you are starting your HIV medications. Data collected during this study like psychosocial assessment data and recommendations by Specialist Physicians will be shared with your hospital or clinic primary care providers to support your care as you initiate or restart HIV medications. Your participation in this study will contribute to our knowledge of the best approaches to use in treating HIV in other patients in the future.

NEW FINDINGS

You will be told of any new information learned during the course of the study that might cause you to change your mind about staying in the study. At the end of the study, you will be told when study results may be available and how to learn about them.

REASONS FOR WITHDRAWAL FROM THE STUDY DRUGS AND/OR STUDY WITHOUT YOUR CONSENT

You may be removed from the study without your consent for the following reasons:

- The study is canceled by the sponsors, The National Institute of Health and Proteus Digital Health, by the UCSD AVRC study doctor, or the UCSD Institutional Review Board (IRB). An IRB is a committee that watches over the safety and rights of research participants.
- You are unable to keep appointments as required by the study.
- Your primary care doctor thinks it is no longer in your best interest to be in the study.
- You experience a high level of HIV medication toxicity.
- You have to start taking other medications that interact with the study medication, or for other clinical reasons as determined by the study doctor.
- You do not follow study instructions, for example, repeatedly fail to attend study visits including telemedicine assessments and not being contactable.
- You fail to wear the wearable sensor for extended periods of time
- You become pregnant or start breastfeeding.

- The study physicians and study staff determine that you are no longer eligible to continue in the study

ALTERNATIVES TO PARTICIPATION
You may choose not to participate in this study. If you change your mind later about being in the study, you can decide not to be in the study at that time. If you decide you do not want to be in the study, your HIV physician will use his or her best judgment to decide what medications to use to treat your HIV and what tests to use.

WITHDRAWAL PROCEDURES
If you decide to stop participating in the study, please contact the study coordinator at (619) 543-8080. If you choose to withdraw from the study, or if you are removed from the study for medical or one of the other reasons listed above, you will be asked to return to the clinic for one final visit to complete the appropriate end of study procedures, including an evaluation of your health and safety. You will also be asked to return any mobile device(s) provided by the study, unused study medications, or study supplies.

COSTS AND COMPENSATION
You will not have to pay anything for the study-related clinic visits, physical examinations, or laboratory tests in this study. The HIV medications used in this study will be provided at no cost to you for the 16 week intervention phase of the study. On completion of the 16 week intervention, you will continue on HIV medication prescribed by your primary care provider but the cost of the HIV medication will be charged to you or your insurance company. The cost of any drugs or treatment you may need outside of this study and any other standard of care (SOC) costs will be charged to you or your insurance company.

You will receive $50 for each study visit that you complete after your screening visit, as compensation for your time and any inconvenience you may experience as a result of your participation in this research study. There are a total of eleven visits, excluding the screen visit, and the last reimbursement will be made after your last visit. If you discontinue early for medical reasons, you will receive a pro-rated reimbursement amount based on the number of study visits completed.

Due to IRS Regulations, study participants who receive $600 or more in a calendar year must submit their name, address and social security number. Subjects who receive $600 or more in a calendar year will be mailed a 1099 form at the end of each calendar year.

CONFIDENTIALITY
We protect your privacy and confidential information with a carefully designed program that has been successful for more than two decades. In addition to the efforts of the study staff to protect your confidential information, we have obtained a Certificate of Confidentiality from the U.S.

Government. With this certificate, researchers cannot be forced to give information about you to others, such as the court system or state officials. This Certificate of Confidentiality does not prevent you from releasing information about yourself or your participation in the study. Also, scientific publications of the findings of this study will not use your confidential information.

We will do everything we can to protect your privacy. Some of the questionnaires you will complete while in this study reveal very personal information about your mental health and substance use. Site staff will do all they can to keep your information private, but if you want referral for treatment or site staff feel referral to other providers for treatment of these conditions is necessary, some of the information may need to be shared with these other providers.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities. If study personnel believe you may harm yourself or others, they are also required to report this to the relevant authorities.

Nearly all healthcare systems, including UCSD, now participate in a health information exchange (HIE) program. The HIE shares your medical records with other doctors outside UCSD to help improve your overall medical care. Research tests that are performed at UCSD, including records from this research study, may be shared on the HIE. By participating in this study, providers outside of UCSD may have access to your medical records, including lab results. To opt out of the HIE, call 619-543-5707 or submit an "opt out" form on http://myucsdchart.ucsd.edu.

People who may review your records include doctors who use the HIE, the Office of Human Research Protection (OHRP) or other government agencies as part of their duties, Food and Drug Administration (FDA), UCSD IRB (a group that protects the rights of people in research), the National Institutes of Health (NIH), study staff, study monitors, other local, US, and international regulatory entities as part of their duties, and their designees.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

RESEARCH-RELATED INJURY

If you are injured as a direct result of participation in this study, the University of California will provide any medical care you need to treat those injuries. Neither the sponsors of the study, The National Institute of Health and Proteus Digital Health, nor the University of California will provide any compensation to you if you are injured. You may call the UCSD Human Research Protection Program Office at (858) 246-4777 for more information about this, to inquire about your rights as a research participant, or to report research-related problems.

PROBLEMS OR QUESTIONS

Dr. Sara Browne and/or _____ has explained this study to you and answered your questions. If you ever have questions about this research study, or in case of research-related problems, you may reach Dr. Browne at (619) 543-8080 or an AVRC doctor on call at (619) 543-6737 after working hours or in an emergency.

Participation in this study is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive from this institution or loss of benefits to which you are entitled.

The study purpose, procedures, possible risks, and benefits as outlined in this consent have been explained to you. You have been invited to ask any questions about the study that you may have, and all your inquiries have been answered. You do not give up any of your legal rights by signing this form.

You have received a copy of this document and a copy of the "Experimental Participant's Bill of Rights" to keep.

You agree to participate.

_____ _____
Participant's Name Printed Date

_____
Participant's Signature

_____ _____
Printed Name of Person Obtaining Consent Date

_____
Signature of Person Obtaining Consent