LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER – NEW ORLEANS (LSUHSC-NO)
AND
OCHSNER CLINIC FOUNDATION (Ochsner)
RESEARCH INFORMED CONSENT

Study Title: (*as it appears on the protocol*)

Sponsor's Protocol # (*as it appears on the protocol*)

Sponsor name: (*if internally funded, enter PI name*)

Principal Investigator: Place name here

Sub-Investigators: List names here

Are you in any other research studies? Yes _____ No _____
please initial your response

You have been invited to participate in a research study. The doctors and staff at LSUHSC-NO and Ochsner study the nature of disease and attempt to improve methods of diagnosis and treatment. This is called clinical research. Understanding this study's risks and benefits will allow you to make an informed judgment about whether to be part of it. This process is called informed consent.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

[*if needed*: In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.]

PURPOSE

The purpose of this study is *(Add explanation)*. You have been asked to participate in this study because *(Add explanation)*.

LENGTH OF STUDY AND NUMBER OF PARTICIPANTS

Your participation in this research study will be for *(indicate number of month/years as appropriate)*. There will be *(indicate number)* sites nationwide *(or worldwide)* enrolling

(indicate number) subjects for participation in this study. At LSU and Ochsner, about *(indicate number)* subjects will be enrolled.

PROCEDURE

(A clear and concise description of the protocol to be followed and the procedures to be performed should be included and written in lay language. Include methods and timetables. For questionnaires, specify the expected amount of time needed to complete them. Identify all parts of the procedure that are experimental. If tissue or blood samples will be stored for future research, or if DNA or genetic studies are involved please insert the language from the "Blood and Tissue Verbiage" document found in the ERSA Forms and Templates folder.)

RISKS

General / Unforeseeable Risks

(List any risks that may be incurred by participation in this study, even if remote. This includes physical, psychological, social, and legal risks. The subject should also be warned that their condition may not improve or may worsen, despite participation. Provide a statement that there may be unforeseeable risks to the subject.)

Louisiana law requires us to set forth the known risks of a medical treatment, including the risks, if any, of death, brain damage, quadriplegia (paralysis in all arms and legs), paraplegia (paralysis of both legs), the loss or loss of function of any organ or limb, and disfiguring scars, which might be associated with a necessary procedure. Any clinical study carries with it risks of which we may be unaware at this time, including those listed in this paragraph. [These complications have never been seen with this investigational drug, and chemically related compounds have not been associated with any of these adverse effects.]

The part in [ ] is added if it is true. (This paragraph should be included as required by Ochsner Legal Staff's interpretation of Louisiana State Law in those informed consents for research that involves more than minimal risk. It should be removed for minimal risk studies, like an observational study, record review, or survey. Do not alter this language without approval from Ochsner Legal Staff.)

Reproductive Risks

Where applicable, indicate whether a particular treatment or procedure may involve currently unforeseeable risks to the subject or the embryo or fetus, if the subject is or may be pregnant. The usual language expected if women with childbearing potential are involved is:
The treatment or procedure may involve unforeseeable risks to the subject, or embryo or fetus, if the subject becomes pregnant. Because the possibility of injury or harmful effects to an embryo or fetus exist, you must not be pregnant or conceive a child while in this clinical trial. Acceptable methods of contraception include intrauterine device, spermicide and barrier (e.g., condom, diaphragm) method, oral contraceptives (birth control pills) and total abstinence." Please discuss the best choice for you and your partner with your study doctor.

If you or your partner become pregnant while participating in this study, you MUST contact your study doctor immediately.

Radiation Risks

When applicable, indicate radiation risk and exposure comparison to daily life and/or routine medical care. If not more than usual care, the following language should be used:
Although you will undergo some tests involving ionizing radiation in this protocol, they are the same you would undergo if you were not in this study, and at the same frequency. Therefore, this study does not involve any additional radiation risk for you.
(Radiation beyond the standard of care for the condition being treated or diagnosed requires approval by the Ochsner Radiation Committee prior to it being submitted to the Ochsner IRB)

Blood Draw Risks

Drawing blood has a small risk of local pain, bruising, infection, swelling and/or bleeding at the needle puncture site.

POTENTIAL BENEFITS

(List all benefits. These should include, but not be limited to, direct medical benefits which the subject may receive, the possible advancement of medical knowledge. It should also be stated that no direct medical benefit to the subject can be guaranteed. If there are no benefits to the patient, this should be stated.)

No direct medical benefit can be guaranteed. No promise can be made concerning the study outcome, because results from a clinical research study cannot be predicted. [*Delete for minimal risk studies if it does not apply*]

COSTS *(This section should concur with the CTA.)*

(*Free medication, laboratory studies, physical examination, etc. should be included under costs. If there are no costs, this should be stated. Any and all known additional costs that will result from the study should be adequately disclosed. If insurance will be billed for anything from the study, this should be stated, and who will be responsible if the insurance does not pay. If there are no known additional costs, it should state that*.)

The Sponsor will pay for medicine and procedures that are specifically related to the study.

Any other tests, procedures, or medications that may be necessary for the treatment of your medical condition will be billed to your insurance in the normal way. You may be responsible for co-payments or deductibles. These costs are not covered by this research study. If you have any questions about treatment for which you may be responsible for paying, please discuss this with your physician or study staff.

PAYMENT FOR PARTICIPATION AND/OR REIMBURSEMENT OF EXPENSES

(This section should concur with CTA.)
(A statement should be included indicating whether or not a subject is to be paid for participation or for reimbursement of expenses. It should explain how the payments will be dispersed over the course of the study and what the payments are being provided for [i.e., participation in the study, reimbursement for travel expenses, reimbursement for time lost from work, etc.]. Payment should not be contingent upon completion of the entire study. Example: "You will receive $10.00 per study visit. This will be paid to you quarterly [4 times per year]. If you complete the entire study, you will be paid a total of $200.00. If you withdraw from the study early, you will be paid for the number of study visits you complete." If payment for participation or reimbursement of expenses will not be provided, state that. Non-dollar amount "incentives" such as gift certificates, etc. should also be included in this section. If there is a chance that total annual payment may reach $600, add:
Study payments that reach IRS limits of $600.00 in a calendar year will be reported to the IRS as required by law.*)*

LSUHSC-NO and/or Ochsner is/are being funded by [*the sponsor, or other wording, as appropriate*] to conduct this research. [*delete if this is an unfunded study, adjust to make it accurate.*]

ALTERNATIVE METHODS/TREATMENTS

(Briefly describe the alternative methods or treatments available. Be specific, and do not just say your doctor will discuss this with you. When appropriate, the alternative of supportive care with no additional disease-directed therapy should be discussed .)

STUDY RELATED QUESTIONS AND COMPENSATION FOR INJURY

If you have any questions concerning your participation in this study or if at any time you feel you have experienced a research-related injury or a reaction to a study drug, contact:
(Must provide two contact names with different contact phone numbers.)

Dr. _____ at _____.
Address:
Phone:

Or

Dr. _____ at _____.
Address:
Phone:

In the event of a research emergency call [insert LSU and Ochsner 24 emergency call numbers]

(This section should concur with CTA.)
In the event of research-related injury from the research procedures or drugs or device, medical treatment and hospitalization, if necessary for injuries or illness, is available. This medical treatment and/or hospitalization *is/is not* free of charge. (*Must select which is appropriate …*

"is" or "is not." If it is provided free of charge, name the company who will be responsible. If it will not be provided free of charge state that "no funds have been set aside" and/or that it "will be billed to you or your insurer in the ordinary manner." Specify if they are responsible for co-pays and deductibles, so they are not surprised when they thought insurance would pay. This paragraph should be included on informed consents for all research involving more than minimal risks.)

QUESTIONS ABOUT YOUR RIGHTS

If you have questions about your rights as a research subject, you may contact:

Chancellor of the LSU Health Sciences Center – New Orleans
Telephone: (504) 568-4801

Or

Ochsner Clinic Foundation Institutional Review Board
Telephone: (504) 842-3535

The Institutional Review Board is a group of people who perform independent review of research for human subject protection.

RELEASE OF INFORMATION AND SUBJECTS' RIGHT TO PRIVACY

The results of the study may be released to the funding agency. *[Provide name of the funding agency or sponsor, if known.]* If the results of the study are published, the privacy of subjects will be protected and they will not be identified in any way. Your personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your study-related medical records for quality assurance and data analysis include:

- The sponsor
- LSUHSC-NO Institutional Review Board
- Ochsner Clinic Foundation Institutional Review Board
- The doctors listed on page 1 of this consent form and their staff
- Food and Drug Administration (FDA)
- U.S. Department of Health and Human Services (DHHS)
- U.S. Office of Human Research Protections (OHRP)

A description of this clinical trial is available on http://www.ClinicalTrials.gov, as required by US law this website will not include information that can identify you but rather includes a summary of the results of the study. You can search this website at anytime.

While every effort will be made to maintain your privacy, absolute confidentiality cannot be guaranteed. Records will be kept private to the extent allowed by law.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THE RESEARCH

Participation in this study is voluntary. You may decide not to participate in this study or you may withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled at this site. If you leave the study before the final regularly scheduled visit, you may be asked by the study doctor to make a final visit for some end of study procedures. If you decide to discontinue participation, data collected about you up to that point may still be used along with data in publically available health registries. However, no new data will be collected from you.

You will be informed of any significant new findings that develop during the investigation that may affect your willingness to continue in the study.

You should tell your study doctor about all of your past and present health conditions and allergies of which you are aware, and all drugs and medications which you are presently using.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent because:

- the study doctor thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have been informed about this study's purpose, procedures, possible benefits and risks, and the use and disclosure of my health care information from this research. All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study. I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above. By signing this consent form I have not waived any of the legal rights that I otherwise would have as a subject in a research study.

CONSENT SIGNATURE

_____

Patient Signature Printed Name Date

_____

Signature of Legally Authorized Representative (*when applicable*) Printed Name Date

_____

Authority of Subject's Legally Authorized Representative or Relationship to Subject

_____

Person Obtaining Consent - Signature Printed Name Date

The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to take part. [Note: This signature block cannot be used for translations into another language. A translated consent form, with the translation approved by the IRB, is necessary for enrolling subjects who do not speak English.]

_____ _____

Signature of Reader Date

_____ _____

Signature of Witness Date

(Remove Assent Signature section for ages 13-17 below, if minors are excluded from participation.)

ASSENT SIGNATURES, for Subjects Ages 13 through 17 years:

Assent:
This research study has been explained to me and I agree to be in this study.

_____ _____
Subject's Signature for Assent Date

I confirm that I have explained the study to the extent compatible with the subject's understanding, and that the subject has agreed to be in the study.

_____ _____ _____
Signature of Person Conducting Assent Discussion | Printed Name | Date