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| --- |
| This template has been developed to assist you with creating an informed consent document that meets regulatory requirements w/ Ochsner approved language.  Instructions: Red text throughout this ICF template is instructional and must be replaced or deleted as applicable – any text that is updated to study specific information must be changed to black. Delete these instructions before submitting or your application will be returned. |

OCHSNER CLINIC FOUNDATION

**RESEARCH INFORMED CONSENT**

**INSERT THE NAME OF YOUR STUDY HERE *–* as it appears on the protocol**

**Principal Investigator: PI Name Here**

**Contact Information: Include mailing address and phone #**

**Alternate Study Contact: Name Here and 2nd phone #**

**Sponsor’s Protocol # as entered in eIRB**

**Sponsor name: if internally funded, enter Ochsner**

You have been invited to participate in a research study. The doctors and staff at 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.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. Being in this study does not replace your regular medical care.

[*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.

**KEY INFORMATION**

This section is required for federally funded studies. It is optional for non-funded studies or studies regulated by the FDA or the Department of Justice. This section must be brief and in lay-person language. The IRB staff will return for revision if these instructions are not followed.

The following is a short summary of this study to help you decide whether you should participate. More detailed information is listed later in this document.

**Why is this research being done and why am I being invited to take part?**

You are being invited to take part in a research study because

*Fill in study specific details. Fill in the circumstance or condition that makes subjects eligible for the research.*

**What should I know about being in a research study?**

* Someone will explain this research study to you.
* Whether or not you take part is up to you.
* You can choose not to take part.
* You can agree to take part and later change your mind.
* Your decision will not be held against you.
* You may discuss whether to participate with family, friends and/or your doctor
* You can ask any questions before making a decision.

**How long will I take part in this research?**

*Outline the expected time commitment to complete the study including the length of time and approximate number of study visits, e.g., “It will take you about 14 months to complete the study. During this time, you will be asked to make 14 study visits*

**What will I be asked to do in this study?**

*Provide a limited number of bullet points with a high-level summary of the procedures that will be done, e.g.,*

* *You will be given an investigational drug.*
* *You will be asked to come to the study clinic for 3 study visits.*
* *You will give a total of 3 blood samples and fill out questionnaires*

More detailed information about the study procedures can be found under the PROCEDURE section of this form.

**Is there any way this study could be bad for me?**

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study some of these risks may include

*Indicate reasonably foreseeable risks. This cannot be a list of* ***all*** *potential risks.*

This is not a complete list of all potential risks. More detailed information about risks can be found under the RISKS section of this form.

**Will being in this study help me in any way?**

*Select* ***one*** *of the options below that describes the potential benefits for participants. Briefly summarize potential benefits*

This study may offer some benefit to you now or others in the future by *explain benefits*

This study may not offer any benefit to you now but may benefit others in the future by *explain benefits*

**What happens if I do not want to be in this research study?**

You can decide not to be in this study. Alternatives to joining this study include

*Briefly address alternatives such as standard of care alternatives or other clinical trials*

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

Please review the rest of this document for more details and important things you should know if you decide to join. Before you agree to be in the study, please ask the study team to answer all your questions.

**DETAILED INFORMATION**

**PURPOSE**

*This section should describe to the potential subject the purpose of the study in LAYPERSON terms and why they have been asked to participate*

*If a drug or device is being used a description of that drug/device and whether it is FDA approved for the indication under study (if applicable) should be added.*

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**

*This refers to an individual subject’s participation not the length of time a study is enrolling.*

Your participation in this research study will be for indicate number of month/years as appropriate. At Ochsner, about (indicate number) subjects will be enrolled.

In total, there will be about indicate number subjects enrolling for participation in this study.

**PROCEDURE**

If you agree to be in this study, we will ask you to do the following things:

*Describe the procedures chronologically* ***using lay language, short sentences, and short paragraphs***

*Include time tables or study schema (if available and appropriate)*

*Specify the assignment to study groups, frequency of procedures, etc.*

***Clearly identify all procedures that are experimental or standard of care procedures done for the research, such as “For the research you will receive a right heart catheterization” if the RHC would be done regardless you could state “You will receive a right heart catheterization, which is standard procedure for your condition”***

*For research involving randomization, specify the randomization procedure. For two groups use “flipping a coin”. If the research includes two or more groups use “like drawing numbers from a hat”*

*For research involving the use of placebo, clearly define the term placebo. Use language like “A placebo is an inactive substance that looks like the study drug, but contains no medication”*

*If appropriate, state that the study will involve long-term follow-up*

**RISKS**

Describe any reasonable risks, discomforts, inconveniences and how these will be managed

List risks in order of relative probability (e.g., “likely,” “less likely” or “unlikely,” and “rare but serious”).

In addition to physiological risks/discomforts, describe psychological, emotional, financial, and social risks that might result

***General / Unforeseeable***

There may be side effects and discomforts that are not yet known. You should tell your study doctor about any side effects your experience even if you think they are not related.

*The following must be included in all greater than minimal risk studies. Do not alter this language without approval from Research Legal office. Attach approval e-mail in eIRB.*

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.

***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 of 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 exists 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 becomes pregnant while participating in this study, you MUST contact your study doctor immediately.

***Radiation Risks*** *–if there are no ionizing radiation/radioactive materials or the radiation that will be received during the study is standard of care then delete this section.*

*Any procedure with ionizing radiation or exposure to a radioactive agent that is required by the research and is not standard of care should be indicated in the eIRB application and will require radiation safety review. Ionizing radiation includes CT Scan, X-ray, fluoroscopy,etc (NOT MRI or U/S)*

This research study involves exposure to radiation from \_\_\_\_\_\_\_\_\_\_\_ (list the procedures). This radiation exposure is not necessary for your medical care and is for research purposes only.

You are exposed to radiation every day. This radiation comes from the sun and the earth. It is called background radiation. The total amount of radiation that you will receive in this study is \_\_\_\_\_\_ mSv and is equivalent to a \_\_\_\_\_\_ (specify days or years) of exposure to natural background radiation. This use involves minimal risk and is necessary to obtain the research information desired.

Radiation safety will complete the mSv and equivalent based on the list YOU provide.

**POTENTIAL BENEFITS**

State the direct benefits, or the possibility of direct benefits, that are likely for research subjects.

If there are no direct benefits, state:

You may not receive direct personal or health benefit from taking part in this study. However, the information gained from your participation in this study may be used to help others in the future.

**COSTS**

*This is the agreed upon language for our consent template. If this section is changed in any way you must upload approval from OSP in eIRB or the language will be reverted back to template language at IRB approval.*

Although the Sponsor may pay for certain study-related items and services, 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**

If payment for participation or reimbursement of expenses will not be provided include the following statement:

You will not be paid or offered any other compensation for participating in this study.

*This part on biospecimens is required for federally funded studies. It is optional for non-funded studies or studies regulated by the FDA or the Department of Justice. For research involving biospecimens, a statement must be added regarding (even if identifiers are removed) whether the biospecimens may be used for commercial profit and whether the subject will or will not share in the commercial profit. Delete this statement if you are not collecting biospecimens.*

Data or biospecimens collected from you for this research may be used to develop new tests, drugs, or devices. Your samples may be used for commercial profit and there is no plan to share these profits with you.

The following must be included if participants are receiving payment for participation or reimbursement of expenses:

A statement should be included indicating whether or not a subject is to be paid for participation or for reimbursement of expenses. Example: “You will receive $XX per study visit. This will be paid to you after the completion of each visit. If you complete the entire study, you will be paid a total of $XXX. If you withdraw from the study early, you will be paid for the number of study visits you complete.”

Non-dollar amount incentives such as gift certificates, etc. should be included in this section.

You will be issued a Greenphire ClinCard, which is a debit card that your study funds are loaded onto at the completion of a study visit. These funds can be used at your discretion. If your card is lost or stolen, you can contact the Ochsner study team for a replacement card. Greenphire will collect information about you, including name, address, social security number, and date of birth. Your information will be kept completely confidential and will be stored in a secured fashion.  *Greenphire collects your social security number and other information to permit the preparation of IRS-1099 form(s) for participants receiving $600 or more in any one calendar year, in accordance with Treasury Regulations, Sub-chapter A, Sec. 1.6041-1.*

By registering with the ClinCard system and using the ClinCard, you consent to participate in the ClinCard program.

This is a required statement for Ochsner ICF’s. Delete only if this is an unfunded study.

Ochsner Clinic Foundation is being funded by [the sponsor, or other wording, as appropriate] to conduct this research.

**ALTERNATIVE METHODS/TREATMENTS**

*Describe any alternatives that should be considered before deciding whether or not to be in the study. If there are no alternatives, state that an alternative is to not take part in the study. Avoid suggesting that participation in the research is the only way to obtain medical care*

You do not have to join this study. If you do not join, your care at Ochsner will not be affected.

**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, contact the study doctor or their alternate contact listed on the front page of this consent form.

*This is the internally agreed upon language for sponsored studies. If this section is altered you must upload approval from Research Legal in eIRB or the language will be reverted back to template language at IRB approval.*

If you believe you are injured as a direct result of your participation in this study, you should seek appropriate medical attention and immediately contact your study doctor on the first page. Medical treatment and/or hospitalization, if necessary for such injuries, is available. This medical treatment and/or hospitalization is not free of charge.  You, your insurance company or the Sponsor may be billed for the care you receive for the injury.  We will try to get these costs paid for you, but you may be responsible for some or all of them.   You may be responsible for all co-payments and deductibles required under your insurance.  If injuries occur that are the result of a medication, device, procedure or test required for this study that is not part of your usual medical care, the Sponsor will reimburse the standard charges for the treatment of these injuries.

By signing this consent form you have not given up any legal rights.

*Below is the acceptable language for Investigator Initiated & federally funded studies ONLY. Delete the paragraph below BEFORE sending to your sponsor. If no sponsor delete the paragraph above. Do NOT leave both injury paragraphs in the final draft.*

If you believe you are injured as a direct result of your participation in this study, you should seek appropriate medical attention and immediately contact your study doctor at the number on the first page. Medical treatment and/or hospitalization, if necessary for such injuries, is available. This medical treatment and/or hospitalization is not free of charge.  You or your insurance company would be billed for the care you receive for the injury. You would be responsible for all co-payments and deductibles required under your insurance.

By signing this consent form you have not given up any legal rights.

**QUESTIONS ABOUT YOUR RIGHTS**

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

Ochsner Clinic Foundation Institutional Review Board

1514 Jefferson Highway

New Orleans, LA 70121

Telephone: 1-504-842-3535

Email: IRB@ochsner.org

The Institutional Review Board (IRB) is a group of people who perform independent review of research for human subject protection. You may contact the IRB to discuss any problems, concerns or questions you have about research. The IRB can assist you in obtaining information about research and encourages input from research subjects.

**VOLUNTARY PARTICIPATION**

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.

Your participation in this study will be entered in your electronic medical record here at Ochsner. 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.

**EMPLOYEES IN RESEARCH**

If you are an employee of Ochsner Clinic Foundation (OCF), you are not required to participate in this research study and any decision to participate is completely voluntary. Participation in this research study is not required to maintain employment and your decision to participate or not participate will not affect your employment status in any way. Should you decide to enroll in this study, you may withdraw your participation at any time, and this decision will not affect your employment or performance evaluations.

By signing this informed consent, you acknowledge that you do not believe that you are being unduly influenced by your employer to participate in this study. You also acknowledge that no statements, threats, or implied threats have been made that your job or performance evaluations will be affected in any way whether or not you participate in this study.

**NEW FINDINGS**

During the study you will be told about any important new information that may change your mind about staying in the study.

**STUDY WITHDRAWAL**

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

* You do not meet study criteria
* 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.

**DNA SEQUENCING**

*This section is required for federally funded studies. It is optional for non-funded studies or studies regulated by the FDA or the Department of Justice*

This research will / will not / might involve whole genome sequencing. Please ask the principal investigator or study team if you have any questions about how your genetic information will be used.

**RETURN OF RESEARCH RESULTS**

*This section is required for federally funded studies. It is optional for non-funded studies or studies regulated by the FDA or the Department of Justice.*

*If clinically relevant results will or will not be returned, insert one the following options. Delete this section if not relevant to the research.*

*If clinically relevant results will be returned, insert the following:* We may learn things about your health as part of this research that may affect your treatment. If this happens, this information will be provided to you. You may need to meet with professionals with expertise to help you learn more about your research results. You can discuss this information with your doctor.

*If clinically relevant results will not be returned, insert the following*: We may learn things about your health as part of the research, however we will not share this information with you because *(describe rationale*).

**FUTURE RESEARCH**

*This section is required for federally funded studies. It is optional for non-funded studies or studies regulated by the FDA or the Department of Justice*

We may use or share your research information and/or biospecimen for future research studies, but it will be deidentified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies. We may also share your deidentified information and/ or biospecimen with other researchers at Ochsner or at other institutions.

**CONFIDENTIALITY**

Your identity and your personal records will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. Confidentiality will be maintained during and after your participation in this study.

*Delete reference to ct.gov if the study does not qualify for registration on ct.gov and you have indicated the same on your eIRB application –if you are unsure about this go to:* <https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf>

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.

The results of this research may also be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

**HIPAA AUTHORIZATION TO RELEASE INFORMATION FOR RESEARCH**

*This is the internally agreed upon language for our consent template. If this section is altered you must upload approval from Research Compliance in eIRB or the language will be reverted back to template language at IRB approval. For minor changes please contact the IRB office x23535.*

Under federal law (the “Privacy Rule”), your Protected Health Information (PHI) that is created or obtained during this clinical research study cannot be “used” to conduct the research or “disclosed” (given to anyone) for research purposes without your permission. This permission is called an “Authorization”. **Therefore, you may not take part in this study unless you agree to this authorization.**

Before you agree to take part in the study, we want to tell you:

* How study information may identify you
* Who may use or share your protected health information
* Why your protected health information will be used or shared
* Your rights concerning use and/or sharing of your protected health information

**How may study information identify me?**

Study information may identify you in the following ways:

* Name, address, telephone number
* Other details about you including your past medical records

Medical information that identifies you and relates to your participation will be created, and may be used and/or shared, including information obtained from:

* Study visits and phone calls
* Physical examinations, blood and urine tests, x-rays, and other procedures or tests
* Your response to any study treatments you receive
* Any other information that you may release to us, including information about your health history.

**Who may use or share my protected health information?**

The Investigator (study doctor) and research staff may give protected health information to others during and after the study, including:

* The study sponsor, including any people or companies working for or with the sponsor or owned by the sponsor.
* Doctors and healthcare professionals taking part in the study
* Government agencies in the United States and in other countries
* Ochsner Clinic Foundation

1. Third party vendors as authorized by Ochsner Clinic Foundation

**Why will this study information be used and/or shared?**

* To carry out the research study
* To analyze and evaluate the results of the study
* To conduct internal research compliance reviews
* To comply with governmental reporting requirements
* To obtain marketing approval for new products

**What are my rights regarding my health information?**

* You have the right to review and copy your health information. However, as a participant in this research study, you would not be allowed to look at or copy your information until after the research is completed.
* You may withdraw or revoke (cancel) your permission to use and disclose your health information at any time. However, unless you revoke your permission by sending written notice to the study doctor, this authorization (permission) will not expire (end) until it is no longer required by the Sponsor.

When you withdraw your permission, no new health information that might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable. **If you withdraw your permission, you will not be able to continue being in this study.**

**Are there possible limitations on the protection of my health information?**

* If your health information is given to the parties listed above and/or to others who are not required to comply with federal privacy laws, your information may no longer be protected, and there is a risk that your information will be released to others without your permission.
* Your personal information may be disclosed if required by law.
* Your records for this study may be sent by facsimile transmission (FAX) or over the Internet. It is possible that your records could be sent to the wrong person.

**How long is my information kept?**

Ochsner Clinic Foundation policy requires that all files related to a research study are stored for ten (10) years after the research study has been closed at the Ochsner site.

**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**

This may be altered but phrases such as, “I understand…” will be deleted and replaced with template language.

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

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Subject Signature Printed Name Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative Printed Name Date

(*when applicable*) DELETE IF NOT USING LAR

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Person Obtaining Consent - Signature Printed Name Date

*Insert Assent Signature Box for ages 13-17 here, if applicable.*

**------------------------------------ Use the following only if applicable -----------------------------**

*This section is a required part of the Ochsner ICF. If you delete this section please provide the rationale in consent section of your application.*

**IMPARTIAL WITNESS STATEMENT (IF APPLICABLE)**

If this consent and authorization document is read to the subject because the subject is unable to read the document, an impartial witness (a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information supplied to the subject) must be present for the consent and sign the following statement:

I attest that the information in this consent and authorization was explained to, and understood by the subject. I also attest that the subject agreed to participate in this research study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Impartial Witness

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Impartial Witness Date

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.

Ochsner Health System complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-928-6247.

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-928-6247.