**RESEARCH SUBJECT INFORMATION SHEET**

**Title:** Title

**Protocol No.:** Sponsor’s protocol number

**Sponsor:** Name

**Investigator:** Name Address

City, State, Zip Code Country

**Daytime Phone Number:** Phone Number

1. **hour Phone Number:** Phone Number

Organize the information in sufficient detail relating to the research in a way that facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate. Do not merely provide lists of isolated facts.

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

When the research involves consent by a legally authorized representative or parent, include the next paragraph:

In this consent form “you” generally refers to the research subject. If you are being asked as the legally authorized representative, parent, or guardian to permit the subject to take part in the research, “you” in the rest of this form generally means the research subject.

# What should I know about this research?

* + Someone will explain this research to you.
  + This form sums up that explanation.
  + Taking part in this research is voluntary. Whether you take part is up to you.
  + You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
  + You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
  + If you don’t understand, ask questions.
  + Ask all the questions you want before you decide.

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# Why is this research being done?

The purpose of this research is to explain in simple terms the main purposes of the research. You can use simple illustrations, diagrams or figures if they are helpful in the explanation.

# How long will I be in this research?

We expect that your taking part in this research will last hours, days, weeks, months, years, or until a certain event

# What happens to me if I agree to take part in this research?

Tell the subject what to expect using simple terms. Include all procedures done because the subject is taking part in this research, including procedures to monitor subjects for safety.

Do NOT describe procedures that will be performed regardless of whether the subject takes part in this research.

When appropriate for your research, include the following items:

* + Describe where this research will be done
  + Provide a time-line description of the tests and procedures that will be done, including screening procedures. You can use tables or charts if they are helpful to explain the schedule.
  + Describe each group or arm
  + If the research involves random assignment describe this and the probability of assignment to each group, For example:

You will be put into a study group by chance (like a coin toss/ like drawing straws). You have an out of chance of being placed in each group. You cannot choose your study group.

If the research involves blinding, include language describing a single (subject only) or double (subject and research team) blind, as appropriate. For example:

During the research, you (or you and the study doctor) will not know which group you are in. (Your study doctor can find out in case of an emergency).

* + Indicate the length and duration of visits and procedures
  + If blood will be drawn, indicate how often and the amount in English units
  + Identify all questionnaires or diaries by name and explain what they involve and how long and how often they will need to be completed
  + Describe any planned future research (extension study, follow-up study, analysis of specimens). Describe them and whether subjects will be asked to sign a separate consent form.
  + If applicable, explain whether the subject will be told clinically relevant research results, and if so, under what conditions.

Include if the research may involve whole genome sequencing:

The research might include whole genome sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code).

# Could being in this research hurt me?

In simple language and in a simple bullet format (whenever possible), explain the known possible risks and discomforts.

Consider:

* + Physical risks (for example, medical side effect)
  + Psychological risks (for example, embarrassment, fear or guilt)
  + Privacy risks (for example, disclosure of private information)
  + Legal risks (for example, legal prosecution or being reported for child abuse)
  + Social risks (for example, social ostracizing or discrimination)
  + Economic risks (for example, having to pay money out-of-pocket for research or medical expenses, losing health insurance, or being unable to obtain a job)

If the possibility of injury exists, add:

The clinic makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the clinic.

# Will it cost me money to take part in this research?

Include for research that may result in additional costs to the subjects:

Taking part in this research may lead to added costs to you, such as: Describe these costs. Include for research where insurance will be billed:

In some cases, insurance does not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

# Will being in this research benefit me?

If there are possible benefits to the subject:

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include . Describe any direct benefits to the subject. If benefits from taking part may not continue after this research has ended, describe them. Possible benefits to others include . Describe any benefits to others.

If there are no expected benefits to the subject but possible benefits to others/ scientific knowledge:

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include . Describe any benefits to others.

# What other choices do I have besides taking part in this research?

If there are alternatives:

Instead of being in this research, your choices may include:

* + List the major approved alternative options such as drugs / devices / procedures
  + Consider, based on the indication and population, whether an alternative might include no active treatment but support and management of pain and other symptoms to be as comfortable as possible through the remainder of life

If there are no alternatives:

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

# What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

* + The research sponsor
  + People who work with the research sponsor
  + Government agencies, such as the Food and Drug Administration
  + The Institutional Review Board (IRB) that reviewed this research
  + List others with whom private information will be shared

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials add the following language verbatim: (If the research does not require listing on www.clinicaltrials.gov, but will be listed anyway, you may use this language or a variation of this language. The IRB does not require this information when not required by FDA, even if the study will be listed.)

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Oklahoma law does require that your Protected Health Information may be disclosed for the following reasons:

**To notify the Oklahoma State Health Department of communicable diseases and conditions as required by law,** **which includes but are not limited to, diseases such as hepatitis, syphilis, gonorrhea, and AIDS. This information will be kept confidential by the Oklahoma State Health Department and may only be released as authorized by law.**

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# Who can answer my questions about this research?

Use the following language verbatim:

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at 918-561-1400 or chsirb@okstate.edu if:

* + You have questions, concerns, or complaints that are not being answered by the research team.
  + You are not getting answers from the research team.
  + You cannot reach the research team.
  + You want to talk to someone else about the research.
  + You have questions about your rights as a research subject.

# What happens if I agree to be in this research, but I change my mind later?

Include if there are procedures for orderly termination of taking part in the research.

If you decide to leave this research, contact the research team so that the investigator can: Describe the procedures for orderly termination by the subject.

Include if there are potential adverse consequences to a subject who withdraws:

If you decide to leave the research early, there may be risks with this decision. These may include: Describe the adverse consequences.

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# Will I be paid for taking part in this research?

If subjects will be paid:

For taking part in this research, you may be paid up to a total of $ . Your compensation will be broken down as follows:

* + Describe payment schedule in terms of amount
  + Describe when payments will be made
  + Describe the amount of payment if the subject drops out
  + Your personal information, including your name, address, and social security number (SSN), will be released to the University for the purpose of payment and income reporting. Any payment you receive for participating in this research study is taxable income and it is your responsibility to report it to the Internal Revenue Service (IRS) as required by law. If the total amount the University pays you in one year is equal to or more than $600, the University will issue a Federal Form 1099-MISC to the IRS listing your payments as reportable income. Federal and state law protects the privacy and security of your SSN and Oklahoma State University will not disclose your SSN without your consent for any other purposes except as allowed by law.

If subjects will not be paid, either delete this section, or include the following statement: You will not be paid for taking part in this research.

If the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit, include the following statement: (Modify if subjects will share in commercial profit.)

Your specimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

Example signature block for studies that only involve adult subjects able to consent

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

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| Signature of adult subject capable of consent |  | Date |
|  |  |  |
| Signature of person obtaining consent |  | Date |