

RESEARCH SUBJECT CONSENT FORM

Title: Title

Protocol No.: Sponsor's protocol number

Sponsor: Name

Investigator: Name

Address

City, State, Zip Code

Country

Daytime Phone Number: Phone Number

24-hour Phone Number: Phone Number (A 24-hour phone number is required for studies that are more than minimal risk)

Instructions for Research Consent Summary

We encourage all research studies whose consent document is longer than 4 pages to include an initial concise summary. (If your research is federally funded or is conducted in New York, Virginia, or Maryland and is not subject to FDA regulations, and the consent document is longer than 4 pages, an initial summary is required.) The initial summary cannot exceed three pages or one third of the length of the remaining consent document (exclusive of face page and signature blocks), whichever is shorter.

The templated statements in the "RESEARCH CONSENT SUMMARY" below provide a guide to the content of the summary. The content should be adjusted to be appropriate for the specifics of the study. Under each heading, limit the description to the key information that is relevant to why one might or might not want to take part in the research. Defer the greater detail to the body of the consent form following the initial summary

For example, with a drug trial the initial summary should identify the most important risks, like the information that a doctor might deliver in the clinical context in telling a patient how sick the experimental drugs will make them. The initial summary should emphasize how those risks are changed by taking part in the study. Include the complete list of reasonably foreseeable risks in the main body of the consent form.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

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.

Why is this research being done?

The purpose of this research is to _____. Explain in no more than a few sentences the main purposes of the research.

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

If you decide to take part in this research study, the general procedures include _____. Briefly outline in simple terms the procedures that are key to the research and are most likely to affect someone's decision about whether to take part in the research study.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include _____. In simple language, explain the risks and discomforts that are most likely to affect someone's decision about whether to take part in the research study. Identify the most important risks, like the information that a doctor might deliver in the clinical context. Emphasize how those risks are changed by taking part in the study. Include the complete list of reasonably foreseeable risks in the main body of the consent form.

Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include _____. In simple language, explain the reasonably expected benefits to subjects that are most likely to affect someone's decision about whether to take part in the research study. If there are no benefits, state: It is not expected that you will personally benefit from this research.

Possible benefits to others include _____. In simple language, explain the reasonably expected benefits to others that are most likely to affect someone's decision about whether to take part in the research study.

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

Instead of being in this research, your choices may include _____. List the major approved alternative options that are available that may be advantageous to the subject. If this is a study in which there is no disease or condition being treated, you can eliminate this section from the summary, and include it only in the body of the consent. If there are no alternatives, this section can be omitted.

What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is _____. Describe any additional information that may be important in this specific study, such as large out of pocket expenses, subject responsibilities that many people might consider burdensome (e.g., abstinence from sexual relations, cigarettes, or alcohol, inability to drive a car while taking study medication, need for overnight stays or admittance to a secure facility), unusual issues related to privacy or confidentiality (e.g., situations where the subject's research participation is likely to be reported in the media), or serious implications for future treatment (e.g., taking the study drug may limit future treatments options.) If there is no other information in this category, this section can be omitted.

DETAILED RESEARCH CONSENT

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.

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.

About [] subjects will take part in this research.

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).

- Identify all hospitalizations, outpatient visits, and telephone or written follow-up
- Indicate the length and duration of visits and procedures
- Identify all unapproved drugs, devices, tests, and procedures as experimental.
- For studies conducted under an IND, IDE, or abbreviated IDE, state:

[name of the product or device] is investigational, which means that it is not approved by the Food and Drug Administration (FDA).

- Identify all approved drugs, devices, tests, and procedures being used in a novel fashion as experimental
- 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
- For research on investigational drugs or devices, list any options for the subject to get the drug/device after the research, and who will pay for this.
- 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.
- Indicate whether the study treatment will be available at the end of the study.

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).

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: Describe the responsibilities of the subject.

- Describe any warning or precautions that the subject needs to know
- Describe any warnings regarding pregnancy or fathering a child
- Describe any requirements to for the subject or the subject's partner to abstain from sexual relations or use contraception
- Describe any requirements to avoid certain activities or refrain from taking certain drugs
- Describe any requirements to keep research articles out of the reach of children or others
- Describe any requirements to promptly report certain side effects to the investigator
- Describe requirements to follow the instructions as provided by the study team and to give them any new information about new medications, new medical issues, etc.
- Describe any requirements to avoid or minimize contact with others
- Describe any situations where the subjects should immediately contact the investigator or immediately seek medical attention

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.

List risks and discomforts in order of most common and most likely to occur, with least likely to occur listed last. Also, list any rare, but serious risks.

If there are many risks, use a bulleted format. If known, provide the percentage or range of occurrence for the risks.

Describe the duration of the risks and discomforts. Note whether the risks and discomforts will go away when the study drug, device, or procedure is stopped.

Describe the side effects of any comparator drugs.

Describe any risks of washout, withholding treatment, or randomization.

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)

It is unnecessary to list details of previous clinical trials.

Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product:

In addition to these risks, taking part in this research may harm you in unknown ways.

Include for research that involves pregnant women or women of child-bearing potential and known risks to an embryo or fetus:

Taking part in this research may hurt a pregnancy or fetus in the following ways:

Include for research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known:

Taking part in this may hurt a pregnancy or fetus in unknown ways. These may be minor or so severe as to cause death.

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
- When the procedures include communicable disease testing, include any disclosures mandated by state-law.

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.)

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.

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.

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 if I am injured because of taking part in this research?

Modify the following language to reflect your study:

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

Describe reasons why the subject may be withdrawn. Include all reasons for withdrawal described in the protocol. For example:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant
- The research is canceled by the FDA or the sponsor
- You are unable to take the research medication
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

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.

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

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.

Statement of Consent:

Use one of the following signature blocks:

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

Your signature documents your consent to take part in this research.

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

Example signature block for studies that may or will involve adult subjects unable to consent and may also include adult subjects that have capacity to consent

Add one of the following:

- All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
- All subjects unable to consent are required to assent.
- Assent of subjects unable to consent is not required.

If assent will be obtained, add one of the following:

- If assent is obtained, have the person obtaining assent document assent on the consent form.
- If assent is obtained, have the subject sign the consent form, unless the investigator determines that the subject is not capable of signing.
- Documentation of assent is not required.

Always add:

Your signature documents your permission for you or the individual named below to take part in this research.

_____ Signature of adult subject capable of consent or adult subject's legally authorized representative	_____ Date
_____ Printed name of subject (not required if subject personally provided consent)	_____ Date
_____ Signature of person obtaining consent	_____ Date

If the person obtaining assent will document assent on the consent form, add:

- ☐ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.
- OR
- ☐ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____ Signature of person obtaining assent	_____ Date
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If documentation of assent is by having the subject sign the consent form, add:

Signature of subject

Date

Example signature block for research that may or will involve children as subjects and may also include adult subjects that have capacity to consent

Add one of the following for children:

- All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted.
- All children are required to assent.
- Assent of children is not required.

If assent of the child will be obtained, add one of the following:

- If assent is obtained, have the child sign an assent form, unless the investigator determines that the child is not capable of signing.
- If assent is obtained, have the person obtaining assent document assent on the consent form.
- If assent is obtained, have the child sign the consent form, unless the investigator determines that the child is not capable of signing.
- Documentation of assent is not required.

Always add:

Your signature documents your permission for you or the individual named below to take part in this research.

Signature of adult subject capable of consent, child subject's parent, or individual authorized under state or local law to consent to the child subject's general medical care

Date

Printed name of subject
(not required if subject personally provided consent)

Date

If applicable, add:

Signature of second parent
(Required unless this subject is an adult, the second parent is deceased, unknown, incompetent, or not reasonably available, or the parent providing consent has sole legal responsibility for the care and custody of the child)

Date

Always add:

Signature of person obtaining consent	Date
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If the person obtaining assent will document assent on the consent form, add:

- ☐ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.
- OR
- ☐ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of person obtaining assent	Date
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If documentation of assent is by having the child sign the consent form, add:

Signature of subject	Date
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Example signature block for witness signature

Add on as needed basis to the last page if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects. Do not add to every consent document unless every subject will have a witness to the consent process.

My signature below documents that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Example signature block for consent to continue participation in research for children who reach the age of majority or adults that regain capacity to consent during their participation in research

Previously, you could not legally agree to take part in research. You took part in research based on the permission of someone else. Now that you can consent for yourself, you are being asked for your consent to continue to take part. Please read the entire document before signing below.

Your signature documents your consent to take part in this research.

_____	_____
Signature of adult subject capable of consent	Date

_____	_____
Signature of person obtaining consent	Date

Example signature block for consent to continue participation in research for adult subjects who have lost capacity during their participation in the research and are unable to continue providing consent

The study doctor has determined that the subject is no longer capable of providing consent and requires consent be provided by a legally authorized representative for the subject to continue participation in the research.

Add one of the following:

- All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
- All subjects unable to consent are required to assent.
- The assent of adult subjects unable to consent is not required.

If assent will be obtained, add one of the following:

- If assent is obtained, have the person obtaining assent document assent on the consent form.
- If assent is obtained, have the subject sign the consent form, unless the investigator determines that the subject is not capable of signing.
- Documentation of assent is not required.

Always add:

Your signature documents your permission for the individual named below to take part in this research.

_____ Signature of adult subject capable of consent or adult subject's legally authorized representative	_____ Date
_____ Printed name of subject (not required if subject personally provided consent)	_____ Date
_____ Signature of person obtaining consent	_____ Date

If the person obtaining assent will document assent on the consent form, add:

- ☐ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.
- OR
- ☐ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____ Signature of person obtaining assent	_____ Date
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If documentation of assent is by having the subject sign the consent form, add:

_____ Signature of subject	_____ Date
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