

## EXPERIMENTAL TREATMENT PLAN INFORMATION AND 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

You are being asked to consider the use of the experimental treatment *[name of drug, biologic, or device]* to try to treat your disease. This treatment is not approved by the U.S. Food and Drug Administration (FDA). Because this treatment is not FDA-approved, FDA considers this treatment to be research.

**When the patient cannot consent, include the next paragraph:**

In this consent form “you” generally refers to the patient. If you are being asked as the legally authorized representative, parent, or guardian to permit the patient to get the experimental treatment, “you” in the rest of this form generally means the patient.

### What should I know about this experimental treatment?

- Someone will explain this treatment to you.
- This form sums up that explanation.
- Getting this treatment is voluntary. Whether you take it is up to you.
- You can choose not to get this treatment. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can get this treatment 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.

### What happens to me if I agree to this experimental treatment?

Tell the patient what to expect using simple terms. Include all procedures done because the patient is getting the treatment, including procedures to monitor patients for safety.

Do NOT describe procedures that will be performed regardless of whether the patient gets the experimental treatment.

Describe the route, frequency and how long the patient will get the treatment. If applicable, you can indicate that the patient will get the treatment for as long as it works. For example: You will continue getting the treatment until you have unacceptable side effects or it stops being helpful.

## **What are the side effects of the experimental treatment?**

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

Always add:

In addition to these risks, this treatment may harm you in unknown ways.

This treatment may hurt a pregnancy or fetus in unknown ways.

## **Will it cost me money to take this experimental treatment?**

You may be charged for the treatment and associated services, such as drug administration, hospitalization, and monitoring. Insurance may not cover the treatment or these associated services. 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 taking this experimental treatment benefit me?**

Getting the treatment may treat your disease. However, we cannot promise any benefits. If the information from your using the treatment is used for research, it might help others in the future.

## **What other choices do I have besides taking this experimental treatment?**

Include a description of the possible alternative treatments.

If appropriate, include the following.

If you decide that you don't want to the experimental treatment, you may want to be given "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home. If you think you might prefer comfort care, please discuss with your family, friends and your doctor.

## **What happens to the information about this treatment?**

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

- The sponsor
- People who work with the sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this treatment
- List others with whom private information will be shared
- When the procedures include communicable disease testing, include any disclosures mandated by Oklahoma.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. If the results from this use are published, your identity will remain confidential.

## **Who can answer my questions about this experimental treatment?**

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

The use of this experimental treatment 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](mailto:chsirb@okstate.edu) if you have questions, concerns, or complaints that are not being answered by your doctor or for information about your rights in this treatment plan.

## **What if I am injured because of taking this experimental treatment?**

If you experience a bad effect of the treatment, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. No other payment is routinely available from the study doctor or sponsor.

## **Can the experimental treatment be stopped without my approval?**

Your doctor can stop the treatment without your approval if it is in your best interest or the sponsor decides to stop supplying the treatment.

We will tell you about any new information that may affect your health, welfare, or choice to continue to get the treatment.

## **What happens if I get the experimental treatment, but I change my mind later?**

If you decide to stop getting the treatment, contact your doctor so that you stop safely.

## **Statement of Consent:**

Use one of the following signature blocks:

Signature block for adult patient able to consent

Your signature documents your consent to take part in this experimental treatment.

_____	_____
Signature of adult patient capable of consent	Date

_____	_____
Signature of person obtaining consent	Date

**Signature block for adult patient unable to consent**

- The assent of the patient is not required.

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

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

### Signature block for a child

- The child is required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted.
- Documentation of assent is not required.

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

_____ Signature of child's parent, or individual authorized to consent to the child's general medical care	_____ Date
_____ Printed name of patient	_____ Date
_____ Signature of person obtaining consent	_____ Date