Informed Consent to Treatment with an Investigational Drug, Product or Device

This is a consent form. Its purpose is to inform you about the risks, benefits and law associated with treatment with an investigational drug, product or device in Ohio. Please consider the information carefully as you make this important decision.

Definition of investigational drugs, products or devices: under Ohio law, these are drugs, products or devices that have successfully completed phase one of the U.S. Food and Drug Administration ("FDA") clinical trials. They remain under clinical investigation. Successful completion of phase one means that the FDA has determined that drug is not so toxic that human testing cannot continue. Further, clinical testing in later phases of the FDA approval process may determine that the drug, product or device has serious side effects that could pose a risk to your health. Investigational drugs, products or devices are not FDA approved. However, they may or may not gain FDA approval in the future depending on further clinical testing.

Your treating physician will complete this form with you regarding the specific terminal condition that you suffer from and the potential treatment with a particular investigational drug, product or device. Your doctor will also discuss with you the potential risks and benefits associated with this treatment.

Your Patient and Treatment Information

Patient Name

Treating Physician Name

Terminal Condition that Patient Suffers from:

Explanation of the approved treatment options for this terminal condition:

Proposed investigational drug, product or device

Best potential outcome of treatment with proposed investigational, drug, product or device

Worst potential outcome of treatment with proposed investigational, drug, product or device

Realistic description of the most likely outcome

There is no proof of the effectiveness of treatment with this proposed investigational drug, product or device. It is possible that you may experience new, unanticipated, different or worse symptoms with the use of this drug, product or device. It is also possible that your death could be hastened with treatment or use of this investigational drug, product or device.

Knowledge of the Law of Investigational Drugs, Products or Devices

It is important that you are aware of Ohio law and FDA regulations regarding investigational drugs, products and devices.

Ohio Revised Code section 4731.97 places the following restrictions on your use of an investigational drug, product or device in Ohio:

1. the manufacturer of the investigational drug, product or device may hold you, the patient, liable for all expenses that arise from your use of the investigational drug, product or device;

2. any health insurance or government program that covers you as the patient may not include coverage of any charges by the treating physician or another health care provider

for any care or treatment resulting from your use of the investigational drug, product or device;

3. the manufacturer of the investigational drug, product or device, the pharmacy or other distributor of the drug, and the patient's treating physician or administering hospital are not liable for or subject to any of the following for an act or omission related to providing, distributing or treating you with an investigational drug, product or device, unless the act or omission constitutes willful or wanton misconduct: damages in any civil action, prosecution in any criminal proceeding or professional disciplinary action.

FDA regulations governing investigational drugs, products or devices: Because an investigational drug, product or device is by definition still under clinical investigation within the FDA approval process, the clinical trials and/or treatment with this investigational drug, product or device are subject to FDA regulations.

FDA regulations state that "[n]o informed consent, whether oral or written may include any exculpatory language, through which the subject [you] or the representative, is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence." 21 C.F.R. 50.20.

Other Terms of Informed Consent

Your personal health information including the results of your treatment may be subject to inspection by or disclosure to the manufacturer of the investigational drug, product or device as well as the FDA. This may occur because the drug, product or device is in clinical trials within the FDA approval process.

Participation in this treatment with an investigational drug, product or device is voluntary. You may begin withdrawal from treatment at any time. Certain investigational drugs, products or devices may necessitate a gradual withdrawal for your health and safety. There is no monetary penalty or loss for withdrawal from treatment other than the cost of the investigational drug, product or device already dispensed.

Your physician is required by Ohio law to get your signature on this form and keep this form in your patient record.

Confirmation of Understanding and Statement of Consent by Patient/Representative

I have read this consent document and have been able to ask questions about my options for treatment and this investigational drug, product or device. Further, my questions and concerns have been addressed.

I give my informed and voluntary consent to participate in treatment with this investigational drug, product or device. I will be given a copy of this consent document for my records.

_____
Printed name of patient or patient's representative

_____ _____
Signature of patient or patient's representative Date

Witness Attestation

I have witnessed the signing of this consent form by _____. Further, I have observed and can attest that the above signed _____ did the following:

1. agreed with the treating physician in believing that all approved treatment options would be unlikely to prolong the patient's life;
2. understood the risks involved with using the investigational, drug, product or device; and
3. willingly desired to use the investigational drug, product or device to treat the terminal condition.

_____
Printed name of witness

_____ _____
Signature of witness Date

Physician

I have explained the above informed consent form to the patient or the patient's representative including the risks involved with using the investigational drug, product or device. A copy of this form has been given to the patient or the patient's representative.

_____ _____
Signature of Physician Date