

**DEPARTMENT OF STATE HEALTH SERVICES INFORMED CONSENT FORM**  
**Investigational Treatments for Patients with Severe Chronic Diseases**

Pursuant to [Texas Health and Safety Code \(THSC\), Chapter 490, Section 490.051](#), a patient is eligible to access and use an investigational drug, biological product, or device (investigational treatment) if the patient has a severe chronic disease that the patient’s treating physician confirms in writing. 25 Texas Administrative Code, Chapter 1, Subchapter A, defines severe chronic disease as a condition, injury, or illness that:

- A) may be treated;
- B) may not be cured or eliminated; and
- C) entails significant functional impairment or severe pain.

Investigational drug, biological product, or device, as defined by [THSC Section 490.001](#), means a drug, biological product, or device that has successfully completed phase one of a clinical trial but the United States Food and Drug Administration (FDA) or its international equivalent has not yet approved for general use and that remains under investigation in the clinical trial. This does not include low-THC cannabis or a product containing marijuana.

[THSC Section 490.052\(a\)](#) requires an eligible patient to sign an informed consent form before receiving treatment. A physician may use a different informed consent form if it contains, at a minimum, the same information as this form.

**PATIENT ACKNOWLEDGEMENT**

Patient Name \_\_\_\_\_

Treating Physician Name \_\_\_\_\_

Investigational Treatment \_\_\_\_\_

**I have read, understand, and acknowledge that (initial below):**

- \_\_\_\_\_ My treating physician has confirmed in writing that I have a severe chronic disease meeting the definition under 25 Texas Administrative Code, Chapter 1, Subchapter A.
- \_\_\_\_\_ My treating physician has recommended or prescribed in writing the investigational treatment listed above.
- \_\_\_\_\_ I discussed all other treatment options currently approved by the FDA for my chronic disease with my treating physician. My treating physician and I have concluded that all other treatment options currently approved by the FDA are unavailable or unlikely to provide relief for the significant impairment or severe pain associated with my severe chronic disease.
- \_\_\_\_\_ I am aware that this investigational treatment is still under investigation in a clinical trial. The FDA has not approved this treatment for general use.
- \_\_\_\_\_ I am aware that the manufacturer of the investigational treatment listed above is not required to make the investigational treatment available to eligible patients.

\_\_\_\_\_ My treating physician gave me information and an opportunity to ask questions related to this investigational treatment, including alternative forms of treatment, risks of nontreatment, steps that will occur during my care related to investigational treatment, and risks and hazards involved with the investigational treatment.

\_\_\_\_\_ I believe I have sufficient information to give informed consent.

\_\_\_\_\_ My physician explained this informed consent form to me. I filled in any blank spaces.

**I acknowledge I have read and understand this consent form. I voluntarily agree to receive the investigational treatment listed on this form.**

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\_\_\_\_\_  
Patient (or Legally Authorized Representative) Signature

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\_\_\_\_\_  
Patient Name (Print)

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\_\_\_\_\_  
Address (Street or P.O. Box)

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\_\_\_\_\_  
Date

### **TREATING PHYSICIAN ACKNOWLEDGEMENT**

**I acknowledge that the patient listed above has a severe chronic disease that meets the definition under 25 Texas Administrative Code, Chapter 1, Subchapter A. I have recommended and discussed the investigational treatment listed on this form to this patient in accordance with THSC Chapter 490.**

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\_\_\_\_\_  
Physician Signature

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\_\_\_\_\_  
Physician Name (Print)

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\_\_\_\_\_  
Address (Street or P.O. Box)

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\_\_\_\_\_  
Date

**Please keep this signed informed consent form, written confirmation of the patient's severe chronic disease, and associated documents in the patient's medical record in accordance with 25 Texas Administrative Code, Chapter 1, Subchapter A.**