DEPARTMENT OF STATE HEALTH SERVICES INFORMED CONSENT

Investigational Stem Cell Treatment

Texas Health and Safety Code, §1003.054, requires an eligible patient to sign a written informed consent before receiving a voluntary investigational stem cell treatment. The Department of State Health Services oversees the informed consent requirements established by this statute.

Investigational stem cell treatment, as defined by Texas Health and Safety Code, §1003.051, means an adult stem cell treatment that (A) is under investigation in a clinical trial and being administered to human participants in that trial; and (B) has not yet been approved for general use by the United States Food and Drug Administration.

The risks and hazards of this treatment have been described to me and I voluntarily agree to receive an investigational stem cell treatment for my documented, diagnosed medical condition. I request and authorize my physician to treat my condition, which is documented in my medical record.

Patient Name ____

Physician Name ____

Treatment Information ____

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

______ This stem cell treatment is under investigation in a clinical trial and has not been approved for general use by the United States Food and Drug Administration.

______ I have read or had read to me, understand, and signed a disclosure of the risks and hazards in continuing my present condition without treatment. The disclosure is attached to this form.

______ The separate disclosure and consent that is attached also sets out the risks and hazards related to the performance of the investigational stem cell treatment planned for me.

______ I have been given an opportunity to ask questions about my condition, alternative forms of treatment, risks of nontreatment, steps that will occur during my care and the procedures, and the risks and hazards involved in the care and procedures and believe that I have sufficient information to give this informed consent.

DRAFT

______ This informed consent form and attached disclosure have been fully explained to me and the blank spaces have been filled in.

By signing this, I acknowledge I have read and understand this consent form. I voluntarily agree to receive the investigational stem cell treatment listed in this form.

____
Patient (or Legally Authorized Representative) Signature

____
Patient Name (Print)

____
Address (Street or P.O. Box)

____
Date

The following physician has ensured that this informed consent was signed in conjunction with the investigational stem cell treatment disclosure form that meets or exceeds the requirements found in 45 CFR §46.116, as applicable.

____
Physician Signature

____
Physician Name (Print)

____
Address (Street or P.O. Box)

____
Date

A copy of this signed informed consent and a copy of the investigational stem cell treatment disclosure must be kept in the patient's medical record.

DRAFT