



Legal Overview

One of the main functions of the Regenerative Care Network is to help its physicians comply with the Texas law.

Texas HB 810 “Charlie’s Law”

The Texas law relating to regenerative therapy is called “Charlie’s Law,” which was effective on September 1, 2017. Under this law, physicians may give stem cell treatments so long as they adhere to a variety of requirements, such as providing treatment according to an approved Institutional Review Board (IRB) protocol and making yearly reports about the outcomes of their treatments to the Texas State Department of Health Services.

Patient Eligibility Under HB 810

If the patient has a chronic, severe disease or a terminal illness, they are eligible for investigational stem cell treatment.

Institutional Review Board

As per Amendment 2 to Charlie’s Law, many requirements exist to comply with an Institutional Review Board (IRB). The following are IRB protocol requirements:

- Statement of Compliance
- Schedule of Activities
- Study Rationale
- Risk/Benefit Assessments
- Overall Design
- Justification for Dose
- End of Study Definition
- Inclusion Criteria
- Exclusion Criteria
- Screen Failures
- Strategies for Recruitment
- Study Intervention
- Efficacy Assessments
- Informed Consent Process
- References

As required by Texas law, and as an integral part of providing the best and safest regenerative treatments for patients,

Regenerative Care Network (RCN) will work closely with a federally-approved IRB on behalf of our physicians.

Clinical Database

Outlined in HB 810, physicians are required to collect data from the treatments to report annually.

Regenerative Care Network will build and maintain a Registry Clinical Database to comply with these requirements.

Additional Guidelines

The Texas Medical Board, which enforces HB810, will follow recommendations of the Federation of State Medical Boards, published in April, 2018.