

# Frequently Asked Questions

## What is regenerative medicine?

National Institutes of Health says: “**Regenerative medicine** is the process of creating living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage, or congenital defects. The field holds the promise of regenerating damaged tissues and organs in the body by stimulating previously irreparable organs to heal themselves.”

## What are the potential benefits of regenerative medicine?

The main benefits are *pain relief* due to reduction of inflammation, and *tissue regeneration*, such as the growth of new cartilage in the treatment of osteoarthritis. These and other benefits are still investigational, and are a key part of the reporting requirement in the new Texas law.

## What are the risks and side effects of regenerative medicine?

The main risks of regenerative therapy *are related to the procedure itself*. Examples include damage to a nerve close to the injection site and transmission of an infection into the site. This is why physicians should be skilled in injections into the body part being treated.

The main side effects are local, temporary pain and tenderness at the injection site. Other complications may occur. The risks of the cells being injected are still being investigated.



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## What are mesenchymal stromal cells (MSCs)?

Mesenchymal stromal cells (MSCs), also called “stem cells”, are cells located in the bone marrow and surrounding blood vessels throughout the body. Their function is to help the healing process by several means, most importantly by reducing local inflammation and aiding regeneration of damaged tissue.

## Where do regenerative cells come from?

There are many sources of MSCs, but Regenerative Care Network (RCN), physicians use only cells from umbilical cord tissue from healthy mothers, provided by manufacturers approved by the FDA for their manufacturing practices. Thus, with RCN-selected cells, you are certain to receive only young, healthy cells that are ready for injection when you come for study treatment – no painful bone marrow procedure involved. Also, *RCN physicians never use embryonic cells.*

## How is RCN different from a stem cell clinic?

*RCN does not practice medicine or manufacture cells.* Rather, RCN provides a large range of services to qualified physicians to help them provide the best possible regenerative treatments and also comply with state law.



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## How do I know if I am a candidate for regenerative study treatment?

Only your physician can tell for certain. However, if you have severe chronic pain or other disability, you are likely eligible under state law. Some of the reasons for not treating you include the presence of an active infection, cancer that is not controlled, severe obesity, pregnancy or breast feeding, and age under 18 years.

## What type of health provider should I see for regenerative medicine?

Ideally, you should see a specialist in the condition for which you are seeking treatment, such as an orthopedist for a joint disease.

## What is the procedure for treating joints with regenerative therapy?

This is simply a local injection of a small amount of fluid into the joint, under local anesthesia, lasting only a few minutes. You can usually leave the facility within an hour after the procedure is complete.

## What should I expect after the study treatment?

The injection of stem cells is investigational so there is no guarantee of a favorable outcome.

Although everyone is different, the expected outcome takes a few weeks or longer before you see improvement in your pain and mobility. Improvement can then continue up to a year or even longer.



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## What can I do to help the study treatment be most effective?

Both physical therapy, which will be prescribed, and eating a healthy diet are important. If you are overweight, weight loss will greatly help.

## Does participating in the study require follow-up visits ?

If you choose to participate in this study, you will be required to see your physician for follow-up visits and respond to questions and allow the findings to be made available for study related purposes only. All data submitted will be de-identified and not use any subject names, contacts, or other personal information. The time commitment associated with the follow-up will be routine office visits every 3 to 6 months for up to 2 years. During this time your physician may want to obtain repeat x-rays or MRIs.

## What is the cost?

The cost of regenerative medical treatments is highly variable depending on the condition being treated. For a single joint injection by physicians in RCN, the cost is on average \$4,500-\$5,500 This is usually not covered by your insurance, but payment plans may be available.



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## What is the Texas law about regenerative medicine?

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. One of the functions of RCN is to help its physicians comply with this law.



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