



## Frequently Asked Questions

The Alliance and NFLA have compiled a list of questions commonly asked by patients—drawing from a series of virtual, interactive panel discussions hosted by both organizations in 2021. Answers to those questions—which were developed with the guidance of nationally recognized experts who comprise the [Alliance Advisory Board](#) and [NFL Alumni Advisory Committee](#)—are summarized below.

### 1. How Do I Know Whether RMCTs are Approved for Use?

- To date, only a small number (29) of RMCTs (regenerative medicine and cell and tissue-based therapies) have been approved by the FDA as safe and effective. The list of products approved by the FDA are located on the FDA website, here, <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>
- Unproven RMCTs may only be used as a treatment in an FDA-authorized clinical trial.

### 2. Does an RMCT Treatment That Consists of My Own Stem Cells Need FDA Approval?

- RMCTs that are exempt from FDA requirements include cells and tissues that are transplanted as part of a fertility treatment or are harvested and reimplanted in the same original form within the same patient during the same surgical procedure, known as the “same surgical procedure exemption” (21 CFR §1271.15(b)(e)).
- Cells and tissues removed for further processing and culturing with media and growth factors, such as MSC-based therapies, are considered investigational RMCT products that must be licensed and approved by the FDA or administered only through FDA-authorized clinical trials.

### 3. How Do I Know if a Treatment is Trustworthy?

Recognizing the potential harms that unproven RMCTs (regenerative medicine and cell and tissue-based therapies) pose to patients, in a [recent article](#), the California Institute for Regenerative Medicine (CIRM) describes the policy framework it has adopted to support the responsible delivery of stem cell treatments.

#### 1. Regulated. Adherence to Regulatory Standards (Product Level)

- **Manufacturing and Processing.** Products should conform to the FDA (or equivalent) and state standards for manufacturing, processing, and facility registration.
- **Product Authorization.** The administration of any product should be authorized or approved by the FDA.

#### 2. Reliable. Administered by Reliable and Qualified Teams of Practitioners (Practitioner Level)

- **Certified Clinicians.** Administration of products should be directed by a doctor with certification in the particular specialty area for that disease or condition.

# Helping Patients Navigate Regenerative Medicine and Cell and Tissue-Based Therapies (RMCTs)

## 3. Reputable. Delivered at Reputable Medical Centers (Organizational Level)

- **Patient Disclosure and Consent.** The medical standard of care for providing stem cell treatments outside a formal clinical trial should include disclosure of essential information consistent with standards for voluntary informed.
- **Claims of Clinical Effectiveness.** Any claims of efficacy should be supported by clinical data published in peer-reviewed journals.
- **Follow-up and Adverse Event Reporting.** Clinics providing stem cell or regenerative medicine products should provide ongoing support and follow-up of patients including monitoring for safety and efficacy. Patients and or provider reported outcome data should be compiled and available for ongoing evaluation of safety and efficacy.
- **Patient Autonomy.** Patients should not be restricted in their right to talk about a medical practice or stem cell treatments.

A full description of the CIRM policy framework can be found in the article cited below:

Lomax, G.P., Torres, A., and Millan, Maria T. (2020). Regulated, reliable, and reputable: Protect patients with uniform standards for stem cell treatments. *STEM CELLS Translational Medicine*, 2020;9:547-553. Available at: <https://academic.oup.com/stcltm/article/9/5/547/6406811>

## 4. Is an “Off-Label” RMCT Treatment Safe and Legal?

- Drugs, biologics, or medical devices that have been **approved by the FDA as safe and effective for a specific indication**, or “on-label” use, may be legally prescribed by a licensed physician for any other purpose (off-label use) as a practice of medicine.

## 5. Where Can I Go to Find Information About RMCT Clinical Trials?

- Search [ClinicalTrials.gov](https://clinicaltrials.gov), which is a database maintained by the National Library of Medicine at the National Institutes of Health (NIH) that lists privately and publicly funded clinical studies. Study site locations are provided for all studies listed. Listing a study does not mean that the study has been evaluated by the U.S. Federal Government.
- Patient and disease advocacy groups may have referral services to help find clinical trials.
- Confirm with the study sponsor or principal investigator that the investigational RMCT for clinical use in humans has an Investigational New Drug (IND) or an Investigational Device Exemption (IDE) in effect as specified by FDA regulations.

### About Alliance for Cell Therapy Now and Alliance for Cell Therapy Foundation

Alliance for Cell Therapy Now and Alliance for Cell Therapy Foundation are independent, non-profit organizations guided by leaders representing academic and medical institutions, industry innovators, and patients, that are working to advance safe and effective regenerative medicine, including cell and tissue-based therapies, for patients in need. For more information, go to <http://allianceforcelltherapynow.org/>

### About NFL Alumni

Founded in 1967 by a small group of successful retired NFL players, NFL Alumni is one of the oldest and well-respected retired player organizations in professional sports. NFL Alumni’s mission is to inform, assist, and serve players in their post-NFL lives. NFL Alumni’s mission is focused on “caring for our own,” “caring for children,” and “caring for the community.” NFL Alumni Health is a wholly-owned subsidiary of NFL Alumni, which is devoted to improving the health and wellness of NFL Alumni members as well as the general public, by providing informational resources, programs, services, and other programs. Visit [www.nflalumnihealth.org](http://www.nflalumnihealth.org).