



Questions to Ask Your Health Care Provider Before Treatment

Patients who are offered an RMCT (regenerative medicine and cell and tissue-based therapies) as a treatment option are advised to ask the following questions of their health care provider offering the treatment regarding safety and effectiveness of the RMCT for their specific condition.

Checklist of Questions to Ask Your Health Care Provider Before Treatment with RMCTs

1	Does the therapy require FDA approval?
2	If “yes” for item #1, is the therapy approved by the FDA and can the clinician provide the FDA-approved drug labeling information?
3	If the treatment does not require FDA approval, what studies have been done to show safety and effectiveness? Can you share the results of individual studies and where they have been published?
4	If the treatment is part of a clinical trial, is there an active IND or IDE or an exemption from the FDA?*
5	If the treatment is part of a clinical trial, has an IRB approved the study?*
6	Was the product manufactured according to cGMP in a facility that is registered with the FDA?
7	Is the treating clinician licensed and certified in the intended area of treatment?
8	Is the treating clinician licensed (or trained) to use these therapies?
9	Is treating clinician promising to cure a full range of conditions with RMCTs (e.g., knee problems, hair loss, traumatic brain injury, Alzheimer’s, etc.)?
10	If there is a charge for participation in a clinical trial, is the charge approved by the FDA as reasonable “cost-recovery”?
11	What is the safety profile of this therapy? Have there been adverse events?
12	What follow-up procedures will be done?
13	How will health care provider measure benefit?
14	What happens if there are any complications?
15	Is there an informed consent form and does it include all of the essential elements for the consent process?*

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 <https://allianceforcelltherapynew.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.