Questions to Ask Before Participating in a Clinical Trial

Patients who are considering participating in a clinical trial are advised to ask the following questions of the sponsor or principal investigator conducting the clinical trial.

Checklist of Questions to Ask Before Participating in a Clinical Trial

1	**Has the FDA evaluated the clinical trial design and authorized the study through approval of an IND or IDE?**
	The FDA does not release any public information regarding an investigational new drug (IND) or investigational device exemption (IDE) application as this is confidential information between the Agency and the sponsor. The only way to know whether an IND or IDE is active/approved for an RMCT used in a clinical trial is to ask the study sponsor or clinical investigator or contact the director of the institutional review board (IRB) that approved the clinical trial. Contact information for each of these individuals should be provided on the informed consent form.
2	**Has the clinical trial received IRB approval?**
	An IRB is a group comprised of scientists and non-scientists that is formally designated under the US Government's Code of Federal Regulations [45 CFR §46, 21 CFR §50 and 21 CFR §56] to review and monitor biomedical research involving human subjects. The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of people who participate in clinical trials that are regulated by the FDA. The FDA is responsible for determining whether an IND or IDE application is required for a drug, biologic or medical device study to proceed, but it is IRB approval that is required before a clinical trial may begin to consent and enroll subjects. For more information about IRB approval, see Appendix.
3	**Have I received a valid informed consent?**
	Before enrolling in a clinical trial, all prospective subjects should be provided an informed consent form (ICF) written in a language that is understandable by the prospective subject that must be carefully read, signed, and witnessed. The informed consent process involves three key features: (1) disclosing to the prospective clinical trial participant information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether to participate in the research. To be valid, the consent process must provide several basic elements within the informed consent form, which are outlined in the Appendix.

4	**What are the qualifications of the team conducting the clinical trial?**
	During the consent process, potential subjects may ask about the training, licensure and prior experience the clinical investigator and study team members have in conducting clinical trials. Potential subjects should ask the clinical investigator to describe how the clinical trial will be monitored for adverse events and whether study data and results will be reported (e.g., to the FDA, at ClinicalTrials.gov, in a scientific publication). Some clinical trials that are potentially high risk may require an independent data safety monitoring board (DSMB), which meets periodically to review study data and recommends to the clinical investigator whether a study may continue. If a health care provider promotes the use of an investigational medical product, including many RMCTs, but declines to provide evidence of training or qualification to use RMCTs, lacks licensure, certification, or training in the intended area of treatment, and/or fails to describe the clinical trial monitoring, then patients are encouraged to seek a healthcare provider who does have the education, training, and experience in the use of RMCTs and the appropriate credentials for treatment.
5	**Does the team have experience in conducting clinical trials?**
	Clinical trials are costly and labor intensive to run and often involve additional procedures, documentation and monitoring that go beyond the standard practice of care. Most academic medical centers have specially trained clinical teams or entire departments dedicated to conducting clinical trials in compliance with FDA regulations. Clinical trials conducted at academic medical centers may be sponsored either by in-house experienced clinical investigators or by private biopharmaceutical and medical device companies, and patients treated at these academic medical centers have easy access to information regarding specific studies and study team qualifications. In addition to an IRB-of-record, a local IRB at an academic medical center may also provide monitoring and oversight of clinical trials. Assessing the clinical trial experience of the team at a private clinic not affiliated with a large academic medical center may require more effort on the part of the potential patient. A list of items that patients should confirm before participating in a clinical trial is provided in the Appendix.
6	**Where are the trials being carried out?**
	Clinical trials should be conducted in a clinical setting appropriate to the study design and under Good Clinical Practices (GCP) in compliance with applicable statutory and regulatory requirements. FDA-regulated clinical trials are required to be registered at ClinicalTrials.gov, which is a database maintained by the National Library of Medicine at 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.

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/

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