Safety management plan for advanced regenerative medicine

Act on Safety and Support for Advanced Regenerative Medicine and Advanced Biopharmaceuticals was enforced in August 2020 to expand treatment opportunities for patients with rare / intractable diseases. Accordingly, the National Institute of Health has been designated as a safety management institute to secure the safety of those who participate in clinical research for regenerative medicine. In March 2021, the safety management institute enacted a notice to provide details of safety management works between regenerative medical institutions and safety management institute. The major duties of the safety management institute under this Act are as follows: (a) supervision of regenerative medical institutions, (b) monitoring of the safety of clinical research, (c) reception of adverse events and investigation of causality, and (d) a long-term follow-up. These duties are performed through the clinical research information system in general. This system will help to monitoring the progress of clinical research in real-time and to report quickly on the occurrence of adverse events. In addition, the Advisory Group for the Safety Management is organized to enhance the expertise on safety management. The safety management system based on the Act will contribute to the progress of advanced regenerative medicine along with ensuring the safety of the subjects participating in the clinical research.

Keyword: Advanced Regenerative Medicine, Safety Management Institute, Adverse Events, Long Term Follow-up