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The Regulation on Clinical Trials of New Medicinal Products for Human Use was published.

17 Aug 2023

With the relevant regulation published in the Official Gazette dated 27.05.2023 and numbered 32203 ("Regulation"), the procedures and principles regarding the conduct of clinical trials and the protection of the rights of volunteers, as well as the establishment, duties, working procedures and principles of the Clinical Trials Advisory Board and ethics committees have been determined in general again.

The prominent regulations in the Regulation are as follows:

- Clinical trials are designed, conducted, recorded and reported in line with the most current version of the World Medical Association Declaration of Helsinki on Ethical Principles in Medical Research on Human Subjects and relevant international standards.The separation of duties determined according to the threshold of the disputable amount has been abolished. As per the former regulation, a distinction was made between metropolitan and non-metropolitan provinces and districts, but now the amount in question has no effect on the determination of the arbitral tribunal.
- For clinical trials and scientific studies within the scope of the Regulation, simultaneous applications can be made to the ethics committee and the Agency. Applications for the research shall be made by the sponsor to the ethics committee and the Agency.
- In single-center clinical trials, a decision must be taken from the ethics committee in the location of the center where the research is conducted or from the ethics committee affiliated to the provincial health directorate in the province where the center is located, and if there is no ethics committee, a decision must be taken from the relevant ethics committee in the closest location to the research center.
- During the review and evaluation of investigations and in the exercise of its powers, the Agency may make use of relevant decisions and/or published reports issued by other medicines authorities or regional or international organizations with comparable standards.
- Clinical trials and scientific studies may be initiated after approval of the ethics committee and permission of the Agency. The applicant submits an initial compliance application to the ethics committee and the Agency for the initiation of clinical trials and scientific studies.
- In cases where the volunteers are children, the scientific and ethical appropriateness of the research must be evaluated and a positive opinion must be obtained by a pediatrician in order to include the relevant group of volunteers in the research. Similar regulations are also included for those who are restricted, in intensive care, unconscious, pregnant, puerperant and breastfeeding.
- Permission is obtained from the Agency for the import of research products to be used in research. Approval of the relevant authorization application is subject to the conditions that each batch of the research product to be manufactured or imported must be manufactured in accordance with the product specifications specified in the dossier under conditions that comply with the standards of good manufacturing practices and that the samples of each batch of the products manufactured or imported for research purposes and the information and documents related to them are kept for at least fourteen years.
- In order to insure volunteers against damages that may arise from clinical research, it is mandatory to have insurance in accordance with the relevant legislation for volunteers who will participate in clinical research, except for volunteers who will participate in low-risk scientific studies.
- The fact that the informed consent form has been obtained from the volunteer participating in the research does not eliminate the right of the volunteer to compensation for damages incurred due to the research.
- The Agency may inspect, with or without prior notice, research conducted in Türkiye or abroad, principal investigators and researchers, places where research is conducted, sponsors, legal representatives and other parties to whom duties are delegated, facilities where research products are manufactured, places where they are stored, laboratories where research-related analyzes are conducted, ethics committees and all persons and places related to research in terms of compliance with the provisions of this Regulation and

other relevant legislation.

You can access the regulations through this link.

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