Amendments to the Clinical Trials of Pharmaceuticals and Biological Products Regulation have been Introduced

30 Sep 2022

Amendments to the Clinical Trials of Pharmaceuticals and Biological Products Regulation ("**Amendment Regulation** ") is introduced in Official Gazette dated 6 July 2022 and numbered 31888. The amendments were made with the purpose that the Turkish Medicines and Medical Devices Agency ("**Agency**") will be among the authorities listed by the World Health Organization.

The main amendments introduced by the Amendment Regulation are as follows:

- The definitions of "selected among responsible researchers", "operation permit", "monitoring", "coordinator center" and "healthcare professional" have been included in the Regulation.
- The Amendment Regulation stated that the most recent version of the World Medical Association Declaration of Helsinki - Ethical Principles For Medical Research Involving Human Subjects and international standards will be used in the conducting, recording, and reporting stages of clinical trials.
- The data of the participating volunteers will be protected within the scope of Personal Data Protection Law numbered 6698.
- Additional measures may be taken for people during their compulsory military service, unable to take part in clinical trials due to a court decision, or who are in nursing homes.
- The application processes of the trials have been amended. In order to initiate clinical trials, an initial application for eligibility must be made to the Ethics Committee and the Agency. There are separate regulations regarding exceptional applications and a guide will be published by the Agency regarding the application process.
- Amendments are allowed to be made by obtaining the necessary approvals and permissions during the conduct of a clinical trial.
- If a trial is ceased or terminated early after it has been started, it shall be reported to the Agency and the ethics committee within 15 days with its grounds.
- The progress report of the trial shall be reported to the ethics committee and the Agency at least once a year.
- The retention period of research-related records has been increased from 5 to 14 years.
- It is stated that the Agency may supervise trials, researchers, and related facilities with or without prior notice.
- In case of detection of one of the following situations, the Agency may cancel the trial permit, terminate the trial, or request amendments:
    - The safety or health of the volunteers is at risk.
    - Failure to conduct the trial in accordance with the approved documents.
    - One of the existing conditions, when the permit was granted, disappears.
    - Reliability and quality of the data obtained in the trial negatively affect the conduct of the trial.
    - Failure to fulfill the application and notification requirements.
- All legal and financial responsibilities of the trial belong to the institution conducting the trial and no fee can be charged from the volunteers.
- Administrative sanctions have been introduced such as warnings and cancellation of permissions regarding ethics committees.
- Ethics committee members were given time until 1 June 2023 to receive the training organized by the Agency.

- The structure, working principles and duties of the ethics committees have been rearranged.

Please see this link for the full text of the Amendment Regulation published in the Official Gazette dated 6 July 2022 and numbered 31888 (only available in Turkish).

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