Definitions / Medical Research Act 488/1999

(unofficial translation, informal summary adapted from the Medical Research Act)

Medical Research

Medical research means research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of health, the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general, and which is not a clinical trial as defined in the regulations on clinical trials of medicinal products.

Researcher

An individual responsible for the conduct of a clinical research at a clinical research site. The researcher must have the appropriate professional and scientific qualifications to carry out the research in question. The person responsible for the medical care of the research subjects must be a duly qualified medical practitioner or, in the case of a dental study, a duly qualified dental practitioner.

Sponsor

An individual, company, institution or organization which takes responsibility for the initiation, for the management and for setting up the financing of the clinical research. The sponsor must ensure that qualified personnel, appropriate facilities, adequate equipment, and facilities are available for the research and that the research can otherwise be carried out under safe conditions. The sponsor must ensure that the medical research takes into account the regulations governing the research.

Research Plan

A document that describes the objectives, design, methodology, statistical considerations and organization of a clinical research; it encompasses successive versions of the protocol and protocol modifications. The medical research must be designed to minimize pain, discomfort, fear and other foreseeable risks to the research subjects. In addition, the research design must be such that the risk threshold and the degree of exposure are explicitly defined in the research protocol and are continuously monitored.

Cluster Research

Medical research in which subjects are divided into groups for interventions rather than having research interventions targeted at individual subjects.

Principal Investigator

An investigator who is the responsible leader of a team of investigators who conduct clinical research at a clinical research site. Medical research must have designated site-specific principal investigators. The principal investigator is the responsible leader of the team of researchers conducting medical research at the site. If there is only one researcher in the research or site, he or she shall also act as the principal investigator. The principal investigator shall ensure compliance with the regulations governing the conduct of research at the research site.

Informed Consent

Informed consent a research subject's free and voluntary expression of his or her willingness to participate in particular clinical research, after having been informed of all aspects of the clinical research that are relevant to the subject's decision to participate.

Consent is considered to be informed consent when the research subject has been given information that enables him or her to understand:

1) the nature, objectives, benefits, implications, risks and inconveniences of the clinical research;

2) the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to provide any justification;

3) the conditions under which the clinical research is to be conducted, including the expected duration of the subject's participation in the clinical research;

4) the possible treatment alternatives, including the follow-up measures if the research subject in the clinical research is discontinued; and

5) that the data contained in the research subject's medical records and the data collected during the study can be processed even if the subject withdraws his or her consent to participate in the study.

Regional Medical Research Ethics Committee

The Regional Medical Research Ethics Committee will evaluate the research plan and other documentation submitted to it. The committee also evaluates amendments to the study. The research must receive a favourable opinion from the Committee before it is initiated or an amendment is introduced. The Ethics Committee must also monitor, guide, and evaluate the handling of research ethics issues in its area.

Administrative Review Division of the National Committee

The Administrative Review Division of the National Committee handles appeals of negative opinions of the Regional Medical Research Ethics Committee.