

S22. ETHICAL and LEGAL REQUIREMENTS in CLINICAL RESEARCH

Nihat VAROL,
Judge
Ankara 8.Ağır Ceza Mahkemesi Üyesi

Aging in our world of medical materials used in the treatment of deteriorating health, alongside the development and the protection of human health (medicine, method, etc.), the presence of legal until the presence of in obtaining medical procedures process an extremely sensitive issue.

Methodology of clinical research, patient participation in research, the results of the review and policy in transforming the social benefits of information obtained; must be at least damage the highest interest.

Medication is actually a poison. The dose is the determining factor here. Accordingly, applying the nature of the benefit or harm people determine the responsibility of the dose. But how it should be implemented in dose should be determined with absolute pre-clinical research, while this research, "Medical Ethics" appropriate while "Proper Law" also has to be.

Law determining factor in eligibility, rights in accordance with the standards of medical and health professionals to fulfill the duties and processing the exposed person to (patient / solid) is to consent to these transactions. This rule is a legal requirement. Standards are subject to legal evaluation with both breach of contract and tort causes.

Essential health services; accordance with the law, in the form required by the profession initiative is based on teamwork.

Legal aspects of clinical research in this context has been drawn. they are;

- Application of Biology and Medicine Respect for Human Rights and the Convention on Protection of Human Dignity: Human Rights and Biomedicine Convention Concerning the Approval of Assent Act No. 5013 (Date of Admission: 03/12/2003) RG09.12.2003- 25311
- Patients' Rights Directive (RG: 01.08.1998 -23 420)
- Regulation on Clinical Trials of Pharmaceutical and Biological Products (RG: 13.04.2013-28617) (worth it. RG: 25/06/2014 -29 041)
- 5237 Turkish Penal Code (OG: 12.10.2004- 25611)

This case will be illustrated with examples of violations of the legal aspects of the conference what we encounter.