

# Situation of Research Ethics Committees in Turkey

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## Summary

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Ethics committees are one of the factors in protecting human honor. Research ethics committees have an important role to play in ensuring the ethical standards and scientific merit of research on human subjects. In this paper situation of research ethics committees are mentioned

**Key words:** Research ethics committee, Regulations, Turkey.

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Ethics is necessary when human action is free from natural. Acts and foundations are also necessary for protecting human honor (1). One of these foundations is ethics committee. Its aim is to solve ethical issues in medical practices in an interdisciplinary way and to counsel (2). In the past, unethical medical trials done on people caused discomfort and conflicts in both the scientific world and the community, so control mechanisms became necessary.

In kind of situations that if there is no parallelism between evolution of ethical values and technological developments, ethical problems are unavoidable. Increasing in application options and facilities in medicine with scientific and technical developments can cause ethical problems. So, fast progress in technology increases requirement in medical ethics. Ethical issues in medical practice and values, which are created by changes in community life such as human rights, patient rights, informed consent and autonomy, require ethics committees in the evaluation of problems between patient-physician and subject-researcher.

### Importance and Necessity of Ethics Committees

Approbation of medical applications from the ethical aspect can be accepted by the community and advocated against acts (3). Therefore, rules and limitations that are conduct human behavior cannot only appear from legal, but also from ethical field. However, ethical evaluation is a counseling service, not a judgment (4). It is necessary to claim and protect et-

hical principles in serving human health. We can say that three conditions are essential in protecting and applying rights and moral values. These are:

*First condition:* to be aware of rights and values (ethical education).

*Second condition:* to provide application of these rights and values, to secure them with legal regulations.

*Third condition:* to examine.

The place of ethics committee in the fulfillment of these conditions is to take the responsibility of education, to make legal and ethical evaluation, to counsel, and to mediate in producing legal regulations in a long date. Thus, we can say that ethics committees fulfill the first and the third conditions and have a place indirectly in the fulfillment of the second one. As a result, ethics committees take place to fulfill these three conditions in protecting and application of rights and moral values.

Ethics committees are especially important and necessary at the following states:

1. To determine hospital policy.
2. Ethical education of health staff, patient and family.
3. To suggest and guide how to use health sources.
4. To protect patient rights.
5. To determine if deontological standards and ethical principles are applying in clinical practices and to declare sentiments.
6. To protect patient and subject rights in researches on humans.

7. To evaluate clinical practices and drug researches from the scientific point of view.

### **Classification of Ethics Committees in Turkey**

Ethics committees are separated into three groups in Turkey:

1. According to its function (such as hospital ethics committees, research ethics committees).
2. According to its members (such as nursing ethics committee, surgery ethics committee)
3. According to institutions (such as central ethics committee, local ethics committees)

There is no legal obligation for hospital ethics committees (HEC). They have a character as an advisory committee and their decisions are not obligatory. Research ethics committees (REC) are founded because of legal obligation for following concordance to ethical principles in biomedical researches for protecting patient and subject rights, publication of research results, and conforming acceptable usage of finance for biomedical researches (5).

### **Research Ethics Committees (REC) in Turkey**

Experimental studies on animals have done in Turkey according to the international standards since 1960. However, the number of clinical studies (especially drug researches), which are suitable according to these standards are not so much. This situation's main reason is detention of structuring in substructure and ethical regulations.

Duties of REC are as follows:

1. To provide volunteer's safety, well-being and to protect human rights.
2. To prevent abuse of volunteers.
3. To guarantee towards public and state.
4. To fulfill revision, evaluation and consecution duties.
5. To prevent scientific fraud.
6. To constitute high standard.
7. To diminish public's anxiety.

According to the Drug and Pharmacy Directorship there are 78 local ethics committees. Forty-two of them are in university hospitals.

The reasons of founding REC in Turkey can be listed as (5-7):

1. To accept ethics committee's approval as evidence that research is performed according to the ethical principles.
2. Journals requirement of ethics committee's approval for publication of scientific articles.
3. To provide performing of international research protocols according to the ethical principles those are projected in the general research protocol and to certificate this.
4. To examine the usage of financial support from local and/or foreign foundations for scientific researches according to the aim of the research and ethical principles.
5. To protect subject and researcher's rights and to counsel if any ethical problems occur by consideration of both of them.
6. Increasing problems especially originate from drug researches that are done in developing countries such as Turkey because of not suitable for ethical principles in developed countries.
7. To retain some researches those do not have any scientific supports in journals and to cause vital problems.

REC allow or not to allow researches according to the *Regulations For Medicine Research* in Turkey. This is not a counseling. Decisions do not offer any choices. They are obligator decisions. Ethics committees do not have any executive functions, but they are decider organs. When the committee decides not to begin or to stop the research, punishments for the researchers whom do not conform this decide are not written in the *Regulations For Medicine Research*. Forbidden actions are guilt from legal aspect so not to conform these are judged according to the general legal authority.

Experimental researches ethics performing on humans should mainly conform international codes. The ethical and scientific standards for carrying out such research have been established in international guidelines, including the WMA Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and the WHO and ICH Guidelines for Good Clinical Practice. According to these, experimental medical researches are divided into two:

1. Researches combined with professional care.
2. Biomedical researches out of treatment or care.

In the first group, volunteer has a benefit. In the second group, patient does not have any directly beneficence but there is a scientific and a social benefit.

According to the international standards, a research's aim is to improve methods of diagnosis, treatment and preventive practice or to clarify etiology and pathogenesis of the disease. Necessity of the application of laboratory findings on human for increasing scientific knowledge and having a good medical care should be the basic reason in researches. Basic principles are:

1. Research on human should be appropriate to the scientific principles, supported by adequate laboratory and animal trials, and literature.

Insufficient literature is the problem about this in Turkey. Insufficient budget and library services in new universities are the reasons.

2. Plan and implementation of every experimental method should be specified in a protocol and should be sent to a committee independent from researcher and supportive. This committee checks and follows the project.

Ethical committees are established in Turkey according to the regulations, but we have some problems regarding to their functions.

3. Research should be performed under the responsibility and observation of the by the expert and competent medical doctors.
4. Stipulate target of the research (benefit and progress) should be at least equal to risks for the subject. This is the vital point for the evaluation of research projects on human.

Important points are:

1. If the research is carrying risks more than benefit than it must not be done. If at the beginning the research has an appropriate risk/benefit ratio but later after the first data if it becomes dangerous than it should be stopped.
2. Primarily, the aim of research must be to provide a contribution to society and science whilst protecting the subject's interest.

Researchers' (as academic), supporters' as (income) and publishers' (as only acceptance of articles with positive results) care should not embarrass volunteer's care regarding to his/her interest.

3. Respect to subject's life and reduces material-moral negativities at least.
4. Take an informed consent of volunteer. Every applicant should be previously informed about the aim, methods, expecting benefit, and possible risks of the research. This information must contain freedom of not to participate or resignation after participation, at that time patient-physician relationship will never damage and quality of medical care will never change. After all these written consent can be taken.

All these points are emphasized in the regulations. However REC naturally are not near the volunteer while taking informed consent. Application of informed consent forms is in initiative of researcher.

5. Approach sensitive to the impressionable group. Necessity, financial requests or being incompetent are in this group.
6. There should be no bias in the preparation, implementation and publication of a research. So, at first bias in selecting must be prevented. For example, choosing cases among the patient whom are not so much ill is a kind of bias in selection. Its meaning from ethical point of view is to destroy balance of benefit-risk ratio and not to obey principle of justice. Bias in evaluation must be also prevented. Concern in academic approach can be cause to evaluate results according to the aim or hypothesis. At last, bias in publication must be prevented. Editors may be more interested in positive results and do not want to publish negative ones. This statement cannot also be acceptable by science and can cause harm according to the ethical approach.
7. Initial assessment, ethical and scientific evaluations are done according to the protocol and supplemental.

However, Helsinki Declaration should sign by all research team (as executive researcher, accessory researchers) in the application of Turkey, Regulations For Medicine Research is not wanted to sign.

### **Legal Regulations about REC in Turkey**

The national ethical applications are the extension of international ones. The first ethics committee in Turkey was established in 1986 and since 1993 there has been a legal requirement to obtain approval from an ethics committee before commencing any medical

research and to continue under its supervision. Now we will list a chronological order of legal regulations in Turkey:

1. *Code of Medical Deontology (1960)*: It is the first legal document about this issue. According to the 11<sup>th</sup> item, neither surgical practices nor chemical, physical and biological interventions never can be done on humans for the aim of getting experience. Here, experimental researches are completely rejected. But again in the same item, it is said that treatment method, which has a beneficial effects can be done if it is known that a classical treatment methods do not have any benefit and animal researches are performed adequately. This expression is in contradiction with the first paragraph of the 11<sup>th</sup> item. Again in the same item, an importance of medical researches on life saving is emphasized.
2. *Constitution (1982)*: Concept of "consent" takes place first time.
3. *Health Services Fundamental Law (1987)*: In the third item, the usage of drugs on human for the purpose of scientific researches is forbidden without consent of subject and Health Ministry.
4. *Regulations For Medicine Research (1993)*: The Ministry of Health published it and Social Services formed the turning point in the constitution of ethics committees in Turkey. *Regulations For the Assessment of Bioprofit and Bioequivalent of Pharmaceuticals* (Official Gazette 1994 May 25, no: 21942) determined the systematic principles of clinical research. However the regulation covers only research on drug, ethics committees serve except drug usage. The rules and methods of observation that should be applied in laboratory practice and/or clinical research were determined by the *Guidelines of Good Clinical Practice* and *Guidelines of Good Laboratory Practice* (Official Gazette 1995 Dec 29, no: 51748) in order to assume that research is carried out in accordance with international scientific and ethical standards. Also there are some expressions such as registration regarding application, insurance of patients, financial of project. Basic concepts and volunteers' protection are emphasized. Responsibilities of REC working principles and mechanism are also specified additional to the sentences in the regulation. How to take informed consent is stated detailed. It

is believed that the "Turkish National Programme About Taking on the Regulations of the European Union" and the "Regulations for Medicine Research and Regulations for the Assessment of Bioprofit and Bioequivalent of Pharmaceuticals" (June 24 2003, no: 25178) will be repealed, and a new regulation in accordance with the 2001/20/EC numbered European Parliament and Directives will be published. With this aim, the *Draft of Regulations for Clinical Research on Medical Products for Humans* has been prepared. This regulation does not cover only drug research.

### Conclusion

1. To eliminate differences between committees and to establish common structure are essential.
2. There should be no delay in the decisions.
3. Scientific and ethical evaluations are the parts of the whole.
4. Characteristics and roles of member of ethics committee should be emphasized.
5. There should be an ethicist and a biostatistician in the ethics committees.
6. Application to the ethics committees is not a formality.
7. Ethical education is necessary.

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