EUROPEAN COMMISSION

Community research

KI-NA-21617-C1-C

National Regulations on Ethics and Research in

Turkey

Türkiye

SCIENCE AND SOCIETY

EUR 21617

Interested in European research?

RTD info is our quarterly magazine keeping you in touch with main developments (results, programmes, events, etc.). It is available in English, French and German. A free sample copy or free subscription can be obtained from:

European Commission
Directorate-General for Research
Information and Communication Unit
B-1049 Brussels
Fax (32-2) 29-58220
E-mail: research@cec.eu.int
Internet: http://europa.eu.int/comm/research/rtdinfo/index_en.html

EUROPEAN COMMISSION

Directorate-General for Research
Directorate C – Science and Society
Unit C3 – Ethics and Science
Helpdesk: research@cec.eu.int

For further information on Science and Society,
please refer to the following Internet site:
http://europa.eu.int/comm/research/science-society/index_en.html

National Regulations on Ethics and Research in

Turkey

Türkiye

by
Gülriz Uygur and Türkan Yalçın Sancar

European Commission contact:
Thierry Bourgeois
Brussels, 2005

Europe Direct is a service to help you find answers to your question about the European Union

Freephone number (*):
00 800 6 7 8 9 10 11
(*) Certain mobile telephone operators do not allow access to 00 800 numbers or these calls may be billed.

A great deal of additional information on the European Union is available on the Internet.

It can be accessed through the Europa server (http://europa.eu.int).

Cataloguing data can be found at the end of this publication.

Luxembourg: Office for Official Publications of the European Communities, 2005

ISBN 92-894-9958-3

PRINTED IN BELGIUM

Foreword

Contemporary society is witnessing astounding progress in the field of technology. Improvements in biomedicine are especially fabulous and capture our imagination.

These technological improvements are certainly leading the progress of humankind and the world we live in, and providing new opportunities for the benefit of all societies. However, we have to foresee and resist all of the effects of these developments on society and individuals, including adverse consequences that might arise. Technological progress saddles us with this responsibility as well.

Within this framework, ensuring the protection of the rights and dignity of the human beings involved as subjects in research projects can be regarded as an important priority. Likewise, the strengthening of an international consensus concerning the protection of animal rights can be addressed within the same context. At this point, the development of a framework of research ethics at the national and international level and integration of the variety of practices on the issue is necessary.

I appreciate the initiative of the Directorate-General for Research for compilation of national regulations on ethics in research. This brochure provides an overview of the legal regulations with regard to research and ethics in Turkey and serves as a guideline that can be referred to by scientists and researchers to ensure the conformity of their research practices with ethical rules and principles. Furthermore, this publication enables the comparison of legal regulations in the Turkish legal system with those of other European countries.

In the forthcoming period, Turkey has to take actions for the improvement of the functioning and networking of local ethics committees, for meeting the standards of international conventions, and for putting Draft Laws relating to ethics and research into effect as soon as possible.

Our government attaches great importance to supporting research in science and technology and has allocated major resources for that purpose. Moreover, we aim to increase sensitivity to ethics in other societal issues right along with science and research ethics. For example, an Ethics Committee of Public Servants has been established based on Act No. 5176. The committee is responsible for specifying the ethical principles to be followed by public servants and for monitoring the implementation of these principles.

Within the process of integration with the European Union, Turkey contributes to the European Research Area by participating in the Framework Programmes. The present study is an important example of the steps already taken towards the creation of a knowledge society.

Assoc. Prof. Hüseyin Çelik
Minister of Education

Introduction

The European Commission is committed to ensuring that research funded under the 6th Framework Programme respects ethical principles. What legal requirements do researchers have to respect in European Commission funded research projects?

The text of the 6th Framework Programmes makes reference to the following international texts:

- The Charter of Fundamental Rights of the European Union
- European Union directives
- Convention of the Council of Europe on Human Rights and Biomedicine (1997) and the additional protocol on the Prohibition of Cloning Human Beings (1998)
- UN Convention on the Rights of the Child (1989)
- Universal Declaration on the human genome and human rights adopted by UNESCO (1997)
- Helsinki Declaration

These regulations and texts are all well known and can be consulted on the website http://europa.eu.int/comm/research/science-society/ethics/legislation_en.html .
Apart from such European legislation and international texts, the Specific Programme for research, technological development and demonstration 'Integrating and strengthening the European Research Area' (2002-2006) requires also that *"In compliance with the principle of subsidiarity and the diversity of approaches existing in Europe, participants in research projects must conform to current legislation, regulations and ethical rules in the countries where the research will be carried out. In any case, national provisions apply and no research forbidden in any given Member State will be supported by Community funding in that Member State.*[(1)]*"*

The specific regulation of ethical issues is a matter of subsidiarity. Rooted in the cultural background of the nation state, there are many ethical rules and guidelines in the national legal system that the scientists have to apply when conducting research in a country.
The guide for proposers of the 6th Framework Programme requires applicants to identify whether workpackages contain one or more of the five following ethical issues, namely whether the research work involves

- humans,
- human tissue,
- personal or private data,
- genetic information,
- or animal experimentation.

Detailed information on how these issues are handled has to be given, including the explanation of the applicable national legal background. Such projects that contain ethical issues may be submitted to an ethical review if they have been shortlisted after the scientific evaluation.
When co-operating in a European research consortium, it is important that researchers from partner countries have easy access to the national regulations on those five areas, where ethical issues may arise. It is an advantage if researchers not only understand the regulation of their own countries, but also those of potential partners and when they seek to collaborate.

(1) COUNCIL DECISION of 30 September 2002 adopting a specific programme for research, technological development and demonstration: 'Integrating and strengthening the European Research Area' (2002-2006).

The Turkish text was written by Dr Gülriz Uygur and Dr Türkan Yalçın Sancar and subsequently approved by the Ministry of Education of Turkey. The Commission has been promoting this project and is now dedicating a bilingual publication (original language and English) to the new Member States and candidate countries in order to facilitate their participation in the 6th Framework Programme. The project was coordinated for the Commission by Dr Canan Ergin from TUBITAK, EU 6th Framework Programme National Coordination Office and Véronique Degraef. The responsibility and credit for the contents rest with the authors and the Ministry of Education of Turkey.

Rainer Gerold
Head of Unit f.f. "Ethics and Science"
Research Directorate-General

Table of contents

1. International instruments in Turkish law

The major international instruments concerning research on human beings and animals, signed by Turkey are:

"European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes (1986)"
"Convention for the Protection of the Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997)"[1]
"Additional Protocol to the Convention for the Protection of the Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998)"
"Protocol of Amendment to the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes (2004)".

Moreover, in several national regulations references are made to the World Medical Association Declaration of Helsinki. For example, in Article 8 of the *Regulation on Medical Research,* it is stated that medical research on human beings will be conducted in line with the Helsinki Declaration and its annexes.

Article 90 of the *Turkish Constitution* defines the place of international instruments in the national legal system. According to this Article: "Ratification of the treaties concluded with other countries and international organisations on behalf of the Republic of Turkey shall be subject to adoption by the Turkish Grand National Assembly of a law approving the ratification". Furthermore, Article 90 stipulates that international agreements duly put into effect shall have the force of law and no appeal to the Constitutional Court can be made with regard to these agreements on the grounds that they are in contradiction to the Constitution.

On the other hand, an amendment made to Article 90 of the Constitution through Law No. 5170 of 7 May 2004 envisages that in conflicts between international treaties concerning basic rights and freedoms and national laws, priority will be given to the international treaties. Therefore, in Turkish law, international treaties concerning basic rights and freedoms are given precedence as compared with national laws and other regulations. "The Convention for Human Rights and Biomedicine", which is an integral part of the Turkish legal system, is an example of such an international document.

(1) The Convention was ratified by the Grand National Assembly of Turkey on 3.12.2003 and the Law on the "Convention for the Protection of the Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Law on the Approval of the Ratification of the Convention on Human Rights and Biomedicine No. 5013" was put into effect with the publication in the official paper No. 25311 on 9.12.2003.

2. National overview

Despite some deficits, legislative instruments regarding research on human beings and animals as well as ethics committees are available in the Turkish legal system.

1) Overview of the national legal system

a. As to the legislative instruments regarding research on human beings in Turkey, *the Regulation on Medical Deontology* of 1960 covers the relevant provisions. Article 11 of the Regulation prohibits the treatment of patients for experimental purposes and subjects the treatment of patients with new methods to certain conditions. In addition, the Constitution and subsequent legislative instruments contain provisions on research on human beings.
Article 17 of the Constitution states that "everyone has the right to life and the right to protect and develop his or her material and spiritual entity. The physical integrity of the individual shall not be violated except in the case of medical necessity and in cases prescribed by laws and shall not be subjected to scientific or medical experiments without his or her consent."

b. Article 3 (k) of the *Health Services Basic Law* No. 3359 subjects the conduct of scientific research concerning medicines on human beings to the authorisation of the Ministry of Health and the consent of the person concerned.

c. In addition to those, there are specific and detailed arrangements with regard to research on medicine. Regulatory essentials for clinical research are defined in the *Regulation on Medical Research* published by the Ministry of Health in 1993 and the *Regulation on Bio-utilization of Pharmaceutical Products and Assessment of Bio-equivalence* published in 1994. *Guidelines* containing detailed arrangements were published in 1995 under these Regulations. *Guidelines for Good Clinical Practice* and *Guidelines for Laboratory Practices* aim to ensure that clinical research which is important for the reliability and effectiveness of medicines is conducted in compliance with international scientific and ethical rules. Moreover, the *Regulation on Patients' Rights* published in 1998 also contains provisions on the issue.

d. Provisions concerning research involving animals can be found in the *Law on the Protection of Animals* enacted in 2004. Article 9 of the Law regulates experiments involving animals. Ministry of Agriculture and Rural Affairs has issued a *Regulation on the Protection of Animals Used for Experimental and Scientific Purposes and on the Methods and Essentials of the Establishment, Functioning and Inspection of Trial Animal Production Facilities and Experiment Laboratories.* This regulation aims to guarantee that the trial animal production facilities are established and run in accordance with technical, health and hygienic standards and that the care necessary for the prosperity and security of the animals is provided. Article 14 of the *Guidelines for Good Laboratory Practices* states that the conditions of trial animals and procedures of treatment have to conform to the international standards and rules.

2) Research ethics committees and other agencies

Concerning research on human beings in Turkey, the Ministry of Health and ethics committees are the authorised agencies. Currently, there are no specific legislative instruments on research ethics committees in Turkey. However, the *Regulation on Medical Research* and *the Law on the Protection of Animals* mention ethics

committees. According to these Regulations, ethics committees concerned with research on human beings and animals in Turkey can be stated as below:

a. *Ethics committees for research involving human beings*
The *Regulation on Medical Research* governs the fundamental principles and responsibilities of ethics committees for research on human beings. According to the regulation, there are two types of ethics committees, the (central) ethics committee and the local ethics committees. The two types of committees are different from each other. Local ethics committees are established at medical institutions where clinical studies are conducted, and generally in universities. The ethics committee is constituted within the Ministry of Health and its members are appointed by the Ministry.
A two-step control system is in use for research on human beings in Turkey. Those willing to conduct medical research on human beings have to receive approval first from the local ethics committee, and then from the central ethics committee.
Ethics committees serve for providing the evaluation and controlling of research with regard to ethics and especially the protection of voluntary research subjects. Article 5 of the *Guideline for Good Clinical Practice* is concerned with ethics committees. According to the Guideline, the ethics committees and informed consent of the volunteering subject are the main tools for the protection of research subjects. The objective of the ethics committees is to safeguard the rights, safety, and well-being of all trial subjects. To serve for that aim, checking by ethics committees prior to the start of the research and for the ongoing research is necessary. The voluntary trial subjects are not included in the research unless the particular ethics committee approves the research protocol and its annexes. Furthermore, the ethics committees have the authority to halt the research. Thereby, ethics committees play an active role concerning research on human beings. According to the *Regulation on Medical Research,* researchers have to receive the approval of the ethics committee and have to execute their suggestions. Only after the approval of the particular ethics committee can researchers make an application to the Ministry. According to Article 5 of the Regulation, the individual or organisation willing to conduct clinical research for scientific purposes is required to obtain permission by submitting an application to the Ministry of Health through local ethics committees. Only those research protocols that are approved by the Ethics Committee of the Ministry can be put into practice. Thus, the Ministry holds the ultimate decision making power regarding conducting clinical research. However, this decision making power is limited to those research proposals that have already been approved by the ethics committee; the opposite case is not under consideration.

b. *Ethics committees for research involving animals*
Article 9 of *the Law on the Protection of Animals* states that conducting research involving animals is conditional upon permission from ethics committees. Relevant ethics committees are to be established in institutions where research shall be conducted. The rules of law concerning the establishment and functioning methods of the particular ethics committees have not been developed yet.

3) Procedures of approval from ethics committees and other agencies
Research protocols concerning research on human beings are evaluated by ethics committees in Turkey. As

mentioned above, conducting research is conditional upon the authorisation of Ministry of Health, once approval from the central ethics committee is received. Article 6 of the *Regulation on Medical Research* specifies the research topics that require authorisation from the Ministry. For example, conducting clinical research with unauthorised drugs is subject to permission from ethics committees, and the Ministry. Authorisation of the Ministry is also necessary for new clinical research with authorised drugs. Furthermore, for particular research, evaluation of local ethics committees is sufficient for authorisation. For example, local ethics committees have the authority to evaluate and decide on the convenience of regular medical research projects aiming to analyse the bio-utility of previously authorised medicine.
On the other hand, conducting animal trial research is also conditional upon authorisation from the ethics committee of the institution where the research is to be conducted.

3. Research involving human beings

Provisions concerning research involving human beings are covered by the *Regulation on Patients' Rights,* the *Regulation on Medical Research,* and the *Guideline for Good Clinical Practice.* Moreover, the *New Turkish Penal Code* includes provisions pertaining to the issue.

1) Provisions relating to informed consent
In the Turkish legal system, research involving human beings is subject to two conditions. These conditions include the authorisation of the Ministry of Health and informed consent from the relevant individuals. Furthermore, the *Regulation on Medical Research* necessitates approval from ethics committees. For example, decision of the particular ethics committee has to be taken concerning the eligibility of the informed consent documents, prior to the start of the research.

The requirement for informed consent is stated in the *Turkish Penal Code, Regulation on Patients' Rights, Regulation on Medical Research,* and the *Guideline for Good Clinical Practice.* According to these provisions, first of all the research subject has to be informed satisfactorily about the intervention. The information provided to the subject includes the purpose and course of research, foreseeable effects and side effects connected to the research, and the fact that the subject has the right to withdraw his/her consent to participate in the research at any time. The information has to be given in oral and written form. Furthermore, when new information related to the subject arises during ongoing research, it has to be declared to the subject. The issue arising has to be documented and approval from the ethics committee has to be obtained. Second, informed

consent has to be obtained from the subject without any physical or spiritual pressure and with the free will of the individual. No research subject can be forced to participate in research. Moreover, subjects are provided with sufficient time to decide on their participation. Third, the particular articles state that the informed consent has to be obtained in written form. For example, the *Regulation on Medical Research* classifies clinical research into four stages. The initial three stages are concerned with research on officially authorised drugs. In such interventions, the consent of the subject has to be obtained in written form. Furthermore, the *Guideline for Good Clinical Practice* states that written consent shall be obtained from the subjects once they are informed. The informed consent form, which is obtained when the subjects are informed on the intervention, documents the approval of the subject. The content of the informed consent form and the information to be provided to the subject are stated in the Guideline. The information to be provided is related to the rights of the subject, right along with the purpose and the positive and negative effects of the research. The written consent includes the signature of the subject. Moreover, the signature of a closely-related person is required. Finally, in non-therapeutic research, the subject has to give consent personally. For example, if there is no direct clinical benefit for the subject, personal consent from the subject is mandatory.

2) Cases where informed consent is insufficient for qualification

As mentioned above, the conduct of medical research is conditional upon the consent of the particular subject and authorisation from the Ministry of Health and relevant ethics committees.

For research to be conducted on human beings, the protection of the individual subjects has to be ensured above all. Therefore, research posing a threat to the physical integrity and the right to life of individuals is not allowed. The conditions where consent of the subject alone is not adequate are defined as related to the well-being, the rights and the dignity of individuals.
The consent of the subject is not sufficient for conducting medical research. According to Article 32 of the *Regulation on Patients' Rights,* the interest of the subject, concerning the living and the physical entity of the individual, should be considered above other concerns such as medical benefits expected from the research or societal interests.

According to Article 33 of the same Regulation, all preventive measures need to be taken for protecting the well-being and individual rights of the research subject. Despite consent, no research project can be carried out if the potential threats of the research cannot be detected beforehand.

Concerning research involving minors, Article 24 of the Regulation has to be referred to in cases where the legally accepted representative does not consent. According to Article 24, "consent from the legal representative or the court is not required when obtaining the consent will take time and the life of the patient or his/her vital organ will be under threat unless a medical intervention is made".

Article 90 of the *New Turkish Penal Code* No. 5237 of 26 September 2004, which will come into force on 1 April 2005, governs research on human beings. The

Article stipulates the conduct of research on conditions such as not violating human well-being and dignity.

3) Research involving minors

Medical research involving minors can be conducted for the direct interest of the minor. Relevant rules of law are available in the Turkish legal system. For example, Article 35 of the *Regulation on Patients' Rights* definitely states that medical research which will not benefit the minor shall not be conducted. However, for research to be conducted on minors, the condition of the benefit of the minor is not sufficient. Furthermore, permission of the parents is a prerequisite for conducting medical research. Thereby, it can be stated that there are two conditions for conducting medical research on minors. The *Guideline for Good Clinical Practice* proposes some additional conditions. Accordingly, the ethics committee has to approve the research intervention and the researcher has to believe that the intervention will benefit the subject. Besides, the minor has to consent, including his/her signature, together with the legal representative, if the minor is capable of understanding the situation.

In cases where the legal representative does not consent, the urgency of the medical intervention shall be considered. If medical research on minors arises from a medical emergency the intervention can be performed with the decision of the court. There are also cases where informed consent is not required. Article 24, mentioned above, states that the consent of the legal representative is not needed in cases of emergency.

There are other provisions concerning research involving minors in the Turkish legal system. For example, the *Regulation on Medical Research* and Article 90 (3) of the *New Turkish Penal Code* stipulate the conducting of research on minors on the existence of definite urgency. Further, Article 90 (3) of the *New Turkish Penal Code* states that the minor has to consent together with the legal representative including his/her signature if the minor is capable of understanding the situation.

4) Individuals lacking contractual capacity for expressing consent

The provisions concerning minors, mentioned above, are also valid for those individuals lacking contractual capacity for expressing consent. The *Regulation on Patients' Rights* and *Regulation on Medical Research* state that the rules related to minors shall apply for persons incapable of giving consent. According to the *Turkish Civil Code*, persons lacking the capacity to express consent include minors and individuals who cannot act reasonably due to a mental illness, mental defect, drunkenness or for other similar reasons. Furthermore, the *Regulation on Medical Research* states that the rules related to minors shall apply also for pregnant women.

5) Other legal requirements concerning research

The relevant rules and specifically the *Guideline for Good Clinical Practice* state that research on human beings shall be conducted in line with the Helsinki Declaration. Besides, it is stated that such research shall consider ethical principles concerning the potential risks, justice and human respect.

Article 90 of the *Penal Code* includes general rules concerning the conduct of trials on human beings. Some of these rules have been stated above. The rest of the rules are related to the conditions under which trials on

human beings shall be conducted. Accordingly, a trial first has to be conducted on an adequate number of animals. Secondly, the results of such trials should necessitate conducting the research on human beings. As a result, conducting the research on human beings must be a necessity.

Similar provisions are present in the *Regulation on Medical Research*. According to the Regulation, research has to be conducted on appropriate test animals and on an adequate number of them depending on the properties and effects of the particular drug, before it can be conducted on human beings. Furthermore, certain qualifications are considered necessary for those who will conduct the research. For example, the eligible researcher shall be a medical doctor and have satisfactory experience in his/her area of specialisation. On the other hand, Article 78 of the *Law on the Enforcement of the Criminal and Security Measures* dated 13 December 2004 prohibits medical experiments on prisoners even with their consent.

4. Research involving human biological material

In Turkish law, provisions concerning human biological material are covered in the *Civil Code,* the *Law on Procurement, Preservation, Grafting and Transplantation of Organs and Tissues, the Regulation on Organ and Tissue Transplantation Services,* the *Law on Blood and Blood Products and the New Penal Code*.

1) Rules concerning the use of biological material removed from living persons

As to removing and using biological material from living persons, the Turkish rules of law stipulate certain conditions. First of all, according to the Civil Code human biological material shall be removed, inoculated and transplanted based on written consent. Therefore, the initial provision for the removal of biological material from living persons is written consent. The *Law on Procurement, Preservation, Grafting and Transplantation of Organs and Tissues* governs the conditions of consent for the removal of organs and tissue. Accordingly, the consent has to be obtained in the presence of two witnesses and without any outside pressure. Secondly, the consent has to be informed consent. The donor must be informed in detail on the potential threats that might arise, and the medical, psychological, familial and social consequences and benefits for the recipient. Other conditions for the removal and use of organ and tissue are as follows:

- Organs and tissue cannot be removed from minors and those individuals not competent to give consent.
- Removal of vital organs and tissues that will pose a threat to the life of the individual when removed is not allowed.
- Removal of organs and tissue for paid transactions, for other interests or for non-human purposes is not allowed.
- Necessary medical examinations must be performed in advance in order not to endanger the life and well-being of the donor and the receiver.
- Removal of organs and tissue must be performed for diagnostic, therapeutic or scientific purposes.

Article 91 of the *New Turkish Penal Code* governs the sanctions to be implemented in cases of removal of organs and tissues using illegal methods and trade in organs and tissues.

Article 3 of the *Regulation on Blood and Blood Products* asserts that blood can be obtained through donations, but when necessary it can be obtained with charge. Moreover, the protection of the well-being of the donor and the receiver is compulsory in blood donations. The drawing and transfer of blood have to be performed under the control and supervision of a physician.

2) Rules concerning the use of biological material removed from a deceased person

According to the *Law on Procurement, Preservation, Grafting and Transplantation of Organs and Tissues,* organ and tissue of a deceased person can be removed only if the deceased person has previously provided written consent or an oral declaration in front of two witnesses. Otherwise, consent of the spouse, children (above age 18), parents, brother or sister of the deceased or consent of his/her next of kin is necessary.

If there is no opposing written statement or testament, tissues that do not lead to any changes in the appearance of the deceased, such as the cornea, could be removed. If the deceased person had objected to it, his/her organs or tissue cannot be removed.

In cases where the death of a person is caused by an accident or a natural disaster, the organ and tissue of the deceased can be removed without consent or testament of the individual. However, it should be the case that above mentioned close relatives of the deceased should not be with him/her. Under these conditions, the organs and tissues of the deceased can be removed for transplantation to a recipient whose survival is dependent on the urgent transplantation.

Scientific research can be conducted on bodies of the deceased that have previously expressed consent for donating their body to be used for research purposes and the bodies of individuals with no surviving family members.

5. Research involving human embryos

The *Regulation on Centres for Medically Assisted Procreation* published in 2001 includes provisions concerning research on human embryos. Moreover, "the Convention on the Protection of the Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine", which is part of Turkish law, covers statements directly related to the issue[2].

The definition of embryo is not clearly made in Turkish law. However, the *Regulation on Centres for Medically Assisted Procreation* defines an embryo as the "fecund state of an egg". This Regulation is related to the medical therapeutic methods used for assisting procreation. The creation of embryos is allowed only for procreation purposes. The use of embryos for other purposes is prohibited.

The Turkish law does not involve legislative instruments regarding cloning. The relevant regulation can be found in the amendment to "the Convention for the Protection of the Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings"[3], which has been signed but not ratified currently by Turkey.

6. Personal data

In Turkish law, once it is put into effect, the most relevant regulation concerned with personal data will be the Draft Law on Protection of Personal Data, prepared in line with European Council Convention No. 108 and recently under review by the Ministry of Justice. Turkey has signed but not yet ratified "the Council of Europe Convention No. 108 for the Protection of Individuals with Regard to Automatic Processing of Personal Data".

Concerning the protection of personal data in Turkish law, Article 17 of the Constitution governs the personal inviolability, material and spiritual entity of the individual and Article 20 covers the privacy and protection of private life. Governing provisions concerning the protection of personal rights are included in the *Turkish Civil Code*[4]. *The Regulation on the Medical Deontology* binds physicians and dentists to secrecy concerning

(2) Article 18 of the Convention is concerned with research on test-tube embryos, and the Convention prohibits creation of human embryos for research purposes.
(3) The relevant protocol states that the genetic creation of entities identical to human beings and treatment of them as an instrument is contrary to human dignity and means the misuse of biology and medicine.
(4) Article 24 of the *Civil Code* is concerned with the protection of personal rights.

occupational execution. *The Guideline for Good Clinical Practice* also states that the secrecy of private life shall be protected in research on human beings. Accordingly, personal data concerning the state of individuals and relevant medical information has to be kept confidential.

Furthermore, the *Regulation on the Patients' Rights* also governs personal data[5]. *The Law on the Right to Information* also includes provisions on the issue.[6] Finally, the New Penal Code gives place to rules concerning the protection of personal data unlawfully. According to these rules, it is a crime to record, to disseminate or to transfer personal data. It is also considered a crime to record sensitive personal data such as the philosophical, political and religious opinions, sexual lives and health status of the persons. Moreover, it is also stated as a crime in the Code not to erase the personal data within the time limit envisaged by the law.

In the following sections, information is provided on the protection of personal data based on the Draft Law on the Protection of Personal Data.

1) Definition

According to Article 3 of the Draft Law on the Protection of Personal Data, personal data includes any information relating to an identified or identifiable natural person. The information may involve all of the properties of reference for identification such as genetic information, name, address and civil status of the individual.

The draft includes two types of personal data. These are personal data and sensitive personal data. According to Article 5 of the draft law, sensitive personal data consist of data revealing political opinions, ethnic or racial origin, religious or other beliefs, and data relating to state of health, private and sexual life.

2) Fundamental Rights and Secrecy of Private Life

The Draft Law on the Protection of Personal Data states the protection of fundamental rights and freedoms in processing personal data as the aim of the law. Within the framework of this aim, the security of sensitive personal data is ensured. Accordingly, data revealing political opinions, ethnic or racial origin, religious or other beliefs, and data relating to state of health, private and sexual life may be processed based on special legal provisions, which provide sufficient security for the individual. In Article 16, it is stated that sensitive personal data can be processed only when there is an open statement in the law or under specific exceptional conditions. These conditions are those in which:

(5) Articles 15, 16, 17, 18, 19 and 20 of the *Regulation on Patients' Rights* are concerned with the patients' right to be informed on their state of health. According to Article 16, a patient has the right to examine his/her health related documents and records and can keep a copy of them. Article 17 governs the right of the patient to ask for the correction of incomplete, ambiguous and flawed personal medical records. Article 19 governs conditions under which providing information to the patient is inappropriate. Accordingly, information on the diagnosis and the condition of the disease may be concealed in order to avoid negative effects on the psychological well-being of the patient. In these circumstances, providing information to the patient and his/her family is left to the physician's discretion. Moreover, the decision to inform the patient on a mortal disease is also left to the physician's discretion and unless the patient asks for the opposite, the physician informs the patient's family.

(6) Article 32 of the *Regulation on the Essentials and Methods Concerning the Law on the Right to Information* published in 2004 states that except for circumstances under which the individual consents, information and records of health or information that might constitute unjust intervention in the family life, privacy, integrity, and occupational and economic values of an individual are excluded from the scope of the right to information. The Article continues with the statement that for the public interest, personal information from organisational records may be declared as long as the individual is informed at least 7 days beforehand and with written consent from the individual.

- The processing is carried out for the performance of obligations prescribed by law;
- The processing is carried out based on the decision of Council of Ministers provided that the rights of the particular individuals are not violated;
- The individual concerned has expressed consent;
- The particular individual has declared personal data and therefore is publicly known.

Moreover, processors of personal data cannot violate the personal rights of the particular individuals unlawfully. In cases where the individual announces personal data publicly and does not make an objection to the processing of personal data, this shall not be considered as a violation of personal rights. Unlawful violations of personal rights are the ones which are not based on consent or public interest or lawful authorisation.

3) Stipulations for the processing of personal data

According to the Draft Law on the Protection of Personal Data, the processing of personal data is the collection, recording, organisation, storage, alteration, consultation, retrieval, use, disclosure, combination, closure, erasure or destruction of personal data or several of the aforementioned operations, regardless of the manner in which the operations are carried out or the means used. Besides, public institutions, natural persons and private legal persons who process personal data are obliged to register with the Personal Data File System Register. The Draft Law differentiates between regulations to be applied to processors of natural person and private legal person data and to public organisations. Personal data have to be processed with respect to the personal rights of the data subjects. Personal data have to bear certain characteristics.

Personal data:

- Should be obtained and processed fairly and lawfully,
- Should be recorded and used for specified, clear, lawful and fair objectives,
- Should be accurate and reliable, and should be revised or erased when necessary,
- Should cover identifiable information on the individuals and must be stored only for the period that the objective necessitates.

Natural or legal persons cannot process personal data by violating the characteristics of personal data and sensitive personal data without just cause. It is forbidden to process personal data despite an objection from the data subject, and personal data cannot be passed on to a third party without just cause. These stipulations can be violated only with just cause. According to Article 14, conditions of just cause include consent of the individual whose personal right is violated, the public interest and lawful authorisation.

The processing of personal data by public organisations can be performed with respect to law. Sensitive personal data may be processed only when there is an open statement in the law or in exceptional cases.

4) Directive on protection of data (95/46/EC) and the draft law on the protection of personal data

The Directive and Council of Europe Convention No. 108 cover provisions concerning personal data and protection of the rights of the data subject. However, the Draft Law on the Protection of Personal Data does not stress protection of the data subject in detail. Therefore, the Draft Law falls short of meeting the standards of the Convention and the Directive. Moreover, the Draft Law

does not cover all the content of the Directive. The work on the Draft law is still continuing currently. As a result, it is not possible to make a complete evaluation of the Directive yet.

5) Exceptions to the draft law on protection of personal data concerning research

Article 2 of the Draft Law states that the legal provisions are not valid for personal data processed by a real person without any commercial or occupational interest and the data is used solely by this individual and is not passed on to others.

7. Genetic information

a. Turkey has ratified "the Convention for the Protection of the Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine". Articles 12, 13 and 14 of the Convention are concerned with genetics. This Convention is part of Turkish Law and its provisions cover tests of genetic diagnosis, intervention seeking to modify the human genome, and choosing a future child's sex[7].

b. *The Regulation on the Centres for Diagnosis of Genetic Diseases* was published in 1998 and governs the establishment of centres for diagnosis and medical treatment of genetic diseases before the child is born. Article 17 of the Regulation states that the sex of the child cannot be determined except where serious hereditary sex-related disease is to be avoided. In Article 19 it is stated that the centres for genetic diagnosis cannot execute a procedure unless informed consent of the applicant is obtained. Concerning the protection of genetic information, it is stated that the results cannot be declared to any third party without consent from the particular individual.

(7) Article 12 of the Convention states that tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling. Article 13 states that an intervention seeking to modify the human genome may be undertaken only for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants. Finally, Article 14 states that the use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

c. The Draft Law on the Protection of Personal Data includes genetic information under the heading of sensitive personal data. Therefore, provisions concerning the protection of sensitive personal data are also valid for the protection of genetic information. Genetic information is part of information covered in medical records. Provisions on patients' rights with regard to medical records are also valid for genetic information.

DNA is the basic genetic material of all living beings and possesses the property of a detailed plan necessary for survival and development. DNA analysis of biological material is a method employed for identification purposes concerning issues covered in the *Penal Code* and the *Civil Code.*

8. Research involving animals

The *Law on the Protection of Animals* and the Regulation on the *Protection of Animals Used for Experimental and Scientific Purposes and on the Methods and Essentials of the Establishment, Functioning and Inspection of Trial Animal Production Facilities and Experiment Laboratories* govern research involving animals.

1) Ethics committees for research involving animals
Article 9 of the *Law on the Protection of Animals* governs the establishment of ethics committees; however, it refers to the preparation of relevant regulations for the detailed governance of the issue. In accordance with the Law, ethics committees constituted within entities themselves are authorised to give permission for the administration of animal experiments.

There are ethics committees constituted within universities. Regulatory principles of these committees are mainly based on "the Animal Rights Convention", "the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes (European Council ETS 123)", and "the Handbook of Maintenance and Use of Laboratory Animals", to a great extent.

2) 3R Tenet of Research on Animals
The 3R Tenet is concerned with the quality of scientific research conducted on animals in respect of ethics. It includes the possible use of a model other than an animal in an experimental system (Replacement), strategies to use a smaller number of animals in research (Reduction)

and the accommodation of animals in environments that fit their physiological properties and the use of procedures appropriate to the physiology of the animals (Refinement).

a. The *Law on the Protection of Animals* governs the provisions related to the 3R Tenet in Turkish Law. Article 9 covers the replacement rule and states that animals may be used in scientific experiments if no other scientifically satisfactory method is available. The *Law on the Protection of Animals,* in line with the Refinement Rule, necessitates the care, nourishing, accommodation and transportation of animals in an environment appropriate for the particular species. Furthermore, animals intended for use in procedures must be provided with appropriate accommodation and general care.
b. The *Regulation on the Protection of Animals Used for Experimental and Scientific Purposes and on the Methods and Essentials of the Establishment, Functioning and Inspection of Trial Animal Production Facilities and Experiment Laboratories* also states that animals cannot be used in research when alternative procedures are available and when the method to be used is not scientifically satisfactory, reasonable or practical.

The Regulation also covers provisions concerning the Rule of Refinement. The aim of the Regulation is to ensure the technical, health and hygienic appropriateness of the production facilities of the animals intended to be used in any experimental or other scientific procedure and to maintain the well-being and security of those animals. Animals used for trial or other scientific purposes have to be provided with appropriate accommodation and general care. Regarding accommodation, the animals have to be provided with an environment with at least a minimum degree of freedom of movement, food, water and care appropriate to their health and well-being. The environmental conditions in which animals are bred, kept or used shall be checked daily. The well-being and health of animals shall be observed and harmful situations shall be prevented. All of the conditions that might be harmful to the animals have to be corrected.

The Regulation also covers provisions related to the Rule of Reduction. Accordingly, when a procedure has to be performed, the method that necessitates the minimum number of animals has to be given preference. Organisations that use trial animals in research have to use the minimum number of animals.

3) Animals used in research

According to the *Law on the Protection of Animals,* animals cannot be used in unscientific diagnosis, therapeutics or experiments. For such experiments and research, use of animals must be compulsory. Furthermore, the selection of the animal species and the sex of the animal must be made with caution. Use for experimental purposes of extinct animals and animals under protection is inappropriate.

4) Regulations concerning research on animals

Article 5 of the *Regulation on the Protection of Animals Used for Experimental and Scientific Purposes and on the Methods and Essentials of the Establishment, Functioning and Inspection of Trial Animal Production Facilities and Experiment Laboratories,* specifies the research topics in which animals can be used for scientific purposes:

a. Avoidance or prevention of disease, ill-health or other abnormality in humans, animals or plants,

b. Avoidance or prevention of the production and the quality, efficacy and safety testing of drugs, substances or products used in humans, animals or plants,
c. Diagnosis or treatment of disease, ill health or other abnormality, or their effects, in humans, animals or plants,
d. Detection of physiological conditions in humans, animals or plants,
e. Protection of the environment and studies on environmental pollution,
f. Education and training,
g. Scientific research,
h. Forensic research.

However, to use animals for such purposes, the use of animals in research has to be compulsory.

9. Genetically modified organisms (GMOs)

"The United Nations Convention on Biological Diversity" is an international instrument that came into effect through Law No. 4177 in Turkey. Although Article 8 of the Convention governs the establishment or maintenance of means to regulate, manage or control the risks associated with the use and release of living modified organisms, no relevant system has been established in Turkey yet.

The *Law on Animal Refinement* enables the modification of animal genes, cloning animals and recreation of new lineages and renders the Ministry of Agriculture and Rural Affairs liable for granting permission on the issue. Furthermore, the Law states that the Ministry is responsible for taking preventive measures for the protection of the gene resources of animals.

The circular by the Ministry of Environment published in 1999 is concerned with genetically modified living organisms. The circular states that the effects of the use of gene technology on plants and animals are not yet known.

Conclusions

In Turkey, there are continuing efforts for the enactment of new legislative provisions concerning research and ethics, within the framework of progress towards integration with the European Union.

As a matter of fact, work on medical research and ethics dates back to recent times in Turkey. The Regulation on *Medical Deontology* can be regarded as the first set of provisions on the issue. The debate on ethics in medical research started in the second half of the 1980s and work on relevant provisions has become intense since then. The state of the issue has improved since several regulations have been enacted. Within this context, the *Regulation on Patients' Rights* (1998) and the *Regulation on Medical Research* (1993) relating to medical research and ethics are presently available. Yet there is still a need for further studies to overcome the shortcomings and contradictions on the issue.

At the same time, another high priority issue is concerned with Draft Laws, such as the one on the Protection of Personal Data, which should be put into effect as soon as possible.

References

1. Regulation No. 41/12578 on Medical Deontology, dated 13.1.1960.
2. Law No. 2238 on Procurement, Preservation, Grafting and Transplantation of Organs and Tissues, dated 29.5.1979.
3. Law No. 2857 on Blood and Blood Products, dated 25.6.1983.
4. Regulation No. 7314 on Blood and Blood Products, dated 23.6.1983.
5. Basic Law No. 3359 on Health Services, dated 7.5.1987.
6. Regulation No. 21480 on Medical Research, dated 29.1.1993.
7. Law No. 3960 on Prevention of Hereditary Diseases, dated 28.12.1993.
8. Regulation No. 23420 on Patients' Rights, dated 1.8.1998.
9. Regulation No. 23368 on Centre for Diagnosis of Genetic Diseases, dated 10.6.1998.
10. Regulation No. 24066 on Organ and Tissue Transplantation Services, dated 1.6.2000.
11. Regulation No. 19551 on Centres for Medically Assisted Procreation dated 21.8.1987
12. Law No. 4631 on Animal Refinement, dated 28.2.2001.
13. Law No. 4982 on the Right to Information, dated 9.10.2003.
14. Regulation No. 25445 on the Essentials and Methods Concerning the Law on Right to Information, dated 27.4.2004.
15. Regulation No. 25464 on the Protection of Animals Used for Experimental and Scientific Purposes and on the Methods and Essentials of the Establishment, Functioning and Inspection of Trial Animal Production Facilities and Experiment Laboratories, dated 16.5.2004.
16. Law No. 5199 on the Protection of Animals, dated 24.6.2004.
17. Law No. 5275 on the Enforcement of the Criminal and Security Measures, dated 13.12.2004
18. Draft Law on Protection of Personal Data.

European Commission

EUR 21617 – National Regulations on Ethics and Research in Turkey

Luxembourg: Office for Official Publications of the European Communities

2005 – 22 pp. – 17.6 x 25 cm

ISBN 92-894-9958-3

Dr Gülriz Uygur, Assistant Professor in the Faculty of Law, University of Ankara, Ankara. She is the Head of the Department of Philosophy and Sociology of Law, Faculty of Law, University of Ankara, Ankara. Among her study interests are law and ethics, ethics, and occupational ethics.

Dr Türkan Yalçın Sancar, Assistant Professor in Criminal Law, Faculty of Law, University of Ankara, Ankara. Among her study interests are medicine and criminal law.

Publications Office
Publications.eu.int

ISBN 92-894-9958-3