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Ethical issues form

Proposers are requested to fill in the following table

Does your proposed research raise sensitive ethical issues related to:	Yes	No
Human beings	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Human biological samples	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Personal data (whether identified by name or not)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Genetic information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Animals	<input type="checkbox"/>	<input checked="" type="checkbox"/>

I hereby declare that the proposed research does not involve:

- any form of human cloning for reproductive purposes;
- any form of human cloning for biomedical research;
- any form of human cloning for the purpose of research or for the creation of embryos for research purposes;
- any form of human cloning with the intention of

National Regulations on Ethics and Research in

Hungary

Magyarország



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National Regulations
on Ethics and Research in

Hungary

Magyarország

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Brussels, 2003

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Foreword

As Hungarian Minister of Education responsible for research, I have pleasure in recommending this brochure about our national regulation on ethics in research.

The European Charter of Fundamental Rights, now about to be included in the new European Constitution, guarantees every individual's right to his or her human dignity, physical and mental integrity, particularly in relation to contemporary medical and biological research. Also, as part of our growing awareness and sense of responsibility towards our environment, efforts are intensifying to spare animals from unnecessary suffering inflicted on them by research carried out for human benefit. Hungary adheres to these principles and our national legislation, coupled with the European *acquis*, ensures that they will be applied in practice.

Naturally, the EU's 6th Framework Programme for Research and Technological Development also requires that all the projects funded from community resources conform to the legislation in force on ethics in research. However, much of this legislation still rests on the shoulders of the Member states, thus leaving room for national differences. It is therefore necessary to take into account the laws of each project partner's country of origin when submitting and evaluating project proposals. Fortunately, Hungarian laws provide for a regulatory framework that is in no way inferior to

any other EU Member State's ethical rules on research involving human or animal rights issues.

The present brochure should be of use to all European projects partners within or outside the Framework Programme seeking information on the compatibility of their project with Hungarian regulations on ethics in research, be it foreign research partners taking part in consortia with Hungarian participation, or Hungarian researchers eager to be up-to-date about the legislation of their own country.

A handwritten signature in black ink, which appears to read 'Bálint Magyar'. The signature is fluid and cursive, written on a white background.

Bálint Magyar
Hungarian 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

(1) See Annex 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).

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.

This document is part of a series that aims to make the regulatory situation in the accession and candidate countries more transparent and better accessible to scientists in Europe.

The Hungarian text has been written by Prof. Judit Sándor, Dr. Ágnes Dósa (all chapters except chapter 6) and Dr. Zsolt Bártfai (chapter 6) and subsequently approved by the Ministry of Education of Hungary. The Commission has been promoting this project and is now dedicating a bilingual publication (original language and English) to the accession and candidate countries in order to facilitate their participation in the 6th Framework Programme. The project has been co-ordinated for the Commission by Alexandra Bitusikova, An Bæyens and David Coles. The responsibility and credit for the contents rest with the authors and the Ministry of Education of Hungary.



Barbara Rhode
Head of Unit "Ethics and Science"
Research Directorate General

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1. International instruments in Hungarian law

In Hungary, the main legal instrument of the health care sector is the Health Care Act (Act CLIV. of 1997), which - among others - contains detailed regulations on the structure of the health care system, the rights of patients, on research of human beings, on the transplantation of tissues from living and from deceased persons, on assisted human reproduction etc. By the time the draft of the Act was prepared, the draft of the "Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine" (hereafter referred to as "Convention") was already available. This is the reason why the principles of the Convention are reflected in the Act, and sometimes even the wording of the Act is identical to that of the Convention.

International treaties and conventions are part of Hungarian law in case they are transposed into a Hungarian source of law, especially into an Act of Parliament, if the consent of Parliament was required to the conclusion of the Treaty. According to the Constitutional Court's interpretation of Art. 7. Para 1. of the Constitution, treaties forming part of Hungarian law ought to be applied even if they are contrary to Hungarian law, except if they would contravene to the Constitution. Hungary promulgated the Convention and its Additional Protocol on the Prohibition of Cloning Human Beings by Act No. VI. of 2002. Being part of the Hungarian legal system, the provisions of the Convention can be applied directly and can be invoked in proceedings in front of Hungarian courts.

Article 67 of the Europe Agreement establishing an association between the European Communities and their Member states, of the one part, and the Republic of Hungary, of the other part - signed in Brussels on December 16, 1991, promulgated by Parliamentary Act No. I. of 1994 - rules on the approximation of Hungary's existing and future legislation to that of the Community. According to it, Hungary shall act to ensure that future legislation is compatible with Community legislation as far as possible.

European legislation is relevant in several fields of research on humans and animals. Detailed community legislation is in force in relation to research on human beings (Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use), and recent Hungarian legislation on the topic contains provisions harmonising with this Directive.

In the area of research on animals, international legal instruments also have to be taken into consideration. The Treaty on the protection of research animals (Strasbourg, 18. March 1986), and the Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member states regarding the protection of animals used for experimental and other scientific purposes was implemented into Act No. XXVIII. on the protection of animals.

2. National overview

2.1. Overview of national legal structure

Research on human beings is regulated on different levels in Hungary. Basic provisions are incorporated in the Health Care Act and in Act No. XXV. of 1998 on Medicinal Products for Human Use. Detailed provisions can be found in different Decrees:

- a) 23/2002.(V.9.) Health Ministry Decree (EüM rendelet) on the biomedical research on human beings;
- b) 24/2002.(V.9.) Health Ministry Decree (EüM rendelet) on the clinical trial of medicinal products for human use and on Good Clinical Practice;
- c) 12/2001.(VI.12.) Health Ministry Decree (EüM rendelet) on licensing and registration of human pharmaceutical products;
- d) 34/203.(VI.7.) Health, Social and Family Affairs Ministry Decree (ESzCsM rendelet) on the Health Science Council.

2.2. General principles of research on humans

Generally, biomedical research (biomedical intervention) can only be carried out with authorisation and with the research purpose of developing diagnostic, therapeutic, preventive and rehabilitation procedures, for elaborating new biomedical procedures and for a better understanding of the aetiology and pathogenesis of illnesses. Concern for the interests of the subjects must always prevail over the interests of science and society.

Research can not be carried out unless the importance of the objective is in proportion to the

inherent risk to the subject. Research can only be undertaken, if there is no alternative of comparable effectiveness to research on humans.

In the process of the biomedical intervention, the scientifically well-established diagnostic and therapeutic procedures accepted in practice shall be provided to the persons participating in the intervention, including the control persons.

Biomedical intervention – including the interventions not carried out for therapeutic and preventive reasons – can only be carried out if it is in the public interest and if it is scientifically sustainable, if the expected results can be verified and if the professional, personal and material circumstances necessary for careful preparation, the verification of the evaluation are satisfied.

Even if a positive ethical-professional opinion has been given, a biomedical intervention can only be started if the person involved in the research, respectively or his/her legal representative, has given informed consent to the research (see below).

Each research protocol, conducted on humans, needs authorisation. If the research concerned is a drug trial involving medicinal products, authorisation is given by the National Pharmaceutical Agency. In all other cases the authorisation is given by the director of the health care institution where the research is intended to be carried out (exceptionally, if the research involves pregnant or breast feeding women, persons under civil commitment, the authorisation has to be given

by the Director of the National Public Health Authority). In any case, the opinion of the ethics committee has to be obtained and authorisation can not be given if the ethics committee does not approve the protocol.

2.3. Ethics committees

Each research protocol intending to involve human beings has usually to be reviewed by two ethics committees.

The structure of the ethics committees is very complex and not easy to deal with. There are three different levels of ethics committees: national, regional and local level.

National Ethics Commissions. Within the Health Science Council (founded in 1951) there are three different National Research Ethics Commissions: the Scientific and Research Ethics Commission (TUKEB), the Clinical Pharmacology Ethics Commission (KFEB) and Human Reproduction Commission.

Regional Research Ethics Board. The 23/2002.(V.9.) Health Ministry decree (EüM rendelet) on biomedical research involving human beings set up 12 regional research ethics boards (RKEB) throughout the country.

Institutional Research Ethics Boards. Each health care institution where research involving human beings is carried out has to set up an institutional research ethics board.

According to the Health Care Act, the review of research protocols that is carried out by the different levels of ethics commissions includes an evaluation both from a scientific and from an ethical point of view. Accordingly, the composition of the ethics commissions has to be multidisciplinary: in addition to medical professionals, representatives of non-health care professions (ethicist, lawyer, clergyman, psychologist) are also members of the commissions.

Different categories of research are reviewed on different levels. One issue they have in common: every single research project has to be reviewed by the institutional research ethics board of the health care institution where the research is intended to be carried out. If the research is carried out at more than one health care institution, each institution's ethics board has to review the protocol. The review performed by the institutional research ethics board is limited as to whether the given health care institution is able to carry out the research (existence of trained personnel, adequate medical equipment etc.). The role of the institutional research ethics board is more relevant in the supervision of the research. The board has to inspect the research continuously, look into the documents, examine if the research is carried out in accordance with the protocol, etc. The board has the power to suspend the research in case of non-compliance with the requirements.

The institutional research ethics board has to appoint one of its members, who will be responsible for the protection of the interests of the research subjects. The name of this person has to be indicated

on the consent form signed by the subjects and they can turn to him/her if any problem occurs during the research. It depends on the nature of the research whether the protocol has to be reviewed on a national or on a regional level.

The Clinical Pharmacology Ethics Commission (KFEB) reviews all clinical trials involving medicinal products.

The Scientific and Research Ethics Commission (TUKÉB) reviews the following research protocols:

1. protocols that apply not yet accepted treatment or diagnostic procedures, if invasive intervention is carried out in connection with the procedure;
2. clinical testing of medical devices;
3. research on the development and characteristics of genetically determined illnesses through population genetics, somatic genetics; genetic epidemiology;

4. if more than one regional research ethics board would be responsible for the review of the protocol;
5. in any case where the regional research ethics board refers the case to the TUKÉB.

The Human Reproduction Commission (HRB) reviews all research protocols, which

1. are aimed at the modification of the human genome;
2. are related to human reproduction;
3. are related to prenatal examinations.

The regional research ethics board reviews all remaining research protocols (epidemiological studies, research based on biological materials taken from deceased persons etc.).

3. Research involving persons

3.1. Requirements for informed consent

Biomedical intervention can only be started if the research subject, or - in case of incompetence - his/her legal representative has given informed consent to the research.

The research subject or -his/her legal representative has to be informed in detail about all facts, circumstances, or events that are connected or can be connected to the intervention by the principal investigator or by another doctor mandated and participating in the research.

Information has to be provided especially about the purpose and the course of the research, the interventions necessary for the participation in the research, the frequency of these interventions, the possible and foreseeable effects and side effects connected to the research, possible advantages and risks and possible consequences. Information shall also be given concerning the fact that the consent to participate in the research can be withdrawn at any time, including orally, and that in case of any damage to his/her health condition the subject may ask for compensation of damages. Information must also include an explanation of the medical terminology used.

The information has to be given in writing.

It should include the following elements:

- data of the research, with straightforward reference to the experimental character of the research;
- object of the research, expected duration of the research, the number of research subjects, biomedical interventions and its frequency;
- other possible available treatments, information about the change of the therapy and its impact on the research subjects' health;
- expected consequences of the research;
- benefits of the research;
- if no benefit is expected then it has to be mentioned why the research is necessary;
- the method of selecting different research groups and the odds to get into one or the other group;
- reference to his/her right to revoke the consent at any time, without giving reason and to the fact

that no disadvantages from such revocation may occur;

- a statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants;
- measures taken for data protection;
- the name of the ethics review committee.

The written consent form that should be signed by each of the research subjects should include at least the following elements:

- the name of the health institute where the research will be conducted;
- the name of the head of the research, name of the staff members who will provide information on the research;
- personal data of the research subject (name, mothers' name, date and place of birth, social security number, address);
- statement of the consent;
- date of the signature;
- signature of the researcher who provided the information;

If the research subject is not competent, the legal representative or a close relative has to be involved into the consent procedure (see above). There is one case, where informed consent is not needed: in research related to emergency conditions - under special circumstances – the research can be carried out without consent. In other cases research can not be carried out even if the competent person consents: detained persons, persons in military service cannot be research subjects.

3.2. Research subjects unable to give consent

While in the case of competent subjects the person wishing to participate in the experiment has to be personally informed and he/she is the one to give consent, this is not the case if the person is not competent.

According to the Civil Code of Hungary, there are two different grades of incompetence. A person is fully incompetent, if under the age of 14, or if under full-guardianship (adjudicated incompetent), or if not being able to make decisions for him/her self due to his/her overall condition.

The Civil Code also distinguishes another grade of incompetence the so called "limited competency". The difference between incompetence and limited competency lies in the extent of the limitations placed on financial and personal matters. While the fully incompetent is not allowed to make a legally valid statement, the person under limited guardianship has the right to dispose over his/her financial matters up to a limit (typically one month's salary) and is allowed to make legal statements in agreement with her guardian. Persons under the age of 18, but above 14 have a similar legal position as adults placed under limited guardianship with the difference that in their case the legal representative can make legal statements by him/her self.

If a medical intervention has to be carried out on incompetent patients, the legal representative (if there is no legal representative, a close relative) has to give consent. The scope of this consent is very limited,

however: the legal representative's or the close relative's decisions may not unfavourably affect the patient's state of health, and in particular may not lead to serious or lasting impairment to the health. If the person is under limited guardianship, both the consent of the patient and the legal representative is needed (except in emergency situations). If the patient is between the ages of 14 and 18, the consent of the legal representative is sufficient.

The rules for consent to research differ somewhat from this general provision. Research on non-competent persons has to fulfil several conditions. It can only be performed, if the results of the experiment have the potential to produce real and direct benefit to the health of the subjects and experiments of comparable effectiveness cannot be carried out on competent subjects. However, in some cases an exception can be made. If the research does not have the potential to produce results or direct benefit to the health of the person concerned, but entails only minimal risk and minimal burden for the subjects, the research can still be carried out on non-competent subjects, if the following condition is met. The research must have the aim of contributing through significant improvement in the scientific understanding of the individual's condition, disease or disorder to the ultimate attainment of results capable of conferring benefit to the person concerned or other persons in the same age category of afflicted with the same disease or disorder, or having the same condition.

The explicit wish of non-competent persons who are capable of forming an opinion and assessing the

received information to refuse participation or to be withdrawn from the research has to be considered by the investigator.

The person not able to give informed consent also has to receive information according to his/her capacity of understanding regarding the research, risks and benefits.

A special case is the performance of experiments on patients in emergency situation. The emergency situation is an accepted exception to the doctrine of informed consent and it is closely related to the exception of incompetent patients. In many situations the two exceptions may even overlap, since in emergency situation a person is often unconscious or is for other reasons not in the position to make decisions for him/her self. Performing research on patients being in emergency situations may raise legal concerns: based upon the incompetence exception there is only limited possibility to involve these patients in any kind of research, as the consent of the legal representative is always required and in emergency situations often cannot be obtained in time. If in an emergency situation the consent of the patient is or his/her legal representative (or close relative) cannot be obtained within reasonable time, research can be carried out nevertheless, if two additional conditions are fulfilled. First, the research has to be directly related to emergency care. Second, it must have the potential to produce real and direct benefit to the subjects' health.

3.3. Legally competent, but vulnerable research subjects

In case of detained persons, it can never be assumed with certainty that the consent was really freely given or whether the person was under any kind of influence e.g. threat to physical integrity, or the consent is being given assuming some benefits or concessions with regard to his/her imprisonment.

According to the Health Care Act, any subject who is not in an independent position (in an official, financial or moral sense) to freely consent to participate in the experiment is excluded. It further states that prisoners and persons in military service are excluded even if they consent.

Persons under civil commitment in psychiatric institutions can only take part in research if two conditions are fulfilled. The first condition is that the experiment has to be of direct benefit to the person involved, or to his/her close relative or to other persons in the same situation. The other condition is that the experiment can only be effectively conducted with the participation of detained patients.

For performing experiments on pregnant and breast feeding women, the Act sets up two conjunctive conditions. They can only participate in experiments if it has the potential to produce direct benefit to their or the baby's health or other pregnant or lactating women and their babies, and if an experiment of comparable effectiveness cannot be carried out on non-pregnant or non-lactating women.

4. Research involving human biological material

As to removing biological material from living persons for research purposes, the patient's written consent is required. According to the Health Care Act, the patient has to consent to the use for any purpose not related to the patient's provision of any of his/her cells, cell components, tissues, organs and body parts removed while alive during an intervention. The patient's consent is not required for the destruction of these materials in the usual manner.

As to removing biological samples from deceased persons, the patient is entitled to dispose over any interventions regarding his/her corpse. The patient may prohibit in advance the removal of any organ and tissue from his/her corpse for the purposes of treatment, research or education (opting out model). If there is no prohibition, however, there is no further legal restriction on the use of any biological material for research purposes. After the removal of the biological material, the corpse has to be restored appropriately.

In the absence of a specific regulation on the use of biological materials from existing collections, the data-protection rules in force at the time of the initiating of the research have to be applied. Accordingly, the consent of the patients has to be obtained for the research.

In the Health Care Act, the patient has the right to gain access to the data contained in the medical record concerning him/her. Parallel to the Health Care Act another important law was adopted, namely Parliamentary Act XLVII. of 1997 "on the processing and protection of health care data and associated personal data" (hereinafter: HDP Act). However, this law does not cover the consent to patenting (that can be understood as a special use health data).

Similarly, the law on patents is also silent about the consent of the concerned individual (Parliamentary Act No XXXIII of 1995 on legal protection of inventions).

5. Research involving human embryos and embryonic stem cells

Embryo is defined as every living human embryo following the completion of fertilisation until the 12th week of the pregnancy. The foetus is the human being developing within the uterus after the 12th week of the pregnancy.

Research on embryos can be carried out on the basis of an authorisation of the Hungarian Reproduction Commission. Embryos can only be used for research purposes and experiments can only be made on embryos for the research purposes that the Health Care Act fixes with regard to medical research (see above 2.2.).

Embryos cannot be created for research purposes, only embryos created in medically assisted human procreation (heretofore referred to as MAP) procedures can be used for research and experiments, either on the basis of the decision of those entitled to decide, or in case of damage of the embryo. If an embryo was donated for a MAP procedure, but not used within 10 years following the donation, the embryo can be used for research purposes.

According to the Criminal Code, any person who performs a medical experiment on a human embryo or gamete without, or in deviation of the license prescribed in the Act on Health Care, or creates a human embryo for scientific purposes, commits a felony offence and shall be punishable with imprisonment of up to five years.

The embryo cannot be implanted in animal bodies, human and animal gametes cannot be fertilised with each other.

The violation of these rules is considered as a criminal offence. According to the Criminal Code, any person who transplants a human embryo into an animal, inseminates a human gamete with an animal gamete, or vice versa, implants a human embryo which was previously experimented with into a human body, uses a human gamete which was previously used for experiment for human reproduction, uses a non-human gamete or embryo for human insemination or for embryo implantation, uses a human embryo to create several human embryos or animal embryos, commits a felony offence and shall be punishable with imprisonment between two to eight years.

The embryo cannot be used for creating more embryos, or - with the exception set in the Health Care Act - for the creation of beings having attributes different from the ones developed by the fertilisation, or having further attributes.

The embryo on which experiments were carried out cannot be implanted into the human body, and cannot be kept alive for more than 14 days - the period of storage not included - counting the duration of the experiment and the period following that.

Procedures directed to the choice of the sex of the descendant before birth can only be applied in case of recognition of sex dependent hereditary illness, respectively for the prevention of development of such illness.

Genetic characteristics of the embryo can only be changed in the case of absolute necessity and to the

extent necessary for preventing or treating the expected illness of the child to be born. For the unique purpose of establishing the probable illness of the child to be born, or damage to the embryo, separation of the cells of the embryo is allowed.

According to the Criminal Code, any alteration of the human genome, including alteration of the human embryo is punishable up to 5 years of imprisonment. If the human genome is successfully changed, the punishment is up to 2-8 years imprisonment. The only exception for punishment is if sex selection of the human embryo is conducted in order to avoid an inheritable disease (Health Care Act 1997.No CLIV Article 182).

Reproductive cloning is prohibited. According to the Health Care Act, any intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited. According to the Criminal Code, any person who creates genetically equivalent human species during experimental research or during a medical procedure commits a felony offence and shall be punishable with imprisonment between five to ten years.

Currently there is no law on stem cell research in Hungary.

There is an ad-hoc group that examines the problems of stem cell research (it is expected that umbilical cords will be used for such research purposes but using embryonic stem cells will be forbidden).

6. Personal data

6.1. The System of the Hungarian Data Protection Law

The Hungarian data protection legislation is now a complex body of law comprising several acts. Its core Act is Act LXIII of 1992 on the protection of personal data and the publicity of data of public interest (Data Protection Act, DPA), which is applicable to any instance of data handling unless the handling of specific data is covered by a separate Act [a so-called sectoral Act, such as Act XLVII of the year 1997 on the handling and protection of medical data and related personal data (the Medical Data Protection Act)], or when there is no provision on a given issue under the applicable sectoral Act. It is especially important to examine the relevant sector-specific data handling rules for social research projects under the Sixth EU Framework Programme for Research and Technological Development.

The Hungarian data protection law is essentially in line with the data protection requirements of the European Union. In 2000, Hungary was recognised by the Commission of the European Union as a third country, which affords protection of personal data at a comparable level to that set forth in the European Union's Data Protection Directive. The amendment to the Data Protection Act in 2003, which entered into force on 1 January 2004, follows both the conceptual and institutional system described in the Directive 95/46/EC. Hungary is also a party to the data protection convention of the Council of Europe (ETS 108).

6.2. Relevant core concepts and provisions of the Data Protection Act

Under the Data Protection Act (hereinafter referred to as "DPA"), personal data is defined as any piece of data related only to a (identified or identifiable) natural person; data related to legal bodies are not protected by the Act.

"Personal data" and other definitions are defined as they are part of the Directive, however the DPA broadens the category of sensitive data (party affiliation, pathological addiction, criminal data), and a special Act further details the concept of criminal data (1) and medical data (2).

The most significant difference between the DPA and the Directive is the legal basis for handling data. Under the Data Protection Act, two legal bases are recognised:

- data handling prescribed by the law;
- consent of the person concerned, which must be given in writing for special data.

It is important to note that the laws regulating scientific research usually require that consents and other statements are given in writing.

Thus, contrary to the Directive, "a valid interest of the data controller or a third party", "public duty", or other interests (see Art. 7 and 8 of the Directive) are not as such sufficient to allow data handling. When the act regulating data handling does not allow the handling (utilisation, transmitting) of the given type of personal data for the purpose of scientific research (3), the consent (in writing,

if necessary) of the persons concerned must be obtained. The affected person must give an informed and voluntary consent, similar to that required by the Directive.

The Hungarian law follows a different philosophy from the Directive: it recognises the right to the protection of personal data as a core constitutional right, also called the right of self-determination for information. The affected person always has the right to decide about the handling of his/her personal data: he/she may amend or revoke his/her consent for data handling at any time, without justification. When consent is revoked, personal data already recorded must be deleted. In case of a dispute between the data controller and the data subject, there is no possibility, theoretically, of comparing the two interests. Moreover, the amendment raised a conceptual question: what is the relationship between the consent given by contract (4) and the concept of equality of contracting parties?

6.3. Recording personal data for the purposes of scientific research

Taking into the account the basic difference between the philosophy of the DPA and the Directive as described above, you will find in this section the basic rules that allow researchers to handle personal data without the data subject's consent.

Prior to starting a scientific research project, the scientific researcher must prepare a research data handling plan, which must include the right

to do research, the research objective, the type and source of personal data to be handled, the procedure of data handling, the guaranties which ensure that the affected persons may in practice enforce their rights, as well as the technical and organisational measures ensuring the protection of data.

- a) Under Act CXIX of 1995 on the handling of names and addresses for research and direct marketing (Direct Marketing Act), a scientific researcher may use the following sources for names and addresses, for the purpose of establishing contact:
- Persons with whom he/she had contact previously.
 - Data contained in collections of data, lists of names and addresses or other publications, which are produced for legal publication and are published legally (e.g. phone book, list of practitioners, statistical name list).
 - Data obtained from other persons or organisations working on the same research. This is only possible, however, if the party transmitting the data had previously informed the affected persons of the transfer and the persons affected had not objected or prohibited it.
 - Data requested from population registration authorities in accordance with the Act LXVI of 1992 on the registration of personal data and the address of citizens (Registration Act). The scientific researcher may specify criteria (e.g. name; citizenship; gender; time and place of birth; mother's name; place and time of death; address; marital status) for the selection of the group of persons whose data are requested.

(If the researcher would like to contact a group of people of more specified characteristics the researcher may ask those data controllers, which are in regular contact with those data subjects, to transmit his/her request to them, in which the researcher informs the data subjects about the aim, conditions, terms of data processing and asks their consent to be involved in the research.)

b) Data handling for other purposes requires either the (written) consent of the affected persons, or a statutory authorisation. The Medical Data Protection Act makes an exception to this rule. On the request of a scientific researcher, the head of the medical institution may authorise the researcher to view the medical records. The scientific researcher may not make a copy of data, which may enable personal identification, and scientific publications may not contain medical or personal identification data, in a way which would allow the identification of the affected person.

c) Personal data may also be procured for social research projects under the 6th Research Framework Programme in accordance with Act LXVI of 1995 on public documents, public archives and the protection of materials in private archives (Archives Act). According to this Act, prior to the expiry of the period of protection (30 years after the death of the person concerned), the archived materials may be used for scientific research if :

- 30 years have elapsed since the date when the document was created, as a general rule

(for archived materials created prior to 2 May 1990, only 15 years is required);

- the researcher attaches a supporting statement issued by a (public) organisation performing scientific research as a public duty;
- the researcher undertakes in writing to treat and process the collected personal data in accordance with the provisions of the Data Protection Act applicable to scientific research, and indicate the place, where data handling takes places in the written statement.

If the scientific researcher is a foreigner, these rules must be applied with the following differences:

- only researchers whose home country provides protection to personal data equivalent to the Hungarian law may receive authorisation to conduct research;
- the researcher needs to hold a supporting statement issued by the sub-organisation of the Hungarian Academy of Sciences relevant to the subject of the research;
- the researcher must undertake in writing to abide by the data protection regulations of his/her own country.

6.4. Using Personal Data

a) Irrespective of the source of personal data, the scientific researcher must meet the data security requirements in the course of handling of personal data, i.e. he/she must ensure that no unauthorised persons may have access to the personal data.

- b) A scientific researcher may use the names and addresses obtained for establishing contact [see Section 3 a)] solely for this purpose. In addition to the measures specified in Art. 11 of the Directive, at the first contact the researcher shall inform the affected person in writing of the following as well:
- the source from which the data were obtained;
 - if the researcher is a foreign scientific researcher, or carries out the research project on a foreign commission, or if personal data are intended to be transmitted abroad;
 - whether the findings are intended to be published in a form which allows personal identification;
 - that the provision of data is voluntary.

Under specific circumstances, the preliminary information about the use of data or the rights of the affected persons may be completely ignored, or given afterwards.

The affected persons may be informed of the use of data and of their rights afterwards if the provision of preliminary information would jeopardise the research objective. The affected persons may still exercise their right to prohibit the further use of their names and addresses.

The requirement for providing the required information may be ignored if the research project is related to social, public health, public education or environmental interests, and if the provision of information or obtaining consent would require a disproportionately high effort in terms of time, costs and human work, due to the large number of affected persons.

- c) The data serving the purpose of scientific research, i.e. data which are obtained by the

researcher in the phase of collecting data, and which are not suitable for the identification of individuals, may only be used for the purpose of scientific research laid down in the research plan. Data used or generated in scientific research must be anonymised as soon as possible – that is, the link between these data and data allowing individual identification of persons needs to be severed. Until anonymisation is carried out, the two types of data need to be stored separately (at different locations or in different databases); the connection between them may be ensured by the use of index numbers, for example. Data allowing individual identification of persons may only be linked with other data if required by the purpose of the research.

- d) Under the Data Protection Act, either the consent of the person concerned, statutory authorisation, or international Convention is needed to allow personal data to be transmitted abroad, provided that the law of the relevant foreign country ensures the necessary level of protection, as specified by the European Union. As of 1 January 2004, transmitting data to EU Member states will not be considered transmitting data abroad. Data may only be transmitted to other third countries not ensuring an equivalent level of protection with the written consent of the person concerned, who must have been duly informed before giving consent.

The Direct Marketing Act stipulates even more stringent requirements: any personal data may only be transmitted abroad upon the written consent of

the person concerned. This regulation in some aspects is contrary to Hungary's international commitments, e.g. to the Council of Europe's data protection convention.

Under the Archives Act, the government may conclude a data protection contract for the presentation of copies of archived materials containing personal data – including special data – with the aim of presenting the findings of research concerning historic events to foreign scientific institutions, prior to the expiry of the period of protection. In this case, transmission of the data may be prohibited by the concerned person or, in the case of his/her death, by any of his/her heirs or family members, until the period of protection expires.

6.5. Other Rules Facilitating Scientific Research

It follows from the concept of personal data that, once the link between a piece of personal data and the natural person concerned has irrevocably been cut, the rules for the protection of personal data will no longer be applicable to that piece of data.

It is possible to provide statistical data, which are not considered personal data, using various criteria, from any database (this is referred to by several Acts on data handling separately). These data are considered data of public interest, provided that they are managed by bodies performing public duties. Additionally, other data managed by such bodies (data about the activities and operation of such bodies) are also considered data of public interest.

Whenever a body performing the relevant public duties receives a request for the provision of certain public data, it must make such public data available to the party submitting the request, within 15 days from the receipt of the request.

7. Genetic information

In Hungary there is no specific law on human genetics. However, important legal rules were adopted in the field of biomedical research, repro-genetics and criminal law. In these three areas important legal norms were formulated that are relevant in the field of human genetics.

Genetic research cannot aim at the creation of a new human being or changing the human genome of an individual. Research that results in intervention of the human genome can be justified only if it aims to preventing a genetically inheritable disease and if it is allowed in the Health Care Act.

Sex selection of the embryo is not allowed unless it aims to prevent a disease that is inheritable only by one of the sexes.

Genetic characteristics of the embryo/foetus can be changed only for purposes related to the child's medical treatment and only up to the limit that is absolutely necessary for the treatment.

Separation of the embryonic cells is allowed only for the purposes of diagnosis of the child or for determination of his/her injury.

The violation of these provisions is considered as a criminal act. According to the Criminal Code, any person who performs a scientific experiment on a human embryo for the purpose of manipulating the genetic structure of the embryo commits a felony offence and shall be punishable with imprisonment of up to five years. Any person who uses a human embryo to create a specimen with characteristics different from those developed by conception or with additional characteristics, separates the cells of a human embryo, commits a felony offence and shall be punishable with imprisonment between two to eight years.

Recently an ad hoc group (appointed by the ETT) has been set up with the task of preparing guidelines for making a law on genetic screening testing, and genetic databanks.

8. Research involving animals

The rules of research on animals are laid down in the Parliamentary Act No. XXVIII of 1998 on the protection of animals; in Government Ordinance No. 243/1998 (XII.31.) on scientific research on animals; and in Order No. 36/1999 (IV.2.) of the ministers responsible in charge of agriculture, environment protection and economy. Each of them refers only to non-human vertebrates. The regulation in force is now in accordance with Council Directive 86/609/EEC.

The basic principles of research on animals are the following:

Experiment means any use of a vertebrate animal for experimental or other scientific purposes, which may cause it pain, suffering, distress or lasting harm.

Animal experiments can only be carried out with authorisation and in registered institutions.

An animal experiment can be authorised if it is necessary for the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in man or animals, or for the purposes of forensic examinations or for any other scientific reason.

The authorisation is given (and the experiment is monitored) by the Veterinary Authority. In the authorisation process, the opinion of the Animal Research Ethics Board of the Animal Protection Consulting Commission must be obtained.

An animal experiment shall not be performed if another scientifically satisfactory method is available to obtain the sought-after result and that does not entail the use of an animal.

While choosing between experiments, those must be selected, which use the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results.

No animal experimentation can be carried out for manufacturing purposes of cosmetics, tobacco, other similar consumption goods, weapons and ammunition.

Animal experimentations have to be carefully documented.

All experiments shall be designed to avoid distress and unnecessary pain and suffering to the experimental animals. All experiments shall be carried out under general or local anaesthesia. This does not apply when anaesthesia is judged to be more traumatic to the animal than the experiment itself or when anaesthesia is incompatible with the object of the experiment.

If anaesthesia is not possible, analgesics or other appropriate methods should be used in order to ensure that pain, suffering, distress or harm are limited as much as possible and that in any event the animal is not subject to severe pain, distress or suffering.

Provided such action is compatible with the object of the experiment, an anaesthetized animal, which suffers considerable pain once anaesthesia has worn off, shall be treated in good time with pain-relieving means or, if this is not possible, shall be immediately killed by a humane method.

During and after the experimentation all experimental animals shall be provided with housing, food, water and care which are appropriate to their health and well-being.

At the end of any experiment, if the animal is permanently or seriously damaged it has to be killed with the minimum of physical and mental suffering.

If the animal is kept alive, it shall receive the care appropriate to its state of health. This is the duty of the institution carrying out the research.

Experiments shall be performed solely by competent authorised persons, or under the direct responsibility of such a person, who has the appropriate training defined by law, experience in this field and who is familiar with the ethical principles and legal rules of animal experiments.

Breeding, keeping, transporting and supplying of animals for the purpose of experimentation needs the authorisation of the Veterinary Authority.

Unless otherwise, authorised, only those animals can be used for experimental purposes that were bred with a view to their use in experiments.

Stray animals can not be used for animal experimentation.

The breeding and supplying establishments should be registered by the Veterinary Authority. Each institution, which carries out animal research, has to set up an Institutional Animal Research Board. It prepares the animal research ethics code of the institution, monitors its implementation and controls the animal research in the institution. The board is entitled to immediately stop the research in case of non-compliance. Basic norms on biotechnology were laid down in the Parliamentary Act No. XXVII. of 1998 on gene technology (as amended in 2002). According to this Act, authorisation is required for the following activities:

- for the installation of laboratories creating genetically modified organisms;
- for the genetic modification of natural organism, with the exception of modification for research purposes;
- for closed-system use, release into the environment, trade, import and export of genetically modified organisms and products made thereof, with the exception of closed-system use for research purposes.

Authorisation can not be given for the genetic modification of the natural organisms specified in the Decree of the Government.

(1) para. 3 Art. 2 of DPA

(2) Act XLVII of the year 1997 on the handling and protection of medical data and related personal data.

(3) E.g. Act XLVII of the year 1997 on the handling and protection of medical data and related

personal data, Act LXVI of the year 1992 on the registration of the personal data and address of citizens, Act CXIX of the year 1995 on the handling of names and addresses for research and direct marketing.

(4) See para. (7) Art. 3 of DPA

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