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Ethical issues form

All Proposers are requested to fill in the following table

Does your proposed research raise sensitive ethical questions related to:	Yes	No
Human beings	V	
Human biological samples	V	
Personal data (includes information by name or not)	V	
Genetic information	V	V
Animals		

I am pleased to certify that the proposed research does not involve:

- any form of cloning for reproductive purposes
- any form of genetic heritage of human beings which could make use of
- any data for the purpose of research on the
- of genetic and related material

National Regulations on Ethics and Research in

Estonia

Eestis



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**National Regulations
on Ethics and Research in**

Estonia

Eestis

by

Prof Parve

Prof. Parve would like to thank

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Brussels, 2003

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Foreword

Ethical problems in scientific research were not very relevant issues in Estonia before the 1990s.

After Estonia had regained its independence, a more systematic approach was adopted.

The first human genetic research ethics committee for evaluating biomedical research was established at Tartu University in 1990. Initially, preliminary review of the ethical aspects of scientific research was based only on public agreement between financiers of scientific research and research institutions. However, in the years that followed, the review process became more extensive and systematic and also started to be based on respective legal documents.

Animal experimentation was also brought into compliance with internationally accepted procedures in the mid 1990s. Today, we now have the necessary basic legal documents for regulating state-of-the-art research primarily in the field of biomedicine in Estonia.

The creation of a legal basis for ethical standards of scientific research, which are in accordance with human rights and internationally recognised norms of a democratic society, started to show its first signs of effectiveness in the middle of the 1990s.

The Republic of Estonia has ratified and/or implemented several relevant documents of the Council of Europe and European Union, which have, hence, become an integrated part of Estonia's legislation (texts of most Estonian acts are available on the Internet both in Estonian and in English). All legislation passed during the recent years is in full accordance with the European Union's related documents and such process continues.

A handwritten signature in black ink, consisting of a large, stylized initial 'T' followed by several loops and a period.

*Professor Toivo Maimets, Ph.D (biol.)
Minister of Education and Research
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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

(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').

only understand the regulation of their own countries, but also those of potential partners and when they seek to collaborate.

The Estonian text has been written by Prof. Valdar Parve and subsequently approved by the Ministry of Education and Research of the Republic of Estonia. 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 Baeyens and David Coles. The responsibility and credit for the contents rest with the author and the Ministry of Education and Research of the Republic of Estonia.



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

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1. International instruments in Estonian law

In 1991, Estonia regained its independence and a state based on the rule of law was re-established. After *de jure* recognition by other countries and the creation of diplomatic relations, the Republic of Estonia became a subject of international law.

The Estonian parliament (*Riigikogu*) has ratified several international documents regulating ethical aspects in scientific research. Several specific laws

regulating to this field have also been drafted and adopted. Since 1997, all the legislation in this field that has been enforced by *Riigikogu* is in full accordance with the European Union's legislative documents. The full texts of the laws indicated in the present report are available on the Internet in both Estonian and English (for almost all texts related to research ethics).¹

2. Overview of legislation

1) The Constitution of the Republic of Estonia

Pursuant to the Constitution of the Republic of Estonia (1992), Estonia is an independent and sovereign democratic republic in which the supreme power of state is vested in the people. The Constitution provides the foundations of the state, which are liberty, justice and law. Paragraph 10 of the Constitution supplements the previous list with the principles of human dignity, social state and democratic state. The first principle reveals that an individual human being has a central focus in Estonian society and his/her dignity prevails over the interests of a group of people or of the state. The second principle refers to a person's right to assistance from the state if need be.

2) The system of legal acts

The Republic of Estonia is a state with a continental legal system, of which the constitution is the most important legal foundation. Other important legal sources are legal acts adopted by the Estonian parliament. Instruments of the executive power may also regulate legal issues, e.g. Presidential decrees, regulations passed by the government, or ministerial orders. These regulations and orders specify certain aspects and ways of implementing the acts. The Ministers' right to issue orders is valid in their administrative field of activity. Generally recognised principles and norms of international law are an essential part of the Estonian legal system.

¹ The legal documents are available at the website of the Estonian Legal Language Centre: <http://www.legaltext.ee/indexen.htm>

3) The procedure of enacting acts

The most important legal sources - acts - are adopted by vote in the parliament. The Estonian parliament has one chamber and consists of 101 members elected by the people. Riigikogu passes acts after two readings. After an act has been passed by the parliament, it has to be proclaimed by the President in order to get conclusive force. Proclaiming is not just a formal procedure as the President has the right to send an act back to *Riigikogu* with a reasoned resolution. All proclaimed acts are published in the State Gazette (*Riigi Teataja*). In principle, an act will enter into force 10 days after it has been published in the State Gazette, unless the act determines the date on which it will enter into force. All government regulations and ministerial orders are also published in the State Gazette.

4) International legislation, conventions and treaties

The Constitution of the Republic of Estonia provides that generally recognised principles and rules of international law, e.g. the principles of the state's sovereignty and equality, the principle of reciprocity, the principle of non-intervention in another state's internal and foreign matters, the prohibition of using force or threatening with force, the principle of resolving disagreements in a peaceful manner and the principle of respecting human rights, are all an inseparable part of the Estonian legal system. International regulations, conventions and treaties signed by the Government must also be ratified by Riigikogu.

Ratifying substantively consists of a one-sided announcement by the state that the national competent state authority has given its approval for adherence to an international treaty and the state is ready to comply with the responsibilities provided therein. After this procedure, the respective treaties, regulations and conventions are legally binding. For instance, the Estonian parliament has ratified the following acts of international law: Convention for the Protection of Human Rights and Fundamental Freedoms (1950), Convention of Human Rights and Biomedicine: the Protection of Human Rights and Human Dignity in Implementing Biology and Medical Science (1997), the latter's Additional Protocol on Prohibiting Human Cloning (1998) and Additional Protocol on Treating Transplantation of Human Organs and Tissues (2002).

After ratification courts can and may use these acts to implement justice as Estonian acts. Pursuant to the Estonian Constitution, the Republic of Estonia shall not enter into international treaties, which are in conflict with the Constitution.

5) Institution of ethics committees

The task of an ethics committee is to guarantee the protection of health, human dignity, identity, security of a person, and other fundamental rights and freedoms of people participating in scientific research.

The main task of the Animal Experimentation License Committee is to guarantee the testing of animals' health and well-being, the most appropriate ways of taking care of them, their

accommodation and the provision of a minimal necessary freedom of movement.

Activities relating to ethics in the field of biomedical research started in Estonia in 1990, when the Ethics Committee for Human Research was established at the University of Tartu with its Rector's direction. The committee consisted of 11 members – representatives from the fields of medical basic research, clinical medicine and society in general. The committee also represented Estonia in international relations in the field of bioethics.

According to an agreement, starting from 1991, ethical expertise has been carried out for all research projects financed by the Estonian Science Foundation, the Ministry of Education and Research and the Ministry of Social Affairs. No research project is discussed unless it has been confirmed by the ethics committee. Another ethics committee of human research was established in Tallinn, in the Institute of Experimental and Clinical Medicine. In 2003, the Institute was re-organised and attached to the Institute of Health Promotion and the committee is now called the Tallinn Ethics Committee of Medical Research.

In 1994, an independent ethics committee for animal experimentation was created at Tartu University consisting of 5 members and assessing in advance, all research projects which planned to carry out animal experiments in Estonia. This committee operated until the new requirement of the Animal Protection Act entered into force on Jan 1, 2002, according to which the state license committee was created in the Ministry of Agriculture

for the inspection of carrying out animal experimentation.

In 1988, the Tartu University ethics committee was re-organised into the Tartu University Ethics Committee of Human Research. The Tartu University human research ethics committee has been multifunctional from the very beginning. In addition to giving expertise concerning research projects, the committee also organised the teaching of bioethics in the Faculty of Medicine from 1991 to 1998 to PhD students and later also to students at BA level. Since 1991, the subject of *Bioethics* has also become a compulsory part of the PhD students' curriculum and it gives 3 credit points according to ECTS.

In 1997, two clinical ethics committees were created – one at the Tartu University Clinics and the other at the Tallinn Children's Hospital. These committees are concerned mainly with clinical issues not with the expertise of scientific research.

The Ethics Committee of the Estonian Medical Association was created in 1995. Consisting of 4 members, the committee handles mainly medical ethical issues according to the Estonian Medical Code of Ethics (1995, 2000).

In 1998, the Estonian Bioethics Council consisting of 11 members was established in the Ministry of Social Affairs functioning as the state committee. Its functions are: 1) forming a unitary attitude concerning bioethical issues in the fields of medicine; 2) introducing principles of bioethics to the society and organising publication of such data; 3) coordinating the work of the Estonian ethics committees of human research and bioethics

committees; 4) making proposals in the process of drafting legislation concerning the field of bioethics; 5) counselling the parliament and the executive power on bioethical issues. The committee members are representatives of medical basic research and more significant fields of clinical medicine. Also one lawyer, one member of the parliament and a representative of the Ministry of Social Affairs are participating in the committee's work. The members' term of office expires in 3 years. The main task of the Bioethics Council is to disseminate knowledge concerning bioethical issues via contemporary media means, to organise meetings and conferences. The Council also develops international cooperation, mainly through the Council of Europe, the European Commission and the Bioethics Committees of the Nordic countries.

In 2000, the Estonian Genome Project Foundation (www.geenivaramu.ee) was established for carrying out a broad population based genetic research, which is operating in accordance with the Human Gene Research Act (2000). The law provides the creation of an ethics committee to the Estonian Genome Project Foundation consisting of 7 members. This committee evaluates the processing of the gene bank, including the provisional assessment of research projects originating from the Genome Project. Pursuant to paragraph 29 of the Human Gene Research Act, the committee's opinion is non-binding. The law also provides an opportunity for premature removal of a member of the committee, if the activities of that member would damage the interests of a responsible processor.

6) Research projects that should be approved by ethics committees or any other competent institutions

There is no legal document existing that provides a list of research projects that need to be approved by an ethics committee or any other competent institutions. The list of human research projects, which must be evaluated by an ethics committee of human research, is provided for by Articles 15 and 16 of the Convention on Human Rights and Biomedicine and paragraph 13 of the Medicinal Products Act (1995, 2001, 2003). Some specific laws also contain provisions requiring ethical review of research projects, for instance the Human Gene Research Act (2000).

7) Duties and rights of ethics committees of human research, their connection with legislation

After ratifying the Convention on Human Rights and Biomedicine (1997) on December 12th, 2001, the document became part of Estonian legislation and is also the only legally binding document putting the requirement for ethics committees' expertise of biomedical human research forward as a general principle.

Activities of human research ethics committees in the field of medicinal products research are regulated by the Medicinal Products Act (1995), which provides that a clinical trial of a medicinal product shall not start without the approval of the regional medical ethics committee for clinical trials. The rules of procedure of such a committee are established by regulations of the Minister of Social

Affairs. These are: the Procedure for Conducting Clinical Trials of Medicinal Products (1996); the Rules of Procedure of Clinical Trials' Medical Ethics Committees (1996); the Requirements for Membership of the Medical Ethics Committee for Clinical Trials, for Committee's Rule of Procedure, for Rate of the Fee for Evaluation of Clinical Trials and for the List of Information To Be Submitted in Order to Obtain Approval (2001) and the Procedure for

Conducting Clinical Trials of Medicinal Products (2001). According to these documents, the planning, conduct and use of the results of medicinal products' research must be in accordance with the Helsinki Declaration and other internationally recognised bioethics documents as well as with the quality requirements of Guidelines of Good Clinical Practice (1995).

3. Research involving humans

As mentioned earlier, a specific act regulating scientific human research in Estonia does not exist. The draft of the Patient Act was submitted to the Parliament in 2002, but the second reading was interrupted on November 19, 2002. After the election of the new *Riigikogu* (in March 2003) the draft act was removed from the agenda and has not been re-submitted yet.

1) Regulations regarding informed consent

The Constitution of Estonia provides in paragraph 18: "Nobody can be subordinated to medical scientific experiments without his or her free consent".

The Law of Obligations Act paragraph 766 provides the requirements for informing patients and the duty for the provider of health care services to

obtain their consent. A patient may be examined and health care services may be provided to him/her only with his/her consent. A patient may withdraw his/her consent within a reasonable period of time after granting consent.

For participation in biomedical research in general, the regulations of the 5th chapter of the Convention on Human Rights and Biomedicine (1997) are applicable in Estonia.

The Medicinal Products Act (1995, 2001, 2003) provides the requirements for research participant's informed voluntary written consent. Before asking for the consent for participating in a medicinal product trial, the researcher must explain to the participant 1) the aim, content and implementation means of the particular clinical trial; 2) the expected benefits and possible risks that may follow the trial;

3) the person's right to refuse from participating and to discontinue participation at any point of time of the trial, and; 4) to give the participant exhaustive information about the means of compensating costs and possible injuries caused by the trial.

The participants must be given this information, in written form, as well as the names and contact addresses of the persons who conduct the clinical trials of medicinal products, and from whom they can obtain additional information. The person responsible for the trial certifies the validity of the given information with his/her signature.

Withdrawal of consent is legal.

Pursuant to the Transplantation of Organs and Tissues Act (2002), an informed consent is necessary for removing organs and tissues from a donor. The act also defines when a person with restricted active legal capacity can be a donor as well.

Pursuant to paragraph 12 of the Human Genes Research Act (2000), in order to become a gene donor of the Estonian Genome Project, an informed consent of the person is necessary. The donor has to consider himself/herself informed that 1) the Estonian Genome Project allows scientific and applied gene and health research for finding genes that influence the occurrence of diseases; 2) granting consent is voluntary; 3) the gene donor is not entitled to request a fee for participating in clinical trials and he/she is informed that his/her tissue samples may have certain commercial value; 4) the Estonian Genome Project may receive information about his/her state of health from other data banks; 5) he/she has the right to be kept informed about his/her personal gene information;

6) he/she has the right for genetic counselling in accessing his/her personal data in the gene bank; 7) he/she has the right to give consent allowing the doctor to access his/her personal decoded data in Estonian Genome Project; 8) the Estonian Genome Project may emit tissue samples, DNA and description of the state of health only in coded form; 9) he/she has the right to apply, at any time, for the destruction of data, which enables decoding his/her personal information; 10) he/she has the right to withdraw the consent until the tissue samples and description of the state of health are encoded. The format of the written consent to be given in order to become a gene donor and the procedure for completion and preservation thereof are defined by the regulation of the Minister of Social Affairs (2001).

The Estonian Penal Code (revised in 2000) provides that conducting medical or scientific research on a person who has not granted his/her valid consent is punishable by a fine, detention or up to one-year imprisonment.

2) When the consent is not sufficient and when it is not necessary

This question is regulated by the Convention on Human Rights and Biomedicine (1997). The same principal ideas are fixed also in paragraph 13 of the Medicinal Products Act (1995). The consent of a person participating in trials is not required in case of data for public use or in case of anonymous research projects, where the person cannot be identified. Consent is also not required in cases provided by the Communicable Diseases Prevention and Control Act paragraph 4.

▪ **Active legal capacity of children**

Pursuant to the General Part of the Civil Code Act (2000), persons who have attained 18 years of age (adults) have full active legal capacity. Persons who are under 18 years of age (minors) and persons who due to mental illness, mental disability or other mental disorder are permanently unable to understand or direct their actions have restricted active legal capacity. A multilateral transaction entered into by a person with restricted active legal capacity without the prior consent of his/her legal representative is void, unless the legal representative subsequently ratifies the transaction. If the person acquires full active legal capacity after entry into the transaction, he/she may ratify the transaction himself/herself.

Although for a person with restricted active legal capacity to participate in a medicinal trial consent must given by his/her legal representative, a person from 7 to 18 years must in addition give his/her own consent too.

Guardianship and patronage of a child is legally based on the Family Law Act (1994, 1996). Pursuant to the Child Protection Act (1992, 1996, 1998), in assisting a child in the form of guardianship or curatorship, social services departments of the local governments are the authorities for guardianship and curatorship.

▪ **Other persons unable to consent**

Paragraph 13, subsection 8 of the Mental Health Act (1997, 2002) provides that persons in involuntary treatment shall not be subjected to clinical trials,

testing of new medicinal products or treatment methods.

Pursuant to the Human Genes Research Act (2000), in case of a potential donor with restricted active legal capacity, the authorised processor must identify personal features of the incapable person and his/her legal representative on ground of their passport and the documents given by the court or by the Social Department of the local municipal self-government. The Chief processor has to be certain that the person with restricted active legal capacity is not opposed to providing a tissue sample or to the collection of descriptions of his/her state of health.

3) Specific legal requirements for conducting research with pregnant women and nursing mothers

Pregnant women and nursing mothers may be involved in biomedical research only if it is highly probable, that the clinical trial will directly benefit the health of the involved pregnant woman, nursing mother, embryo or new-born child or a breast-fed child or results of the clinical trial benefit persons belonging to a similar group of people, including embryos, new-born children and breast-fed children and therefore involving a pregnant woman or a nursing mother in the clinical trial is necessary.

4. Research involving human biological material (blood, organs, tissues, cells, DNA)

The Additional Protocol on Transplantation of Human Organs and Tissues (2002) of the Convention on Human Rights and Biomedicine was ratified by the Estonian Parliament on June 7, 2003.

The second reading of the Blood Act was cancelled in the parliament. The Blood Establishment Development Programme (1995) provides technical and ethical guidelines, including the clause that a blood donor has no right to determine for what purposes his/her blood will be used. This provision contradicts the Human Gene Research Act at the moment.

Pursuant to the Human Genes Research Act (2000), the Gene Bank may be used only for scientific research, research and treatment of illnesses of gene donors, public health research and statistical purposes. Using the Gene Bank for other purposes is prohibited. Blood of a gene donor cannot be used as a tissue sample in genetic research without a written informed consent of the gene donor.

1) Laws regarding use of biological material from live patients

Relevant regulations exist in a number of acts and conventions, e.g. Additional Protocol to the Convention on Human Rights and Biomedicine on Transplantation of Organs and Tissues of Human Origin (2002) ratified by the Parliament in June 2003, Transplantation of Organs and Tissues Act (2002) and Penal Code (2002) paragraph 150. Offering reward or seeking financial gain from donation of organs or tissues is prohibited and punishable pursuant to the Transplantation of Organs and Tissues Act paragraph 3 and to the Penal Code.

An organ may be removed from a donor, if: 1) informed consent for transplantation has been obtained from the donor; 2) medical investigations performed on the donor ascertain that the risk to life or health of the donor implied by the removal is not higher than the risk implied by any other surgical operation of the same degree of complexity; 3) the purpose of the removal of the organ is its implantation for therapeutic purposes into the donor's descendant, spouse, cohabitee, parent, grandparent or their descendants; 4) there is no suitable organ available from a deceased person for implantation.

Persons with restricted active legal capacity may be donors of regenerative tissues, if: 1) there is no compatible donor with active legal capacity available; 2) the recipient is the donor's brother or sister; 3) consent of the donor's legal representative and permission of the administrative court judge for transplantation has been obtained; 4) the potential donor concerned does not object to the transplantation.

Donation of organs or tissues, if the donor or his/her legal representative has derived financial gain from it, is punishable by a fine of up to 300 fine units (paragraph 17).

2) Laws regarding use of biological material from deceased persons

There is no specific act regulating these issues. Provisions can be found in several legal documents, e.g. Additional Protocol on Transplantation of Organs and Tissues of Human Origin (2002), Penal Code (2002) paragraph 150. The Transplantation of Organs and Tissues Act (2002) provides that an

organ or tissue may be removed from a deceased person, if: 1) the death of the person has been certified according to the procedure provided for in paragraph 12 of this Act; 2) the deceased person was an Estonian citizen, or if he/she stayed in Estonia with a permanent residence permit; 3) during lifetime, the deceased person had expressed his/her wish to donate organs or tissues for transplantation after his/her death, or if no information is available that the person had objected to it. The person's wish does not have to be in written form. Other persons cannot prohibit the removal of an organ or tissue if the deceased person during his/her lifetime had expressed his/her will to donate organs or tissues after death. Other persons cannot permit the removal of an organ or tissue if the deceased person during his/her lifetime had refused to donate organs or tissues after death. If suitable recipients for organs and tissues removed from deceased persons cannot be found in Estonia, such organs and tissues may be used in the international exchange of organs and tissues. Donation of organs or tissues, if the donor or his/her legal representative has derived financial gain from it, is punishable by a fine of up to 300 fine units. Doctors who treated the deceased person during his/her lifetime or who were members of the committee of doctors who certified his/her death cannot participate in the removal of organs or tissues from the deceased person.

3) Laws regulating keeping and using of existing collections of biological material

There is no special act regulating existing collections of biological data banks. There are some provisions

in different acts, e.g. in Additional Protocol on Transplantation of Organs and Tissues of Human Origin (2002), Organs and Tissues Transplantation Act (2002), Databases Act (1997, 2002), Penal Code (2002) and Human Genes Research Act (2000).

4) Directive 98/44/EC on legal protection of biotechnological inventions clause 26 – requirement for person's consent concerning patents developed from or containing human biological material

This area is regulated by the Patents Act (1994, 2003), the Personal Data Protection Act (2003), and the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (1981). There is no direct provision in Estonian legal acts that states whether consent is necessary. Presuming that in the patent application no data will be given that would subsequently enable someone to identify the data subject and/or tissue subject, it is possible to build up a legally valid argument that the consent of a donor person is not needed in Estonia. Concerning data on tissue samples collected by the Estonian Genome Project Foundation, the Human Genes Research Act provides in paragraph 15 (3) that a gene donor is not entitled to request a fee for providing a tissue sample, preparation and study of a description of his/her state of health or genealogy, or for use of the research results. The donor certifies his/her awareness of the fact with his/her signature on the informed consent formula.

5. Research involving human embryos and embryonic stem cells

1) Definition of embryo in acts

The Artificial Insemination and Embryo Protection Act (1997, 2003) does not provide a biological definition of embryo, but states that an embryo is a foetus in its very early stage of development. Pursuant to the Act's paragraph 3, an embryo exists from the moment of fertilisation of ovum. On the 15th day after fertilisation of ovum, an embryo obtains human dignity.

2) Using human embryos for research

In-vitro fertilisation is allowed only with the intention of implanting the ovum into a woman. Pursuant to the Artificial Insemination and Embryo Protection Act (1997, 2003), an embryo can be preserved or used for implantation until 14 days after fertilisation. Preserving or using embryos after that time is prohibited. This does not concern the keeping of frozen embryos. Embryos that are not used for a parental project due to earlier success of fertilisation or due to a child's or mother's health as well as in case of too many embryos can be used for scientific research. According to amendments made to the Artificial Insemination and Embryo Protection Act in 2003, frozen embryos can be preserved for 7 years (instead of 5 in the previous version of the act) in an institution, which has the license issued by the Minister of Social Affairs for storage and research on embryos. If during this period the embryo was not used for implantation for reasons concerning the success of fertilisation or child's or mother's health, it can be used for scientific research. Also if there are too many embryos, those can be used for scientific research, as a woman has the right to give up

embryos prior to the artificial insemination and it is allowed to implant up to 3 embryos in the course of one implantation. Persons, from whom germ cells originate, have to give consent for using the embryo in scientific research. Consent of an anonymous sperm donor is not necessary.

3) Illegal procedures with embryos

Commercial transactions with embryos are prohibited.

Implantation of an embryo, which has been previously used for research, into a woman is prohibited. Provided by the Additional Protocol to the Convention on Human Rights and Biomedicine on Prohibition Human Cloning (1998) and the Artificial Insemination and Embryo Protection Act (1997), it is prohibited to create an embryo by replacing the fertilised ovum nucleus with any somatic cell from another embryo or foetus or living or deceased person or with similar genetic information taken from the same embryo, foetus or a living or deceased person. It is prohibited to compound embryos with different genetic information into a cell fusion if at least one of them is a human embryo, or to fuse with a human embryo a cell that is carrying genetic information that is different from the genetic information of the embryo. Creating an embryo by fertilising human ovum with animal sperm or animal ovum with human sperm is prohibited.

4) What are sources of embryonic stem cells

There is no experience of research with embryonic stem cells in Estonia and also no specific legal regulations for the use of human embryonic stem cells in scientific research.

5) Regulations regarding human reproductive cloning

Reproductive cloning is prohibited. The regulation is provided by the Penal Code (2002) and the Additional Protocol of the Convention of Human Rights and Biomedicine Prohibiting of Human Cloning (1998) ratified by the Estonian Parliament.

6. Personal data

1) How is personal data defined

The Personal Data Protection Act (2003) determines which data are interpreted as personal data and how they must be protected. Personal data are information relating to an identified natural person or a natural person identifiable by reference to the person's physical, mental, physiological, economic, cultural or social characteristics, relations and associations. Sensitive personal data are: 1) data revealing political opinions or religious or philosophical beliefs, except for data related to being a member of a legal person in private law registered pursuant to the procedure provided by law, e.g. membership in a political party; 2) data revealing ethnic or racial origin; 3) data relating to the state of health or disability, genetic information, sexual life; 4) information collected in criminal proceedings before a public court session.

2) Using personal data

The Personal Data Protection Act defines also the chief processor of data, the authorised processor of data and conditions for third persons, regulated their work with public and sensitive data and determines the procedural, organisational and technical conditions for personal data protection. An authorised processor is a natural or legal person, or a state or local government agency, which processes personal data at the request of a chief processor. The chief processor is a natural or legal person, or a state or local government agency who processes personal data or at whose request personal data are processed. The chief processor may be appointed by an act or regulation and unless it is provided otherwise, determines: 1) the purposes of processing personal data; 2) the categories of personal data to be processed; 3) the

procedure for and manner of processing personal data; 4) the permission for transmission of personal data to third persons. The Human Genes Research Act (2000) specifies that an authorised processor of the Estonian Genome Project is a natural or legal person or an Estonian state agency or local government agency who may receive all processing rights, except the right to code and decode, from the chief processor on the basis of a contract.

The Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (1981) is ratified by the Estonian Parliament (2000).

Consent for the processing of personal data must be given freely with a specific and informed indication of agreement that personal data relating to him/her may be processed after he/she is being notified of the following: 1) the purpose of and legal basis for the processing the personal data; 2) the content and source of the personal data; 3) third persons or categories thereof to whom transfer of personal data is permitted; 4) the list of personal data for public use; 5) the name of the chief processor or a representative thereof and the address of the place of business of the chief processor.

For the processing of personal data, a chief processor signs the contract with an authorised processor by which both are bound to observe the provisions that are determined in the Personal Data Protection Act (2003) as well as other acts and regulations.

Transfer of personal data from an authorised processor to third persons is not allowed, except where the chief processor has given his/her written approval or if the transfer of personal data is provided by obligations prescribed by law. There are several limiting conditions for the documentation of the processing personal data in the Personal Data Protection Act. If an authorised processor applies for an activity license in a field involving the processing of sensitive personal data, the institution issuing such license has to obtain a registration document of sensitive personal data processing from the Data Protection Inspectorate first.

Upon the request of a person, the chief processor must inform him/her about following: 1) the presence or absence of any data concerning that person; 2) the aim and legal ground of the processing; 3) the content and sources of personal data; 4) third persons or categories thereof to whom transfer of the personal data is permitted; 5) the name of the chief processor or a representative thereof and the address of the place of business of the chief processor. A person has the right to receive his/her personal data from the chief processor.

3) Using data rendered anonymous

Anonymous data, i.e. data not concerning identifiable person, are not considered personal data and the processing of such data is not limited by the Personal Data Protection Act, as it does not apply.

4) Personal Data Protection Act and scientific research

Pursuant to paragraph 11 of the Personal Data Protection Act (2003), personal data may be processed only with the permission of the data subject and if the processing does not contradict legal acts. Exceptional processing of personal data without the consent of the data subject is permitted if the personal data are processed: 1) for fulfilling obligations provided by the law; 2) for the protection of life, health or freedom of the data subject or another person; 3) for the performance of an obligation of the chief processor or third person, to whom data are delivered, towards society as prescribed by law.

According to Art. 8 of the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, all Member states must prohibit the processing of personal data, which reveals information about the state of health. The aforementioned does not apply in cases of preventive medicine, medical diagnoses, organising cure and treatment or for purposes of health services and in cases data are being processed by professionals of health care field or other people, who provided by legal acts or regulations are tied with the duty of confidentiality.

The difference between the Estonian law and EU Directive 95/46/EC Art. 8 is that under Estonian law the purposes of using data and requirements for asking consent have been very strictly formulated.

7. Genetic information

1) Regulation of genetic information

The area of genetic information is specifically regulated by the Human Genes Research Act (2000), which is available also in English on the web page of the Estonian Genome Project Foundation (www.geenivaramu.ee). The aim of the act is to provide specific terminology of human genetic research and determine the rights of gene donors. The following are provided in this act: 1) the conditions for the processing of tissue samples,

descriptions of DNA, descriptions of state of health and genealogies in the Gene Bank; 2) the rights and obligations of gene donors, chief processor and authorised processors of the Gene Bank and genetic researchers relating to tissue samples, descriptions of DNA, descriptions of state of health and genealogies; 3) conditions for the establishment and maintenance of the Gene Bank; 4) restrictions on the use of tissue samples, descriptions of DNA, descriptions of state of health and genealogies collected in the Gene Bank; 5) conditions for genetic

research relating to the Gene Bank and the organisation of supervision thereof.

Informed Consent Form for a Gene Donor, its Filling and Depositing Procedure (2001) and Conditions for Deposition of Coded Tissue Samples, DNA Descriptions and Descriptions of State of Health (2001) are validated with the regulations of the

Minister of Social Affairs. It is important to understand that the Human Genes Research Act (2000) does not regulate gene research outside the Estonian Genome Project Foundation and in such cases other provisions and relevant documents have to be relied upon, e.g. The Convention on Human Rights and Biomedicine chapter 4 concerning human genome.

8. Research involving animals

1) Structure, Role and Scope of Animal Experimentation Ethics Committee

The first Animal Experimentation Ethics Committee in Estonia was established in 1995 by the Rector of the University of Tartu consisting of five members: two medical doctors, one veterinarian, one representative of sport physiology and one biologist, i.e. representatives of the faculties carrying out most experimental studies on animals. Later on, a similar committee was also founded at the Estonian Agricultural University in Tartu.

Following a general agreement between the financing institutions (Estonian Science Foundation, Ministry of Education and Research and Ministry of Social Affairs) the financing of projects is only possible with positive approval from a Committee. Research projects had to meet the requirements described in the European Convention on the Protection of Vertebrate Animals Used for

Experimental and Other Scientific Purposes (1984) and in the Animal Protection Act (2001, 2002), which provides also the list and description of actions that are not permitted with animals.

The Animal Experimentation Ethics Committees collaborate effectively with the respective organisations in the other Baltic and Nordic Countries. The establishment of these Committees has significantly improved activities in the field of animal experiments. Since 2000, the Animal Protection Act (2001, 2002) provides guidelines for a specific license committee. The Governmental Regulation No 187 July 2003 instituted the legal basis for the statute, structure, goals and rules of procedure of the Animal Experimentation License Committee in the Ministry of Agriculture consisting of 8 members and also new application formulas. The Animal Experimentation License Committee provided by this regulation has not convened yet; the acting Animal Experimentation Ethics

Committees continue working without legal grounds. Paragraph 67 of the Animal Protection Act also refers to the liability of natural and legal persons for violating legal regulations.

2) Application of the “3Rs” (reduction, refinement and replacement)

There is no specific regulation in Estonia concerning these principles. General guidelines are provided by the European Convention on the Protection of Vertebrate Animals for Experimental and Other Scientific Purposes (1984) and by the EC Directive 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 (86/609/EEC). These documents are ratified by the Estonian Parliament.

3) Rules for keeping and using test animals

This field is regulated by the Animal Protection Act (2001). Animals, which are subject to experiments, should be born and bred in a farm or a similar institution that has the license for breeding animals with the aim to produce subjects for experiments. The right for supervision of such institutions is given to the Veterinary and Food Board of the Ministry of Agriculture. All test animals (except apes) who are possible subjects of experiments, have to be branded before weaning in a way causing minimum pain. Regarding the use of animals of endangered species in experiments, according to the Animal Protection Act such activity is legal if the experiment will be performed in full accordance with the Act on Protected Natural Objects (1994, 2001).

The Animal Protection Act (2001) provides that the Government of Estonia must determine the requirements, which must be followed by a person who is applying for the permit of breeding animals as subjects of experiments. The details of this provision are given in the Government Regulation No. 187 from July 1, 2003. Persons or institutions performing experiments on animals are obliged to record all their activities either in written or electronic form. Recordings must include data about the number of test animals, the nature of those experiments, information about the conductors of the experiments and explain what has happened to test animals after the experiment was completed. The conductor of animal experimentation is obliged to store the record and protocol for three years after completion of the experiment.

Pursuant to the Animal Protection Act, animals should be kept in suitable conditions. They must be provided with adequate space, microclimate, feed, drinking water, care and or structure, which satisfy the need for movement characteristic to the given species. The Animal Protection Act provides a number of subsequent executive regulations, but many of those have not been issued yet.

The Animal Protection Act does not prohibit the use of specific species of animals in scientific experiments. The Government Regulation No.187 (2003) specifies that apes can be used for experiments only in very exceptional and well-reasoned cases. Paragraph 37 of the Animal Protection Act prohibits animal experiments for the purposes of development of weapons and ammunition, development of the production of tobacco products, detergents and cosmetic products.

4) Using genetically modified animals

The Animal Protection Act determines that a genetically modified animal is every organism, whose gene factors have been modified in a manner which would be impossible under natural conditions and which are listed in the Deliberate Release of Genetically Modified Organisms into the Environment Act (1999).

The scientific researcher, who intends to use transgenic animals for experiments, must also submit a risk analysis when applying for the permit to conduct such research. The animal experimentation risk analysis must, pursuant to the Government Regulation No.187 from July 1, 2003, contain an analysis of any possible dangers and their results, in conducting experiments with genetically modified animals and an action plan to minimise this risk.

The responsible researcher must immediately inform the Animal Experimentation License Committee of the following circumstances: 1) accidents; 2) information concerning the hazards of the premises to be used for the experiment or the animals involved in the experiment which have become evident during application processing period or later; 3) intention to use genetically modified animals in a manner different than applied for. In the latter case, a new application for the permit must be submitted and new risk analysis carried out.

The authority, which grants permits, must publish a notice concerning the grant of each permit for the conduct of animal experiments involving genetically modified animals, in the official publication *Ametlikud Teadaanded* (www.ametlikudteadaanded.ee).

5) Precautionary measures

Before commencing experiments with genetically modified animals, the chief researcher must prepare a plan of extraordinary measures for the protection of people and environment in case of accident. This plan must be submitted to the local rescue service. The researcher must inform in an appropriate manner all potentially endangered persons of the safety measures to be applied and of correct actions to be taken in case of accident. This information must be updated at appropriate intervals and made available to the public.

Pursuant to paragraph 57 of the Animal Protection Act, an accident is a large-scale and unintentional escape of genetically modified animals in the course of an animal experiment, which may present a danger to human health or the environment. In the case of an accident, the person conducting the animal experiment shall immediately inform the Animal Experimentation Licence Committee thereof and submit the following information: 1) details of the accident; 2) identification and number of genetically modified animals involved in the accident; 3) any other information which would help to determine the effect of the accident to human health or the environment; 4) applied measures. The authority, which grants the permits, must record all accidents. Information concerning an accident shall be preserved together with the materials related to the corresponding application for conduct of an animal experiment for a period of three years. The researcher is obliged to remove genetically modified animals from the environment. If an institution performing animal experiments will not do this, then the supervising institution must.

In accordance with paragraph 23 of the Genetically Modified Organisms into the Environment Act, an applicant for the permit has the right to make a reasoned proposal in the application for handling the information as confidential.

The Gene Technology Commission decides which data has to remain confidential and informs the applicant and the Minister of Environment of the decision. The Commission must not treat the following data as confidential: 1) description of the genetically modified organism; 2) information concerning applicant name and location and the purpose and time of transferring this organism into the environment; 3) information concerning observing methods of the GMOs and plans and actions in a case of accident; 4) presumable impact.

6) Laws on safety regulations of workplace and labs

This is regulated by the Occupational Health and Safety Act (1999, 2003). This Act provides the occupational health and safety requirements for work, the duties of employers and workers in creating and ensuring a working environment which is safe for health, the organisation of occupational health and safety in enterprises and at state level, the procedure for conduct of challenge proceedings, and liability for violation of the occupational health and safety requirements.

Conclusion

In the current overview the following acts regulating the ethical aspects of scientific research have been presented: the Human Genes Research Act, the Transplantation of Organs and Tissues Act, the Artificial Insemination and Embryo Protection Act, the Medicinal Products Act, the Mental Health Act, the Republic of Estonia Child Protection Act, the Personal Data Protection Act, the Database Act, the Animal Protection Act and the Deliberate Release of Genetically Modified Organisms into the Environment Act.

These acts regulate most areas of the scientific research in Estonia. Additionally, international documents, which have been ratified by the Estonian Parliament, also regulate this field. Hence, necessary basic documents for regulating state-of-the-art biomedical scientific research are in force in Estonia. All legislation passed during recent years is in full compliance with the European Union's documents and this process continues. At this stage, the most important tasks for the moment are to continue the legislative proceeding of the Patient Act and regulate the use of stem cells in scientific research.

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