EUROPEAN COMMISSION

Community research

KI-56-03-861-B3-C

National Regulations on Ethics and Research in Latvia

Latvija

SCIENCE AND SOCIETY

Interested in European research?

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

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

EUROPEAN COMMISSION

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

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

National Regulations on Ethics and Research in

Latvia

Latvija

by
Oskars Rozenkopfs and Laima Rudze

European Commission contacts:
Barbara Rhode, An Baeyens and David Coles
Brussels, 2003

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

New freephone number:
00 800 6 7 8 9 10 11

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

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

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

Luxembourg: Office for Official Publications of the European Communities, 2003

ISBN 92-894-6695-2

Printed in Belgium

Foreword

"*The basic goal of science is to understand the world and to discover new truths of phenomena and processes. The process of scientific knowledge should be based on ethical principles of both research and discussion ….*". These words from the preamble of the Scientist's Code of Ethics accepted in 1997 by the Latvian Academy of Science and the Latvian Council of Science are today as important as ever.

The tremendous progress in genome research, advances in medical technology, the use of human stem cells, the rapidly developing area of gene therapy and recent developments in gene transfer technology and therapeutic cloning have raised a lot of ethical issues and dilemmas that have as yet been insufficiently studied and pose challenges for our understanding of fundamental human values. The possibilities for copying and using a particular human genome via reproductive cloning technology have created unprecedented issues concerning human dignity and rights.

For the promotion of ethical principles and standards to guide scientific progress as well as defining the ethical, safety and regulatory issues related to clinical implementation of new gene technologies, relevant national legislation has been developed. At present, six ethics committees have been set up in Latvia in order to review biomedical research projects, clinical trials of drugs, pharmaceutical products and biomaterials, and the use of laboratory animals in biomedical studies.

The current publication provides general information on the national regulations regarding biomedical and genome research as well as on international conventions signed by Latvia and gives an overview on the tasks and range of activities of the ethics committees established in Latvia.

Kārlis Šadurskis
Minister of Education and Science

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

(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).

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 Latvian text has been written by Dr. Laima Rudze and Mr. Oskars Rozenkopfs and subsequently approved by the Ministry of Education and Science of Latvia. The Commission has been promoting this project and is now dedicating a 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 authors and the Ministry of Education and Science of Latvia.

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

Table of contents

1. International instruments in Latvian law

There is full recognition by Latvia of the importance of data protection in connection with its accession to the Schengen Convention and its cooperation with Europol. National data protection legislation, transposing Directive 95/46/EC on the protection of individuals with regard to the processing of personal data, was adopted on 23 March 2000. The Council of Europe Convention was ratified on 5 April 2001. The State Data Inspection - the implementation institutions - was established on 1 January 2001.

At present, there is an ongoing discussion with the Commission regarding the Inspection, in particular whether institutional subordination to the Ministry of Justice complies with the independence criteria envisaged by the Directive.

Setting the time frame for the process of adoption and implementation of the European Union's "acquis communautaire", the Latvian government adopted on 1 January 2003 as the date when Latvia will be prepared for accession to the European Union.

2. National overview

1) Overview of the national legal structure

Latvia is a democratic, parliamentary republic. Its legislative power is in the hands of a single chamber parliament - the Saeima, consisting of 100 deputies. Parliamentary elections take place every four years. The country's head of state is the President, who is elected by the Saeima for a period of 4 years. The President signs laws, appoints the Prime Minister (who heads the government) and performs representative functions. The Ministry of Justice is the central executive institution, through which the Cabinet of Ministers implements the tasks and functions prescribed by the Satversme (Constitution) and laws. The Ministry of Justice develops and implements the State policy in the field of justice. In accordance with the aforementioned by-laws, the Ministry of Justice has the following functions:

- to formulate drafts of laws and other normative acts, co-ordinating them with European Union norms and international agreements binding on Latvia;
- to evaluate the compliance of normative acts with the European Union norms and international agreements binding on Latvia and to prepare relevant proposals regarding their improvement;
- to ensure; in accordance with its competence; the implementation of international agreements binding on Latvia;
- to validate legal documents.

2) Ethics Committees

The following ethics committees review biomedical research in Latvia:

- Central Medical Ethics Committee of Latvia
- Independent Ethics Committees for Investigation of Drugs and Pharmaceutical Products
- Ethics Committee of the Latvian Institute of Cardiology for Clinical and Physiological Research, and Drug and Pharmaceutical Product Clinical Investigation
- Ethics Committee of Medical Academy of Latvia
- Ethics Committee on Laboratory Animal Use in Biomedical Research

Central Medical Ethics Committee of Latvia

The central ethics committee of Latvia was set-up by the Cabinet of Ministers of the Republic of Latvia on 25.03.1998. The legal basis of the committee is a Rule of the cabinet of ministers of Latvia. The committee consists of 14 members and is composed of doctors, nurses, scientists, pharmaceutics, lawyers, a representative of religion, a representative of disabled persons and a representative of retired persons. The statute of the ethics committee governs the recruitment of its members. The elected candidates are appointed by the cabinet of ministers on the basis of proposals from the Ministry of Welfare.

The committee is a standing body. It is independent and once established serves for 4 years with the possibility of renewal for a further 4 years. Referral of matters to the Committee must be done in written form.

The committee releases its views as opinions or recommendations in writing. Resolutions are adopted by majority vote. Minority or divergent opinions must be reflected in the protocol. Debates within the Committee are open to the public. Also, the Committee organises events open to the general public. Moreover, the Committee makes its recommendations public on TV, Radio and through newspapers. The main area of its activities lies in the field of biomedical research.

The main topics on which the Committee has given its views are the following: evaluation of research projects, evaluation of medical devices, recommendation to refine experimental techniques.

The Committee is convened by its chairman once a month or more frequently if needed. The cabinet of ministers approves the chairman. Members of the committee elect the vice-chairman. The vice-chairman exercises the authority of the chairman in his/her absence. The chairman presents cases verbally. The committee is legally competent when the chairman or vice-chairman and more than half of the members are present.

During the evalution of a project the committee may obtain additional information from the investigator or summon the investigator to a meeting of the committee. Each decision regarding a protocol is voted with a simple majority. In case of parity of votes, the chairman's vote is decisive. A member shall inform the committee of any possible conflict of interest. A member cannot participate in the review of a project that concerns his/her personal or

commercial interest. The committee decides whether a member has a conflict of interest. In that case the member is excluded from participation in the review of the protocol concerned.

The committee shall obtain a consultant statement in cases where it lacks the necessary professional expertise. The decisions of the committee shall be given within 4 weeks in writing. The secretary of the committee registers the cases received and takes minutes of the committees meetings.

The tasks of the committee are to ensure that:
- the risks connected with the implementation of a project have been properly assessed;
- patients or healthy volunteers, participating in the project will be informed in writing about its content, foreseeable risks and advantages, and that their free and explicit consent will be obtained and given in writing;
- where patients are not able to consent, information will be given to, and consent obtained from, the closest relatives, or guardian;
- the information leaflets should clearly mention that patients and healthy volunteers or relatives, guardian or donor can withdraw their consent at any time.

The committee follows up individual projects and requires the final scientific report or publication to be submitted to them.

According to the Law of Pharmacy (approved on 10.04.1997, into force as of 05.08.1997 and amended on 19.03.1998, 17.12.1998 and 01.06.2000), committees of clinical trials of drugs and pharmaceutical products are set up by the cabinet of ministers of the Republic of Latvia.

The Minister for Welfare shall, within the scope of his/her competence:
- approve the by-law model for ethics committees reviewing clinical studies involving medicinal products and co-ordinate the membership of such committees;
- determine the requirements for good manufacturing practice, good distribution practice, good clinical practice of drugs, for the supervision of side-effects caused by the use of drugs, as well as the procedures for co-ordination of the advertising of drugs;
- determine the auxiliary substances to be indicated on the labelling, as well as the instructions for use of drugs and the legibility requirements with regard to the labelling and instructions for use of drugs.

The Minister of Welfare confirms the master statutes of ethics committees for Clinical Trials of Drugs and coordinates the personnel of the above-mentioned committees. The master statutes of ethics committees (enacted by the Minister of Welfare on 6 August 1998) and the Pharmaceutical Law established independent ethics committees to give an ethical assessment prior to the start of a clinical trial. Ethics committees must include both medical persons and non-medical laypersons.

The ethics committee on clinical trials of drugs consists of 14 members (physicians, pharmacologist, journalist, lawyer and computer specialist).

The ethics committee on clinical trials of drugs of the Latvian Institute of Cardiology consists of 9 members (6 physicians, biologist, biochemist and laboratory assistant).

The independent ethics committee for the investigation of drugs and pharmaceutical products consists of 12 members (physicians, economists, pharmacologists, lawyers, psychologist, expert from drug agency, laypersons).

A clinical trial of drugs and pharmaceutical products may start only after a written approval from the independent ethics committee for clinical trials and drugs and a written permission from the State Agency of Medicines have been obtained. Applications for approval can be submitted to the State Agency of Medicines and the independent ethics committee for clinical trials of drugs in parallel.

3. Research involving persons

1) Clinical trials of drugs and pharmaceutical products

Research involving persons is governed by the regulation on clinical trials of drugs and pharmaceutical products (Nr 312, 12.09.2000- cabinet of ministers).

A clinical trial can be initiated only where the anticipated benefits from the clinical trial justify the risks to the healthy person or patient who voluntary participates in the clinical trial (hereinafter referred to as "trial subject") either receiving the investigational product or participating in the control group and receiving a comparator product (product with a known effect or pharmaceutical form without an active substance used for the clinical trial data control).

The medical care given to, and all medical decisions made on behalf of subjects, shall be the responsibility of an appropriately qualified health care practitioner with a certificate entitling the practitioner to provide without any assistance medical care in the specific field of the clinical trial (hereinafter: "investigator"). The investigators are selected by the sponsor taking into account his/her qualification and experience. The sponsor must ensure further training for the investigator, if required.

Prior to the initiation of the clinical study, the investigator shall inform the trial subject in writing of the trial objectives, methods to be used, anticipated benefits and risks, trial duration, compensation for participating in the clinical trial, if any, as well as of the compensation foreseen in the event of a trial-related injury. Written information and other materials to be provided to the trial subject shall be in a language of which he/she has a good command off.

Written information for the trial subject must clearly mention that the trial subject may withdraw from the trial, at any time, without mentioning motives, and that withdrawal from the trial will not affect further medical care negatively.

When deciding about participation of a child in a clinical trial, the child's own desire shall be taken into account if the child has reached seven years of age.

Inclusion of unconscious persons or persons without legal capacity in a clinical trial is possible only if the investigator is justified in believing that participation benefits the respective person and in as far as the medicinal product's clinical trial ethics committee (hereinafter: "ethics committee") gave its approval. In the event the person is unconscious, written consent for participation in the clinical trial shall be obtained from the closest relatives of the person, in the priority order of spouse, parents, children; in case the person is unable and without legal capacity written consent must be obtained from the legal representative (see above).

A clinical study is forbidden in women during pregnancy and lactation, except in cases where clinical investigation is otherwise impossible, on the condition that the risks during the clinical study are proportional to the anticipated benefits to the embryo, foetus or infant.

Trial subjects in need of active disease treatment shall not be included in a control group where the trial subject receives a reference product that does not contain the active substance.

To ensure the protection of the trial subject's identification data, the investigator attributes an identification code to each trial subject, which is used instead of the trial subject's name and surname whenever the sponsor reports to the State Agency of Medicines and Ethics Committee.

To ensure trial subject's rights and protection in the clinical trial, the sponsor is responsible for taking out insurance for the trial subject covering possible injury and damages due to participation in the trial.

The sponsor shall ensure that the supply of the investigational products for the clinical trial are manufactured, packed and labelled in compliance with the respective normative requirements.

In order to obtain a favourable opinion from an ethics committee, the sponsor or the person authorised to act on behalf of the sponsor shall submit the following documents to the ethics committee :

- application for the approval of clinical trial, signed by the sponsor (hereinafter: "application");

- protocol and if any, amendments to the protocol, in Latvian signed by the sponsor and the investigator (for foreign applicants the referred documents shall be submitted in compliance with the requirements stipulated by Language Law);
- trial subject's informed consent form written in Latvian by the sponsor, and also in other languages if required;
- any other written information regarding the specific clinical trial that is to be provided to the trial subjects, in Latvian, and also in other languages if required;
- description of recruitment procedures for trial subjects in Latvian (for foreign applicants, the referred document shall be submitted in compliance with the requirements stipulated by Language Law);
- compilation of data from previous investigational product studies (hereinafter: "Investigator's Brochure") in Latvian, (for foreign applicants, the referred document shall be submitted in compliance with the requirements stipulated by Language Law);
- descriptions of experience and qualification of investigators and other staff involved in the clinical trial (selected and supervised by the investigator at the trial site (hereinafter: "subinvestigator");
- documents regarding any reward or compensation of trial subjects for their participation in the clinical trial, if provided, as well as the insurance conditions and a copy of the policy, or a certificate confirming insurance of trial subjects in case of injury related to their participation in the clinical trial;
- authorisation by the medical institution for performing the clinical trial;
- power of attorney statement issued by the sponsor, if the clinical trial documents are submitted by another person than the sponsor.

The ethics committee shall issue its opinion in writing within 30 days upon receipt of the legally required documents.

If during the examination of the application the ethics committee considers that the submitted documentation is incomplete or additional information on the planned clinical trial is needed, the ethics committee has the right to require additional documents or information. The ethics committee shall provide a written opinion no later than within 30 days after receipt of all required documents.

In order to ensure that the clinical trial is conducted in compliance with the applicable regulations, the activities of every person involved in the clinical trial will be subject to an adequate quality control and surveillance by the State Agency of Medicines.

2) Human genes research

Research on human genes is regulated by the Latvian Human Genes Research Act (approved by Saeima in 03.07. 2002, into force from 01.01.2004).

The 'Gene donor' shall receive:

- information about aims and content of the Genome project;

- information about taking of tissue sample, questionnaire, medical records;
- information about potential informational risks;
- information about the right to withdraw his/her consent, the right to apply for the destruction of tissue samples or data which enables decoding;
- information about the fact that there will be no personal financial benefits for gene donors;
- information about the system of data protection.

Two copies of the written informed consent of the gene donor shall be prepared and signed by the gene donor and the main processor. One copy shall be stored at the State Genome Register; the other copy is given to the gene donor.

The main processor shall give a unique code to each tissue sample, DNA description, health description and genealogy. The code shall be indicated on the written informed consent of the gene donor. The main processor shall appoint specific persons, who perform the coding, and who issue coded tissue samples, DNA descriptions or health descriptions. The State Data Inspection shall approve the method of generating the codes. The main processor shall deliver the written consent together with the code indicated thereon to the State Genome Register, which will be the only body to hold the key for decoding. Thereto, the State Genome Register shall appoint specific persons to perform the decoding and have access to written consents of gene donors.

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

1) Latvian Human Genes Research Act

Objectives:

1. to regulate the creation and functioning of the Genome Database and genetic research connected with the database;
2. to ensure the voluntary nature of gene donation and the confidentiality of the identity of gene donors;
3. to protect gene donors from misuse of their data and from discrimination based on interpretation of their DNA.

The council of ministers authorises the main processor of the Genome Database. The main processor organises the collection of tissue samples, preparation of health descriptions and genealogies,

the coding, storage and destruction of tissue samples and health descriptions and genealogies, and also organises the performance of genetic research through the generation of genetic data, their collection, storage, and destruction.

The main processor must store the coded tissue samples, DNA descriptions and health descriptions within the territory of the Republic of Latvia. The Central Medical Ethics Committee may grant permission for a limited number of tissue samples to be stored abroad if appropriate research methods are not available in Latvia.

Supervision of the collection, coding and decoding, and processing of tissue samples, descriptions of DNA, health descriptions and genealogical data is ensured by the State Data Inspection. The Central Medical Ethics Committee shall supervise the ethical issues during the creation of the Genome Database and the processing of the data according to generally recognised ethical rules and international conventions.

2) Law on Protection of Dead Human Being and use of Human Organs and Tissue

The Law on the Protection of Dead Human Being and use of Human Organs and Tissue was adopted on 15.12.1992, into force since 01.01.1993 and amended on 21.09.1995 and 06.12.2001) and is complemented by the regulations of the cabinet of ministers on Kidney Transplantation. Regulation of Cabinet of Ministers nr 398 on storage and use of human organ and tissues, adopted 15.07.2003, in forse 19.07.2003.

A living person may, under certain conditions, consent to the removal of an organ or tissue for the purpose of implantation into another person; live organ donation primarily concerns kidney transplantation. The transplantation of organs removed from a living donor to a recipient generally takes place between persons having a close personal relationship.

Organs or tissues may be removed from a deceased person and implanted into another person in as far as this person is registered on an official waiting list. Following an agreed procedure the doctors must confirm and certify the death. Only this form of death certification can permit the performance of such transplantation. The retrieval team must ensure that the required procedure has been completed before any retrieval operation is started.

The medical team certifying the death should not be involved in any stage of the transplant process. A person who is undergoing a procedure for his/her own medical benefit may consent to any removed organ or tissue being implanted into another person.

If during their lifetime a person has made known their wishes for giving or denying consent, these wishes should be respected after his/her death. If there is an official facility for recording these wishes and a person has registered consent to donation, such consent should prevail: removal should be performed, if possible. By the same token, it may not proceed if the person is known to have objected. Nonetheless, consultation of an official register of last wishes is valid only in respect of the persons entered in it.

The human body and its parts must not, as such, give rise to financial gain or comparable advantage.

Reproductive organs and tissues (comprising ova, sperm and their precursors) are excluded from the scope of the regulations because organ and tissue transplantation is deemed to have different implications from those of medically assisted procreation and therefore should not be governed by the same rules.

Transplantation of embryonic and foetal organs and tissue, including embryonic stem cells are also excluded from the scope of these regulations.

The person from whom the material is removed is generally called 'donor' and the person into whom the material is implanted is called the recipient. Furthermore tissues such as bone may be processed and the resulting products implanted into more than one recipient. Similarly, cells may be cultured to supply more than one recipient.

The safeguards in the Regulations apply to all possible steps in the transplant process and to all possible recipients.

The competence of a doctor or other health care worker to take part in a transplant procedure is determined by the Act.

Regulations require that organ and tissue implantation is only performed if there is a clear and specific medical indication for the recipient and not for any other reason than for the therapeutic benefit of the recipient. Before a transplant can be performed, the recipient must have a defined medical problem that should be improved by a successful transplantation. The potential benefit of the procedure to the recipient must outweigh any risk. At all times, a decision to transplant must be taken only in the best interests of the patient.

The recipient shall be informed beforehand of the purpose and nature of the implantation, its consequences and risks, as well as of the alternatives. Where the recipient is too ill to be able to give informed consent, in particular in emergency cases, the information shall also be given to the person or body providing the authorisation to the implantation.

3) Regulation of Ministry of Welfare of Latvia on Blood Safety No. 260, September 20, 1995
These regulations cover blood and the products derived from blood for use in transfusion medicine, preparation, use and quality assurance of blood components.

5. Research involving human embryos and embryonic stem cells

There are no regulations, which define embryo in Latvia.

Law on Reproductive and Sexual Health (approved 31.01.2002, in force on 01.07.2002)
Regulation of Ministry of Welfare of Latvia on Human Medical Assisted Reproduction (No173/1999).

According to these regulations, it is prohibited to create human embryos for research purposes or to clone a human being. Regulation of the Ministry of Welfare, is now under preparation that will allow in vitro research on embryos.

6. Personal data

The Council of Europe's Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data and Personal Data Protection Law applies to the processing of all types of personal data. The Personal Data Protection Law implements the Directive 95/46/EC into national legislation.

In accordance with Art. 2 of Personal Data Protection Law, personal data is any information related to an identified or identifiable natural person. In principle, it does not matter who can identify the data subject. Data could be considered and treated as not identifiable and accordingly not as personal data, only if they contain information that cannot reasonably be used by anyone to identify the individuals to whom the data relate.

The Personal Data Protection Law does not give a direct answer to the question about its extension to dead persons. However, in practice it is accepted to consider that in separate cases the Personal Data Protection Law covers proceeding with dead data (for instance, genetic research or operations involving use of health records).

The national legislation contains some exceptions to the data subject's rights in order to protect the public safety or patient's interests in case of medical intervention.

In accordance with the Law On Medical Treatment only medical practitioners shall provide patient information related to his/her health. According to

Art. 41 of this Law, a doctor may provide incomplete information to the patient regarding the diagnosis and prognosis of the disease, if he/she considers that fuller information may cause deterioration in the state of health of the patient.

Law on Medical Treatment

Art. 50.

"(1) Information regarding the medical treatment of a patient, the diagnosis and prognosis of a disease (hereinafter – information regarding a patient), as well as information obtained by medical practitioners during the medical treatment process regarding the private life of a patient and his or her closest relatives, shall be confidential.

(2) Information regarding a patient may be provided to:

- other medical practitioners for the purpose of achieving the objectives of the medical treatment;
- the Medical Commission for Expert-Examination of Health and Working Ability(MCEEHWA); and
- the Quality Control Inspection for Expert-Examination in Medical Care and Ability to Work.

(3) Information regarding a patient shall be provided to a court, the Office of the Prosecutor, the police, the State Centre for the Protection of the Rights of the Child (inspectors), an Orphan's court (a parish court), as well as to investigative institutions only at the written request of such institutions if there is a permission signed by the head of the medical treatment institution.

(4) Information regarding a patient may be used in scientific research if the anonymity of the patient is guaranteed or his/her consent has been received.

(5) State military service administrations of the Ministry of Defence are entitled to request from medical treatment institutions."

Law on Data Protection

Art. 7.

"Personal data processing is permitted only if not prescribed otherwise by law, and at least one of the following conditions exist:

1) the data subject has given his or her consent;
2) the personal data processing results from contractual obligations of the data subject;
3) the data processing is necessary to a system controller for the performance of his or her lawful obligations;
4) the data processing is necessary to protect vitally important interests of the data subject, including life and health;
5) the data processing is necessary in order to ensure that the public interest is complied with, or to fulfil functions of public authority for whose performance the personal data have been transferred to a system controller or transmitted to a third person;
6) the data processing is necessary in order to, complying with the fundamental human rights and freedoms of the data subject, exercise lawful interests of the system controller or of such a third person as the personal data have been disclosed to."

Art. 11.

"The processing of sensitive personal data is prohibited, except in cases where:

1) the data subject has given his or her written consent for the processing of his or her sensitive personal data;

2) special processing of personal data, without requesting the consent of the data subject, is provided for by regulatory enactments which regulate legal relations regarding employment, and such regulatory enactments guarantee the protection of personal data;
3) personal data processing is necessary to protect the life and health of the data subject or another person, and the data subject is not legally or physically able to express his or her consent;
4) personal data processing is necessary to achieve the lawful, non-commercial objectives of public organisations and their associations, if such data processing is only related to the members of these organisations or their associations and the personal data is not transferred to third parties;
5) personal data processing is necessary for the purposes of medical treatment, is carried out by a medical practitioner or a medical treatment institution and an adequate level of protection of personal data is ensured; or
6) the processing concerns such personal data as necessary for the protection of lawful rights and interests of natural or legal persons in court proceedings."

Art. 16.
"A data subject has the right to request that his or her personal data be supplemented or rectified, as well as that their processing be suspended or that the data be destroyed if the personal data is incomplete, outdated, false, unlawfully obtained or are no longer necessary for the purposes for which they were collected. If the data subject is able to substantiate that the personal data included in the personal data processing system is incomplete, outdated, false, unlawfully obtained or no longer necessary for the purposes for which they were collected, the system controller has an obligation to rectify this inaccuracy or violation without delay and notify third parties who have previously received the processed data of such."

Art. 29.
"The protection of personal data shall be carried out by the State Data Inspection which shall be subject to the supervision of the Ministry of Justice. The State Data Inspection shall be managed by a director who shall be appointed and released from his or her position by the Cabinet pursuant to the recommendation of the Minister for Justice."
There are some specific requirements that need to be fulfilled prior to the performance of medical research. In particular, the Human Genome Research Law regulates the usage of codes or identification numbers in genetic research.
In order to ensure the highest standard of data protection, the main processor shall provide each tissue sample, each DNA description, each health description and each genealogy with a unique code immediately upon receipt of these data in the Genome Database. The main processor shall replace all data, which enables the reverse identification of the gene donor, including the name, personal code and residence, with a code. The code shall be indicated on the written informed consent of the gene donor. The main processor must organise the taking of tissue samples, preparation of health descriptions and genealogies, code, store and destroy tissue samples, code, store,

destroy and issue health descriptions and genealogies, perform genetic research, and collect, store, destroy and issue genetic data. The State Data Inspection shall approve the method generating the codes.

7. Genetic information

***L**atvian Human Genes Research Act – (approved by Saeima in 03.07, 2002, into force from 01.01. 2004)*

The Council of Ministers granted the Main Processor of the Genome Database an authorisation.
The main processor organises the taking of tissue samples, the preparation of health descriptions and genealogies, the coding, storage and destruction of tissue samples, the coding, storage, destruction and issuing of health descriptions and genealogies, the performance of genetic research, and collection, storage, destruction and issuing of genetic data.
The main processor has the right to delegate the rights of processing, except for coding and decoding, to an authorised processor. The main processor must store in the Genome Database the coded tissue samples, the DNA descriptions and the health descriptions within the territory of the Republic of Latvia.

Supervision over the collection, coding and decoding, and processing of tissue samples, descriptions of DNA, health descriptions and genealogical data shall be exercised by the State Data Inspection.

Under the supervision of the Ministry of Health and State Data Inspection, the State Genome Register shall be founded to create a database of personal data of gene donors.

The Central Medical Ethics Committee may grant permission for a limited number of tissue samples to be stored abroad, if appropriate research methods are not available in Latvia. The Central Medical Ethics Committee shall oversee ethical issues during the establishment of the Genome Database and the processing of the data according to generally recognised ethical rules and international conventions.

Supervision of the collection, coding and decoding, and processing of tissue samples, descriptions of DNA, health descriptions and genealogical data shall be performed by the State Data Inspection.

Gene donors have the right to access their data stored in the Genome database and the right to genetic counselling. Gene donors have the right to submit additional personal information to the main processor, as well as the right to prohibit the supplementation, renewal and verification of descriptions of their state of health stored in the Genome Database. A Gene donor has the right to withdraw his or her consent to be a gene donor for the Latvian Genome Database at any time.

8. Research involving animals

***E**thics Committee on Laboratory Animal Use in Biomedical Research*

The Ethics Committee on Laboratory Animal Use in Biomedical Research is a Committee of the Latvian Council of Science and acts in accordance with the rules of the Latvian Council of Science. Its activities touch upon all aspects related to the use of laboratory animals in biomedical and veterinary medical investigations, including sources for obtaining laboratory animals, laboratory animal breeding, transportation, housing, and use in experiments. The major task of the ethics committee is to review from an ethical point of view, all new scientific projects, which plan the use of laboratory animals, and which have applied for possible financing to the Latvian Council of Science, or any other expert committee.

The overall objectives and activities are the following:

1. To support certified and competent specialists in their activities - as well as all others involved in the breeding and use of laboratory animals - in the implementation and application of the recommendations, directives and regulations of the European Convention of 1986 on the Protection of vertebrate animals used for experimental and other scientific purposes by
   - co-operating with the corresponding laboratory animal breeding facilities and research institutions in any field connected with laboratory animals;
   - giving recommendations and consultations to researchers, who apply to the Latvian Council of Science, or any other expert

committee for financing and whose research projects plan the use of laboratory animals.

2. To ensure that scientific projects planning to involve laboratory animals:
   - limit the numbers of laboratory animals used and their suffering as much as possible, as well as unnecessary use of animals or their organs, on the basis of the high quality of the scientific experiments as well as laboratory animals;
   - use laboratory animals economically and in a humane way;
   - promote the development and use of alternative methods;
   - use thoroughly elaborated methods in experiments with laboratory animals, which should include appropriate analgesia, anaesthesia and euthanasia, and which should provide the implementation of improvements in routine practice.

3. To participate actively in the development of policy concerning the protection of laboratory animals used in biomedical and veterinary medical research.

4. To optimise the welfare conditions of laboratory animals:
   - in co-operation with the State Veterinary Department to develop regulations on the inspections of laboratory animal breeding facilities and the research laboratories, where laboratory animals are used for investigations, in order to control routine conditions and improvements of the environment;
   - to supply the scientific community with information regarding the current animal welfare situation in laboratory animal science in order to provide researchers with insight into the level of welfare of laboratory animals that they use in their experiments;
   - to follow-up and ensure that training and practical workshops are organised on a regular basis to obtain basic skills for laboratory animal research.

5. To promote knowledge about laboratory animal welfare:
   - by ensuring that every researcher using laboratory animals directly or indirectly, is informed about the problems of laboratory animal welfare;
   - by supporting the promotion and understanding of knowledge about laboratory animals, and by organising constructive discussions on ethical issues;
   - by ensuring that every researcher, who works with laboratory animals, is able to express his/her concern, thoughts or ideas about his/her work.

The Ethical Committee is composed of 13-15 members:
- representatives of the Latvian Council of Science;
- laboratory animal breeders;
- representatives of the State Veterinary Department;
- representatives of the Ministry of Welfare;

- laboratory animal users from different research institutions;
- representatives of the environment protection organisations;
- representatives of the Baltic Laboratory Animal Science Association.

It is the Latvian Council of Science that accepts the list of the members of the Ethical Committee and appoints the Chairperson.

Law on Animal Protection (accepted January 1, 2000, amendments on 27.12.2002 Regulation of Cabinet of Ministers Nr. 576)

Cruel treatment of animals is prohibited, that is:
1. the killing of an animal, except in the cases provided for in this Law;
2. the mutilating, tormenting and torturing of an animal;
3. leaving an animal without care;
4. leaving an animal in a helpless situation;
5. annoying and baiting an animal, except in the cases when it is necessary for the training of a work animal;
6. the organisation of animal fights, the involvement of animals in such fights and support of such fights;
7. the use of animals for religious rituals, lotteries and giving animals as gifts at public events except for farm exhibitions;
8. the use of an animal as a target for training in shooting or in competitions;
9. the use of animals for the training of animals of other species, except for the training of hunting dogs;
10. the use of animals, making them exceed their natural capabilities;
11. the showing of animals in travelling menageries;
12. the offering and use of a female animal for the sexual satisfaction of a male animal without the intent of obtaining offspring;
13. the carrying out of other such actions, which cause or may cause mutilation or death, or create suffering for an animal, except in cases when such actions have been carried out for treatment, experimental or scientific purposes or in cases when the life or health of a human being is under threat.

The Animal Protection Ethics Council is a consultative authority, which shall educate the general public and give recommendations to State institutions in the sphere of animal protection.
It is comprised of representatives of the State, scientific institutions and public organisations.

Art. 24.

"1. Specially raised animals (laboratory animals), or where the permission of owners is obtained, other animals, may be used for experimental and scientific purposes.

2. Wild animals may be used for experimental and scientific purposes if it is not possible to achieve the objective by other means.

3. The number of animals to be used for experimental and scientific purposes shall be reduced by improving experimental methods and, if possible, experiments with animals shall be replaced by alternative methods of research."

Art. 25.
"After evaluation of an opinion by the Animal Protection Ethics Council, the State Veterinary Service shall issue a permit for the use of animals for experimental and scientific research."

Art. 26.
"In acquiring professional education in biological, medical and veterinary medicine it is permitted to use laboratory animals and other animals during the study process, if it is not possible to achieve the objective by other means."

Art. 32.
"1. Collections of wild animals (zoological gardens, animal parks, aquariums, terrariums and others) may be established for scientific, educational and species-saving purposes.
2. Wild animal collections may be established only with a permit from the Ministry of Environmental Protection and Regional Development and a permit from the State Veterinary Service."

Art. 36.
"1. An animal shall be transported by an appropriate means of transport, ensuring conditions not harmful to its health."

European Commission

National Regulations on Ethics and Research in Latvia

Luxembourg: Office for Official Publications of the European Communities

2003 – 22 pp. – 17.6 x 25 cm

ISBN 92-894-6695-2

OSKARS ROZENKOPFS obtained a Master degree in Faculty of Biology of the University of Latvia. He is Medical representative in Latvian mission of Pharmaceutical Company GlaxoSmithKline.

DR. LAIMA RUDZE obtained a Master degree in Medical Institue of Latvia. She is expert on health care in European issues Unit of Health Compalsory Insurance State Agency of Latvia, expert from Latvia in Steering Committee on Bioethics of Council of Europe, Secretary General of Central Medical Ethics Commitee of Latvia, Member of World Association of Bioethics and Member of Federation of International Gyneacologists and Obsyetricians.

Publications Office
Publications.eu.int

ISBN 92-894-6695-2