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issues related to:

	Yes	No
Human beings	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Human biological samples	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Personal data (whether identified by name or not)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Genetic information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Animals	<input checked="" type="checkbox"/>	<input type="checkbox"/>

National Regulations
on Ethics and Research in

Czech Republic

České Republice



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National Regulations
on Ethics and Research in

Czech Republic

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by
Kludie Součková

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

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Foreword

Research activities in biomedical research together with their rapid progress in new technologies, are more closely followed by the general public than other branches of research. This reflects the fact that any action and development within these very sensitive sectors of life sciences is basic and life-crucial.

As society as a whole is the main stakeholder in such developments, the research together with the potential impacts of its results and their practical use, need to be provided within an ethical framework. Europe, however divided by different views on bio-ethics, either with rather liberal attitudes on one hand or with strong opposition on the other, should lead the research in such a way as to ensure benefit to humankind.

To avoid potential misuse of the results and their negative consequences in these sensitive scientific fields involving human beings and animals it is necessary to have a well developed legal background of rules, requirements and regulations. There is no doubt about the need for strict control and the setting up of conditions under which this research could take place. It is evident, that such research requires strong moral responsibility not only of researchers; but also society as a whole should be the strongest supervisor.

In the context of the goals of the Lisbon Strategy I believe in the valuable contribution of Czech science and its active participation within the framework of the European Research Area. National and international cooperation for implementing these objectives is highly important. History and the recent results of Czech researchers show that the Czech Republic can become a valuable partner in this process.

This publication will help the scientists and the general public to become more aware of the recent legal provisions in this area in the Czech Republic. I wish all participants involved, the researchers, the politicians and the public, to cooperate in such a way that the results of their work bring only benefits to society.

A handwritten signature in black ink, appearing to read 'Petra Buzková'.

Petra Buzková
 Minister of Education, Youth and Sports
 Czech Republic

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 Czech text has been written by Mrs. Klauďie Součková and subsequently approved by the Ministry of Education, Youth and Sports of the Czech Republic. 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, Youth and Sports of the Czech Republic.



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

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1. International instruments in Czech law

The Czech Republic signed and ratified an important international document – Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe which entered into force in the Czech Republic on 1 October 2001.

According to the Constitution of the Czech Republic it is an international agreement promulgated in the Collection of Laws, whose ratification has been approved by both chambers of the Parliament, after which it was ratified by the President. The Convention on Human Rights and Biomedicine is binding for the Czech Republic and is part of the legislation of the Czech Republic. The rule that, if an international treaty is at variance with national legislation, the international treaty shall overrule the national legislation, applies also in this case. The above shows that the Convention on Human Rights and Biomedicine has priority over national rules and regulations.

The Convention on Human Rights and Biomedicine is not the only document in the sphere of ethics and research.

As the process of integration of the Czech Republic into the European Union is underway, all the documents of the European Union shall be considered in our national legislation. The said sphere is also regulated by instruments of the European community whose number tends to increase and which shall be implemented into our

national legislation. Two examples are the Directive 95/46/EC of the European Parliament and of the Council on the Protection of individuals with regard to processing of Personal Data and on the Free Movement of such Data and the Directive 98/44/EC of the European Parliament and of the Council on the legal Protection of Biotechnological Inventions.

Also, national and international ethical codes exist. The Nuremberg Code and the World Medical Association Declaration of Helsinki rank among the most important ones. A reference to these international documents is made in the Ethical Code of the Czech Medical Chamber in Article 2 (17) which stipulates that “a new method of treatment may be implemented in a patient only after sufficient biological studies have been performed and under the conditions of the Declaration of Helsinki and the Nuremberg Code, under direct supervision and only if it does not harm patients”. Thus, violation of the provision of the World Medical Association Declaration of Helsinki means also the violation of the Ethical Code of the Czech Medical Chamber, which is subject to sanctions specified in the Act No. 220/1991 Coll., on the Czech Medical Chamber.

In the Czech Republic, other documents are also known, i.e. World Medical Association Declaration on the Rights of the Patient in Europe (Amsterdam, March 28-30, 1994), Directive for Ethics Committee dealing with Biomedical Research of the World Health Organization (2000), Guidelines for Biomedical Research involving Human Subjects of the Council of International Organizations of

Medical Sciences (CIOMS), the UNESCO Universal Declaration on the Human Genome and Human Rights.

These documents are not binding for the Czech Republic; however, researchers should be familiar with them and should be guided by them.

It is also necessary to follow the development of other documents of the Council of Europe, i.e. recommendations and Additional Protocols to the Convention on Human Rights and Biomedicine. The Additional Protocol on Transplantation has been released for signature and the Additional Protocol on Biomedical Research should be finalised this year.

2. National overview

In research, ethics committees play a most vital role in the Czech Republic. Their role may be categorised as follows: clinical trials with medicinal products, clinical trials with medical devices and research in the field of so-called unapproved methods (clinical and preventive medicine).

The Ethics Committee of the Ministry of Health has been established as an advisory body to the Ministry of Health for ethical issues in medicine and health care which are entailed in health care and in some related activities, including ethical aspects of biomedical research. In case no other relevant ethics committee is available, the Ethics Committee of the Ministry of Health is competent in the field of medicinal products, medical devices, as well as of unapproved methods and it also evaluates the

projects of biomedical research in compliance with the relevant legal rules and regulations.

1) Clinical evaluation of medicinal products

With regard to the field of the clinical evaluation of medicinal products, the following rules apply which are laid down by the Act No. 79/1997 Coll., on Medicinal Products:

All Ethics committees must have at least five independent members and must be established either by a health care facility or, if a health care facility has not established an ethics committee under the set conditions, by the Ministry of Health. The members of an ethics committee may be the

only people of integrity with no personal interest in the performance of clinical trials.

Ethics committees approve clinical trials of human medicinal products and are responsible for the supervision of trials with respect to safety and the rights of clinical study subjects.

The main task of individual ethics committees is to protect the subjects involved in clinical research, their lives, physical and mental health, privacy, reputation and dignity. For this purpose, ethics committees evaluate the conditions of studies and information provided to subjects with the aim of gaining their consent. Ethics committees should not approve a study in which inadequate risk is entailed, research performed by incompetent medical professionals and scientists or research performed in an inadequate facility. They should not approve a study about which the subjects do not receive all important information.

Ethics committees may permanently or temporarily withdraw their approval of a clinical study if new information is available which is important with respect to the safety of study subjects or if a sponsor or researcher violate their duties in a grave manner.

Another condition for the performance of clinical trials is the approval of the State Institute for Drug Control which not only approves clinical trials but also takes a view with respect to reported clinical trials and decides upon termination or suspension, as appropriate, of clinical trials. In the case of immunobiological products, such an approval may

only be granted after a positive statement of the main hygiene officer of the Czech Republic has been obtained. In the case of radiopharmaceutical products, such an approval may only be granted after a positive statement has been issued by the State Office for Nuclear Safety. And, if the human medicinal products contain genetically modified organisms that are not yet contained in any human medicinal product, which has been registered, such an approval may be granted only if such a genetically modified organism is entered into the list of genetically modified organisms and products approved for the introduction into circulation in the Czech Republic.

2) Clinical evaluation of medicinal products

With regard to the field of clinical evaluation of medical devices, the following provisions of the Act No. 123/2000 Coll., on Medical Devices apply:

A written approval of the protocol of a clinical study by the ethics committee of the provider competent to perform clinical research must be obtained. If needed, the ethics Committee may be established by the Ministry of Health.

Ethics committees approve clinical trials of medical devices and are responsible for the supervision of these trials with respect to safety and rights of clinical study subjects.

Similar rules apply to these ethics committees as in the case of registration of medicinal products.

The Amendments to the above-mentioned acts, prepared by the Ministry of Health, contain more detailed rules governing, i.e. the membership of ethics committees. They clearly define that at least one member of an ethics committee has to be a medical layman with no professional scientific qualifications and at least one member of an ethics committee must be a person who is not employed and is not in any industrial or dependent position with regard to the health care facility in which the proposed study will be performed.

3) Unapproved methods and scientific research

New legal rules and regulations should govern the approval of so-called unapproved methods and scientific research in clinical and preventive medicine. The evaluation of new information on living subjects using methods unapproved so far in clinical practice is governed by the Act No. 20/1966 Coll., on the Care of People's Health, with reference to the Guideline of the Ministry of Health No. 4/1985 for the activities of health care facilities in evaluation of new information on bodies of living persons using methods unapproved so far in clinical practice. However, the consent to the method is bound only to the approval by the Ministry after the statement has been obtained from the Scientific Council (1). This shortcoming should be remedied by the current draft bill on health care (2), which should stipulate the conditions for the evaluation of new information using the methods (procedures) which have not been approved in the clinical practice in living humans or have not been used in the Czech Republic. Based on this Act, the Ministry

of Health will be able to approve of a trial with a method unapproved so far only after receiving a favourable opinion of both the Scientific Council and the Ethics Committee of the Ministry of Health.

The issues of biomedicine are also dealt with by the Bioethics Committee of the Governmental Council for Research and Development, which is a professional advisory body of the government for dealing with the tasks related to bioethical aspects of research and development in the field of current biology and medicine. It also makes statements concerning some prepared bills in the field of biomedicine. Based on the request by the Governmental Council for Research and Development, the members of the Bioethical Committee discussed, for example, the current ethical issues related to embryonic stem cells.

3. Research using human beings

1) Informed consent

The issue of informed consent is generally governed by the Act. No. 20/1966 Coll., on the Care of People's Health, which stipulates that any medical procedure which is in the interest of the person, in whom it should be performed, may only be performed after a prior written consent of the person has been obtained. Before consenting, the person has to be duly informed about the nature of the procedure and risks thereof.

In the field of research, informed consent is required in all cases, based on three acts covering different research areas.

The first one is the Act No. 79/1997 Coll., on Medicinal Products, which deals with clinical studies of human medicinal products, i.e. with their systematic testing performed *in treated patients or in healthy volunteers* in order to establish or prove the therapeutic effects of human medicinal products, establish adverse events and/or pharmacokinetic characteristics thereof. Systematic testing is such an evaluation of human medicinal products which is performed according to a prepared protocol that is binding for researchers, sponsor and study subjects in terms of the product and treatment method used. Clinical evaluation is usually preceded by preclinical evaluation performed in animals or on biological systems and in these cases the rules of good laboratory practice apply.

Clinical evaluation of medicines must always be based on written informed consent which has to be provided freely by a study subject, or by his/her legal representative and has to be signed by a study subject or by his/her legal representative. This consent may only be granted after the provision of prior information and has to be provided before any clinical procedures in the subjects are commenced.

The information provided has to be undoubted, understandable and has to be in a language which is understandable to a study subject. The informed consent form must contain information on the clinical study, including its objectives, on possible advantages for the study subjects, on foreseeable risks and possible difficulties related to the clinical study, on other treatment options, on data protection, on rights and duties of study subjects, on the possibility for the trial subject to withdraw from the study at any time and how to do so and on what are the consequences of such a withdrawal.

The informed consent has to be valid for the entire period of a clinical study. In case, the trial subject has withdrawn his consent, the study may not continue in this particular subject.

If new information is obtained that is important with respect to the consent of a study subject to participate in the study, the study subject must be informed about such information without delay.

The Regulation No. 472/2000 Coll., governing good clinical practice and detailed conditions for the

performance of clinical studies, provides more detailed information with regard to good manufacturing practice, good laboratory practice, good clinical practice, the conditions for the performance of clinical trials, registration of medicinal products, etc.

The second regulation is the Act No. 123/2000 Coll., on Medical Devices. The content of the Act is mainly of a preventive nature and it has vastly improved the safety of patients, employees of health care facilities, and of third parties in the case of health care services being provided with the use of medical devices.

The clinical evaluation of medical devices, including its clinical study, comprises a systematic application thereof in patients or in healthy volunteers, who are used as a comparator arm and who freely participate in such studies, complying with a certain purpose for use under the conditions set by the manufacturer and performed according to the prepared clinical study protocol.

The issue of informed consent is governed by the same rules as mentioned in the case of the Act No. 79/1997 Coll., on Medicinal Products.

The third one is the Act No. 20/1966, on the Care of People's Health which stipulates that written consent of the person who will be involved in a study, and a previous approval by the Ministry of Health are preconditions for the evaluation of methods in living persons that are so far unapproved for clinical practice. Prior to consenting, such a person has to

be duly informed about the nature, applied method, duration and purpose of the unapproved method, as well as of the risks thereof.

For research using removed parts of a patient's body or research on the body of a deceased person governed by Article 26 of the above Act, undisputable written consent has to be granted by the patient. The undisputable written consent is a consent provided by a patient or a deceased person, or by a person having a close relationship with the deceased, by an authorized signature or the provision of a written consent of a patient or a person having a close relationship with the deceased given in a health care facility signed by the patient, by a witness appointed by the patient and by his/her treating physician or a person having a close relationship with the deceased and a physician of the health care facility, or the provision of consent by the patient in a health care facility which is recorded in the form for the provision of an undisputable written consent. In this case, the consent shall be signed by the patient, a witness appointed by the patient and by his/her treating physician. In cases where the patient, due to his/her medical condition, is not able to sign the consent or appoint a witness, as appropriate, the patient's undisputable will shall be verified by his/her treating physician and another witness who is not a medical professional. A record shall be kept on how the patient's will has been expressed and on the medical reasons which have prevented the patient from signing the consent or appointing a witness.

The draft bill of the Act on Health Care also stipulates that one of the preconditions for evaluation of an unapproved method is written, free and informed consent. Furthermore, a specific additional consent will be needed for each individual examination or treatment procedure that is performed as part of the evaluation of an unapproved method.

The draft shall also make provisions for scientific research in the sphere of clinical and preventive medicine, which may only be performed after having obtained a written, free and informed consent.

2) Legal competency of a person

Generally, a natural person's legal competency shall be governed by the Civil Code. The competency to obtain rights through one's own legal deeds, as well as to assume obligations, is in full extent reached at the lawful age, i.e. at the age of eighteen. Before this age, lawful age may only be reached through marriage.

Minors are only competent to such legal deeds which are in their nature adequate to their intellectual and volitional maturity corresponding to their age.

A natural person's legal competency may be withdrawn or limited. A natural person's legal competency shall be withdrawn if a person due to his/her mental disturbance, not being of a transient

nature, is absolutely not able to perform legal actions.

In case a natural person, due to a mental disturbance which is not of a transient nature, or due to excessive use of alcoholic beverages or of narcotics or poisons, is only able to perform some legal deeds, the court shall limit his/her legal competency and the limitation shall be defined in its decision. The court shall amend or revoke the withdrawal and limitation of legal competency, if the reasons leading thereto have changed or terminated.

If natural persons are not legally competent, all legal actions shall be performed on their behalf by their legal representatives.

- a) In accordance with the Act No. 94/1963 Coll., on Family, a legal representative of a minor is his parent. If none of the parents may act as a legal representative of a minor, a guardian of the minor, who will represent the minor in procedures and certain legal acts, shall be appointed by the court. This guardian shall usually be appointed by a body providing social-legal protection of children.
- b) A legal representative of a natural person, whose legal competency was withdrawn by a decision of the court or whose legal competency was limited by a decision of the court, shall be a guardian appointed by the court.

In case of conflict of interest between the legal representative and the represented person or between those who are represented by the same legal representative, it shall be dealt with by the court through appointing a special representative.

3) Research in specific groups of people

Research in certain specific groups of people is not governed by one individual legal rule or regulation, but by different rules and regulations governing different types of research.

Firstly, clinical evaluation of human medicinal products may not be performed in case no preventive or therapeutic advantage thereof is expected

- a) in persons whose legal competency was withdrawn or whose legal competency was limited, in persons whose consent may not be obtained due to their state of health, in foreigners, in minors,
- b) in pregnant and breast-feeding women,
- c) in dependent persons (3).

Secondly, the clinical evaluation of medical devices may not be performed in case no preventive or therapeutic advantage thereof is expected in persons whose legal competency has been withdrawn or whose legal competency has been limited and in persons whose consent may not be obtained due to their state of health and in dependent persons (for definition, see above). In the following groups, clinical studies may be performed if they are expected to be of direct

benefit for the study subjects and, in as far as the evaluated medical devices will be based on medical knowledge, save the life of a patient or improve the state of health thereof or alleviate pain thereof.

- a) In minors, clinical studies may only be performed if, according to current medical knowledge, the set use of a medical devices is to establish a diagnosis and protect health (mainly prevention against diseases) in these study subjects, or if a clinical study would not yield satisfactory results in people older than 18 years and if a legal representative of a study subject provided his/her written informed consent. If the study subject is able to understand the character, importance and impact of a clinical trial to a satisfactory extent and, based on this ability, to make a free decision and provide this decision in writing, it is necessary to obtain such consent.
- b) Clinical studies in pregnant and breast-feeding women shall only be performed if, according to current medical knowledge, the set use of medical devices is to protect health (mainly prevention against diseases) and to establish a diagnosis, treat or alleviate a disease in pregnant and breast-feeding women or in unborn children and the performance of a clinical study entails only a minor risk for unborn children, and it is thought that satisfactory results of the clinical study may only be obtained if it is performed in pregnant and breast-feeding women.

Thirdly, Studies evaluating new information may not be performed in persons in detention or in persons who are serving their sentence, persons carrying out basic, alternative military or civil service.

Moreover, consent in the field of research on removed parts of the body of patients or research on the body of a deceased person or in persons who were minors when they were living, or whose legal competency was limited or withdrawn, shall be provided by a legal representative thereof. If the patient is able to understand to a satisfactory extent the reasons of use of a removed part of the body, it is necessary to provide him/her with information also on the removal of body parts. It is necessary to respect the provision or non-provision of consent thereof.

The draft of the Act on Health Care also provides guidance for studies in patients who are minors, whose legal competency is limited or withdrawn and patients who suffer from a severe mental disease or are in a state when they are not able to consent. However, these studies may only be performed based on a written, free and informed consent provided by their legal representatives and provided additional conditions are fulfilled. These conditions are as follows: evaluation having comparable efficacy cannot be performed in patients able to provide their written, free and informed consent; the results of such studies may provide real and direct advantage in terms of health of study subjects; these persons, with respect to their intellectual maturity or abilities, did not disagree with the study and the study represents only a minor risk and minor burden for these subjects.

The draft also modifies the conditions for study performance in people in detention, and in persons who are serving their sentence, persons carrying out basic, alternative military or civil service, when, according to the draft, a study may not be performed unless it is the only possible alternative treatment in otherwise untreatable conditions.

4. Research comprising human biological materials (blood, organs, tissues, cells, DNA)

The definition of biological material is based on the Convention on Administration of European Patents (European Patent Convention) which entered into force in the Czech Republic on July 1, 2002. Biological material is any material containing genetic information and able of self-reproduction or reproduction in a biological system. The same wording is also comprised in the Act No. 206/2000 Coll., on the Protection of Biotechnological Inventions and on the Amendment of the Act No. 132/1989 Coll., on the Protection of the Rights to New Plant and Animal Species, as amended by the Act No. 93/1996 Coll.

Related to this issue, also the provision concerning the patentability of biotechnological materials needs to be mentioned. Biotechnological materials are patentable if they are isolated from their natural environment or produced using a technological procedure, even if it occurs in the nature.

Based on this Act, patents shall not be granted for:

a) inventions whose business use would contradict public order or good manners, namely for methods of cloning of human beings, for methods of modification of the basic stem line of the genetic identity of human beings, methods when human embryos are used for industrial and business purposes, or methods of the modification of genetic identity of animals, which may cause them suffering without substantial advantage for people or animals, and for animals which are the results of these methods of modifications;

- b) for the human body in different stages of creation or development and the mere invention of some of its elements, including the sequence or partial sequence of a gene (this shall not apply to elements isolated from human bodies or otherwise produced using a technical manner, including the sequence or partial sequence of a gene, even if the structure of this element is identical with the structure of a natural element) and;
- c) for plant and animal species or basically genetic methods of plant growing or animal breeding.

Individual types of biological materials are specified in more detail in the Act No. 285/2002 Coll., on Donation, Removal and Transplantations of Tissues and Organs and on the Amendment of some Acts (Transplant Act) which provides the definitions of organs, tissues and cells.

Organ is a part of the human body comprised by structured tissues which, removed from the body, may not be replaced by the organism.

Tissues and cells are building elements of the human body, including remains resulting from surgical procedures, blood-producing cells obtained from the bone marrow, peripheral and umbilical blood, excluding organs, blood and its parts, sexual cells, embryonic and foetal tissues and organs, hair, nails, placenta and waste products of body metabolism.

For all procedures of use or storage of a patient's body parts or the body of a deceased, the condition has also to be fulfilled that no danger shall be posed to health of another person. For this purpose, health safety of patients or deceased persons shall be evaluated.

Generally, a rule applies that the use of a patient's body parts or the body of a deceased may not be source of financial or any other advantages for the patient or for the deceased in his/her lifetime, or for natural or legal persons after death thereof, or for a health care facility. The payment of costs incurred in relation with the handling of a removed body part or the body of a deceased, i.e. with the preservation, storage and processing of the removed body part or the body of a deceased shall not be considered as a financial advantage.

- The removal of biological materials from living patients shall be governed by the Act. No. 20/1966 Coll., on the Care of People's Health, which in Article 26 stipulates that blood collection and removal of the human body part shall be performed and organized by health care facilities only for the purpose of therapeutic preventive care and medical sciences, research and education.

The removal and donation of tissues and organs for transplantation is governed by the Transplantation Act.

Blood collection may be performed with the consent of a donor, may not endanger the health state

thereof and has to be performed in such a manner which shall not endanger the health of another person.

If, in connection with therapeutic preventive care, any part of the body of a patient has been removed, it may be stored and used:

- a) for the purposes of medical sciences, research and education;
- b) for the production of medical devices;
- c) for the production or preparation of medicinal products; or
- d) for the production of bio implants (4);

provided that the patient has been duly informed by his/her treating physician about the possibility to store and use the body part for medical purposes and the patient has provided an undisputable written consent therewith (see below).

Health care facilities shall report all patients, including the deceased, whose body parts will be used for implant preparation, and the deceased whose body shall be used for implant preparation, to the National Registry of Tissue and Organ Donors; more in particular information shall be given on the identification of the patients and the deceased, on the removed body parts and on their provision to a hospital based in the Czech Republic which has a tissue bank. Tissue banks serve to perform the removals, further processing, examinations, preservation, storage and distribution of tissue grafts.

- The removal of biological materials from deceased patients shall be governed by the Act.

No. 20/1966 Coll., on the Care of People's Health, which stipulates that blood or tissue for diagnostic purposes may only be collected or removed from the body of a deceased to the least extent necessary and observing respect to the deceased.

The body of a deceased may only be used for medical purposes and only if undisputable written consent (see below) was provided *by the deceased him/herself* or if undisputable written consent with the use of the body of a deceased was provided by *a person having a close relationship* with the deceased, in case that the deceased has not made his/her will known during his/her lifetime. A person having a close relationship with the person in question shall be his/her direct kin, sibling or spouse. Other family members or similar persons shall be considered as persons having a close relationship with each another, if harm caused to one of these persons would be felt by another person as harm caused to him/herself.

If a health care facility does not establish that the consent has been provided by a deceased or if a person having a close relationship with the deceased does not provide consent, the body of the deceased may not be used for medical purposes.

Furthermore, no suspicion may arise that the cause of death was due to an infectious disease, the deceased may not be a person in detention or a person serving his/her sentence and the use of such a body may not hinder the performance of an autopsy in cases when there is a suspicion that the

death of a person has been caused by a criminal offence or suicide.

Undisputable written consent (or non-consent of a patient) or the record of undisputable written consent (or non-consent of the deceased person having a close relationship with the deceased) have to be part of the medical records of the patient or the deceased. The medical records of the patient or the deceased must contain a record of the use of a body part.

Undisputable written consent shall be a written consent of the patient or the deceased or of a person having a close relationship with the deceased with his/her authorised signature or a written consent of the patient or of a person having a close relationship with the deceased expressed in a health care facility signed by the patient, witness appointed by the patient and by his/her treating physician, or by a person having a close relationship with the deceased and a physician of the health care facility, or a written record of a patient's undisputable consent. In this case, the consent shall be signed by the patient, witness appointed by the patient and his/her treating physician. If the patient, due to his/her state of health, is not able to sign the record or appoint a witness, as appropriate, his/her undisputable will shall be verified by the signature of his/her treating physician and by another witness who is not a medical professional. The record shall provide the manner in which the patient made his/her will known and medical reasons preventing the patient from signing or appointing a witness.

5. Research on human embryos and embryonic stem cells

- **T**he Czech legislation does not contain a legal rule or regulation that would only apply to embryos and, therefore, it is necessary to establish its status using more general provisions. The Czech legislation does not unambiguously define the legal status of the embryo.

The Chart of Basic Rights and Freedoms stipulates that “the human life is worth protection before birth”. In another legal regulation, in the Civil Code, there is a reference made saying that a conceived child is competent to have rights and duties, if it is born alive.

- Since the issue of research using embryos is not sufficiently covered by the national legislation, the Convention on Human Rights and Biomedicine and its Additional Protocol on the Prohibition of Cloning of Human Beings has to be observed.

There is no doubt about the issue of human cloning for research purposes, as according to the Convention on Human Rights and Biomedicine human cloning for research purposes is forbidden. However, it has to be borne in mind that such human cloning most probably also applies to human cloning for therapeutic purposes. Thus, cloning techniques comprised in nuclear transfer or in an embryo division are, according to Article 18 of the Convention on Human Rights and Biomedicine and its Additional Protocol on the Prohibition of Cloning of Human Beings, not acceptable either.

Neither is the issue of embryo research unambiguous. Article 18 of the Convention on Human Rights and Biomedicine does not address the issue of in vitro embryo research. If we base our ideas on the notion that the above-mentioned Article stipulates the following: “If law allows in vitro embryo research it also has to provide for corresponding protection of the embryo.”, and that there is no legislation in the Czech Republic governing the field of embryo production and research thereupon; the situation may be described as the prohibition of in vitro embryo research.

If, according to Article 26 (4) of the Act No. 20/1966, on the Care of People’s Health, we consider the so-called supernumerous embryo to be a part of the body removed in connection with therapeutic preventive care, these provisions would also apply to the use of embryos in research. The same rules apply to handling the foetus after abortion, the foetal egg with no envelope, placenta or pregnant mucous membrane as to handling another body part, i.e. the rules described in the part for the collection of biological materials.

The issue of insufficient governing of embryo research shall also be governed by the draft of the Act on Health Care. At present, discussions are being held on the details of the provisions.

There are two variants: the first one strictly defines the possibilities to use stem cells and embryos as one of the paragraphs of the Chapter on assisted reproduction stipulates the following: “Stem cells and embryos may only be used for the purpose of

assisted reproduction after having obtained written consent of the donor. The health care facility which has performed the removal shall have the right to use the removed stem cells or embryos for the purpose of assisted reproduction or to transfer these to another health care facility to perform assisted reproduction. Stem cells and embryos may not be used for cloning", i.e. cell and tissue cloning is only admissible for the purposes of scientific research aiming at medicinal use (i.e. for the purposes of therapeutic preventive care).

Based on this provision, it would not be possible to use supernumerous embryos for research purposes.

According to the second variant, the issue of embryo research remains open and stem cells and embryos may only be used for the purpose of assisted reproduction upon obtaining written consent of the donor, if not stipulated otherwise by a special act.

The issue of artificial insemination is at present governed by the Binding Guideline "Conditions for Artificial Insemination" as a by-law promulgated in the Bulletin of the Ministry of Health and in the Recommended Standard Procedures of Provision and Recording of Assisted Reproduction Procedures.

- In the area of human cloning, the Additional Protocol on the Prohibition of Cloning of Human Beings applies, which outlaws any procedure aiming at creating a human being that would be identical with another human being (i.e. would have the same set of genes in the nucleus identical with another human being), living or dead.

This obligation is also contained in the draft of the Act on Health Care¹.

6. Personal data

The Act No. 101/2000 Coll., on the Protection of Personal Data and on the Amendment of some Acts governs the protection of personal data of physical persons, the rights and duties when processing these data and stipulates the conditions under which transfer thereof is allowed into other countries. The Act is a set of provisions passed in order to guarantee the basic human rights and freedoms.

The Act applies to all personal data processing, both automated and performed in another manner. The Act does not apply to personal data processing performed by a person for his/her personal use and to random data collection, if these data are not further processed.

- Personal data shall be all data related to an identified or identifiable natural person. An identified or identifiable natural person shall be a person whose identity can be directly or indirectly established using at least one piece of personal data. Data shall not be considered as personal, if the identification of these persons would require an inadequate amount of time, efforts and/or material. So-called sensitive personal data, i.e. data documenting racial or ethnic origin, political preferences, membership in political parties or movements and in trade unions or employee organisations, religion and philosophical views, criminal offences, state of health and sexual life or persons to whom the data are related, shall rank among personal data.

Based on this classification, the Act distinguishes between two types of consent with personal data processing (see below).

Anonymous data are data which in their original form or after processing may not be related to an identified or identifiable subject of the data.

For statistical or scientific purposes it is necessary to anonymise personal data whenever it is possible. When processing personal data for these purposes, it is necessary to ensure the required level of their security, i.e. to take such measures which would protect unauthorised or random access to these personal data, to their alteration, destruction or loss, unauthorised transfers, other unauthorised processing or misuse.

- When processing personal data, it is necessary to ensure that the person to whom the data are related is not harmed, namely with respect to his/her right to human dignity and that he/she is protected from unauthorised infringement of his/her private and personal life. It has to be borne in mind that the right of disposition to personal data primarily dwells on the person to whom the data are related, not on the administrators.

In cases when an administrator or processor breaches his/her obligations and the natural person to whom the data are related learns about the breach, this person has the right to address the Institution for the Protection of Personal Data asking for the provision of remedy. This person has the

right to require that the administrator or processor refrain from such acts, provide remedy and provide an apology or another satisfaction at one's own expense. He/she also has the right to require that personal data be modified or amended to make them correct and accurate and that the personal data are blocked or removed. This person may also ask for financial reimbursement if the breach of obligations resulted in the breach of the right to human dignity, personal honour, reputation, or the right to name protection.

- Personal data processing (namely the collection, storing on information carriers, access, modification, identification, use, transfer, dissemination, publishing, storage, exchange, sorting or combining, blocking and disposing of) may only be performed in accordance with the purpose for which they were collected, if not stipulated otherwise by a special act. It is only allowed to process data for another purpose if it was permitted by the person concerned.

An administrator may only process data upon the consent of the natural person to whom the personal data are related. The consent for personal data processing is one of the basic notions introduced by this Act. The establishment of the purpose of relevant personal data processing shall be an integral part of the consent. However, the establishment of the purpose is de facto the basis for the establishment of basic obligations when processing personal data in accordance with the Act on Personal Data Protection.

If the purpose of personal data processing is not or not duly established, not only relevant provisions related to consenting but also a number of other basic principles related to data processing would be breached.

Consent has to be made in writing and has to document to which extent it has been provided, to whom, for what purpose, for what period of time and who is consenting. Consent may be withdrawn at any time.

An administrator may process personal data without consent only if it is performed according to a special law or it is necessary in order to fulfil the duties stipulated by a special law, if it is necessary for the person to whom personal data are related to enter negotiations on contractual relationship or if he/she fulfilled the provisions of the contract concluded with an administrator, if it is necessary for the protection of important interests of persons, if personal data are concerned which have been duly published in accordance with a special legal regulation, and if it is necessary for the protection of administrator's rights.

Without consent of a natural person to whom personal data are related, personal data may only be processed for statistical or scientific purposes.

Sensitive personal data may be processed only in case that an explicit consent has been provided. If no consent has been given, these data may be processed in as far as consent cannot be obtained due to physical, mental or legal incompetence, or

because the person is missing, or in similar cases, and in as far as the processing is necessary for the protection of the life or health of people or in order to avert immediate grave danger to their property, in case of health care, as well as other health evaluation is concerned as per the Act No. 20/1996 Coll., on the Care of People's Health, namely for the purposes of social security or if it is stipulated by a special law.

Provisions governing the consenting procedure have to be understood as parallel to other obligations mentioned herein and concerning personal data processing.

The administrator is obligated to process only true and accurate data. The truthfulness and accuracy of data have to be verified. If he/she learns that the data processed by him/her are not true and accurate with respect to the established purpose, he/she is obligated to block them and to modify or correct them with no undue delay.

The administrator shall only collect data which corresponds to the set purpose and to the extent necessary for the fulfilment of the purpose. Also, the data may only be stored for the time period which is necessary for the purpose of their processing. As a part of the task, a time period has to be established in which the data may be processed in a given manner.

After the expiry of this period, personal data may only be kept for statistical, scientific and archiving purposes.

All persons who, in the process of data processing, come into contact with personal data are obligated to ensure confidentiality about the personal data and the safety measures, if publication of the latter would endanger the safety of personal data. Confidentiality also has to be maintained after the termination of employment or relevant work. Confidentiality does not have to be maintained if there is a reporting obligation as per special laws, e.g. the Act No. 140/1961 Coll., Penal Code, and the Act No. 21/1992 Coll., on Banks. Confidentiality provisions shall not apply to anonymised data or to generalised information.

Act No. 20/1996 Coll., on the Care of People's Health

According to the Act on the Care of People's Health, personal data processing is the processing of personal data when keeping medical records and the further handling of these records and the processing of personal data within the National Health Care Information System.

Health care facilities are obligated to keep medical records. Rights and obligations concerning the processing of personal data related to health care provision shall be governed by the Act No. 101/2000 Coll., on Personal Data Protection.

The Act on the Care of People's Health defines the persons who may study medical documentation in the extent necessary for the fulfilment of a given task within the extent of their powers.

Confidentiality maintenance is only specified in case of medical professionals who are obligated to ensure confidentiality about the facts they have learnt in connection with their work, except if facts are disclosed with the consent of the treated person or if the medical professional is relieved of this obligation by their superior body in the state interest.

7. Genetic information

The issue of genetic information is generally governed by the above-mentioned Act No. 101/2000 Coll., on Personal Data Protection, in which it ranks among so-called sensitive personal data (see above).

Genetic information may be part of information entered into medical records. Medical records shall contain personal data of patients to the extent necessary to identify these patients and to obtain the history thereof and information on patients' diseases, the course and results of examinations, treatment and other important information pertinent to patients' health state and to the procedures of health care provision.

DNA is the basic genetic material of human and other living beings. Identifying suspects, the Czech Republic is governed by the Recommendation of the Council of Ministers of the Council of Europe to

Member States on the use of deoxyribonucleic acid (DNA) analysis within the system of penal justice. The Recommendation expressly stipulates that samples collected for DNA analysis and information derived from such analysis for investigation purposes and for offence punishment may not be used for other purposes.

Samples collected for DNA analysis and information obtained may be useful for research and statistical purposes. Such use is only admissible if no individual may be identified. Therefore, before using this information, all names and other identifications have to be removed.

8. Research comprising animals

The most important legal rule and regulation governing the research comprising animals is the Act No. 246/1992 Coll., on the Protection of Animals against Abuse, whose purpose is to protect animals and living creatures able to feel pain and suffering, against abuse, health injuries and their purposeless killing, if caused by a man, even by negligence. An animal shall be all vertebræ excluding humans, with the exception of foetuses and embryos. The Act bans the abuse of animals both living freely in the nature, as well as those kept by people and all kinds of animal abuse promotion. Regulation No. 311/1997 Coll., on Breeding and Use of Experimental Animals, is an implementation regulation, stipulating concrete rules for Breeding and Use of Experimental Animals. It protects the animals which are part of testing experiments and identifies the bodies responsible for the protection of animals. It also defines the methods for animal experimenting, animal handling, protection of these animals and contents of experimental projects.

The prohibition of abuse of animals is also contained in some other regulations, such as the Act No. 87/1987 Coll., on Veterinary Care, and the Penal Law No. 140/1962 Coll., which defines the offence of the abuse of animals as follows: a person abusing an animal, who was punished for a similar offence in the last year or who was sentenced in the last two years or a person who has abused an animal to death shall be punished with imprisonment of up to one year or with the ban of activities or with a financial fine. More strict punishment is applied if a person commits this offence publicly or on publicly accessible sites.

User facilities are established by professional committees that comment on submitted projects of basic research, identifying research, test and safety guarantees and submit them to the relevant state body. The professional committees also allow the employees of user facilities to perform experiments; they verify professional qualifications of employees having a completed secondary education and of tenders of experimental animals and provide relevant certificates.

A draft test protocol is submitted to the professional committee of user facilities by the principal researcher who shall keep records of the tests, in case these are approved, in which the tasks required by the project protocol shall be documented.

A professional committee shall have at least four members, including a person who governs the work of the committee, a person who is responsible for the care of animals, a professional having completed higher education and a veterinary doctor. The committee shall provide its written statement on the submitted project protocol which shall be submitted to the relevant state body and on which the submitting person shall be notified.

The relevant state bodies are the central bodies of state administration, if the government of legal persons, whose activities concern testing in animals as part of their jurisdiction, as well as the Academy of Sciences of the Czech Republic. The tasks of these bodies are to issue a permission to use test animals for projects of basic research, identifying research, tests,

safety guarantees and education, to legal and natural persons based on the statement of professional committees, to keep records on the number of species of animals used for experimental purposes and to regularly publish statistical data on the use of experimental animals to the extent required.

The relevant state body may also allow the use of animals for such experimental projects, which do not comply with the conditions for breeding and the use of animals stipulated by the Regulation No. 311/1997 Coll., on Breeding and Use of Experimental Animals, if the aim of the test is to follow these changed conditions and is in accordance with the purpose of the test, i.e. the evaluation of a hypothesis and obtaining of new information or education and training purposes.

Experiments and tests may only be performed in user facilities which have been granted accreditation by the Central Committee for Animal Protection, and which have necessary professionally qualified personnel and are suitable for the relevant species and number of experimental animals.

The Central Committee discusses, coordinates and controls the tasks related to the protection of freely living, farm and experimental animals, as well as animals in interest for breeding, including animals in zoological gardens, and submits to the relevant state bodies a proposal of necessary measures, keeps central records of the number of experimental animals used for testing, safety guarantees, basic research projects, identifying research and educational purposes, stipulates the conditions for

accreditation of user facilities and for the issuance of certificates for breeding facilities and supplier facilities, defines the area and the extent of knowledge necessary for work with experimental animals, decides upon accreditation of user facilities, checks general reports on the activities of relevant state bodies, controls the issuance of permits to use experimental animals and approves the orders for the breeding and testing of animals.

Procedures on a living animal, its observation or manipulation therewith for experimental purposes and the activities closely related thereto shall only be performed to the extent and under the conditions stipulated in the approved experimental project, and if it is not excluded by special legal regulations.

Each project has to contain the characteristics of study aims and identify a concrete expected benefit.

The user facility submitting an experimental project for single collections from farm animals and animals in interest breeding groups in order to obtain biological material for manufacturing of serums, inoculation products, diagnostic products and medicines, shall also supply a written contract between the user facility and the owner of the animal. Biological material collection under these conditions may only be performed on one animal twice a year.

During the entire period of testing, persons performing experiments on animals are obligated to ensure the reasonable care of animals, namely their suitable breeding, nutrition, feeding, adequate space, microclimate and veterinary care.

Persons performing testing in animals shall ensure that no pain, suffering or harm is caused to the animals beyond the extent necessary with respect to the purpose for which animals are observed. Also, they are obliged to perform the experiments and tests which may cause greater pain than minimal only under local or general anaesthesia unless the purpose of experimenting does not allow anaesthesia, and to use animals for experiments causing pain only once if repetition of these procedures is not part of experimentation.

Anaesthesia and other pain-killing methods shall be governed by the needs of animals with regard to animal species and test purposes.

Experiments have to be performed preferably in animals bred for these purposes, which fulfil given quality criteria, and which are defined and standardised in terms of genetic information, state of health and their living conditions. Waif animals and stray domestic animals may not be used for experimenting.

Experiments and tests on animals living in freedom that have been trapped may only be performed if the purpose of experimentation may not otherwise be achieved. Endangered species may only be used for experimentation, if these experiments aim at preservation of the species.

The following animals are used for experimentation: Insectivore (Insectivora), chiropters (Chiroptera), laboratory mouse (*Mus musculus* var.), laboratory rat (*Rattus norvegicus* var.), guinea-pigs (*Cavia*

porcellus), other rodents (Rodentia), rabbit (*Oryctolagus cuniculus*), hominoids (Hominoidea), apes (Cercopithecoidea, Ceboidea), half-apes (Prosimii), dogs (*Canis familiaris*), cats (*Felis catus*), other carnivores (Carnivora), horses, donkeys and crossbreeds (domestic equidae), pigs (*Sus scrofa* var.), goats and sheep (domestic species *Capra*, *Ovis*), bovine cattle (*Bos taurus*), cervides (Cervidae), other mammals (Mammalia), birds (Aves) reptiles (Reptilia), amphibians (Amphibia) and fish (Pisces).

Procedures in living animals or manipulation therewith for the purpose of the evaluation of a hypothesis and obtaining new information, establishment of diagnosis, development and evaluation of biological product, including the evaluation of its effects and obtaining products having these characteristics, testing, use of animals for the purpose of testing of their reactions or for educational purposes shall be considered as 'testing in animals'.

Testing may only be approved after clearing that, given the current situation, information may not be obtained or used by means of other methods or procedures, and if the expected pain, suffering or harm done to experimental animals is ethically acceptable with regard to experimental objectives and is unavoidable in order to:

- a) prevent, learn or treat diseases, suffering, injury to health, physical complaints, or to learn how physiological states and the function of humans and animals can be influenced;
- b) learn about harm done to the environment;
- c) perform basic research and identifying research;

- d) verify the safety of substances and products for health of humans and animals and efficacy thereof against pests;
- e) manufacture serums, inoculation products, and other biological materials and drugs,
- f) save or reproduce living material for scientific purposes;
- g) provide education at secondary schools and higher educational facilities, in postgraduate studies or life-long education and training of people, namely in the field of medicine and natural sciences, if the purpose may not be served otherwise.

It is forbidden to perform experiments aiming at the development of arms, ammunition and related equipment.

The breeding of experimental animals is only allowed if a given temperature is provided, the period of adaptation is complied with, and the minimal conditions for space are complied with in accordance with the Regulation No. 311/1997 Coll., on Breeding and Use of Experimental Animals.

Generally, the conditions for breeding and the use of animals are specified in the operational order that shall be prepared by breeding, supplying and user facilities. It has to be guaranteed that only such materials are used which cause no harm, irritation or discomfort in animals, that no unauthorized persons are allowed to enter such premises, that admission points to animal premises are equipped with potent disinfection, that technical equipment control is performed on a regular basis, disinfection,

disinsection, deratization (deactivation) is provided, as well as separate cubicles in breeding premises, comprising at least 5% of the capacity of breeding premises for animals requiring extraordinary care, namely for animals which are injured, sick, suspicious of being infected, etc.

After the termination of tests and experiments, animals have to be provided due care. Farm animals, animals living in freedom trapped for experimental purposes, and animals corresponding to animals of interest breeding groups shall be returned to their original milieu, if it is specified in the experimental project and if allowed by the health state of animals, environmental conditions and conditions laid down by special legal rules and regulations (e.g. by the Act No. 87/1987 Coll., on Veterinary Care, the Act No. 114/1992 Coll., on the Protection of Nature and Landscape).

In case an infection occurs having clinical signs of the disease, or in case of deaths and if an infection has been confirmed, using laboratory methods, which is transferable from animals to other animals or to humans, the experiment shall be terminated, if the experimental project does not aim at observing such signs.

It is not allowed to dispose of dead bodies of animals before the onset of post-mortem rigidity.

Conclusion

In conclusion, I would like to wish all researchers success in their work and to appeal that they should be serious about their experimentation and testing, but also about ethical and legal aspects entailed in them.

It is my belief that this brochure will contribute to education in the field of research and ethics, and to the understanding that these are serious topics. I would like to support the intensive work of all those who may contribute to the creation of better legislation, and of clearer and more accurate rules in areas not being clearly defined so far.

References

1. The Scientific Council is a professional advisory body of the Ministry of Health in the field of further development of health care.
2. Draft bill of 2003 on Health Care when Providing Health Services and on the Amendment of Some Acts (Act on Health Care). At present, the bill is going through the procedure of comments; afterwards it will be submitted to the Government.
3. Depending persons shall be the persons in detention or during execution of punishment or who are serving their sentence, persons carrying out basic, alternative military service or civil service and persons who are provided medical care without their consent.
4. Bio implant is the tissue of human origin in which the presence of living cells may not be established after its processing. Bio implant is not the tissue of human origin processed by mere freezing and intended for transplant use.

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