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

## National Regulations on Ethics and Research in

# Poland

Polsce



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**National Regulations  
on Ethics and Research in**

**Poland**

**Polsce**

by  
Jacek A. Piątkiewicz

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Brussels, 2005

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## Foreword



The issue of ethics in medical research in today's world is becoming more and more crucial. One can clearly observe that economic considerations increasingly influence research and too often endanger the maintenance of high ethical standards in the science sector. Moreover, there is a real prospect that the commercialisation of research results will extend to entire research areas. Medical research is certainly one of the most spectacular examples of this. Therefore, clear and precise regulations aiming to prevent and punish research misconduct in medical research are of great importance for the development of medicine and the welfare of patients.

In fact, national regulations in the field are not sufficient. A coordinated European approach is expected to give the issue a proper dimension. Indeed, strict co-operation and harmonisation of regulations based on joint experience and knowledge can only protect us from the above-mentioned threat. Moreover, it is worth stressing that although the adaptation of adequate international and European regulations to national systems has begun successfully, sharing best

practices in the form of a publication series on the national regulations on ethics in medical research is a considerable step forward in the process of preparing a common European base for regulations in medical research.

Therefore, I very much appreciate the initiative of the European Commission's Research DG, and Mr Rainer Gerold himself, which I am sure will have an important effect as far as improving the overall system is concerned.

A handwritten signature in black ink, appearing to read 'Jerzy Langer', with a long horizontal line extending from the top right of the signature.

*Prof. Jerzy Marian Langer  
Deputy Minister  
Ministry of Science  
and Information Society Technologies*

# Introduction

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

The text of the Sixth Framework Programmes refers 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/sciencesociety/ethics/legislation\\_en.html](http://europa.eu.int/comm/research/sciencesociety/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) also requires 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."*

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 particular country.

The Sixth Framework Programme guide for proposers requires applicants to identify whether work packages contain one or more of the following five ethical issues, namely whether the research work involves:

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

Detailed information on how these issues are handled has to be given, including the explanation of the applicable national legal background. 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 concerning those five areas, where ethical issues may arise. It is an advantage if

researchers not only understand the regulations of their own countries, but also those of potential partners when they seek to collaborate.

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

The Polish text is based on the document prepared by Prof Jacek A. Piątkiewicz and subsequently approved by Poland's Ministry of Science and Information Society Technologies. The Commission has promoted this project and is now dedicating a bilingual publication (original language and English) to the new Member States and candidate countries in order to facilitate their participation in the Sixth Framework Programme. The project has been coordinated for the Commission by Mr Dariusz Drewniak, director, and Mr Andrzej Stolarczyk, acting Deputy Director, Ministry of Science and Information Society Technologies, and Véronique Degraef. The responsibility and credit for the contents rest with the authors and Poland's Ministry of Science and Information Society Technologies.



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

## Table of contents

Foreword	3
Introduction	4
<input type="checkbox"/> 1. International instruments in	6
Polish law	
<input type="checkbox"/> 2. Overview of national regulations	7
<input type="checkbox"/> 3. Research involving human beings	11
<input type="checkbox"/> 4. Research involving human	14
biological material	
<input type="checkbox"/> 5. Experiments relating to human	17
embryo and embryo stem cells	
<input type="checkbox"/> 6. Personal data	18
<input type="checkbox"/> 7. Genetic information	20
<input type="checkbox"/> 8. Experiments with animals	21
<input type="checkbox"/> 9. Additional information	23

# 1. International instruments in Polish law

The fundamental legal act in Poland is the Constitution of the Republic of Poland, which was passed by the National Assembly on 2 April 1997 (Dz. U. Nr 78 poz.483). In accordance with Art. 87 paragraph 1 of the Constitution, all ratified international agreements are also a binding source of law in Poland. As stated in Art. 91 paragraph 1 of the Constitution "a ratified international agreement, upon its publication in the *Journal of Laws of the Republic of Poland*, constitutes a part of the national legal system and will be applied directly, unless its application requires issuance of a Regulation".

On 7 May 1999, Polish Minister of Justice, Mrs Hanna Suchocka, signed the Convention of the Council of Europe on Protection of Human Rights of the Human Being with Regard to the Application of Biology and Medicine and Additional Protocol on

the Prohibition of Cloning Human Beings. Currently, this convention is being prepared for ratification by Sejm (Lower Chamber of Poland's Parliament).

In the process of Poland's accession to the European Union, as part of the adjustment of Polish law, some Union regulations relating to research, particularly research into medicinal products, within the Act – The Pharmaceutical Law (Dz. U. Nr 126 poz.1381 z późn. zm.), have been introduced into the binding regulations.

The professional rules relating to medical research, which are included in the Act on the Medical Profession, comply to a significant degree with the norms set by the World Medical Association Declaration of Helsinki.

## 2. Overview of national regulations

### 2.1 Overview of legal regulations relating to medical experiments

The fundamental Polish norm relating to experiments is the ruling in Art. 39 of the Constitution: "Nobody can be subject to scientific experiments, including medical, without one voluntarily giving consent."

The issue of medical experiments is regulated in the **Act of 5 December 1996 on the Medical Profession** (Dz. U. z 2002 r. Nr 21 poz. 204 z późn. zm.), which includes a separate chapter 4 "Medical experiment" (Art. 21-29).

According to Art 21 of this Law, medical experiments conducted on human beings can be either of a therapeutic or a scientific nature. The regulation is also binding under the Pharmaceutical Law and Law on Medical Devices.

A therapeutic experiment is defined as the introduction of new or only partially proven diagnostic, therapeutic or preventive methods in order to achieve direct benefit for an individual subject to the experiment. It can be carried out when hitherto applied methods are ineffective or their effectiveness is insufficient.

A scientific experiment, aimed mainly at broadening medical knowledge, can be performed when participation in it is not bound with risk or this risk is inconsiderable.

Medical experiment can be performed (Art. 22) when the anticipated benefits are considerable, and

the anticipated achievement of the benefits, as well as expediency and the way the experiment is executed, are justified in the light of contemporary knowledge and are consistent with the principles of ethics. A similar provision has been formulated in Art. 27 of the Criminal Code of 6 June 1997 (Dz. U. Nr 88 poz. 553).

The objective of a medical experiment executed on humans could be: the examination of new therapeutic products, introduction of new clinical methods, preventive and related to public health, as well as the examination of new medical devices.

The issue of examination of the new therapeutic products is regulated by the Act of 6 September 2001 – Pharmaceutical Law in Art. 6. In general matters, this Law refers to the above-mentioned chapter "Medical Experiment" in the Act of 5 December 1996 on the Medical Profession. According to Art. 6 of this Law, the subject responsible for clinical examination of a medicinal product reports it to the Central Registry of Clinical Experiments, which belongs to the Medicinal Products, Medical Devices and Biocide Products Registration Office, which is the government's administration body. Entry in the Central Registry is subject to a fee. Clinical examination of a medicinal product starts by obtaining the Minister of Health's decision.

Clinical examination of a medicinal product should be performed in compliance with the principles of good clinical practice. These requirements are defined in the **Order of the Minister of Health of**

**10 December 2002 on the Detailed Description for the Requirements of Good Clinical Practice** (Dz. U. Nr 221 poz. 1864).

During its execution, the clinical experiment is subject to supervision by the Clinical Examination Inspection empowered by the President of the Registration Office. Should the clinical examination of a therapeutic product constitute a life or health hazard to the participants of the examination, or should it be executed inconsistently with the approved protocol, then the Minister of Health will take a decision regarding its discontinuation.

Examination of new medical devices is regulated by the Law of 27 July 2001 on the Medical Devices in chapter 5 "Clinical examination of medical devices" (Art.21-25). In Art. 24 of this Law there is a reference to regulations of the medical experiment in the Act of 5 December 1996 on the Medical Profession, which are binding accordingly.

In compliance with Art. 29 of the Act on the Medical Profession, medical experiments can only be executed following a positive opinion about the project from an independent bioethical commission. Additional regulations on the subject of clinical examinations of medicinal products are in the Act of 27 July 2001 on Medical Devices (Dz. U. Nr 126 poz. 1380).

Art. 21 of this Law states that clinical examinations of medical devices are performed when they are indispensable either for the evaluation of clinical usefulness of medical devices, or for an evaluation

of whether the application of the medical devices constitutes excessive risk for a patient. Once again, clinical examinations cannot start without the Minister of Health's consent.

Detailed rules of conduct regarding the clinical examination of medical devices are defined in the **Order of the Minister of Health of 20 December 2002** (Dz. U. z 2003 r. Nr 21 poz. 183) on Clinical Examination of Medical Devices. In accordance with this regulation, a physician conducting clinical examinations should submit the project being examined to obtain the opinion of the bioethical commission, and should also secure from this commission an opinion on every change noted in the examination programme.

## 2.2 Bioethical commissions

This same Art. 29 of the Act on the Medical Profession defines the organisation of bioethical commissions in Poland.

Bioethical commissions in Poland act on a regional basis and are appointed by the:

- 1) Regional council of physicians (executive body of the regional chamber of physicians – the institution of physicians' professional autonomy) within the area of its activity;
- 2) Rector of a higher medical school (Poland has distinct higher medical schools – medical academies);
- 3) Director of a medical research and development institute.

Bioethical commissions examine all types of medical experiments reported, by individuals or other applicants intending to execute such projects, respectively to the area of activity of the regional chamber of physicians, in a medical academy or in a medical research and development institute.

Apart from the regional bioethical commissions, the Minister of Health appoints an Appeal Bioethical Commission which considers appeals from resolutions by regional bioethical commissions.

A bioethical commission expresses its opinion about a medical experiment project by way of a resolution considering the ethical criteria, purposefulness and feasibility of the project.

The procedural rules for bioethical commissions are defined in the **Order of the Minister of Health and Social Welfare of 11 May 1999 on the Detailed Rules of Appointment, Financing and Mode of Operation of the Bioethical Commissions** (Dz. U. Nr 47 poz. 480).

A bioethical commission is appointed for a tenure of three years. Members of the bioethical commission include expert physicians and a representative from various professional backgrounds, such as a clergyman, a philosopher, a lawyer, a pharmacist, and a nurse – they must have at least ten years of work experience in their profession.

The commission counts 11-15 members from which a president, vice-president and secretary are elected. The president of the commission is a physician and the vice-president a non physician.

The commission members appointed are individuals with high moral authority and high professional qualifications.

A person intending to perform a medical experiment applies to the appropriate bioethical commission for an opinion, including the documentation. The commission president designates a member of the commission and may call experts to prepare the proposal of an opinion. The bioethical commission may ask the person submitting the project to complement it with additional conditions.

Once the project has been discussed and explanations have been received, in a secret vote with at least half of its members present – including two non physicians – the commission passes a resolution expressing an opinion. The resolution should be passed within three months from the date the complete documentation on the projected experiment is received.

Appeal against the resolution of the bioethical commission can be filed by:

- 1) The person intending to carry out a medical experiment;
- 2) The manager of the health care unit where the experiment is to be performed;
- 3) Any bioethical commission issuing an opinion about the project following the resolution of another bioethical commission which has issued an opinion about the same project, in the case of multi-centre research.

The Appeal Bioethical Commission investigates the appeal within two months of its filing. Funding assigned to finance the activities of the bioethical commission comes from fees paid by the subject applying for the commission's opinion. Fees should cover the bioethical commission's operational costs.

In Poland, hitherto, a draft creating a National Bioethical Committee has been prepared twice. However, to date these projects have not been executed.

## 3. Research involving human beings

### 3.1 Regulations regarding informed consent

As mentioned above, Art. 39 of the Constitution includes a requirement to obtain voluntary consent for participation in a clinical trial.

A general requirement defining the patient's right to express consent for provision of a health service, or to express refusal, upon obtaining adequate information, is in Art. 19 of the Act of 30 August 1991 on Health Care Units (Dz. U. Nr 92 poz. 408 z późn. zm). This is consistent with the provision of Art. 32 of the Act on the Medical Profession, according to which patient's consent is required for any medical treatment.

The problem of obtaining the consent from individuals participating in the clinical trial is regulated by Arts. 24, 25 and 27 of the Act of 5 December 1996 on the Medical Profession.

In Art. 24 of this Law, it is stated that an individual being subjected to a clinical trial is informed beforehand about its objectives, methods and the conditions of its execution, the anticipated medical or scientific benefits and risks, and about the possibility of discontinuing his/her participation in the experiment at any stage.

Execution of a clinical trial requires a written consent from the examined individual (Art. 25). In cases where it is impossible to obtain a written consent, an oral consent expressed in the presence of two witnesses is considered as an equivalent.

According to Art. 27, an individual participating in a clinical trial may withdraw his/her consent at any stage of the experiment. If a life or health hazard for the participating individual occurs during the trial, the physician conducting it is obliged to discontinue the trial.

According to the paragraph 8 of the Order of the Minister of Health of 10 December 2002 on the Detailed Description for the Requirements of the Good Clinical Practice, an individual conducting the trial is obliged to obtain a written, conscious, personally signed and dated consent from the participant of the trial on a form which has been approved by the bioethical commission and the Central Registry of Clinical Trials.

Before obtaining the consent, the person conducting the clinical trial informs the participant in full about the research project. Information is provided both orally and in a written form either to the participant of the trial or to his/her legal representative.

Significant aspects of a clinical trial should also be considered in the application form for a conscious consent from the individual participating in the trial.

The Order of 10 December 2002 on Good Clinical Practice also defines other responsibilities of the individual in charge of the trial, the responsibilities of a sponsor, and the type and content of the documentation connected with the clinical trial.

For the clinical examination of medical devices it is required, according to the grounds of the Order of

the Minister of Health of 20 December 2002 on Clinical Examinations of Medical Devices, to obtain in writing a conscious and voluntary consent for participation in a clinical trial, according to the rules defined in regulations of the clinical trial in the Act of 5 December 1996 on the Medical Profession.

### **3.2 Participation in the medical trial of individuals unable to express consent**

Art. 25 of the Act on the Medical Profession allows for the execution of a clinical trial without the participant's consent if there is a life hazard in a situation of great urgency and there is no possibility to obtain immediate consent.

In Poland, full eligibility for legal actions is gained at the age of 18. Parents are the legal representatives for children and teenagers up to 18 years of age.

The case of minors in clinical trial is regulated by Art. 25 of the Act on the Medical Profession. According to this regulation, participation of a minor in a clinical trial is only possible on written consent from his/her legal representative. If the minor is over 16 years of age or is under 16 years of age but is capable of expressing a conscious opinion about participation, his/her written consent is also necessary.

The participation of a minor in a clinical trial is permissible if the anticipated benefits have direct importance for the minor's health and the risk is small. Scientific experiments involving the

participation of a minor is not permissible where there is the possibility of conducting such experiments, with comparable effectiveness, with the participation of an individual who is fully eligible for legal action.

In the case where a legal representative refuses to give consent for a minor to participate in a clinical trial, an appropriate court guardian can be approached to give permission.

Art. 25 of the **Act on the Medical Profession** also regulates the participation in a clinical trial of other individuals unable to express consent.

In the case of an individual who is completely incapacitated, the consent for his/her participation in a therapeutic experiment is given by his/her legal representative. If such an individual is capable of expressing a conscious opinion, it is also necessary to obtain a written consent from him/her. If the legal representative of an incapacitated individual refuses to give consent for the participation of the said person in the experiment, an appropriate court guardian can be approached to obtain this consent.

In the case of a person who is fully eligible for legal actions, but is incapable of expressing a conscious opinion, it is possible to obtain consent for his/her participation in therapeutic experiments from an appropriate court guardian.

### **3.3 Regulations on participation in a clinical trial by certain groups of individuals**

Art. 26 of the Act on the Medical Profession includes regulations concerning participation in clinical trials by certain groups of individuals.

The participation of pregnant women in a clinical trial requires a particularly acute evaluation of risk for both mother and the unborn child. Pregnant and nursing women can only participate in scientific experiments that are without risk or carry a minor risk.

Prison inmates, draft soldiers and incapacitated individuals cannot participate in scientific experiments. Scientific experiments cannot be performed on unborn children. Meanwhile, the Code of Ethics for physicians allows, as an exception, for the participation of an incapacitated individual or enrolled soldier or prisoner in an experiment if it is for the well-being of these groups (Art. 43.3).

## 4. Research involving human biological material

Use of human biological materials in Poland is regulated by the Act of 22 August 1997 on the Public Blood Service (Dz. U. Nr. 106 poz. 681) and by the Act of 26 October 1995 on the Collection and Transplantation of Cells, Tissues and Organs (Dz. U. Nr 138 poz. 682).

The Act of 22 August 1997 on the Public Blood Service defines the rules for the collection and processing of human blood into blood-derived products and rules on blood transfusion.

In accordance with Art. 2 of this Law, blood may be collected for the following purposes: therapeutic, processing into blood-derived products, diagnostics, scientific, and research.

The collection of blood for scientific and research purposes should then be regulated by the articles of this Law.

Art. 3 of the Act states that blood collection is based on the voluntary and free donation of blood, with the exception of the financial reimbursement of rare groups of donors who, prior to collection, have been subjected to immunisation and are entitled to a financial reimbursement for collected blood. In accordance with Art. 4 of the Act, the task of collecting blood in order to supply blood and blood-derived products is executed exclusively by the Public Blood Service.

Art. 15 of the Act states that the donor must be fully eligible for legal action and must express in writing his/her consent for the collection of blood.

The Law does not stipulate any obligation by the donor to give consent as regards the way his/her blood will be used, including its use in a clinical trial.

Similarly, in the case of individuals other than blood donors, from whom blood is usually collected for diagnostic purposes, consent for particular usage of the blood is not required, including its use in a clinical trial.

The issue of cell, tissue and organ collection is regulated by the Act of 26 October 1995 on the Collection and Transplantation of Cells, Tissues and Organs (Dz. U. Nr 138, poz. 682 z późn. zm.). The Law does not refer to the collection of embryonic stem cells and gonads, embryonic and foetal tissue, as well as blood.

According to Art. 2 of this Law cells, tissues and organs may be collected from human corpses for diagnostic, therapeutic, scientific and educational objectives. Cells, tissues and organs can also be collected during an autopsy (Art. 3), performed in the hospital after the death of an individual who has been treated there, upon rules defined in Art. 24 and 25 of the Act of 30 August 1991 on Health Care Units.

The collection of cells, tissues and organs from human corpses for scientific research can be executed when the deceased individual has not expressed an objection during his/her lifetime (Art. 4 of the Law on Collection and Transplantation of Cells, Tissues and Organs). In the case of a minor or

other person who is not fully eligible for legal action, objection can be expressed by the legal representative of such a person during his/her lifetime. If a minor over 16 years of age, or a person over 18 years of age is not fully eligible for legal actions, they themselves can express an objection during their lifetime.

In the case of the collection of cells, tissues and organs from a corpse during an autopsy, regulations concerning the possibility of an objection are not applied. In addition, there is no rule defining the principles of conduct concerning biological substances collected in this way. Therefore, it may be utilised for experimental purposes.

The objection against the collection of cells, tissues and organs from corpses for the purpose of transplantation can be expressed by means of (Art. 5):

- 1) An entry in the Central Registry of Notified Objections;
- 2) A written declaration;
- 3) An oral declaration made in the presence of at least two witnesses.

The collection of cells, tissues and organs for transplantation is permissible upon ascertaining the permanent and irreversible halt of brain stem functions (Art. 7).

The regulations referring to the collection of cells, tissues and organs from living individuals pertain only to the collection for the purpose of transplantation and are included in the Law on the

Collection and Transplantation of Cells, Tissues and Organs (Art. 9-12). The collection of cells, tissue and organs from living individuals for other purposes, including clinical trial is not regulated by the Polish law, except for blood collection as discussed above.

Experiment with the use of cells, tissue and organs collected from the living donor, and referring to a transplantation of this biological substance to another individual requires the application of Art. 9 of the Act on the Collection and Transplantation of Cells, Tissues and Organs. According to this article, among others, the following conditions must be fulfilled:

- 1) Collection is executed for a relative, spouse or someone close to the deceased, and in the case of bone marrow or other regenerating biological material, for the benefit of another person;
- 2) Collection is preceded by examinations to establish the risk of intervention and the risk of deterioration of the donor's health;
- 3) The candidate for a donor has been advised about the possible consequences of transplantation by a physician other than the physician collecting the biological substances and the physician performing the transplantation;
- 4) The candidate for a donor has voluntarily given his/her written consent;
- 5) The patient subject for transplantation has been advised about the risk to the donor resulting from the collection, and has given his/her consent to accept this biological material.

In accordance with Art. 18, one cannot request or accept payment or any other material benefit for biological material collected from a living donor or from a human corpse.

In Polish law, there are no regulations defining the principles of usage of the existing stock of human biological material for experimental purposes. Similarly, there are no regulations referring to the usage of genetic material (DNA) included in the human biological material in clinical trials.

In the Act of 31 January 1959 on Cemeteries and Burial of the Deceased (Dz. U. z 2000 r. Nr 23 poz. 295), it is stated that the right to burial of human mortal remains belongs to the closest living relatives of the deceased (Art. 10). Unburied mortal remains can be transferred to medical academies for scientific purposes following a decision by an organisation from the autonomous district (powiatowy) administration.

In the Order of the Minister of Health of 7 December 2001 on the Procedures with Human Corpses and Mortal Remains (Dz. U. Nr 153 poz. 1783), issued upon the Act on Cemeteries and Burial of the Deceased, it is established (paragraph 8) that as regards conduct with parts of a human body separated from the whole, regulations referring to conduct with the deceased are applied accordingly. This means that if such parts are not buried in the cemetery or cremated by health care units they can, following a decision by the organisation referred to above, be transferred to medical academies for scientific purposes.

In the Act of 30 June 2000 – the Law of Industrial Property (Dz. U. z 2001 Nr.49 poz. 508), regulating the rules of granting patents, no separate rules have been introduced defining the use of human biological material, with reference to an invention reported for patent protection. Art. 29 of this Law states only that no patents are granted for treatment and diagnostic methods for humans and animals. However, the regulation does not refer to products applied during diagnosis or treatment, whereas the Law does not define whether or not the term “product” can also be understood as human biological material.

## 5. Experiments relating to human embryo and embryo stem cells

Polish legal rules do not include separate regulations with respect to the human embryo and human embryo stem cells. There is also no legal definition for the embryonic stage of life. Regulations referring to legal protection and conduct rules in the pre-birth stage of human life are included in the Act of 7 January 1993 on Family Planning, Protection of Human Foetus and Admissible Conditions for an Abortion (Dz. U. Nr 17 poz. 78 z późn. zm).

In accordance with Art. 1 of this Law, the right to life is protected, including the prenatal stage, in the scope stipulated by the Law.

The Law also includes regulations concerning the unborn child from the moment of conception through the embryo and foetal stages until birth.

According to Art. 157 $\alpha$  of the Criminal Code, anyone except a child's mother who commits any infringement to an unborn child will be punished. The rule does not include a physician who undertakes any medical action necessary to exclude the threat of danger to either the mother's or child's health or life.

In accordance with Art. 26 of the Act on the Medical Profession, unborn children cannot participate in scientific experiments, which means indirectly that the participation of unborn children in therapeutic experiments is permissible, although there is no regulation on this issue.

Poland has no legal regulations relating to the prohibition of human cloning but, as mentioned above, in 1999, Poland signed the Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings of the Council of Europe. Nevertheless, the Code of Ethics for physicians forbids the participation of any physician in cloning proceedings (Art. 39 $\alpha$ ).

## 6. Personal data

**Art. 51** of the Constitution of the Republic of Poland states that nobody can be compelled, other than by the Law, to disclose any information related to him/her, and public authorities cannot collect, store or disclose any information about the citizens other than is necessary in the democratic state of law.

The Act of 29 August 1997 on the Protection of Personal Data (Dz. U. z 2002 r. Nr 101, poz. 926) is a fundamental legal act on this subject. The Law establishes for every individual the right to protect personal data related to him/her. The Law defines personal data (Art. 6) as all information relating to a person who has been or can be identified.

According to Art. 27 of the Law, it is forbidden to process particular types of personal data. These are data on racial or ethnic origin, political opinions, religious notions, political party affiliations, health status, addictions, sexual preferences and criminal records.

Processing this data is possible only under specific circumstances, including a situation where a person related to this information gives his/her written consent for this. Processing data related to health status is only possible when it is performed by individuals exercising their medical professions to protect health and to apply health services, and when a full guarantee for the protection of personal data is provided. Processing personal data is permissible when it is indispensable to the conduct of scientific research, provided that the publication of the research results precludes identification of individuals related to this data.

The protection of personal data related to health status is also stipulated by the Act on the Medical Profession, the Act on the Professions of a Nurse and a Midwife, and in the Act on Health Care Units.

According to Art. 40 of the Act on the Medical Profession, a physician is responsible for maintaining the confidentiality of information relating to the patient and obtained in the course of professional conduct. This also refers to information gathered as the result of the clinical trial carried out. Art. 28 of this Law states that information obtained in relation to a clinical trial may be used for scientific purposes in a manner precluding the identification of the individual examined. Maintaining confidentiality is also binding after the death of the person to whom the information relates.

Similar responsibilities concerning the confidentiality of information relating to a patient and pertaining to nurses and midwives are included in the Act of 5 July 1996 on the Professions of a Nurse and a Midwife (Art. 21) and the Code of Ethics for Physicians (Art. 28).

In the Order of Minister of Health of 10 December 2002 on the Determination of Detailed Requirements for Good Clinical Practice, one of the conditions for conducting the clinical examination of a medicinal product is the preservation of the confidentiality of participants' data in compliance with the binding regulations on the protection of personal data.

Exemptions from the duty to maintain confidentiality as regards information relating to the

health status of an individual participating in a clinical trial arise from Art. 40 of the Act on the Medical Profession and include, among others, cases where:

- 1) An individual participating in the examination gives his/her consent;
- 2) It results from Parliamentary Acts of Law;
- 3) Maintaining confidentiality may create a life or health hazard for the participant or other people.

## 7. Genetic information

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**A**s mentioned above, the Act on Protection of Personal Data (Art. 29) forbids the processing of data related to the genetic code of a given person, unless it is indispensable for the protection of such an individual's health or he/she gives his/her written consent.

In Polish regulations relating to the health protection system, there is no specific regulation on genetic examination and access to genetic data.

In the Act of 22 May 2003 on Insurance Activities, in Art. 22, which concerns the access by insurance companies to data relating to the health of insured individuals, the transfer of genetic data to these companies by those in possession of such information (e.g. hospitals) is excluded.

## 8. Experiments with animals

The legal act regulating experiments with animals is the Act of 21 August 1997 on the Protection of Animals (Dz. U. Nr 111, poz. 724 z późn. zm.).

An experiment with an animal is defined in Art. 4 of the Law as any form of utilisation of an animal (vertebrate) in scientific research, tests and for educational purposes.

According to Art. 28 of the Act, experiments with animals are permissible only when they are indispensable for scientific research, teaching methods in universities and medical academies, or for the protection of the health of humans or animals, and these objectives cannot be achieved in any other way because of the lack of suitable alternative methods.

The National Ethical Commission for Experiments with Animals and local ethical commissions have been created in order to look at experiments on animals. The National Ethical Commission has been appointed by the Minister of Scientific Research and Information Technologies and comprises 15 members. It is composed of representatives from the biological, medical, veterinary, and human sciences professions and representatives of non-governmental organisations engaged in the protection of animals. The National Ethical Commission appoints local ethical commissions, comprising five to 15 members, with a similar profile to its own.

The National Ethical Commission sets out general operational rules for local ethical commissions and rules for issuing opinions about the admission of

experiments with animals, and investigates appeals against opinions given by local ethical commissions.

Experiments on animals may be performed by organisational units of universities and medical academies, research and development institutes, veterinary laboratories, drug manufacturers listed in a register administered by the Minister of Scientific Research and Information Technologies, and by adequately qualified personnel with individual permits from the manager of an organisational unit. In consultation with the local ethical commission, the manager of such a unit appoints a person to be responsible for taking care of animals and for carrying out an experiment, in compliance with the protocol approved by the ethical commission. The organisational unit is obliged to produce documentation on animals used in experiments as well as documentation on experiments performed on these animals.

The operational principles for ethical commissions are defined in the Regulation by the Council of Ministers dated 2 September 2003 on the National Commission for Experiments with Animals and Local Ethical Commissions for Experiments with Animals.

Generally speaking, according to Art. 29 of the Law on the protection of animals, animals originating from laboratory breeding are being used in experiments. It is permissible to use wild animals or those from stock-raising farms, providing the objective of such an experiment cannot be achieved by using other animals. It is forbidden to use homeless animals in experiments.

Experiments causing pain or other suffering should be performed under general or local anaesthesia and only once on the same animal, unless the nature of the experiment requires its repetition (Art. 30). An animal at a higher development stage of mental activity, capable of living after the experiment, should be treated in order to enable its further existence. If the animal has been subjected to excessive surgical intervention and the objective of the experiment does not require its survival, the animal's life must be terminated before it wakes from anaesthesia.

It is forbidden (Art. 31) to:

- 1) Perform on animals any research on cosmetics and matters of hygiene when alternative methods are available,
- 2) Take away from animals used in experiments the capacity to express themselves or to react.

The conditions as regards keeping animals on experimental animal farms and during the execution of experiments should provide for proper care and living conditions, including the minimum space necessary to enable the freedom of movement, proper feeding and watering, as well as humane treatment.

The Act on the Protection of Animals does not regulate the use of genetically modified animals in experiments. The issue of genetically modified animals is regulated by the Act of 22 June 2001 on Genetically Modified Organisms (Dz. U. Nr 76 poz. 811). However, this Law only establishes

principles for the contained use of genetically modified organisms and the deliberate release of these organisms into the environment, and does not relate to the rules of experiments with animals.

## 9. Additional information

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**T**he information presented above is based on the regulations of Acts and Orders which are binding in Poland. The legal status described is binding as of 1 October 2003.

Only the general substance of legal regulations has been presented with individual comments kept to the minimum.

European Commission

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