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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"/>
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## National Regulations on Ethics and Research in

# Slovenia

Slovenija



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National Regulations  
on Ethics and Research in

# Slovenia

Slovenija

by  
Jože Trontelj  
Damjan Korošec

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

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## Foreword

The Republic of Slovenia is proud of its long and respectable tradition in the ethical review of research on human beings. This is mainly a merit of the exemplary work in medical ethics by the late Janez Milčinski, doctor of medicine and law, professor of forensic medicine and medical deontology, an outstanding figure in Slovenian science and society in the second half of the last century. The fact that during the past decades we have not seen any cases of seriously unethical medical research can undoubtedly be attributed to the dedicated efforts of the late Professor in educating generations of Slovenian medical students and doctors in professional ethics and deontology, and also to the careful ethical review of all medical research on human subjects since the mid-sixties.

Thanks to Professor Milčinski, Slovenia has also one of the oldest ethical committees at the national level in Europe having been, in continuous operation since the late seventies. The Committee and its members have helped in developing ethical guidelines, such as the Slovenian Code of Medical Deontology, as well as national legislation concerning a number of ethical issues, ranging from transplantation of human organs, medically assisted procreation and gene technology to protection of animals in research. It was also helpful in the early accession of Slovenia to the Convention on Human Rights and Biomedicine of the Council of Europe; in fact, Slovenia was among the first five countries to ratify the Convention - the number required for this important legal

instrument to enter into force. The coming Additional Protocol to the Convention, on Biomedical Research, in the preparation of which Slovenia actively participated, will provide another comprehensive and uniquely detailed guidance to researchers. As an instrument with the power of law, it will establish a legal framework within which the researchers will be able to work freely and safely.

With new developments in science presenting mankind with novel and often complex ethical dilemmas, and in the light of an increasing awareness of human rights, such guidance is becoming increasingly important. It is the responsibility of the scientific community, funding agencies, independent ethics committees and regulatory authorities not only to ensure ethical conduct of scientific research within national boundaries and on the territory of the European Union, but also to prevent the export of ethically objectionable research to countries in which legislation and practice of ethical review and supervision are less well established. Slovenia welcomes the international co-operation in this important area where societal interests have to have a say in science.

*Slavko Gaber*

*Minister of Education, Science and Sport of the  
Republic of Slovenia*

# 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](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.<sup>(1)</sup>"

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 Slovenian text has been written by Prof. Jože Trontelj and Dr. Damjan Korošec and subsequently approved by the Ministry of Education, Science and Sport of the Republic of Slovenia. 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, Science and Sport of the Republic of Slovenia.



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

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# 1. International instruments in Slovenian law

**E**thical review of biomedical research on human subjects has been practised in Slovenia since the mid-sixties, when an ethics committee was established at the Ljubljana Medical School and the rule was adopted that no thesis for D.Sc. Degree may be accepted unless the research was previously reviewed for ethical acceptability. The Helsinki Declaration was then already strictly observed, and the Ethics Committee - some years later elevated to the rank of a state supervisory body - issued official guidelines for researchers that are in accordance with the Tokyo revision of the Helsinki Declaration in 1978. This was accompanied by excellent courses in medical ethics and deontology for medical students, with an appropriate emphasis on ethics and good practice in research. As a result, there have been practically no cases of serious misconduct in medical research on human subjects in Slovenia during the last 40 years, although a considerable amount of research activity has been going on.

Slovenia was one of the first five countries to ratify the Council of Europe's Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine (the Oviedo Convention, 1,2). Thus, the Convention has been in force in Slovenia since December 1, 1999. It contains important provisions on ethics of biomedical research on human beings, which are observed in the ethical review of research projects. Slovenia's delegate to the Steering Committee on Bioethics in the Council of Europe is a member of the Working Party drafting the Additional Protocol to the Convention, on

biomedical research (3), and the principles of the draft protocol have been a basis for the national guideline to prospective researchers, published in 1998 (4). It is foreseen that a comprehensive national law on biomedical research will be drafted after the Additional Protocol to the Convention has been adopted (5).

In July 2000, a national directive was adopted on clinical drug testing (6), based on the EU Directive on good clinical practice in the conduct of clinical trials on medicinal products for human use (7), which was then in the drafting stage. In addition, this regulation has favourably influenced ethics in pharmaceutical research.

Thus, the current practice in assuring observance of ethical principles in biomedical research to a large extent relies on the Helsinki Declaration (8), on the Oviedo Convention (1) and the provisions of the Draft Protocol to the Oviedo Convention, on biomedical research (3). The National Medical Ethics Committee (NMEC), which reviews most of the biomedical research on human subjects, is the main body responsible for ethics of biomedical research in the country (9). It relies heavily upon the Oviedo Convention and its principles as elaborated in the Draft Protocol on Biomedical Research. Therefore, the following overview will mainly *reflect the current practice* on how the ethical conduct of biomedical research on human subjects is assured rather than the relatively incomplete actual legislation in this area. It should be emphasised that the current absence of specific legal regulation in the formal national legislation does not, in effect,

imply a legal vacuum with space for liberal behaviour in research on humans. Mechanisms, in particular ethical review of research protocols, are

in place which, with the assistance of international legal instruments, assures ethical conduct of medical research involving human subjects.

## 2. National overview

As mentioned above, Slovenia has at present no specific law regulating biomedical research on human subjects. However, provisions related thereto can be found in several laws, such as:

- Law on Biomedically Assisted Fertilisation (10), e.g. in Art. 38: "scientific research on [...] early embryos, created for the purposes of biomedically assisted fertilisation is allowed exclusively for the purposes of protecting and improving human health" and "only when the research cannot be performed, with comparable effectiveness, on animal embryos or by other methods,..." .
- Law on Medical Practice (11), where according to Art. 47 every medical intervention must be covered by an informed consent of the patient or, in case of a child or incompetent adult, the patient's parents or guardians, and finally in the
- Penal Code (12), where, according to Art. 190, every negligent medical malpractice resulting in the serious damage to a person's health is punishable with up to one-year's imprisonment. The Code does not contain any explicit provisions incriminating unlawful research on humans or human embryos.

Other legal instruments which apply to the current practice are:

- The Directive on Clinical Drug Testing (6) regulates good clinical practice in the field of pharmaceutical research and research on medical devices. It is based on the Directive 2001/20 EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (7).
- The Slovenian Code of Medical Deontology (13) contains, in Articles 47-50, provisions on ethical conduct of biomedical research on human subjects.
- The Helsinki Declaration of the World Medical Association (8) continues to provide an essential guidance for researchers, drafters of protocols of clinical studies, and for ethical review, and has in Slovenia a de facto status of obligatory guideline.

### **1) Role and remit of research ethics committees or other competent bodies and their power with respect to the law**

The National Medical Ethics Committee (NMEC) currently reviews most biomedical research on human subjects. The multidisciplinary composition, appointment of members, duration of their mandate, duties and responsibilities have been determined by the Ministerial Order, published in the Official Gazette of the Republic of Slovenia No. 30, 2nd June 1995 (9).

Based on the respective internal regulations, all research for obtaining an M.Sc. or D.Sc. Degree at the Faculty of Medicine, as well as all biomedical research projects funded by the state agencies such as the Ministry of Education, Science and Sports, must obtain an approval by the NMEC. In addition, all multi-centre and multinational controlled clinical trials must be reviewed by the NMEC.

There are two regional ethical committees linked to regional medical centres (Maribor and Celje). They review some of the biomedical research conducted in their area, but are not authorised to grant independent approvals for projects in research categories mentioned in the preceding paragraph. They may, however, in certain cases provide relevant information to the NMEC, e.g. on whether adequate local conditions exist for the performance of a successful and scientifically sound study. Such conditions may include sufficiently experienced researchers, adequate number of patients, adequate facilities. They can follow up the development of ongoing studies and assess and

report on any ethical, safety or other issues appearing during the conduct of the project.

At present, 2 specialised RECs exist in Slovenia: an REC for oncological research taking place at the National Institute of Oncology, and a State Committee on Biomedically Assisted Procreation, which is responsible for pre-assessment of research projects in this field, reporting its opinion to the NMEC, which then takes the final decision. As soon as the new Law on protection of human rights with regard to genetics (14) is adopted, a specialised REC will also be established for pre-reviewing research projects in this field. It is likely that the final decision for these projects will remain within the responsibility of the NMEC.

### **2) What kinds of projects or procedures should go to ethics committees or other competent bodies for approval?**

All research involving intervention on or interaction with living persons has to be reviewed and approved before the actual work may be started. This also applies to research on biological materials of human origin, i.e., tissue and blood samples, both prospectively collected and archived, even if anonymous. Ethical review is also obligatory for research on personal medical data, including epidemiological studies. Sociological and psychological studies based on questionnaires, which invade privacy with potential harmful effects for persons involved, are also subject to ethical review.

The NMEC is authorised to review novel treatment procedures on their ethical acceptability. However,

only a proportion of all advanced new medical methods and technologies are actually submitted for such a review. This is mainly due to the fact that, in most cases, they are transferred from other countries where they have already reached the status of an established form of diagnostic, therapeutic or preventive medicinal substances, medical devices, procedures or technologies.

Following a recent discussion about post-registration drug studies, the NMEC decided to recommend to medical researchers to insist on sponsors of such studies to obtain an ethical approval (which is in contrast to some European countries, such as Germany).

### 3. Research using human beings

#### 1) Laws regarding informed consent

Specific legal regulations related to informed consent do not exist. However, it is common practice of the NMEC to require the consent in all cases of direct intervention on, or interaction with, persons concerned.

In principle, informed consent is also required for research on archived personal medical data or biological samples. This requirement may be waived by the NMEC if seeking consent would involve unreasonable efforts and in as far as the risk of undue invasion of privacy is minimal.

In some cases of so-called observational research, where data is rendered anonymous and where there is no possibility of violation of human rights, in particular the right to private life, informed consent is not needed. It is, however, for the research ethics

committee to decide whether the duty of obtaining consent is there or not. In principle, observational research has to be reviewed for ethical acceptability; as mentioned, this is already the case for Phase IV clinical drug studies, where patients are not subjected to any other than routine procedures which would be carried out regardless of their participation in the study. However, exactly in these studies the right to privacy is often inadequately observed. This is one of the reasons why the NMEC insists on reviewing such research, and also on obtaining informed consent.

#### 2) When is consent not sufficient and when is it not necessary?

Consent by the person concerned may not be sufficient when he/she is legally or *de facto* incompetent or unable to take decisions in his/her best interest. Such is the case with children and

adolescents below the age of legal competence or persons with a mental disorder.

In emergency situations, when a person is not in a state to give consent and even proper authorisation cannot be obtained, the Slovenian practice follows the provision of Article 20 of the Draft Protocol to the Oviedo Convention, on biomedical research (3): "Persons participating in the emergency research shall be provided with all the relevant information as soon as it becomes possible. Consent for continued participation shall be obtained as soon as reasonably possible".

As indicated above, there are observational studies that cannot be considered to invade privacy or give rise to other infringements upon human rights and dignity of the persons concerned; seeking their consent may therefore be unnecessary.

### **3) Children**

Children are considered legally competent beyond the age of 15 (Law on health services, Art. 47/II (11)). For younger children where authorisation is sought from their legal representatives, the NMEC requires that the child takes part in the decision process (Article 17 of the Draft Research Protocol: "The opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity"). Research on a child who objects to the procedures proposed may not be started nor continued.

### **4) Other persons unable to consent**

An adult not able to consent, e.g. because of a mental disorder, must be allowed to take part in the authorisation procedure as far as possible (Article 17 of the Draft Research Protocol, 3).

### **5) Other legal requirements for research**

Again, the existing regulations are not containing any specific provisions offering a special protection for the vulnerable groups of persons involved in research. However, the practice of ethical review in these situations relies on the essential requirements of Articles 16 and 17 of the Oviedo Convention and Articles 17, 20, 21 and 22 of the Draft Research Protocol, namely:

- (1) that "results expected cannot be obtained from research on persons who are not members of these vulnerable groups";
- (2) that "research has the potential to produce a direct benefit to the persons included into research or at least to members of the same groups", and
- (3) that "risks are not disproportionate to the potential real and direct benefits of that research".
- (4) Moreover; "in case of persons unable to consent the risks and burdens should be minimal; in case of research on pregnant women and nursing mothers, the risks and burdens should be minimal for the embryo or foetus or infants". Particular attention is paid to the need
- (5) that "dependent position is not allowed to influence consent".

## 4. Research involving human biological material

No specific national regulations exist in this regard, except for the ones related to blood transfusion and organ transplantation. As regards research, development of legislation is expected to be drafted after the Instrument on the use of biological materials of human origin will have been adopted by the Council of Europe, presently in the drafting stage (15, 16).

### 1) Laws regarding use of biological material from live patients

Articles 21 (prohibition of financial gain) and 22 (on disposal of a removed part of the human body) of the Oviedo Convention apply.

### 2) Laws regarding use of biological material from deceased persons

Under Art. 191 of the Penal Code (12), any physician, who unlawfully removes a part of a human body or implants such a part or removes such a part before death had been legally certified or without having obtained the informed consent of the donor and/or recipient or anyone other person who unlawfully deals in parts of a living or dead person for transplantation purposes for money, is punishable with up to five or three years imprisonment, respectively. There are no other specific criminal provisions for unlawful use of biological material from deceased persons. Several provisions on the removal procedures of organs and tissues are contained in the Law on Transplantation of Parts of Human Body for Therapeutic Purposes (17). In principle, removal is unlawful if a valid refusal of the deceased person or close relations exists at the time of the removal.

### 3) Laws regarding old collections of biological material, pre-existing and ongoing research.

No legal regulation exists in this regard. Once more, the development of legislation is expected after the guideline on the use of biological materials of human origin will have been adopted by the Council of Europe.

### 4) With reference to recital 26 of Directive 98/44/EC - is consent required for patents developed from or containing human biological material?

This question was raised on a few occasions. The NMEC decided that informed consent is required. However, the donors of the biological material were not considered to have a right to financial benefit (apart from reimbursement for actual expenses incurred by them), in accordance with Article 21 of the Oviedo Convention (the human body and its parts shall, as such, not be a source of financial gain).

## 5. Research involving human embryos and embryonic stem cells

### 1) How is the embryo defined?

According to the Law on Biomedically Assisted Fertilisation (10), an embryo is regarded to come into existence as soon as fusion of the gametes has occurred (Art. 4). For the purposes of the law, the "early embryo" is used for the zygote and the embryo, which develops outside the uterus during the first 14 days or until the appearance of the primitive streak.

### 2) Can human embryos be used for research?

The Law on Biomedically Assisted Fertilisation (10) (Art. 38) allows the use of those early embryos that were created for the purpose of biomedically assisted procreation that are not suitable for transfer into the woman's body or for cryopreservation for future reproductive purposes. The Law also allows the use for research of cryopreserved embryos that will no longer be used for a parental project and would otherwise be destroyed (embryos may be stored for up to 5 years - Art. 35 of the Law of Biomedically Assisted Fertilization. For medically justified reason, the storage period may be extended, according to Art. 35 of the same Law).

Research on early embryos is only justified when it cannot be performed, with similar effectiveness, on animal embryos or otherwise.

Research on 'spare' early embryos originating from the IVF procedure for a parental project may only be allowed with the written consent of the couple that is being assisted with this procedure. An approval must be obtained from the State

Commission on Biomedically Assisted Fertilisation and confirmed by the NMEC, who is also responsible for the supervision of the research (Art. 38).

The same Article also requires that in research on early embryos, contemporary medical knowledge and experience, the internationally established practice and the general principles of medical ethics must be taken into account.

### 3) What are permitted sources of embryos?

In Slovenia, the creation of human embryos for research is prohibited (Art 18 of the Oviedo Convention, Art. 33 of the Law on Biomedically Assisted Fertilisation). Thus, IVF for parental projects is the only permitted source, and only embryos unsuitable for procreation or those that are no longer required for a parental project may be used in research that will result in their destruction. It is unlawful to allow in vitro development beyond 14 days or after the appearance of the primitive streak (Art. 33/1).

### 4) What (if any) are permitted sources of embryonic stem cells?

Early embryos that may be used for research (see above) may be a legitimate source of embryonic stem cells. The product of abortions is another legitimate source; however, the indications, timing, and methods of the abortion may not be modified in the interests of acquiring the material.

**5) Law regarding human reproductive cloning.**

Slovenia is a party to the Oviedo Convention and its Additional protocol on the prohibition of cloning of human beings (18). The Law on Biomedically Assisted Fertilisation (10) in its Art. 33 explicitly

prohibits the creation of embryos genetically identical to another human being, living or dead. This implies that also therapeutic cloning is illicit.

## 6. Personal data

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**1) How are personal data defined?**

Personal data is a legal category that is defined in a very broad sense in the Personal Data Protection Act (19). It includes any data that may reveal properties, capacity, state or relationships of a person, regardless of the form of those data (Art. 2).

**2) Regulatory approach to data rendered anonymous**

Anonymous data are not subject to legal restrictions (19).

**3) Fundamental rights and privacy**

According to Art. 38 of the Constitution of the Republic of Slovenia (20), the protection of personal data shall be guaranteed. In particular, the Constitution forbids any use of personal data, which may be in disagreement with the original purpose for which they were collected. Everybody has the right to be informed of any personal data

collected from him. Everybody has the right to legal protection against any misuse of his/her personal data.

**4) Conditions for data processing**

As mentioned above, the Personal Data Protection Act forbids any use of personal data in disagreement with the original purpose for which they were collected. The misuse of personal data is a crime under Art. 154 of the Penal Code and punishable with up to two year's imprisonment. In the ethical review of biomedical research on human beings, particular attention is paid to assuring adequate protection of personal medical data, as well as other personal data. Early anonymisation is recommended. The NMEC requires the proposer of a research on sensitive data, such as HIV epidemiology, to describe the arrangements for data protection and anonymisation, whilst ensuring the latter to be irreversible.

**5) Description of any regulations that are not in the Directive on Data Protection but which the directive allows**

No particular differences between the Directive and the legal regulations in Slovenia could be found.

**6) Identify any regulations which are contrary to the Directive**

No disagreement between the provisions of the EU Directive and those of the Slovenian Personal Data Protection Act could be identified.

**7) What exemptions from data protection law are there for research?**

In research, all general provisions of the Personal Data Protection Act (19) apply. In some research situations,

unexpected information can be generated which may be important for the present or future health of the participants. In such instances, the code may be broken in the interest of the person concerned and with the approval of the NMEC. The researchers are obliged to observe the provisions of paragraphs 2 and 3 of Article 10 of the Oviedo Convention: "Everyone is entitled to know any information collected about his or her health. However, the wishes of the individuals not to be informed shall be observed. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient".

## 7. Genetic information

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Some protection is enshrined in the Personal Data Protection Act (19). A more detailed regulation will be provided in the future Law on protection of human rights with regard to genetics (14), as well as in the future Law on biomedical research on human beings (5).

In the current practice of ethical review, the NMEC insists on the principles enshrined in the Oviedo

Convention and elaborated on in more detail in the Draft Additional Protocol to the Convention, on Human Genetics (21). Among those principles is the requirement of genetic counselling whenever results of genetic tests are (intended to be) communicated to the persons involved, the need for particularly careful confidentiality and data protection, the unacceptability of predictive testing of children and adolescents for disorders manifested in adulthood, the

need for special arrangements for communicating the relevant information to relatives, etc.

## 8. Research involving animals

**A**ccording to Art. 342 of the Penal Code (12), torturing animals is a crime punishable with up to three months imprisonment. Torturing is defined as the cruel treatment of animals or inflicting unnecessary suffering upon them. Similar provisions are also contained in the Animal Protection Act (22), Art. 4. This Act establishes an Animal Ethics Committee (Committee for Ethics of Experimentation on Animals), from which a written approval must be obtained for every experimental study on animals.

The Animal Protection Act regulates several substantive and procedural aspects of experiments on animals (Chapter 4) in a detailed manner. Only organisations registered for experimenting on animals are authorised to perform such experiments. Every experimental study on vertebrate animals must be individually approved (Art. 21). It can be approved if it is scientifically justified (and there are no reasonable alternatives). Art. 21 of the Animal Protection Act states that the Committee for Ethics of Experimentation on Animals is set up jointly by the minister responsible for the veterinary service,

the minister for science and technology, the minister for education and the minister for environment.

Art. 21 of the Animal Protection Act forbids experiments with ethically unacceptable aims, in particular experiments with weapons, tobacco, cosmetics and alcoholic beverages.

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16. Draft Explanatory Report to the draft instrument on the use of archived human biological materials and related personal data in biomedical research CDBI (2002) 4.
17. Law on Transplantation of Parts of Human Body for Therapeutic Purposes (Zakon o presaditvi delov človeškega telesa zaradi zdravljenja, Ur.l. RS, No.:12/00.
18. Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning of Human Beings.
19. Personal Data Protection Act (Zakon o varstvu osebnih podatkov), Ur.l. RS, No.:59/99, 57/01, 59/01 and 52/02.
20. Constitution of the Republic of Slovenia (Ustava Republike Slovenije), Ur.l. RS, No.:33/91 and 42/97.
21. Draft Additional Protocol to the Convention on Human Rights and Biomedicine, on Human Genetics
22. Animal Protection Act (Zakon o varstvu živali), Ur.l. RS, No.:98/99.



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