URADNI LIST

Uradni list RS, št. 70/1998 z dne 16. 10. 1998

42. Zakon o ratifikaciji Konvencije o varstvu človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine (Konvencija o človekovih pravicah v zvezi z biomedicino) in Dodatnega protokola o prepovedi kloniranja človeških bitij h Konvenciji o varstvu človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine (MVCPB), stran 277.

Na podlagi druge alinee prvega odstavka 107. člena in prvega odstavka 91. člena Ustave Republike Slovenije izdajam

U K A Z
O RAZGLASITVI ZAKONA O RATIFIKACIJI KONVENCIJE O VARSTVU ČLOVEKOVIH PRAVIC IN DOSTOJANSTVA ČLOVEŠKEGA BITJA V ZVEZI Z UPORABO BIOLOGIJE IN MEDICINE (KONVENCIJA O ČLOVEKOVIH PRAVICAH V ZVEZI Z BIOMEDICINO) IN DODATNEGA PROTOKOLA O PREPOVEDI KLONIRANJA ČLOVEŠKIH BITIJ H KONVENCIJI O VARSTVU ČLOVEKOVIH PRAVIC IN DOSTOJANSTVA ČLOVEŠKEGA BITJA V ZVEZI Z UPORABO BIOLOGIJE IN MEDICINE (MVCPB)

Razglašam Zakon o ratifikaciji Konvencije o varstvu človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine (Konvencija o človekovih pravicah v zvezi z biomedicino) in Dodatnega protokola o prepovedi kloniranja človeških bitij h Konvenciji o varstvu človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine (MVCPB), ki ga je sprejel Državni zbor Republike Slovenije na seji 24. septembra 1998.

Št. 001-22-90/98
Ljubljana, dne 2. oktobra 1998

Predsednik
Republike Slovenije

Milan Kučan l. r.

Z A K O N
O RATIFIKACIJI KONVENCIJE O VARSTVU ČLOVEKOVIH PRAVIC IN DOSTOJANSTVA ČLOVEŠKEGA BITJA V ZVEZI Z UPORABO BIOLOGIJE IN MEDICINE (KONVENCIJA O ČLOVEKOVIH PRAVICAH V ZVEZI Z BIOMEDICINO) IN DODATNEGA PROTOKOLA O PREPOVEDI KLONIRANJA ČLOVEŠKIH BITIJ H KONVENCIJI O VARSTVU ČLOVEKOVIH PRAVIC IN DOSTOJANSTVA ČLOVEŠKEGA BITJA V ZVEZI Z UPORABO BIOLOGIJE IN MEDICINE (MVCPB)

1. člen

Ratificirata se Konvencija o varstvu človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine (Konvencija o človekovih pravicah v zvezi z biomedicino), sklenjena v Oviedu (Asturija) 4. aprila 1997 in Dodatni protokol o prepovedi kloniranja človeških bitij h Konvenciji o varstvu človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine, sklenjen v Parizu 12. januarja 1998.

2. člen

Konvencija in dodatni protokol se v angleškem izvirniku in v slovenskem prevodu glasita:

C O N V E N T I O N
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

Oviedo, 4. IV. 1997

Preamble

The Member States of the Council of Europe, the other States and the European Community signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the European Social Charter of 18 October 1961;

Bearing in mind the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights of 16 December 1966;

Bearing in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing also in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine;

Have agreed as follows:

Chapter I - General provisions

Article 1 - Purpose and object

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

Article 2 - Primacy of the human being

The interests and welfare of the human being shall prevail over the sole interest of society or science.

Article 3 - Equitable access to health care

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

Article 4 - Professional standards

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

Chapter II - Consent

Article 5 - General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.
This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.
The person concerned may freely withdraw consent at any time.

Article 6 - Protection of persons not able to consent

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.
2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.
The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.
3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.
The individual concerned shall as far as possible take part in the authorisation procedure.
4. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above

shall be given, under the same conditions, the information referred to in Article 5.
5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

Article 7 - Protection of persons who have mental disorder

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

Article 8 - Emergency situation

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 9 - Previously expressed wishes

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

Chapter III - Private life and right to information

Article 10 - Private life and right to information

1. Everyone has the right to respect for private life in relation to information about his or her health.
2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.
3. 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.

Chapter IV - Human genome

Article 11 - Non-discrimination

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

Article 12 - Predictive genetic tests

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

Article 13 - Interventions on the human genome

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

Article 14 - Non-selection of sex

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child’s sex, except where serious hereditary sex-related disease is to be avoided.

Chapter V - Scientific research

Article 15 - General rule

Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.

Article 16 - Protection of persons undergoing research

Research on a person may only be undertaken if all the following conditions are met:
i) there is no alternative of comparable effectiveness to research on humans,
ii) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research,
iii) the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability,
iv) the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,
v) the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Article 17 - Protection of persons not able to consent to research

1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:
i) the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled;
ii) the results of the research have the potential to produce real and direct benefit to his or her health;
iii) research of comparable effectiveness cannot be carried out on individuals capable of giving consent;
iv) the necessary authorisation provided for under Article 6 has been given specifically and in writing, and
v) the person concerned does not object.
2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:
i) the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.
ii) the research entails only minimal risk and minimal burden for the individual concerned.

Article 18 - Research on embryos in vitro

1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.
2. The creation of human embryos for research purposes is prohibited.

Chapter VI - Organ and tissue removal from living donors for transplantation purposes

Article 19 - General rule

1. Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.
2. The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.

Article 20 - Protection of persons not able to consent to organ removal

1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.
2. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:
i) there is no compatible donor available who has the capacity to consent,
ii) the recipient is a brother or sister of the donor,
iii) the donation must have the potential to be life-saving for the recipient,
iv) the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the competent body,
v) the potential donor concerned does not object.

Chapter VII - Prohibition of financial gain and disposal of a part of the human body

Article 21 - Prohibition of financial gain

The human body and its parts shall not, as such, give rise to financial gain.

Article 22 - Disposal of a removed part of the human body

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

Chapter VIII - Infringements of the provisions of the Convention

Article 23 - Infringement of the rights or principles

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Article 24 - Compensation for undue damage

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 25 - Sanctions

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

Chapter IX - Relation between this Convention and other provisions

Article 26 - Restrictions on the exercise of the rights

1. No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.
2. The restrictions contemplated in the preceding paragraph may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21.

Article 27 - Wider protection

None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention.

Chapter X - Public debate

Article 28 - Public debate

Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

Chapter XI - Interpretation and follow-up of the Convention

Article 29 - Interpretation of the Convention

The European Court of Human Rights may give, without direct reference to any specific proceedings pending in a court, advisory opinions on legal questions concerning the interpretation of the present Convention at the request of:
– the Government of a Party, after having informed the other Parties,
– the Committee set up by Article 32, with membership restricted to the Representatives of the Parties to this Convention, by a decision adopted by a two-third majority of votes cast.

Article 30 - Reports on the application of the Convention

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

Chapter XII - Protocols

Article 31 - Protocols

Protocols may be concluded in pursuance of Article 32, with a view to developing, in specific fields, the principles contained in this Convention.
The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying accepting or approving the Convention.

Chapter XIII – Amendments to the Convention

Article 32 – Amendments to the Convention

1. The tasks assigned to “the Committee“ in the present article and in Article 29 shall be carried out by the Steering Committee on Bioethics (CDBI), or by any other committee designated to do so by the Committee of Ministers.
2. Without prejudice to the specific provisions of Article 29, each member State of the Council of Europe, as well as each Party to the present Convention which is not a member of the Council of Europe, may be represented and have one vote in the Committee when the Committee carries out the tasks assigned to it by the present Convention.
3. Any State referred to in Article 33 or invited to accede to the Convention in accordance with the provisions of Article 34 which is not Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.
4. In order to monitor scientific developments, the present Convention shall be examined within the Committee no later than five years from its entry into force and thereafter at such intervals as the Committee may determine.
5. Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, to the European Community, to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 33 and to any State invited to accede to it in accordance with the provisions of Article 34.
6. The Committee shall examine the proposal not earlier than two months after it has been forwarded

by the Secretary General in accordance with paragraph 5. The Committee shall submit the text adopted by a two-thirds majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

7. Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

Chapter XIV – Final clauses

Article 33 – Signature, ratification and entry into force

1. This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration and by the European Community.

2. This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3. This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present article.

4. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 34 - Non-member States

1. After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d, of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2. In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 35 - Territories

1. Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.
2. Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.
3. Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 36 - Reservations

1. Any State and the European Community may, when signing this Convention or when depositing the instrument of ratification, acceptance, approval or accession, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article.
2. Any reservation made under this article shall contain a brief statement of the relevant law.
3. Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 35, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.
4. Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 37 - Denunciation

1. Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.
2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 38 - Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council, the European Community, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a) any signature;

b) the deposit of any instrument of ratification, acceptance, approval or accession;

c) any date of entry into force of this Convention in accordance with Articles 33 or 34;

d) any amendment or Protocol adopted in accordance with Article 32, and the date on which such an amendment or Protocol enters into force;

e) any declaration made under the provisions of Article 35;

f) any reservation and withdrawal of reservation made in pursuance of the provisions of Article 36;

g) any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at Oviedo (Asturias), this 4th day of April 1997, in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.

ADDITIONAL PROTOCOL
to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings

Paris,12. 1. 1998

The member States of the Council of Europe, the other States and the European Community Signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine,

Noting scientific developments in the field of mammal cloning, particularly through embryo splitting and nuclear transfer;

Mindful of the progress that some cloning techniques themselves may bring to scientific knowledge and its medical application;

Considering that the cloning of human beings may become a technical possibility;

Having noted that embryo splitting may occur naturally and sometimes result in the birth of genetically identical twins;

Considering however that the instrumentalisation of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of

biology and medicine;
Considering also the serious difficulties of a medical, psychological and social nature that such a deliberate biomedical practice might imply for all the individuals involved;
Considering the purpose of the Convention on Human Rights and Biomedicine, in particular the principle mentioned in Article 1 aiming to protect the dignity and identity of all human beings,
Have agreed as follows:

Article 1

1 Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
2 For the purpose of this article, the term human being “genetically identical“ to another human being means a human being sharing with another the same nuclear gene set.

Article 2

No derogation from the provisions of this Protocol shall be made under Article 26, paragraph 1, of the Convention.

Article 3

As between the Parties, the provisions of Articles 1 and 2 of this Protocol shall be regarded as additional articles to the Convention and all the provisions of the Convention shall apply accordingly.

Article 4

This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 5

1 This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 4.
2 In respect of any Signatory which subsequently expresses its consent to be bound by it, the

Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 6

1 After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.
2 Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 7

1 Any Party may at any time denounce this Protocol by means of a notification addressed to the Secretary General of the Council of Europe.
2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 8

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the Convention of:
a) any signature;
b) the deposit of any instrument of ratification, acceptance, approval or accession;
c) any date of entry into force of this Protocol in accordance with Articles 5 and 6;
d) any other act, notification or communication relating to this Protocol.
In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol.
Done at Paris, this twelfth day of January 1998, in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Protocol, to any State invited to accede to the Convention and to the European Community.

K O N V E N C I J A
O VARSTVU ČLOVEKOVIH PRAVIC IN DOSTOJANSTVA ČLOVEŠKEGA BITJA V ZVEZI Z UPORABO BIOLOGIJE IN MEDICINE: KONVENCIJA O ČLOVEKOVIH PRAVICAH V ZVEZI Z BIOMEDICINO

Oviedo, 4. IV. 1997

Preambula

Države članice Sveta Evrope, druge države in Evropska skupnost, podpisnice te konvencije, so se ob upoštevanju Splošne deklaracije o človekovih pravicah, ki jo je 10. decembra 1948 razglasila Generalna skupščina Združenih narodov;
ob upoštevanju Konvencije o varstvu človekovih pravic in temeljnih svoboščin z dne 4. novembra 1950;
ob upoštevanju Evropske socialne listine z dne 18. oktobra 1961;
ob upoštevanju Mednarodnega pakta o državljanskih in političnih pravicah ter Mednarodnega pakta o ekonomskih, socialnih in kulturnih pravicah z dne 16. decembra 1966;
ob upoštevanju Konvencije o varstvu posameznikov glede na avtomatsko obdelavo osebnih podatkov z dne 28. januarja 1981;
tudi ob upoštevanju Konvencije o otrokovih pravicah z dne 20. novembra 1989;
glede na to, da ima Svet Evrope za cilj ustvariti tesnejšo povezanost med svojimi članicami in da je eden od načinov za doseganje tega cilja ohranjanje in nadaljnje uresničevanje človekovih pravic in temeljnih svoboščin;
ker se zavedajo vse hitrejšega razvoja v biologiji in medicini;
prepričane, da je treba spoštovati človeka kot posameznika in kot pripadnika človeške vrste, in ker priznavajo pomen zagotavljanja dostojanstva človeškega bitja;
ker se zavedajo, da bi neustrezna uporaba biologije in medicine lahko privedla do dejanj, ki bi ogrozila človekovo dostojanstvo;
ker trdijo, da je treba napredek v biologiji in medicini uporabiti v korist sedanjih in prihodnjih generacij;
ker poudarjajo potrebo po mednarodnem sodelovanju, zato da bo vse človeštvo lahko imelo koristi od biologije in medicine;
ker se zavedajo pomena spodbujanja javne razprave o vprašanjih, ki se zastavljajo v zvezi z uporabo biologije in medicine, in o odgovorih, ki jih je treba dati nanje;
v želji, da vse pripadnike družbe spomnijo na njihove pravice in odgovornosti;
ob upoštevanju dela Parlamentarne skupščine na tem področju, vključno s Priporočilom št. 1160 (1991) o pripravi konvencije o bioetiki;
odločene, da v zvezi z uporabo biologije in medicine sprejmejo ukrepe, potrebne za zaščito dostojanstva človeka ter temeljnih pravic in svoboščin posameznika,
sporazumele o naslednjem:

I. poglavje – splošne določbe

1. člen – namen in predmet

Pogodbenice te konvencije varujejo dostojanstvo in identiteto vseh človeških bitij in vsakomur brez razlikovanja jamčijo spoštovanje njegove duševne in telesne nedotakljivosti in drugih pravic in temeljnih svoboščin v zvezi z uporabo biologije in medicine.
Vsaka pogodbenica sprejme v svojo notranjo zakonodajo ukrepe, potrebne za uresničitev določb te konvencije.

2. člen – prvenstvo človeškega bitja

Koristi in skrb za človeka morajo prevladovati nad izključno koristjo družbe ali znanosti.

3. člen – pravična dostopnost zdravstvenega varstva

Pogodbenice ob upoštevanju zdravstvenih potreb in razpoložljivih virov sprejmejo ustrezne ukrepe, da v okviru svoje jurisdikcije zagotovijo pravično dostopnost zdravstvenega varstva ustrezne kakovosti.

4. člen – poklicne norme

Vsak zdravstveni poseg, vključno z raziskavami, se mora opraviti v skladu s poklicnimi dolžnostmi in normami.

II. poglavje – privolitev

5. člen – splošno pravilo

Zdravstveni poseg se sme opraviti šele potem, ko je bila oseba, ki jo to zadeva, o njem poučena in je vanj prostovoljno privolila.
To osebo je treba predhodno ustrezno poučiti o namenu in naravi posega kot tudi o njegovih posledicah in tveganjih.
Oseba, ki jo to zadeva, lahko privolitev kadar koli svobodno prekliče.

6. člen – varstvo oseb, ki niso sposobne privoliti

1. Ob upoštevanju 17. in 20. člena se sme poseg opraviti na osebi, ki ni sposobna privoliti, le v njeno neposredno korist.
2. Kadar mladoletna oseba po zakonu ni sposobna privoliti v poseg, se sme poseg opraviti samo z dovoljenjem njenega zastopnika ali zavoda ali osebe ali organa, kot je določeno z zakonom.
Mnenje mladoletne osebe se sorazmerno z njeno starostjo in stopnjo zrelosti upošteva kot vedno

bolj odločilni dejavnik.

3. Kadar odrasla oseba zaradi duševne nesposobnosti, bolezni ali podobnih razlogov po zakonu ni sposobna privoliti v poseg, se sme poseg opraviti le z dovoljenjem njenega zastopnika ali zavoda ali osebe ali organa, kot je določeno z zakonom.

Posameznika, ki ga to zadeva, je treba v največji možni meri pritegniti v postopek pridobitve dovoljenja.

4. Zastopnika, zavod, osebo ali organ, ki so omenjeni v 2. in 3. odstavku tega člena, je treba poučiti pod enakimi pogoji, kot je navedeno v 5. členu.

5. Dovoljenje, predvideno v 2. in 3. odstavku tega člena, je mogoče v korist osebe, ki jo to zadeva, kadar koli preklicati.

7. člen – varstvo oseb z duševnimi motnjami

Osebi s hudo duševno motnjo se sme brez njene privolitve opraviti poseg z namenom zdravljenja te motnje le, kadar bi opustitev takšnega zdravljenja verjetno znatno škodovala njenemu zdravju; pri tem je treba upoštevati varovalne pogoje, ki jih predpisuje zakon, vključno s postopki za nadzor, kontrolo in pritožbo.

8. člen – nujna stanja

Kadar zaradi nujnega stanja ni mogoče dobiti ustrezne privolitve, se sme takoj opraviti vsak medicinsko potreben poseg v korist zdravja posameznika, ki ga to zadeva.

9. člen – predhodno izražene želje

Upoštevajo se želje, ki jih je glede zdravniškega posega predhodno izrazil bolnik, ki ob posegu ni sposoben izraziti svoje volje.

III. poglavje – zasebnost in pravica do obveščenosti

10. člen – zasebnost in pravica do obveščenosti

1. Vsakdo ima pravico do spoštovanja zasebnosti, ko gre za podatke o njegovem zdravju.

2. Vsakdo ima pravico zvedeti za vsak podatek, pridobljen o njegovem zdravju. Spoštovati pa je treba tudi željo posameznika, da se mu ti podatki ne povedo.

3. Izjemoma se lahko uresničevanje pravic iz 2. odstavka tega člena zaradi koristi bolnika zakonsko omeji.

IV. poglavje – človeški genom

11. člen – nerazlikovanje

Prepovedana je vsaka oblika zapostavljanja posameznika na podlagi njegove genetske dediščine.

12. člen – napovedne genetske preiskave

Preiskave, ki lahko napovedo dedne bolezni ali omogočajo določiti nosilstvo gena, odgovornega za bolezen, ali odkriti genetsko nagnjenost ali dovzetnost za bolezen, se smejo opravljati le za zdravstvene namene ali za znanstvene raziskave v zdravstvene namene in samo ob ustreznem genetskem svetovanju.

13. člen – posegi na človeškem genomu

Poseg, katerega namen je spremeniti človeški genom, se sme opraviti le za preventivne, diagnostične ali terapevtske namene, in to samo, če njegov cilj ni uvesti kakršne koli spremembe v genom potomcev.

14. člen – prepoved izbire spola

Metode oploditve z medicinsko pomočjo se ne smejo uporabiti za izbiro spola bodočega otroka, razen če naj bi se s tem izognili hudi dedni bolezni, vezani na spol.

V. poglavje – znanstveno raziskovanje

15. člen – splošno pravilo

Znanstveno raziskovanje na področju biologije in medicine je svobodno ob upoštevanju določb te konvencije in drugih pravnih določb, ki zagotavljajo varstvo človeka.

16. člen – varstvo oseb, na katerih se opravljajo raziskave

Raziskave na ljudeh se smejo opravljati le, če so izpolnjeni vsi naslednji pogoji:
i) da raziskave na ljudeh ni mogoče nadomestiti z drugo, podobno uspešno raziskavo,
ii) da nevarnosti, ki jim utegne biti izpostavljena oseba, niso v nesorazmerju z možnimi koristmi raziskave,
iii) da je načrt raziskave odobril pristojni organ, potem ko je neodvisno proučil njeno znanstveno vrednost, pretehtal pomembnost cilja raziskave in z vidika več različnih strok ocenil njeno etično sprejemljivost,
iv) da je oseba, na kateri se bo opravljala raziskava, seznanjena s svojimi pravicami in jamstvi, ki jih

predvideva zakon za njeno varstvo,
v) da je bila privolitev, določena s 5. členom, dana izrecno, posebej v ta namen in je dokumentirana. Ta privolitev se lahko kadar koli svobodno prekliče.

17. člen – varstvo oseb, ki niso sposobne privoliti v raziskavo

1. Raziskava na osebi, ki ni sposobna privoliti v skladu s 5. členom, se sme opravljati le, če so izpolnjeni vsi naslednji pogoji:
i) da so izpolnjeni pogoji, navedeni v pododstavkih i) do iv) 16. člena,
ii) da je od izsledkov raziskave mogoče pričakovati resnično in neposredno korist za njeno zdravje,
iii) da primerljivo uspešne raziskave ni mogoče opraviti na osebah, ki so sposobne privoliti,
iv) da je bilo dovoljenje, določeno s 6. členom, dano posebej v ta namen in pisno in
v) da oseba, ki jo to zadeva, ne nasprotuje.
2. Izjemoma in pod varovalnimi pogoji, ki jih predpisuje zakon, se lahko dovoli raziskava, od izsledkov katere ni mogoče pričakovati neposredne koristi za zdravje osebe, ki jo to zadeva, če so izpolnjeni pogoji, navedeni v pododstavkih i), iii), iv) in v) prvega odstavka tega člena, in naslednji dodatni pogoji:
i) da je cilj raziskave z znatno boljšim znanstvenim razumevanjem stanja, bolezni ali motnje posameznika prispevati k izsledkom, ki bodo naposled lahko koristili osebi, ki jo to zadeva, ali drugim osebam enake starostne skupine ali osebam, ki imajo enako bolezen ali motnjo ali so v enakem stanju,
ii) da raziskava pomeni minimalno nevarnost in minimalno obremenitev za osebo, ki jo to zadeva.

18. člen – raziskave na zarodkih in vitro

1. Kadar zakon dopušča raziskave na zarodkih zunaj materinega telesa (in vitro), mora zagotaviti ustrezno varstvo zarodka.
2. Ustvarjanje človeških zarodkov v raziskovalne namene je prepovedano.

VI. poglavje – odvzem organov in živih tkiv darovalcem zaradi presaditve

19. člen – splošno pravilo

1. Organi ali tkiva se smejo živemu darovalcu odvzeti zaradi presaditve samo za zdravljenje prejemnika in kadar ni na voljo primernega organa ali tkiva umrle osebe niti nobenega drugega možnega načina zdravljenja, ki bi bil primerljivo uspešen.
2. Potrebna privolitev, določena s 5. členom, mora biti dana izrecno in posebej v ta namen bodisi pisno ali pred uradnim organom.

20. člen – varstvo oseb, ki niso sposobne privoliti v odvzem organa

1. Organ ali tkivo se ne sme odvzeti osebi, ki ni sposobna privoliti v skladu s 5. členom.
2. Izjemoma in pod varovalnimi pogoji, ki jih predpisuje zakon, se sme dovoliti odvzem obnovljivega tkiva osebi, ki ni sposobna privoliti, če so izpolnjeni naslednji pogoji:
i) da ni na voljo nobenega biološko primernega darovalca, ki je sposoben privoliti,
ii) da je prejemnik brat ali sestra darovalca,
iii) da gre za darovanje, ki lahko reši življenje prejemnika,
iv) da je bilo dovoljenje, določeno v 2. in 3. odstavku 6. člena, dano posebej v ta namen in pisno v skladu z zakonom in z odobritvijo pristojnega organa in
v) da možni darovalec ne nasprotuje.

VII. poglavje – prepoved pridobivanja premoženjske koristi in razpolaganje z deli človeškega telesa

21. člen – prepoved pridobivanja premoženjske koristi

Človeško telo in njegovi deli sami po sebi ne smejo biti predmet pridobivanja premoženjske koristi.

22. člen – razpolaganje z odvzetim delom človeškega telesa

Kadar je bil pri nekem posegu odvzet kak del človeškega telesa, se lahko shrani in uporabi za kak drug namen, kot je bil odvzet, samo če je to storjeno skladno z ustreznimi postopki poučitve in privolitve.

VIII. poglavje – kršenje določb konvencije

23. člen – kršenje pravic ali načel

Pogodbenice zagotavljajo primerno sodno varstvo za takojšnjo preprečitev ali ustavitev nezakonitega kršenja pravic in načel, opredeljenih v tej konvenciji.

24. člen – odškodnina za neupravičeno škodo

Oseba, ki je zaradi posega utrpela neupravičeno škodo, ima pod pogoji in na način, ki ga določa zakon, pravico do pravične odškodnine.

25. člen – sankcije

Pogodbenice zagotovijo ustrezne sankcije, ki jih je treba uporabiti, če se kršijo določbe te konvencije.

IX. poglavje – razmerje med to konvencijo in drugimi predpisi

26. člen – omejitve pri uresničevanju pravic

1. Uresničevanje pravic in zaščitnih določb, ki jih vsebuje ta konvencija, se sme omejevati samo s takimi omejitvami, ki so predpisane z zakonom in so v demokratični družbi potrebne za javno varnost, preprečevanje kaznivih dejanj, za varovanje zdravja ljudi ali za varstvo pravic in svoboščin drugih.
2. Omejitve iz prejšnjega odstavka tega člena se ne smejo uveljavljati za 11., 13., 14., 16., 17., 19., 20. in 21. člen.

27. člen – širše varstvo

Nobena določba konvencije se ne sme razlagati tako, kot da omejuje ali drugače prizadene možnost kake pogodbenice, da zagotovi širše varstvo glede uporabe biologije in medicine, kot ga predpisuje ta konvencija.

X. poglavje – javna razprava

28. člen – javna razprava

Pogodbenice konvencije poskrbijo za primerno javno razpravo o temeljnih vprašanjih, ki jih porajajo razvojni dosežki biologije in medicine, še zlasti z medicinskega, družbenega, gospodarskega, etičnega in pravnega vidika in tudi za ustrezno posvetovanje o njihovi možni uporabi.

XI. poglavje – razlaga in spremljanje izvajanja konvencije

29. člen – razlaga konvencije

Evropsko sodišče za človekove pravice lahko – brez neposrednega sklicevanja na konkreten postopek, ki teče pred kakim sodiščem – da svetovalna mnenja o pravnih vprašanjih, ki se nanašajo na razlago konvencije, in sicer na zaprosilo:
– vlade pogodbenice, potem ko je o tem obvestilo druge pogodbenice,
– odbora, ustanovljenega na podlagi 32. člena, ki ga sestavljajo samo predstavniki pogodbenic konvencije, na podlagi sklepa, ki je bil sprejet z dvetretjinsko večino oddanih glasov.

30. člen – poročila o izvajanju konvencije

Vsaka pogodbenica mora na zahtevo generalnega sekretarja Sveta Evrope pojasniti, kako s svojo notranjo zakonodajo zagotavlja učinkovito uresničevanje katere koli določbe konvencije.

XII. poglavje – protokoli

31. člen – protokoli

V skladu z določbami 32. člena je mogoče sprejemati protokole, katerih cilj je, da na posameznih področjih razvijajo načela, ki jih vsebuje konvencija.
Protokoli bodo na voljo za podpis podpisnicam konvencije. Treba jih je ratificirati, sprejeti ali odobriti. Podpisnica ne sme ratificirati, sprejeti ali odobriti protokolov, če ni pred tem ali sočasno ratificirala, sprejela ali odobrila konvencije.

XIII. poglavje – spremembe konvencije

32. člen – spremembe konvencije

1. Naloge, ki so po tem členu in po 29. členu dodeljene “odboru“, izvaja Usmerjevalni odbor za bioetiko (CDBI) ali kateri koli drug odbor, ki ga za to določi Odbor ministrov.
2. Ob upoštevanju posebnih določb 29. člena ima lahko vsaka država članica Sveta Evrope kot tudi vsaka pogodbenica konvencije, ki ni članica Sveta Evrope, svojega zastopnika in en glas v odboru, če ta odbor opravlja naloge, ki so mu bile zaupane s konvencijo.
3. Vsako državo iz 33. člena ali državo, ki je bila povabljena, da pristopi h konvenciji v skladu z določbami 34. člena, in ki ni pogodbenica konvencije, v odboru lahko zastopa opazovalec. Če Evropska skupnost ni pogodbenica, jo v odboru lahko zastopa opazovalec.
4. Da bi sledili razvoju znanosti, bo odbor ponovno presodil ustreznost konvencije najpozneje pet let po začetku njene veljavnosti, nato pa v takih presledkih, kot jih določi odbor.
5. Vsak predlog za spremembo konvencije kot tudi vsak predlog za protokol ali za spremembo protokola, ki ga predložijo pogodbenica, odbor ali Odbor ministrov, se sporoči generalnemu sekretarju Sveta Evrope, ta pa ga pošlje državam članicam Sveta Evrope, Evropski skupnosti, vsaki podpisnici, vsaki pogodbenici, vsaki državi, ki je bila povabljena k podpisu konvencije v skladu z določbami 33. člena, in vsaki državi, ki je bila povabljena, da pristopi h konvenciji v skladu z določbami 34. člena.
6. Odbor prouči predlog po preteku najmanj dveh mesecev potem, ko ga je prejel od generalnega sekretarja v skladu s 5. odstavkom tega člena. Odbor predloži besedilo, sprejeto z dvetretjinsko večino oddanih glasov, v odobritev Odboru ministrov. Po njegovi odobritvi se besedilo pošlje pogodbenicam v ratifikacijo, sprejetje ali odobritev.
7. Za tiste pogodbenice, ki so spremembo sprejele, začne ta veljati prvi dan meseca, ki sledi izteku enomesečnega obdobja po dnevu, ko je pet pogodbenic, od katerih so najmanj štiri države članice Sveta Evrope, obvestilo generalnega sekretarja, da so jo sprejele.

Za vsako pogodbenico, ki spremembo sprejme pozneje, začne ta veljati prvi dan meseca, ki sledi izteku enomesečnega obdobja po dnevu, ko je ta pogodbenica obvestila generalnega sekretarja, da jo je sprejela.

XIV. poglavje – končne določbe

33. člen – podpis, ratifikacija in začetek veljavnosti

1. Konvencija je na voljo za podpis državam članicam Sveta Evrope, državam nečlanicam, ki so sodelovale pri njeni pripravi, in Evropski skupnosti.
2. Konvencijo je treba ratificirati, sprejeti ali odobriti. Listine o ratifikaciji, sprejetju ali odobritvi se hranijo pri generalnem sekretarju Sveta Evrope.
3. Konvencija začne veljati prvi dan meseca, ki sledi izteku trimesečnega obdobja po dnevu, ko je pet držav, od katerih so najmanj štiri države članice Sveta Evrope, privolilo, da jih konvencija zavezuje v skladu z določbami 2. odstavka tega člena.
4. Za vsako podpisnico, ki pozneje privoli, da jo konvencija zavezuje, začne ta veljati prvi dan meseca, ki sledi izteku trimesečnega obdobja po dnevu deponiranja njene listine o ratifikaciji, sprejetju ali odobritvi.

34. člen – države nečlanice

1. Po začetku veljavnosti konvencije lahko Odbor ministrov Sveta Evrope po posvetovanju s pogodbenicami povabi katero koli državo nečlanico Sveta Evrope, da pristopi k tej konvenciji, in sicer na podlagi sklepa, ki ga sprejme večina, določena v odstavku d) 20. člena Statuta Sveta Evrope, in soglasnega sklepa predstavnikov držav pogodbenic, ki imajo pravico biti zastopane v Odboru ministrov.
2. Za vsako državo, ki h konvenciji pristopi, začne ta veljati prvi dan meseca, ki sledi izteku trimesečnega obdobja po dnevu deponiranja listine o pristopu pri generalnem sekretarju Sveta Evrope.

35. člen – ozemlja uporabe

1. Vsaka podpisnica lahko ob podpisu ali ob deponiranju svoje listine o ratifikaciji, sprejetju ali odobritvi določi ozemlje ali ozemlja, na katerih se ta konvencija uporablja. Vsaka druga država lahko da enako izjavo ob deponiranju svoje listine o pristopu.
2. Vsaka pogodbenica lahko kadar koli pozneje z izjavo, naslovljeno na generalnega sekretarja Sveta Evrope, razširi uporabo konvencije na katero koli drugo ozemlje, ki je določeno v izjavi in za katerega mednarodne odnose je odgovorna ali v imenu katerega je pooblaščena prevzemati obveznosti. Za tako ozemlje začne konvencija veljati prvi dan meseca, ki sledi izteku trimesečnega obdobja po dnevu, ko je generalni sekretar prejel tako izjavo.

3. Z notifikacijo, naslovljeno na generalnega sekretarja, je mogoče umakniti vsako izjavo, dano po prejšnjih dveh odstavkih za katero koli ozemlje, določeno v taki izjavi. Umik začne veljati prvi dan meseca, ki sledi izteku trimesečnega obdobja po dnevu, ko je generalni sekretar prejel tako notifikacijo.

36. člen – pridržki

1. Vsaka država in Evropska skupnost lahko ob podpisu konvencije ali deponiranju listine o ratifikaciji, sprejetju, odobritvi ali pristopu izrazi pridržek glede katere koli določbe konvencije, kolikor kak zakon, ki takrat velja na njenem ozemlju, ni skladen s to določbo. Splošni pridržki po tem členu niso dovoljeni.
2. Vsak pridržek, izražen v skladu s tem členom, mora vsebovati kratek izvleček ustreznega zakona.
3. Vsaka pogodbenica, ki razširi uporabo konvencije na ozemlje, navedeno v izjavi iz 2. odstavka 35. člena, lahko za to ozemlje izrazi pridržek v skladu z določbami prejšnjih odstavkov.
4. Vsaka pogodbenica, ki je izrazila pridržek v skladu s tem členom, ga lahko umakne z izjavo, naslovljeno na generalnega sekretarja Sveta Evrope. Umik začne veljati prvi dan meseca, ki sledi izteku enomesečnega obdobja po dnevu, ko je generalni sekretar prejel tako izjavo.

37. člen – odpoved

1. Vsaka pogodbenica lahko konvencijo kadar koli odpove z notifikacijo, naslovljeno na generalnega sekretarja Sveta Evrope.
2. Taka odpoved začne veljati prvi dan meseca, ki sledi izteku trimesečnega obdobja po dnevu, ko je generalni sekretar prejel notifikacijo.

38. člen – notifikacije

Generalni sekretar Sveta Evrope uradno obvesti države članice Sveta, Evropsko skupnost, vsako podpisnico, vsako pogodbenico in vsako drugo državo, ki je bila povabljena, da pristopi h konvenciji, o:
a) vsakem podpisu,
b) deponiranju vsake listine o ratifikaciji, sprejetju, odobritvi ali pristopu,
c) vsakem datumu začetka veljavnosti konvencije v skladu s 33. ali 34. členom,
d) vsaki spremembi ali protokolu, sprejetem v skladu z 32. členom, in datumu začetka veljavnosti te spremembe ali protokola,
e) vsaki izjavi, dani na podlagi določb 35. člena,
f) vsakem izraženem pridržku in umiku pridržka na podlagi določb 36. člena,
g) vsakem drugem dejanju, notifikaciji ali sporočilu v zvezi s to konvencijo.
V potrditev tega so podpisani, ki so bili za to pravilno pooblaščeni, podpisali to konvencijo.
Sklenjeno v Oviedu (Asturija) 4. aprila 1997 v angleščini in francoščini, pri čemer sta obe besedili

enako verodostojni, v enem samem izvodu, ki se hrani v arhivu Sveta Evrope. Generalni sekretar Sveta Evrope pošlje overjeno kopijo vsaki državi članici Sveta Evrope, Evropski skupnosti, državam nečlanicam, ki so sodelovale pri pripravi konvencije, in vsaki državi, ki je povabljena, da pristopi k tej konvenciji.

DODATNI PROTOKOL
o prepovedi kloniranja človeških bitij h Konvenciji o varstvu človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine

Paris, 12. 1. 1998

Države članice Sveta Evrope, druge države in Evropska skupnost, podpisnice tega dodatnega protokola h Konvenciji o varstvu človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine,
opažajo znanstveni razvoj na področju kloniranja sesalcev, zlasti s cepitvijo zarodka in s prenosom jedra,
se zavedajo napredka, ki ga nekatere tehnike kloniranja same po sebi lahko prispevajo k znanstvenim spoznanjem in njihovi uporabi v medicini,
upoštevajo, da kloniranje ljudi utegne postati tehnično možno,
so ugotovile, da se cepitev zarodka lahko zgodi naravno in ima včasih za posledico rojstvo genetsko istovetnih dvojčkov,
vendar pa upoštevajo, da je izrabljanje človeških bitij z namernim ustvarjanjem genetsko istovetnih ljudi v nasprotju z dostojanstvom človeka in zato pomeni zlorabo biologije in medicine,
upoštevajo tudi resne medicinske, psihološke in socialne težave, ki bi jih takšna namerna biomedicinska praksa lahko povzročila vsem posameznikom, ki jih to zadeva,
upoštevajo namen Konvencije o človekovih pravicah v zvezi z biomedicino, zlasti načelo iz 1. člena, katerega cilj je varovati dostojanstvo in identiteto vseh človeških bitij, zato
so se dogovorile o naslednjem:

1. člen

1. Prepovedan je vsak poseg, katerega namen je ustvariti človeško bitje, ki je genetsko istovetno z drugim človeškim bitjem, živim ali mrtvim.
2. Izraz človeško bitje, “genetsko istovetno“ z drugim človeškim bitjem, za namene tega člena pomeni to, da imata obe isti jedrni genom.

2. člen

Omejitve določb tega protokola v skladu s 1. odstavkom 26. člena konvencije niso dovoljene.

3. člen

Pogodbenice upoštevajo določbe 1. in 2. člena tega protokola kot dodatna člena h konvenciji in zato se uporabljajo vse določbe konvencije.

4. člen

Protokol je na voljo za podpis državam podpisnicam konvencije. Treba ga je ratificirati, sprejeti ali odobriti. Podpisnica ne sme ratificirati, sprejeti ali odobriti tega protokola, če prej ali sočasno ni ratificirala, sprejela ali odobrila konvencije. Listine o ratifikaciji, sprejetju ali odobritvi se hranijo pri generalnem sekretarju Sveta Evrope.

5. člen

1. Protokol začne veljati prvi dan meseca, ki sledi izteku trimesečnega obdobja po dnevu, ko je pet držav, od katerih so najmanj štiri države članice Sveta Evrope, privolilo, da jih ta protokol zavezuje v skladu z določbami 4. člena.
2. Za vsako podpisnico, ki pozneje privoli, da jo protokol zavezuje, začne ta veljati prvi dan meseca, ki sledi izteku trimesečnega obdobja po dnevu deponiranja listine o ratifikaciji, sprejetju ali odobritvi.

6. člen

1. Po začetku veljavnosti tega protokola sme vsaka država, ki je pristopila h konvenciji, pristopiti tudi k protokolu.
2. Pristopi se tako, da se pri generalnem sekretarju Sveta Evrope deponira listina o pristopu, ki začne veljati prvi dan meseca, ki sledi izteku trimesečnega obdobja po dnevu deponiranja take listine.

7. člen

1. Vsaka podpisnica lahko kadar koli odpove ta protokol z notifikacijo, naslovljeno na generalnega sekretarja Sveta Evrope.
2. Taka odpoved začne veljati prvi dan meseca, ki sledi izteku trimesečnega obdobja po dnevu, ko je generalni sekretar prejel tako notifikacijo.

8. člen

Generalni sekretar Sveta Evrope uradno obvesti države članice Sveta Evrope, Evropsko skupnost, vsako podpisnico, vsako pogodbenico in vsako drugo državo, ki je bila povabljena, da pristopi h konvenciji, o:

a) vsakem podpisu,

b) deponiranju vsake listine o ratifikaciji, sprejetju, odobritvi ali pristopu,

c) vsakem datumu začetka veljavnosti protokola v skladu s 5. in 6. členom,

d) vsakem drugem dejanju, notifikaciji ali sporočilu v zvezi s tem protokolom.

V potrditev tega so podpisani, ki so bili za to pravilno pooblaščeni, podpisali ta protokol.

Sklenjeno v Parizu 12. januarja 1998 v angleščini in francoščini, pri čemer sta obe besedili enako verodostojni, v enem samem izvodu, ki se hrani v arhivu Sveta Evrope. Generalni sekretar Sveta Evrope pošlje overjeno kopijo vsaki državi članici Sveta Evrope, državam nečlanicam, ki so sodelovale pri pripravi tega protokola, vsaki državi, ki je bila povabljena, da pristopi h konvenciji, in Evropski skupnosti.

3. člen

Za izvajanje konvencije in dodatnega protokola skrbi Ministrstvo za zdravstvo.

4. člen

Ta zakon začne veljati naslednji dan po objavi v Uradnem listu Republike Slovenije – Mednarodne pogodbe.

Št. 500-01/98-8/1
Ljubljana, dne 24. septembra 1998

Predsednik
Državnega zbora
Republike Slovenije
Janez Podobnik, dr. med. l. r.