



DIR/JUR (98) 7

**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 (ETS No. 168)**

**and**

**Explanatory report to the Protocol**



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.

**Explanatory report to the Additional Protocol  
to the Convention on Human Rights and Biomedicine  
on the Prohibition of Cloning Human Beings**

1. This Protocol builds on certain provisions of the Convention on Human Rights and Biomedicine, in particular the following: Article 1 provides that 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; Article 13, which provides that 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 18.1, which ensures the protection of the embryo *in vitro* in the framework of research and Article 18.2 which prohibits the creation of embryos for research purposes.

2. Cloning of cells and tissue is considered worldwide to be an ethically acceptable valuable biomedical technique. However, there are different views about the ethical acceptability of cloning undifferentiated cells of embryonic origin. Whatever attitudes towards such cloning techniques exist, the standards set forth in the Convention on Human Rights and Biomedicine as mentioned above form clear barriers against the misuse of human embryos, as their adequate protection is guaranteed and their creation for research purposes is prohibited by Article 18 of the Convention. Therefore, one has to distinguish between three situations: cloning of cells as a technique, use of embryonic cells in cloning techniques, and cloning of human beings, for example by utilising the techniques of embryo splitting or nuclear transfer. Whereas the first situation is fully acceptable ethically, the second should be examined in the protocol on embryo protection. The consequences of the third situation, that is the prohibition of cloning human beings, are within the scope of this Protocol.

3. Deliberately cloning humans is a threat to human identity, as it would give up the indispensable protection against the predetermination of the human genetic constitution by a third party. Further ethical reasoning for a prohibition to clone human beings is based first and foremost on human dignity which is endangered by instrumentalisation through artificial human cloning. Even if in the future, in theory, a situation could be conceived, which might seem to exclude the instrumentalisation of artificially cloned human offspring, this is not considered a sufficient ethical justification for the cloning of human beings. As naturally occurring genetic recombination is likely to create more freedom for the human being than a predetermined genetic make up, it is in the interest of all persons to keep the essentially random nature of the composition of their own genes.

4. This Protocol does not take a specific stand on the admissibility of cloning cells and tissue for research purposes resulting in medical applications. However, it can be said that cloning as a biomedical technique is an important tool for the development of medicine, especially for the development of new therapies. The provisions in this Protocol shall not be understood as prohibiting cloning techniques in cell biology.
5. However, the Protocol does enshrine clear barriers against any attempt artificially to produce genetically identical human beings. The Protocol is not concerned with hormone stimulation to treat infertility in women and which might result in the birth of twins. It explicitly restricts genetic identity to sharing the same nuclear gene set, meaning that any intervention by embryo splitting or nuclear transfer techniques seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
6. In conformity with the approach followed in the preparation of the Convention on Human Rights and Biomedicine, it was decided to leave it to domestic law to define the scope of the expression "human being" for the purposes of the application of the present Protocol.
7. The term "nuclear" means that only genes of the nucleus – not the mitochondrial genes – are looked at with respect to identity, which is why the prohibition of cloning human beings also covers all nuclear transfer methods seeking to create identical human beings. The term "the same nuclear gene set" takes into account the fact that during development some genes may undergo somatic mutation. Thus monozygotic twins developed from a single fertilised egg will share the same nuclear gene set, but may not be 100% identical with respect to all their genes. It is important to note that the Protocol does not intend to discriminate in any fashion against natural monozygotic twins.
8. This Protocol is an important step in drawing up clear ethical and legal provisions in the area of reproductive medicine. Together with the provisions in Articles 1, 13, 14 and 18 of the Convention, it enshrines important ethical principles which should form the basis for further developments of biology and medicine in this field not only today but also in the future.