



**Explanatory Report
to the 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.I.1998

I. The Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings was opened to signature by Signatories to the Convention, in Paris, on 12 January 1998.

II. The text of the Explanatory Report does not constitute an instrument providing an authoritative interpretation of the text of the Protocol, although it might be of such nature as to facilitate the understanding of the provisions contained therein.

Commentary

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.

(*) The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

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.