COUNCIL OF EUROPE

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SUMMARIES OF THE COUNCIL OF EUROPE TREATIES

The summaries available hereunder are designed to meet a practical need, that of supplying the public at large with concise descriptions of the Council of Europe treaties. The summaries are necessarily short and can therefore only give a first introduction to the main features of each treaty.

Subject-matter: BIOMEDICINE

Convention 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 (ETS No. 164), open for signature, in Oviedo, on 4 April 1997.

Entry into force: 1 December 1999.

The Convention is the first legally binding international text designed to preserve human dignity, rights and freedoms, through a series of principles and prohibitions against the misuse of biological and medical advances. The Convention's starting point is that the interests of human beings must come before the interests of science or society. It lays down a series of principles and prohibitions concerning bioethics, medical research, consent, rights to private life and information, organ transplantation, public debate etc.

It bans all forms of discrimination based on the grounds of a person's genetic make-up and allows the carrying out of predictive genetic tests only for medical purposes. The treaty allows genetic engineering only for preventive, diagnostic or therapeutic reasons and only where it does not aim to change the genetic make-up of a person's descendants. It prohibits the use of techniques of medically assisted procreation to help choose the sex of a child, except where it would avoid a serious hereditary condition.

The Convention sets out rules related to medical research by including detailed and precise conditions, especially for people who cannot give their consent. It prohibits the creation of human embryos for research purposes and requires an adequate protection of embryos where countries allow in-vitro research.

The Convention states the principle according to which a person has to give the necessary consent for treatment expressly, in advance, except in emergencies, and that such consent may be freely withdrawn at any time. The treatment of persons unable to give their consent, such as children and people with mental illnesses, may be carried out only if it could produce real and direct benefit to his or her health.

The Convention stipulates that all patients have a right to be informed about their health, including the results of predictive genetic tests. The Convention recognises also the patient's right not to know. The Convention prohibits the removal of organs and other tissues which cannot be regenerated from people not able to give consent. The only exception is, under certain conditions, for regenerative tissue (especially bone marrow) between siblings.

The Convention recognises the importance of promoting a public debate and consultation on these questions. The only restrictions are those prescribed by law and which 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. Additional Protocols are foreseen to clarify, strengthen and supplement the overall Convention.

The Steering Committee on Bioethics (CDBI), or any other committee designated by the Committee of Ministers or the Parties may request the European Court of Human Rights to give advisory opinions on legal questions concerning the interpretation of the Convention.

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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), open for signature, in Paris, on 12 January 1998.

Entry into force: 1 March 2001.

The Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings is the first and only binding international legal instrument developed in this area. Reacting to the successful cloning of mammals in particular by the embryo splitting and nuclear transfer, the Council of Europe wanted to prevent further drift of applying this technique to human possibility.

Article 1 of Protocol prohibits "any intervention seeking to create a human being genetically identical to another human being alive or dead." Article 2 excludes exemption from this prohibition (eg, for reasons of public safety, prevention of crime, protection of public health or the protection of the rights and freedoms of others).

These absolute prohibitions are based on the need to protect the identity of the human being to preserve the randomness of natural genetic combination that gives it its freedom and uniqueness, and to prevent its exploitation.

The scope of the Protocol is exclusively that of cloning human beings. It is therefore not intended to comment on the ethical acceptability of cloning cells and tissue for research purposes and for use in medicine, a field in which these techniques can prove to be valuable tools.

Finally, the Protocol leaves the domestic laws of the States to define the scope of the term "human being."

Along with the Convention, certain of whose provisions it supplements, the Protocol enshrines important principles which provide the ethical basis for further biological and medical developments, both now and in the future.

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Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186), open for signature, in Strasbourg, on 24 January 2002.

Entry into force: 1 May 2006.

The aim of this Protocol is to protect human dignity and integrity, as well as rights and fundamental freedoms, in the face of scientific and medical advances.

The Additional Protocol contains general principles and specific provisions regarding the transplantation of organs and tissues of human origin for therapeutic purposes.

The general principles set out in the Additional Protocol include equitable access to transplantation services for patients, transparent rules for organ allocation, health and safety standards, the prohibition of financial gain by donors, and the need for donors, recipients, health professionals and the public to be properly informed.

The specific provisions cover the removal of organs from living and deceased persons, the use made of the organs and tissues removed, the prohibition of financial gain, confidentiality, and sanctions and compensation.

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Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS No. 195), open for signature, in Strasbourg, on 25 January 2005.

Entry into force: 1 September 2007.

This Protocol is intended to build on the principles embodied in the Convention, with a view to protecting human rights and dignity in the specific field of biomedical research. Its purpose is to define and safeguard fundamental rights in biomedical research, in particular of those participating in research.

The Protocol is to cover the full range of biomedical research activities involving interventions on human beings.

The fundamental principle for research involving human beings, as in the Convention itself, is the free, informed, express, specific, and documented consent of the person(s) participating. The Protocol addresses issues such as risks and benefits of research, consent, protection of persons not able to consent to research, scientific

quality, independent examination of research by an ethics committee, confidentiality and the right to information, undue influence, safety and duty of care.

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Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (CETS No. 203), open for signature, in Strasbourg, on 27 November 2008.

Entry into force: 1 July 2018.

The Protocol sets down principles relating inter alia to the quality of genetic services, prior information and consent and genetic counselling. It lays down general rules on the conduct of genetic tests, and, for the first time at international level, deals with the directly accessible genetic tests for which a commercial offer could develop in future. It specifies the conditions in which tests may be carried out on persons not able to consent. Also covered are the protection of private life and the right to information collected through genetic testing. Finally, the Protocol touches on genetic screening.