

**No. 37266. Multilateral**

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. OVIEDO, 4 APRIL 1997 [*United Nations, Treaty Series, vol. 2137, I-37266.*]

ADDITIONAL PROTOCOL TO THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE, CONCERNING GENETIC TESTING FOR HEALTH PURPOSES. STRASBOURG, 27 NOVEMBER 2008\*

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**N° 37266. Multilatéral**

CONVENTION POUR LA PROTECTION DES DROITS DE L'HOMME ET DE LA DIGNITÉ DE L'ÊTRE HUMAIN À L'ÉGARD DES APPLICATIONS DE LA BIOLOGIE ET DE LA MÉDECINE : CONVENTION SUR LES DROITS DE L'HOMME ET LA BIOMÉDECINE. OVIEDO, 4 AVRIL 1997 [*Nations Unies, Recueil des Traités, vol. 2137, I-37266.*]

PROTOCOLE ADDITIONNEL À LA CONVENTION SUR LES DROITS DE L'HOMME ET LA BIOMÉDECINE RELATIF AUX TESTS GÉNÉTIQUES À DES FINS MÉDICALES. STRASBOURG, 27 NOVEMBRE 2008\*

**Entrée en vigueur :** 1<sup>er</sup> juillet 2018, conformément à l'article 25

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**Additional Protocol to the Convention on Human Rights and Biomedicine,  
concerning Genetic Testing for Health Purposes**

Strasbourg, 27.XI.2008

**Preamble**

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 (hereinafter referred to as "the Convention on Human Rights and Biomedicine", ETS No. 164),

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

Considering that the aim of the Convention on Human Rights and Biomedicine, as defined in Article 1, is to 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;

Bearing in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108) of 28 January 1981;

Bearing in mind the work carried out by other intergovernmental organisations, in particular the Universal Declaration on the Human Genome and Human Rights, endorsed by the General Assembly of the United Nations on 9 December 1998;

Recalling that the human genome is shared by all human beings, thereby forming a mutual bond between them while slight variations contribute to the individuality of each human being;

Stressing the particular bond that exists between members of the same family;

Considering that progress in medical science can contribute to saving lives and improving their quality;

Acknowledging the benefit of genetics, in particular genetic testing, in the field of health;

(\*) 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 Economic Community shall be read as the European Union.

Considering that genetic services in the field of health form an integral part of the health services offered to the population and recalling the importance of taking appropriate measures, taking into account health needs and available resources, with a view to providing equitable access to genetic services of appropriate quality;

Aware also of the concerns that exist regarding possible improper use of genetic testing, in particular of the information generated thereby;

Reaffirming the fundamental principle of respect for human dignity and the prohibition of all forms of discrimination, in particular those based on genetic characteristics;

Taking into account national and international professional standards in the field of genetic services and the previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to genetic testing for health purposes,

Have agreed as follows:

## **Chapter I – Object and scope**

### **Article 1 – Object and purpose**

Parties to this Protocol 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 tests to which this Protocol applies in accordance with Article 2.

### **Article 2 – Scope**

- 1 This Protocol applies to tests, which are carried out for health purposes, involving analysis of biological samples of human origin and aiming specifically to identify the genetic characteristics of a person which are inherited or acquired during early prenatal development (hereinafter referred to as "genetic tests").
- 2 This Protocol does not apply:
  - a to genetic tests carried out on the human embryo or foetus;
  - b to genetic tests carried out for research purposes.
- 3 For the purposes of paragraph 1:
  - a "analysis" refers to:
    - i chromosomal analysis,
    - ii DNA or RNA analysis,
    - iii analysis of any other element enabling information to be obtained which is equivalent to that obtained with the methods referred to in sub-paragraphs a.i. and a.ii.;
  - b "biological samples" refers to:
    - i biological materials removed for the purpose of the test concerned,

- ii biological materials previously removed for another purpose.

## **Chapter II – General provisions**

### **Article 3 – Primacy of the human being**

The interests and welfare of the human being concerned by genetic tests covered by this Protocol shall prevail over the sole interest of society or science.

### **Article 4 – Non-discrimination and non-stigmatisation**

- 1 Any form of discrimination against a person, either as an individual or as a member of a group on grounds of his or her genetic heritage is prohibited.
- 2 Appropriate measures shall be taken in order to prevent stigmatisation of persons or groups in relation to genetic characteristics.

## **Chapter III – Genetic services**

### **Article 5 – Quality of genetic services**

Parties shall take the necessary measures to ensure that genetic services are of appropriate quality. In particular, they shall see to it that:

- a genetic tests meet generally accepted criteria of scientific validity and clinical validity;
- b a quality assurance programme is implemented in each laboratory and that laboratories are subject to regular monitoring;
- c persons providing genetic services have appropriate qualifications to enable them to perform their role in accordance with professional obligations and standards.

### **Article 6 – Clinical utility**

Clinical utility of a genetic test shall be an essential criterion for deciding to offer this test to a person or a group of persons.

### **Article 7 – Individualised supervision**

- 1 A genetic test for health purposes may only be performed under individualised medical supervision.
- 2 Exceptions to the general rule referred to in paragraph 1 may be allowed by a Party, subject to appropriate measures being provided, taking into account the way the test will be carried out, to give effect to the other provisions of this Protocol.

However, such an exception may not be made with regard to genetic tests with important implications for the health of the persons concerned or members of their family or with important implications concerning procreation choices.

## **Chapter IV – Information, genetic counselling and consent**

### **Article 8 – Information and genetic counselling**

- 1 When a genetic test is envisaged, the person concerned shall be provided with prior appropriate information in particular on the purpose and the nature of the test, as well as the implications of its results.
- 2 For predictive genetic tests as referred to in Article 12 of the Convention on Human Rights and Biomedicine, appropriate genetic counselling shall also be available for the person concerned.

The tests concerned are:

- tests predictive of a monogenic disease,
- tests serving to detect a genetic predisposition or genetic susceptibility to a disease,
- tests serving to identify the subject as a healthy carrier of a gene responsible for a disease.

The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family, including possible implications concerning procreation choices.

Genetic counselling shall be given in a non-directive manner.

### **Article 9 – Consent**

- 1 A genetic test may only be carried out after the person concerned has given free and informed consent to it.

Consent to tests referred to in Article 8, paragraph 2, shall be documented.

- 2 The person concerned may freely withdraw consent at any time.

## **Chapter V – Persons not able to consent**

### **Article 10 – Protection of persons not able to consent**

Subject to Article 13 of this Protocol, a genetic test on a person who does not have the capacity to consent may only be carried out for his or her direct benefit.

Where, according to law, a minor does not have the capacity to consent, a genetic test on this person shall be deferred until attainment of such capacity unless that delay would be detrimental to his or her health or well-being.

### **Article 11 – Information prior to authorisation, genetic counselling and support**

- 1 When a genetic test is envisaged in respect of a person not able to consent, the person, authority or body whose authorisation is required shall be provided with prior appropriate information in particular with regard to the purpose and the nature of the test, as well as the implications of its results.

Appropriate prior information shall also be provided to the person not able to consent in respect of whom the test is envisaged, to the extent of his or her capacity to understand.