



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.

A qualified person shall be available to answer possible questions by the person, authority or body whose authorisation is required, and, if appropriate, the person in respect of whom the test is envisaged.

- 2 The provisions of Article 8, paragraph 2, shall apply in the case of persons not able to consent to the extent of their capacity to understand.

Where relevant, appropriate support shall be available for the person whose authorisation is required.

Article 12 – Authorisation

- 1 Where, according to law, a minor does not have the capacity to consent to a genetic test, that test 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.

- 2 Where, according to law, an adult does not have the capacity to consent to a genetic test because of a mental disability, a disease or for similar reasons, that test 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.

Wishes relating to a genetic test expressed previously by an adult at a time where he or she had capacity to consent shall be taken into account.

The individual concerned shall, to the extent of his or her capacity to understand, take part in the authorisation procedure.

- 3 Authorisation to tests referred to in Article 8, paragraph 2, shall be documented.
- 4 The authorisation referred to in paragraphs 1 and 2 above may be withdrawn at any time in the best interests of the person concerned.

Chapter VI – Tests for the benefit of family members

Article 13 – Tests on persons not able to consent

Exceptionally, and by derogation from the provisions of Article 6, paragraph 1, of the Convention on Human Rights and Biomedicine and of Article 10 of this Protocol, the law may allow a genetic test to be carried out, for the benefit of family members, on a person who does not have the capacity to consent, if the following conditions are met:

- a the purpose of the test is to allow the family member(s) concerned to obtain a preventive, diagnostic or therapeutic benefit that has been independently evaluated as important for their health, or to allow them to make an informed choice with respect to procreation;
- b the benefit envisaged cannot be obtained without carrying out this test;
- c the risk and burden of the intervention are minimal for the person who is undergoing the test;
- d the expected benefit has been independently evaluated as substantially outweighing the risk for private life that may arise from the collection, processing or communication of the results of the test;

- e the authorisation of the representative of the person not able to consent, or an authority or a person or body provided for by law has been given;
- f the person not able to consent shall, in proportion to his or her capacity to understand and degree of maturity, take part in the authorisation procedure. The test shall not be carried out if this person objects to it.

Article 14 – Tests on biological materials when it is not possible to contact the person concerned

When it is not possible, with reasonable efforts, to contact a person for a genetic test for the benefit of his or her family member(s) on his or her biological material previously removed for another purpose, the law may allow the test to be carried out in accordance with the principle of proportionality, where the expected benefit cannot be otherwise obtained and where the test cannot be deferred.

Provisions shall be made, in accordance with Article 22 of the Convention on Human Rights and Biomedicine, for the case where the person concerned has expressly opposed such test.

Article 15 – Tests on deceased persons

A genetic test for the benefit of other family members may be carried out on biological samples:

- removed from the body of a deceased person, or
- removed, when he or she was alive, from a person now deceased,

only if the consent or authorisation required by law has been obtained.

Chapter VII – Private life and right to information

Article 16 – Respect for private life and right to information

- 1 Everyone has the right to respect for his or her private life, in particular to protection of his or her personal data derived from a genetic test.
- 2 Everyone undergoing a genetic test is entitled to know any information collected about his or her health derived from this test.

The conclusions drawn from the test shall be accessible to the person concerned in a comprehensible form.

- 3 The wish of a person not to be informed shall be respected.
- 4 In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraphs 2 and 3 above in the interests of the person concerned.

Article 17 – Biological samples

Biological samples referred to in Article 2 shall only be used and stored in such conditions as to ensure their security and the confidentiality of the information which can be obtained therefrom.

Article 18 – Information relevant to family members

Where the results of a genetic test undertaken on a person can be relevant to the health of other family members, the person tested shall be informed.

Chapter VIII – Genetic screening programmes for health purposes

Article 19 – Genetic screening programmes for health purposes

A health screening programme involving the use of genetic tests may only be implemented if it has been approved by the competent body. This approval may only be given after independent evaluation of its ethical acceptability and fulfilment of the following specific conditions:

- a the programme is recognised for its health relevance for the whole population or section of population concerned;
- b the scientific validity and effectiveness of the programme have been established;
- c appropriate preventive or treatment measures in respect of the disease or disorder which is the subject of the screening, are available to the persons concerned;
- d appropriate measures are provided to ensure equitable access to the programme;
- e the programme provides measures to adequately inform the population or section of population concerned of the existence, purposes and means of accessing the screening programme as well as the voluntary nature of participation in it.

Chapter IX – Public information

Article 20 – Public information

Parties shall take appropriate measures to facilitate access for the public to objective general information on genetic tests, including their nature and the potential implications of their results.

Chapter X – Relation between this Protocol and other provisions and re-examination of the Protocol

Article 21 – Relation between this Protocol and the Convention

As between the Parties, the provisions of Articles 1 to 20 of this Protocol shall be regarded as additional articles to the Convention on Human Rights and Biomedicine, and all the provisions of the Convention shall apply accordingly.

Article 22 – Wider protection

None of the provisions of this Protocol shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant persons concerned by genetic testing for health purposes a wider measure of protection than is stipulated in this Protocol.

Article 23 – Re-examination of the Protocol

In order to monitor scientific developments, the present Protocol shall be examined within the Committee referred to in Article 32 of the Convention on Human Rights and Biomedicine no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

Chapter XI – Final clauses

Article 24 – Signature and ratification

This Protocol shall be open for signature by Signatories to the Convention on Human Rights and Biomedicine. 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 25 – Entry into force

- 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 24.
- 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 26 – Accession

- 1 After the entry into force of this Protocol, any State which has acceded to the Convention on Human Rights and Biomedicine 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 27 – Denunciation

- 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 28 – Notification

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 on Human Rights and Biomedicine 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 25 and 26;
- 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 Strasbourg, this 27th day of November 2008, 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 on Human Rights and Biomedicine and to the European Community.