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Strasbourg, 7 February 2003

WORKING PARTY ON HUMAN GENETICS  
(CDBI-CO-GT4)

**Working document  
on the applications of genetics for health purposes**

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**Explanatory note**  
to the [working document](#)  
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## **VORBEMERKUNG**

Wie erst jetzt zu erfahren war, existiert seit Februar ein Entwurf einer Arbeitsgruppe des Lenkungsausschusses für Bioethik des Europarates für ein weiteres Zusatzprotokoll zur seit 1994 umstrittenen Biomedizinikvention des Europarates. Deutschland hat sie nicht unterzeichnet und auch nicht ratifiziert.

Der vorliegende Entwurf trifft Vorkehrungen für Gentests an Lebenden und Verstorbenen, für Zwecke der Gesundheit, der Forschung, in Arbeitswelt und Versicherungen und - was immer wieder auftaucht - zum Zwecke der Nachwuchs"planung" .

Da in Deutschland kein Gendiagnostikgesetz existiert, jedoch überfällig ist, hat dieses Papier aktuelle Bedeutung für jeden. Kritische Rückmeldungen von NGOs oder Einzelpersonen müssen bis 30. April an 2 E-Mailadressen gehen, die im vorderen Teil des Papiers genannt werden. Falls es jemanden gibt, der eine vorläufige Übersetzung fertigen kann, könnte diese hier ebenfalls veröffentlicht werden.

(Ursel Fuchs, Düsseldorf)

## **Zusammenstellung und Quelle**

Diese Texte wurden zusammengestellt am 09.04.03 von Christian Frodl, InteressenGemeinschaft Kritische Bioethik Bayern nach den Originalquellen und sind abrufbar auf dem Gemeinschaftsportal der InteressenGemeinschaften Kritische Bioethik Deutschland unter

**[http://www.kritischebioethik.de/deutschland\\_downloads.html](http://www.kritischebioethik.de/deutschland_downloads.html)**

Eine deutsche Übersetzung existiert bislang leider noch nicht.

### **Quelle der Original-Dokumente:**

[http://www.coe.int/T/E/Legal%5FAffairs/Legal%5Fco%2Doperation/Bioethics/Activities/Human\\_genetics/INF\(2003\)3e\\_genetics\\_working\\_doc.asp#TopOfPage](http://www.coe.int/T/E/Legal%5FAffairs/Legal%5Fco%2Doperation/Bioethics/Activities/Human_genetics/INF(2003)3e_genetics_working_doc.asp#TopOfPage)

[http://www.coe.int/T/E/Legal%5FAffairs/Legal%5Fco%2Doperation/Bioethics/Activities/Human\\_genetics/INF\(2003\)4e\\_genetics\\_expl\\_note.asp#TopOfPage](http://www.coe.int/T/E/Legal%5FAffairs/Legal%5Fco%2Doperation/Bioethics/Activities/Human_genetics/INF(2003)4e_genetics_expl_note.asp#TopOfPage)

WORKING PARTY ON HUMAN GENETICS  
(CDBI-CO-GT4)

**Working document  
on the applications of genetics for health purposes**

This working document is made public under the responsibility of the Working Party on Human Genetics (CDBI-CO-GT4). The Council of Europe Steering Committee on Bioethics (CDBI), which agreed with the publication of the document, has not yet examined it. The document therefore does not necessarily reflect the views of the CDBI. It is the outcome of the Working Party's discussions so far on applications of genetics for health purposes, with a view to the elaboration of an additional Protocol to the Convention on Human Rights and Biomedicine.

This document is being made public, together with an [explanatory note](#), to obtain comments from European non-governmental organisations, which will be taken into account for the elaboration of the draft additional Protocol. **Comments should be submitted to the Secretariat by e-mail before 30 April 2003 to [laurence.lwoff@coe.int](mailto:laurence.lwoff@coe.int) or [terry.journiac@coe.int](mailto:terry.journiac@coe.int).**

Comments should be as precise and concise as possible. They should refer to specific provisions in the document or, if appropriate, make proposals for complementary provisions.

**Working document on the applications of genetics for health purposes**

**Chapter I  
General provisions**

**Article 1 - Object and purpose**

Parties 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 such applications of genetics to the human being as specified in Article 2.

**Article 2 - Scope**

1. This Protocol extends to the applications of genetics in the field of health, including research, as well as in the fields of employment and insurance, which involve an intervention concerning the human genome, carried out on living persons or on the body of deceased persons.

This Protocol also extends to the applications of genetics in the field of health, excluding for research purposes, as well as in the fields of employment and insurance, which involve:

- an intervention on identified or identifiable human biological material, or
- the collection, processing or communication of personal genetic data.

2. This Protocol does not extend to the applications of genetics to the human embryo and foetus or any biological material derived from them.

**Article 3 - Primacy of the human being**

In the applications of genetics covered by this Protocol, the interests and welfare of the human being shall prevail over the sole interest of society or science.

**Article 4 - Non-discrimination**

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.

**Article 5 - Professional standards and obligations**

In the applications of genetics covered by this protocol, relevant professional obligations and standards shall be respected.

**Chapter II  
Applications for health purposes**

**Section I - General provisions**

***Sub-section A - Information, consent and authorisation***

## **Article 6 - Information to be given prior to consent or authorisation**

1. Prior to consent or authorisation to an application of genetics, appropriate information shall be given to the person concerned or, where appropriate, to the person, authority or body whose authorisation is requested. This information shall include, when relevant to the application concerned:

On the intervention:

- the purpose and the nature of the intervention;
- risks arising from the intervention;
- as appropriate, the consequences of not undergoing the intervention;

On the consequences of the intervention:

- the diagnosis and prognosis for the person concerned;
- the implications for the person concerned;
- the possible consequences for future reproductive choices;
- the implications for other family members;

On support:

- the forms of support available.

2. Information shall also be provided on any foreseen potential further uses of biological material removed during the intervention and of any personal genetic data derived from that material.

3. The information shall be given in a comprehensible and non-directive manner.

## **Article 7 - General rule on consent**

1. An application of genetics to human beings may only be carried out after the person concerned has given free and informed consent to it.

Additional conditions as to the form of consent may be required depending on the nature of the application and its implications.

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

## **Article 8 - Persons not able to consent**

1. Subject to Article 17 paragraph 2 of the Convention on Human Rights and Biomedicine and Article 16 paragraph 1 of this Protocol, an application of genetics may only be carried out on a person who does not have the capacity to consent for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an application of genetics, that application 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.

However, genetic tests shall be deferred until the attainment of legal capacity unless that delay would be detrimental to the minor's health or well-being.

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.

3. Where, according to law, an adult does not have the capacity to consent to an application of genetics because of a mental disability, a disease or for similar reasons, that application 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 individual concerned shall, as far as possible, take part in the authorisation procedure.

4. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

## **Sub-section B - Genetic services**

### **Article 9 - Quality of genetic services**

Parties shall take measures to ensure that preventive, diagnostic or therapeutic genetic services are of appropriate quality, and in particular to ensure that:

- a. a quality assurance and monitoring programme for services, including quality control of laboratory procedures, is in place;
- b. professional staff involved in genetic services have appropriate qualifications and training to enable them to perform their role within the services in accordance with professional

obligations and standards;

c. genetic tests provided within such a service meet professional standards of scientific and clinical validity.

#### **Article 10 - Equitable access to genetic services**

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to preventive, diagnostic and therapeutic genetic services.

#### **Article 11 - Genetic counselling**

Genetic counselling and support appropriate to the application of genetics and its implications for the person concerned or the members of the person's family shall be offered to the person who may receive the application.

#### **Article 12 - Respect for private life and access to the results of an application of genetics**

1. Everyone has the right to respect for his or her private life, in particular with regard to his or her personal data derived from an application of genetics.

2. Everyone undergoing an application of genetics is entitled to know any information collected about his or her health derived from this application. The information shall be accessible to the person concerned in an understandable form.

Information derived from a genetic application and not related to health shall be made available to the person concerned, subject to the conditions and procedures determined by law.

3. The wishes of individuals not to be informed shall be observed.

4. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 and 3 in the interests of the person concerned.

#### **Article 13 - Storage of biological materials and personal genetic data**

The conditions and duration of the storage of human biological materials and personal genetic data shall be regulated, in particular to ensure security and confidentiality.

### **Section II - Individual genetic test on living persons**

#### **Article 14 - Scope of Section II**

The provisions of this section apply to genetic tests on a living person or materials removed from a living person performed in order to diagnose a genetic disease or disorder and/or to determine whether the person possesses one or more genetic traits which may lead that person to develop a disease or a disorder in the future or may result in a disease or disorder if transmitted to that person's progeny or which are relevant to medical treatment.

#### **Article 15 - Purposes of predictive genetic tests**

Tests which are predictive of genetic diseases or disorders or which serve either to identify a person as a carrier of a gene responsible for a disease or disorder, or to detect a genetic predisposition or susceptibility to a disease or disorder may be performed only for health purposes or for scientific research linked to health purposes.

#### **Article 16 - Exception for family members**

1. Exceptionally, a genetic test can be carried out on a person not able to consent for the health benefit of family members, only if the following conditions are met:

a. the purpose of the test is to allow the family member or members to obtain an important preventive, diagnostic or therapeutic health benefit, or to allow them to make an informed choice with respect to procreation;

b. the implementation of such a test is essential to obtain the benefit envisaged;

c. the importance of the benefit envisaged has been independently assessed;

d. the risk and burden of the intervention, and risks to private life that may arise from the collection, processing or communication of the results of the test are minimal for the person who is to undertake the test;

e. the person undergoing the test does not object;

f. the authorisation of their representative, or an authority or a person or body provided for by law has been given.

2. If the person tested has expressed the wish not to be informed of the result of the test, this wish shall be observed.

#### **Article 17 - Genetic tests on biological materials**

1. A genetic test shall only be carried out on biological material previously removed from a human body if this is done in conformity with appropriate information and consent or authorisation procedures.

2. To that end, to obtain the consent or authorisation, reasonable effort shall be made to contact the person concerned.

#### **Article 18 - Tests directly sold to the public**

##### **Alternative A**

Genetic tests shall not be directly sold to the public.

##### **Alternative B**

The provisions of Chapter I and Sections I and II of Chapter II of this Protocol shall apply to genetic tests directly sold to the public.

##### **Alternative C**

Where the law permits direct sale of genetic tests to the public, there shall be adequate regulation, in particular to ensure proper information and understanding of the implications of the test by the person concerned.

#### **Section III - Genetic tests on deceased persons**

##### **Article 19 - Genetic testing on deceased persons**

1. A genetic test may only be carried out on the body of a deceased person or on biological material removed from the body of a person after death if the consent or authorisation required by law has been obtained.

2. The genetic test shall not be carried out if that person had objected to it.

#### **Section IV - Genetic screening for health purposes**

##### **Article 20 - Scope of Section IV**

The provisions of this section apply to specific tests offered for health purposes in an authorised programme, to an entire population or section of a population in order to identify asymptomatic persons with an increased risk of developing a genetic disease or disorder or transmitting such a disease or disorder to his or her descendants.

##### **Article 21 - Additional criteria to be met before performing screening**

A genetic screening programme for health purposes may only be undertaken if the following additional specific conditions are met :

- a. The scientific validity of the programme has been established;
- b. The programme is recognised for its relevance to health;
- c. Effective preventive or treatment measures can be taken in respect of the disease or disorder which is the subject of the screening;
- d. Measures shall be taken to adequately inform the population or section of population concerned on the existence, purposes and means of accessing the screening programme;
- e. No payment shall be given for participation in the screening programme.

##### **Article 22 - Approval of the screening programme**

A genetic screening programme for health purposes may only be undertaken in accordance with the criteria established in this Protocol and with the approval of an independent authorised body taking into account the principle of proportionality with respect to health needs.

##### **Article 23 - Equitable access to screening programmes**

Parties shall take appropriate measures to ensure equitable access to authorised screening programmes.

## **Article 24 - Non-stigmatisation**

Parties shall take appropriate measures in order to protect populations or sections of populations offered screening, and their members undergoing screening, against any stigmatisation.

## **Section V - Research**

### ***Sub-Section A - General rule***

#### **Article 25 - General rule**

Genetic research linked to health purposes shall be carried out freely, subject to the provisions of this Protocol and the other legal provisions ensuring the protection of the human being.

### ***Sub-Section B - Somatic gene therapy***

#### **Article 26 - Scope of Section V**

The provisions of this section apply to interventions with the aim of modifying the genome of human somatic cells for preventive, diagnostic or therapeutic purposes, in particular by the deliberate introduction of genetic material into those somatic cells.

#### **Article 27 - Interventions on the human genome**

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 28 - Assessment**

The Parties shall ensure that the committees involved in the procedure of assessment of gene therapy research projects have all the expertise required to assess such projects.

#### **Article 29 - Minimisation of unintentional genomic modification**

Before a somatic gene therapy research project is approved by the competent body, as referred to in Article 16 of the Convention, the risk of unintentional modification of the genome which can be transmitted to any descendants as a result of that project, shall be assessed and minimised as far as possible.

#### **Article 30 - Long term follow-up**

A long term follow up shall be proposed to all persons having received an intervention seeking to modify the genome in order to assess the effects of the intervention, including long term effects.

#### **Article 31 - Clinical practice**

1. An intervention seeking to modify the genome of human somatic cells may only be introduced in clinical practice, subject to regulatory provisions provided by law, if the results of clinical research have established, in accordance with internationally accepted standards:

- the therapeutic benefit of the intervention considered;
- that the risk is not disproportionate to the therapeutic benefit for the person concerned, and
- there is adequate evidence that no risks to the general population exist.

2. An intervention seeking to modify the genome of human somatic cells shall only be undertaken by an appropriately qualified team comprising all the necessary scientific and medical expertise.

Quelle der Dokumente:

[http://www.coe.int/T/E/Legal%5FAffairs/Legal%5Fco%2Doperation/Bioethics/Activities/Human\\_genetics/INF\(2003\)3e\\_genetics\\_working\\_doc.asp#TopOfPage](http://www.coe.int/T/E/Legal%5FAffairs/Legal%5Fco%2Doperation/Bioethics/Activities/Human_genetics/INF(2003)3e_genetics_working_doc.asp#TopOfPage)

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The additional Protocol will also cover non-medical applications of genetics, particularly in the fields of employment and insurance. The Working Party has already begun work on this second part of the protocol.

It is hoped that response to this paper will bring the Working Party comments and remarks which it will take into consideration in preparing the draft protocol on human genetics, which will then be submitted to the CDBI for adoption.

Although the Working Party has agreed on most of the questions covered in this text, some remain under discussion. These include in particular individual genetic tests sold directly to the public (Article 18), concerning which three wordings, corresponding to the three possible approaches, are here presented for comment.

**Comments on this document can be sent by e-mail to the Secretariat General of the Council of Europe by 30 April 2003 at the latest to [laurence.lwoff@coe.int](mailto:laurence.lwoff@coe.int) or [terry.journiac@coe.int](mailto:terry.journiac@coe.int).**

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## Introduction

In 1991, in its Recommendation 1160 on the preparation of a convention on bioethics, the Parliamentary Assembly of the Council of Europe, pointing out the hopes but also the concerns over the most basic rights of the human person raised by the combined applications of biology, biochemistry and medicine, recommended that, in particular, the Committee of Ministers "envisage a framework convention [in the field of bioethics] comprising a main text with general principles and additional protocols on specific aspects".

The Convention on Human Rights and Biomedicine (ETS N° 164) lays down the general principles which provide a common framework for the protection of human beings with regard to developments in biomedical sciences. Article 31 of the Convention states: "Protocols may be concluded ..., with a view to developing, in specific fields, the principles contained in this Convention".

At the Deputies' 573<sup>rd</sup> meeting (4-7 June 1996), the Committee of Ministers entrusted the CDBI with drawing up a protocol to the Convention on Human Rights and Biomedicine to cover the problems linked to genetics and approved the terms of reference of the Working Party on Human Genetics (CDBI-CO-GT4).

The following experts were appointed to the Working Party:

Dr Stefan Winter (Germany), Chair  
Dr Elaine Gadd (United Kingdom), Vice-Chair  
Mr André Albert (France)  
Ms Lena Jonsson (Sweden)  
Prof Adriano Bompiani (Italy)  
Prof Jan Helge Solbakk (Norway)  
Prof Tadeus Mazurczak (Poland)  
Prof Vladimir Ivanov (Russian Federation).

The Project Group on Data Protection (CJPD), the European Health Committee (CDSP) and



the European Commission were invited to attend the Working Party's meetings as observers. The Working Party held its first meeting in September 1998. It set the general framework of the preliminary draft protocol and agreed to deal separately with questions relating to medical applications of genetics and questions relating to non-medical applications. It first dealt with questions concerning medical genetics - genetic tests, genetic counselling, gene therapy and genetic research - taking particular account of the results of a hearing of patients' organisations held on 8 June 1998. For the elaboration of a binding legal instrument, it recognised the need to lay down a normative framework which allowed account to be taken of the rapid development of techniques and knowledge in the field of genetics and developments in the use of applications.

### **Framework set by the Convention**

The Working Party based itself on the principles which the Convention establishes to protect human rights and the dignity of the human being with regard to the developments in biology and medicine, particularly genetics. It included the relevant provisions of the Convention in the general and specific provisions of the working document.

Thus, Chapter I (General provisions), Article 1 (Object and purpose) includes the text of Article 1 of the Convention, although it limits its scope to the application of genetics to human beings. Article 3 (Primacy of the human being) is based on the text of Article 2 of the Convention. Article 4 (Non-discrimination) includes the provision found in Article 11 of the Convention. Finally, Article 5 (Professional standards and obligations) is extensively based on Article 4 of the Convention.

In Chapter II (Applications for health purposes), several articles are extensively based on provisions of the Convention. This includes the articles relating to consent - Article 7 (General rule on consent) and Article 8 (Persons not able to consent) - which follow the wording of Articles 5 and 6 of the Convention. The same applies to Article 10 (Equitable access to genetic services) and Article 12 (Respect for private life and access to the results of an application of genetics), which are based on Articles 3 and 10 of the Convention respectively.

Also included in this document are Articles 12 and 13 of the Convention relating specifically to genetics, whose respective provisions are found in Article 15 (Purposes of predictive genetic tests) and Article 27 (Interventions on the human genome).

### **Taking existing legislation into account**

In addition to the principles laid down in the Convention, the Working Party took into account the other relevant Council of Europe legal instruments, particularly in matters of personal data protection. On certain specific questions, it also recognised the need to take into account the different systems in place at national level, for example for obtaining consent, and the disputes which may arise, particularly in the case of tests on deceased persons.

***The aim of the following comments, prepared by the Secretariat, is to explain certain provisions introduced by the Working Party and to underline possible issues which are still under discussion.***

## **Chapter I - General provisions**

### **Scope**

The Working Party excluded from the scope those fields which are already covered or on which specific legal instruments are planned.

In addition to applications of genetics which involve an intervention on living or deceased persons or on identified or identifiable human biological material, it agreed, on account of the important and specific ethical questions involved, to also cover applications of genetics involving the collection, processing or communication of personal genetic data. However, the question was raised within the Working Party whether it was appropriate to extend the scope in this way, given that genetic data are sensitive data already subject to other regulations.

## **Chapter II - Application for medical purposes**

### **Section I - General provisions**

In Article 6 relating to information prior to consent or authorisation, the Working Party, taking account of developments in the field concerned, agreed on the need also to provide information on planned further uses of any biological material removed or of genetic data derived from that material. However, the consent requested for the particular application does

not encompass all potential further uses, for which there have to be separate consent processes.

In [Article 8](#), with regard to tests on minors, the Working Party introduced the notion of "well-being", relating to physical and psychological comfort, to justify exceptions to the postponement of genetic testing since a very early genetic test can produce a negative result that makes invasive examinations unnecessary, as for example in the case of a polyposis.

The Working Party extended the genetic-counselling requirement ([Article 11](#)) to all applications for health purposes by including it in the general provisions. It took the view that such a service was potentially relevant to all such applications, even though its extent and form might vary according to the particular application and its implications for the person concerned.

The Working Party raised the question of communicating information resulting from an application of genetics but not, for example, concerning filiation. A provision to this effect was inserted into paragraph 2 of [Article 12](#). In the Working Party's view, however, this question did not directly come within the scope as specified in [Article 2](#) and it therefore confined the provision to a reference to national law.

The Working Party recognised the need to deal with the question of the conservation of biological samples and personal genetic data, on account, among other things, of the related security and confidentiality issues. However, here again, recognising the limits of the protocol's scope, it limited itself in [Article 13](#) to requiring that the matter be regulated.

## **Section II - Individual genetic test on living persons**

The scope as laid down in [Article 14](#) includes pharmacogenetic tests.

The Working Party introduced an exception to the direct-benefit rule laid down in [Article 6](#) paragraph 1 of the Convention, considering the envisaged "important benefit" for family members. However, in [Article 16](#), it laid down very strict conditions governing this exception.

It also considered the question of communicating information resulting from a genetic test on a patient to members of the family when it was relevant to their health. In this context it foresaw possible clashes between the rights of the person concerned, in particular the right not to know, and the rights of his/her family members. The need to provide legal solutions was underlined. The Working Party did not, however, consider it necessary to introduce a provision to this effect and decided that this question could be dealt with in the explanatory report to the draft protocol.

[Article 17](#) deals with tests on biological material outside a biomedical research project: the use of preserved biological material of human origin is the subject of another draft instrument.

The Working Party took account of the difficulties which could arise in obtaining consent or authorisation, in particular in the case of biological materials which have been preserved for long periods.

On the question of tests sold directly to the public, it noted the diversity of views and would like to discuss the matter further in the light of the **comments submitted**. With this in mind it drafted three alternative wordings of [Article 18](#) reflecting the possible approaches.

## **Section III - Genetic test on deceased persons**

The Working Party recognised the problems likely to be posed by disagreements between family members about carrying out a genetic test on a deceased close relative. It did not insert a provision on this matter into [Article 19](#) but agreed to refer to it in the explanatory report to the draft protocol, underlining the need to provide a solution in national law that could settle such disagreements.

## **Section IV - Genetic screening for health purposes**

[Article 20](#) specifies the scope of this section. A clear distinction is made between tests carried out under a screening programme - which fall within the scope of this section - and individual tests carried out systematically, which are not covered in this section.

The Working Party agreed that screening for health purposes also covered healthy carrier screening.

The requirements listed in [Article 21](#) supplement those already laid down in Section I (General provisions), which apply at the individual level, particularly access to the results of

screening and genetic counselling.

Scientific validity of the screening programme (sub-paragraph a.) is accepted here as an essential criterion. Scientific validity must be established in relation to the aim of the screening and on the basis of the sensitivity, specificity and reliability of the tests.

In addition the Working Party introduced into Article 22, as an essential consideration in evaluating scientific validity, the notion of proportionality with respect to health needs.

In drawing up the list of supplementary requirements (Article 21), it also took account of the following factors: availability to all the population in question; availability of preventive or therapeutic measures with regard to the illness; the need to present the benefits and implications in such a way that the individual can seek more personalised additional information; voluntary participation; non-remuneration (not precluding minimal material advantages - for example a drink or a toy in the case of a child).

### **Section V - Research**

In drafting the provisions for this section, the Working Party was guided by a desire to ensure that protocols were independent of one another. For this reason, Article 25 refers to "the other legal provisions". These provisions are in particular those of the Convention, but also those of the additional Protocol on biomedical research (currently being examined by the CDBI for adoption) in the case of the states that become Parties to it.

The Working Party included gene therapy in this section, recognising that in the large majority of cases it came within the province of research. In accordance with Article 13 of the Convention, which bans germ line gene therapy, only somatic gene therapy is covered. In Article 26, the scope is defined accordingly.

In the following articles (Articles 28 and 29), the Working Party sought to draw attention to factors of particular importance in terms of the special requirements and implications of gene therapy research.

In laying down the conditions for introducing gene therapy intervention into clinical practice (Article 31), it agreed to place particular emphasis on the requirements with regard to the results of clinical research as to the therapeutic reliability, security and efficiency of intervention. In addition, recognising the different types of expertise required for such intervention, it specified certain requirements concerning the team performing it.

Quelle der Dokumente:

[http://www.coe.int/T/E/Legal%5FAffairs/Legal%5Fco%2Doperation/Bioethics/Activities/Human\\_genetics/INF\(2003\)4e\\_genetics\\_expl\\_note.asp#TopOfPage](http://www.coe.int/T/E/Legal%5FAffairs/Legal%5Fco%2Doperation/Bioethics/Activities/Human_genetics/INF(2003)4e_genetics_expl_note.asp#TopOfPage)