

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

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DH-BIO/INF (2017) 5

COMMITTEE ON BIOETHICS (DH-BIO)

Information document concerning the DH-BIO

**Secretariat memorandum
prepared by the Bioethics Unit
Human Rights Policy and Cooperation Department
Directorate of Human Rights**

I. INTRODUCTION

Set up in 1949, the Council of Europe is an intergovernmental organisation which fosters political, legal, and cultural cooperation between its 47 member European pluralistic democracies. It is distinct from the European Union (However, the member states of the European Union are also members of the Council of Europe).

The Council of Europe's aims, as specified by its Statute, are to protect human rights and strengthen pluralist democracy, to enhance European cultural identity and seek out solutions to the major problems of our time. The work of the Council of Europe may result in international conventions and in recommendations for CE member States.

The Council of Europe operates through three main bodies, the Committee of Ministers, the Parliamentary Assembly and the Congress of Local and Regional Authorities of Europe. A Secretariat General serves these bodies and is headed by a Secretary General elected for a five-year period. The current Secretary General is Thorbjørn Jagland (Norway).

The Committee of Ministers comprises the Ministers of Foreign Affairs of the 47 member States. It votes binding and non-binding texts addressed to member States. The Ministers' Deputies are the governments' Permanent Representatives to the Council of Europe. They have the same decision-making powers as the Ministers and supervise the Council's activities. They meet at least twice a month. The Deputies set out the Council of Europe's programme of activities and adopt its budget. They also decide what action should be taken on proposals from the Parliamentary Assembly, the Congress of Local Authorities of Europe and from conferences of specialised ministers that the Council of Europe regularly holds. The Committee of Ministers also serves as a permanent forum to discuss European co-operation and common political problems.

Set up under the direct authority of the Committee of Ministers in 1985, the Ad hoc Committee of experts on Bioethics (CAHBI), which became in 1992 the Steering Committee on Bioethics (CDBI) (see Appendix I), was, responsible for the intergovernmental activities of the Council of Europe in the field of bioethics. The work of CAHBI, and then of the CDBI, has led to the adoption of Recommendations of the Committee of Ministers (see Appendix II) and to the preparation of the Convention on Human Rights and Biomedicine, the first international treaty in this field (adopted by the Committee of Ministers on 19 November 1996 and entered into force on 1 December 1999) as well as the additional Protocol on the Prohibition of Cloning Human Beings (adopted by the Committee of Ministers on 6 November 1997 and entered into force on 1 March 2001), the additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (adopted by the Committee of Ministers on 8 November 2001 and came into force on 1 May 2006), and the additional Protocol on Biomedical Research (adopted by the Committee of Ministers on 30 June 2004 and entered into force on 1 September 2007), and the Protocol concerning Genetic Testing for Health Purposes (adopted by the Committee of Ministers on 7 May 2008, opened for signature on 27 November 2008).

Since 2012, the Steering Committee on bioethics (CDBI) has become the Committee on Bioethics (DH-BIO) and is a subordinate body of the Steering Committee for Human Rights (CDDH), except for the tasks assigned to the Steering Committee of Bioethics (see terms of reference) with regard to the Convention on Human Rights and Biomedicine.

II. TERMS OF REFERENCE

1. **Name of committee:** COMMITTEE ON BIOETHICS (DH-BIO)
2. **Type of committee:** Subordinate body
3. **Source of terms of reference:** Committee of Ministers
4. **Terms of reference:**

Set up by the Committee of Ministers under Article 17 of the Statute of the Council of Europe and in accordance with Resolution CM/Res(2011)24 on intergovernmental committees and subordinate bodies, their terms of reference and working methods

Type of committee: Subordinate body

Terms of reference valid from: **1 January 2018 until 31 December 2019**

PILLAR/SECTOR/PROGRAMME
<p>Pillar: Human Rights Sector: Promoting Human Rights and Dignity Programme: Bioethics</p>
MAIN TASKS
<p>Under the authority of the Committee of Ministers, the DH-BIO shall carry out the tasks assigned to the Steering Committee on Bioethics (CDBI) by the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.</p> <p>Under the supervision of the Steering Committee for Human Rights (CDDH), the DH-BIO will conduct intergovernmental work on the protection of human rights in the field of biomedicine assigned to it by the Committee of Ministers. The DH-BIO will in particular:</p> <ol style="list-style-type: none"> (i) conduct regular re-examinations foreseen in the Convention and its Additional Protocols; (ii) develop further the principles laid down in the Convention on Human Rights and Biomedicine, as appropriate, also in the light of the relevant case-law of the ECHR; (iii) contribute to raising awareness and facilitating the implementation of these principles; (iv) assess ethical and legal challenges raised by developments in the biomedical field; (v) co-operate with the European Union and relevant intergovernmental bodies, in particular with a view to promoting consistency between the normative texts; (vi) in accordance with decisions CM/Del/Dec(2013)1168/10.2 of the Committee of Ministers, carry out, at regular intervals, within the limits of the available resources and bearing in mind its priorities, an examination of some or all of the conventions¹ for which it has been given responsibility and report back to the Committee of Ministers.
SPECIFIC TASKS
<ol style="list-style-type: none"> (i) A draft Additional Protocol on the protection of human rights and dignity of persons with mental disorders with regard to involuntary placement and involuntary treatment is finalised. (ii) On the basis of the results of the international conference organised on the occasion of the 20th anniversary of the Oviedo Convention, a draft Strategic Action Plan on human rights and technologies is finalised. (iii) A training course on essential principles for the protection of human rights in the biomedical field intended for legal and health professionals is launched in the framework of the HELP programme. (iv) A round table is organised, in co-operation with the Consultative Committee of the Convention for the protection of individuals with regard to automatic processing of personal data (T-PD), on the challenges for human rights raised by developments in the field of genetics, including for children's rights. (v) Subject to the results of the international conference organised on the occasion of the 20th anniversary of the Oviedo Convention, draft guidelines for the promotion of public debate on human rights challenges raised by developments in science and technologies are developed.
COMPOSITION
<p>Members:</p> <p>Governments of the member States are invited to designate one or more representatives of the highest possible rank, with appropriate expertise in the various aspects of bioethics, including in relation to emerging technologies, and able to consider these from a human rights perspective.</p>

¹ Cf. Relevant decision of the Committee of Ministers ([CM/Del/Dec\(2013\)1168/10.2](#)) and list of Conventions in [Appendix I](#).

The Council of Europe will bear the travel and subsistence expenses of one representative from each member State (two in the case of the State whose representative has been elected Chair).

Each member of the committee shall have one vote. Where a government designates more than one member, only one of them is entitled to take part in the voting.

In accordance with decisions CM/Del/Dec(2013)1168/10.2 of the Committee of Ministers, in cases where there is no convention-based body including all the Parties, non-member States are invited to take part, with a right to vote, in the committee meetings pertaining to the conventions to which they are Parties.

Participants:

The following may send representatives, without the right to vote and at the charge of their corresponding administrative budgets:

- Parliamentary Assembly of the Council of Europe;
- Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD), Committee (Partial Agreement) on Transplantation of Organs and Tissues (CD-P-TO) and Committee (Partial Agreement) on Blood Transfusion (CD-P-TS);²
- Council of Europe Commissioner for Human Rights;
- Conference of INGOs of the Council of Europe;
- Committees or other bodies of the Council of Europe engaged in related work, as appropriate.

The following may send representatives, without the right to vote and without defrayal of expenses:

- European Union;
- Observer States to the Council of Europe: Canada, Holy See, Japan, Mexico, United States of America;
- Other international organisations: European Science Foundation (ESF), OECD, UNESCO and WHO.

Observers:

The following may send representatives, without the right to vote and without defrayal of expenses:

- Australia, Israel;
- the Conference of European Churches (KEK);
- other non-governmental organisations, including professional organisations, which could be invited by the DH-BIO to attend specific meetings of the DH-BIO in accordance with CM/Res(2011)24.

WORKING METHODS

Meetings:

48 members, 2 meetings in 2018, 4 days

48 members, 2 meetings in 2019, 4 days

Bureau

7 members, 2 meetings in 2018, 2 days

7 members, 2 meetings in 2019, 2 days

The Chair or Vice-Chair of DH-BIO may be invited to attend the meetings of the CDDH and its Bureau in order to inform on progress with its work.

The Committee will also appoint a Gender Equality Rapporteur from amongst its members.

The rules of procedure of the Committee are governed by Resolution CM/Res(2011)24 on intergovernmental committees and subordinate bodies, their terms of reference and working methods (see Appendix III).

APPENDIX 1 - RELEVANT DECISION OF THE COMMITTEE OF MINISTERS AND LIST OF CONVENTIONS

CM/Del/Dec(2013)1168/10.2 (Review of Council of Europe conventions)

9. [The Deputies] instructed the steering and ad hoc committees to carry out, at regular intervals, within the limits of the available resources and bearing in mind the priorities of each committee, an examination of some or all of the conventions for which they have been given responsibility, in co-operation, where appropriate, with the relevant convention-based bodies, in order to:

- propose ways of improving the visibility, impact and efficiency of some or all of the conventions for which they have been given responsibility;

² European Directorate for the Quality of Medicines and Healthcare.

- draw the attention of member States to the relevant conventions;
- where necessary, identify any operational problems or obstacles to ratification of the relevant conventions, and draw the attention of member States to reservations which impact substantively on the effectiveness of their implementation;
- encourage States to regularly examine the possibility and/or desirability of becoming a Party to new Council of Europe conventions;
- assess the necessity or advisability of drafting amendments or additional protocols to the conventions for which they have been given responsibility or drafting supplementary conventions;
- and to report back to the Committee of Ministers.

DH-BIO

164	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
168	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
186	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin
195	Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research
203	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes

III. MEMBERSHIP

The governments of the 47 member States³ may appoint experts. Such members are entitled to vote (1 vote per delegation) on matters arising within the DH-BIO. Furthermore the Parliamentary Assembly of the Council of Europe and the European Union may appoint representatives, as well as the Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD), the European Committee on Organ Transplantation (CD-P-TO), the European Committee on Blood Transfusion (CD-P-TS), the Commissioner for Human Rights, the Conference of INGOs, the Ad Hoc Committee on the rights of persons with disabilities (CAHDPH) and other committees or bodies of the Council of Europe engaged in related work, as appropriate.

In addition to the member States, the following countries may send representatives as observers: Australia, Canada, Holy See, Israel, Japan, Mexico, United States of America.

The following international organisations may also send representatives: UNESCO (United Nations Educational, Scientific and Cultural Organization), OECD (Organization for Economic Co-operation and Development), WHO (World Health Organization), the European Science Foundation and the KEK (Church and Society Commission of the Conference of European Churches).

IV. BUREAU

In accordance with the provisions of Articles 12 and 13 of the Rules of Procedure for Council of Europe Committees (Resolution (2011) 24 on committees and subordinate bodies, their terms of reference and their working methods) the DH-BIO elected:

- Dr Beatrice Ioan (Romania), Chair (re-elected in October 2017)
- Ms Tesi Aschan (Sweden), Vice-Chair (re-elected in October 2017)
- Dr Ritva Halila (Finland), member of Bureau (elected in December 2016)
- Prof. Miguel Oliveira da Silva (Portugal), member of Bureau (elected in December 2016)
- Prof. Constantinos Phellas (Cyprus), member of Bureau (elected June 2016)
- Dr Givi Javashvili (Georgia), member of Bureau (re-elected in December 2016)
- Ms Maria Concepción Martín Arribas (Spain), member of Bureau (re-elected in December 2016).

³ The following countries are member States of the Council of Europe: Albania, Andorra, Armenia, Austria, Azerbaijan, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Republic of Moldova, Monaco, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Russia, San Marino, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom.

V. SECRETARIAT

The Secretariat prepares necessary documentation prior to meetings of the DH-BIO and prepares the meeting reports afterwards. Other duties include assisting in the drafting of documents during the meetings and in the periods between meetings. Utilising its presence at the Council of Europe in Strasbourg, the Secretariat coordinates the flow of information between the DH-BIO and the Steering Committee for Human Rights as well as other relevant intergovernmental committees, drafting groups and entities operating at the Council of Europe such as the Parliamentary Assembly's Committee on Culture, Science, Education and Media, Committee on Social Affairs, Health and Sustainable Development, Committee on Legal Affairs and Human Rights, and General Rapporteur on science and technology impact assessment. Information about relevant legal instruments currently in force or in the drafting process is provided by the Secretariat. During the meeting, the Secretary General or his/her representative may at any time make an oral or written statement on any subject under discussion (Committee of Ministers Resolution (2011) 24, Article 15 b). Initiation of consensus or compromise within the meetings is one of the main functions of the Secretariat.

VI. MEETINGS

The DH-BIO usually meets twice a year at the headquarters of the Council of Europe in Strasbourg (France). The working languages are English and French. All DH-BIO documents are in English and French and during the meeting simultaneous interpretation is provided (English-French and vice-versa).

Resolution (2011) 24 of the Committee of Ministers (adopted by the Committee of Ministers on 9 November 2011 at the 1125th meeting of the Ministers' Deputies) "on intergovernmental committees and subordinate bodies, their terms of reference and working methods" sets out the working methods used by the DH-BIO.

VII. PARLIAMENTARY ASSEMBLY

The Parliamentary Assembly is the deliberative body of the Council of Europe and is composed of 318 representatives (and the same number of substitutes) appointed by the 47 member States' national parliaments. The Parliamentary Assembly has been represented in the intergovernmental committees responsible for bioethics activities since 1990 (the CAHBI, the CDBI and then the DH-BIO) and was asked to give its opinion and propose amendments to drafts of the Convention on Human Rights and Biomedicine. The Recommendations of the Parliamentary Assembly on issues relevant to bioethics over the past 20 years were also taken into account during the drafting of the Convention and of its Protocols. The Parliamentary Assembly has given an opinion for each draft Protocol to the Convention as soon as they were finalised (four Protocols have already been transmitted to it: the Protocol on the Prohibition of Cloning Human Beings, the Protocol concerning Transplantation of Organs and Tissues of Human Origin, the Protocol on Biomedical Research and the Protocol concerning Genetic Testing for Health Purposes).

VIII. RECENT AND ONGOING WORK OF THE DH-BIO

A. Work of the DH-BIO

The main work in 2016 concerned:

- (i) The continuation of the work on the protection of human rights and dignity of persons with mental disorders with regard to involuntary placement and involuntary treatment;
- (ii) The elaboration of proposals for clarification of key notions with a view to facilitate the implementation of the principle in Article 21 of the Oviedo Convention (prohibition of financial gain);
- (iii) A Seminar on International case-law in Bioethics: Insight and foresight organised on 5 December 2016;
- (iv) A Conference on Ethical and legal aspects of organ donation organised on 26 April 2016 in Moscow on the occasion of the 20th anniversary of the membership of the Russian Federation in the Council of Europe;
- (v) Two cooperation activities in Armenia and Turkey in October 2016 on decision-making process regarding medical treatment in end-of life situations.

The main work in 2017 concerned:

- (i) The continuation of the work on the protection of human rights and dignity of persons with mental disorders with regard to involuntary placement and involuntary treatment;

- (ii) The finalisation of a Guide for the implementation of the Principle of the Prohibition of Financial Gain with respect to the human body and its parts, as such, from living or deceased donors;
- (iii) An international conference to mark the 20th anniversary of the Oviedo Convention: relevance and challenges;
- (iv) The development of a HELP course on bioethics addressed to legal and health professionals;
- (v) In the framework of the Action Plan of the Council of Europe for Belarus, the launching of a number of cooperation activities in the country aimed at the protection of human rights in biomedicine.

B. Drafting Groups responsible for the preparation of texts

- Strategic Group for the follow-up of the Conference on the 20th anniversary of the Oviedo Convention

The Strategic Group has been entrusted with the task of following-up the outcome of the Conference on the 20th anniversary of the Oviedo Convention, with a view to elaborating a Strategic Action Plan aimed at defining the main axes and objectives of the work of the DH-BIO in the next few years, to address key human rights challenges raised by developments in the biomedical field.

- Strategic Group for the follow-up of the Conference on emerging technologies

The Strategic Group was entrusted with the task to concentrate on the outcome of the Conference on emerging technologies and to consider initiatives which could be taken at the Council of Europe level and, if necessary, those which would be the most relevant for other intergovernmental organisations.

- Ad hoc Working group on “The prohibition of financial gain”

The Committee on bioethics (DH-BIO) had decided to set up an ad hoc group as a follow-up to the Statement on the prohibition of any form of commercialisation of human organs adopted by the DH-BIO and the CD-P-TO in May 2014, and then taken over by the Committee of Ministers of the Council of Europe. The DH-BIO was entrusted with the task of preparing proposals for clarification of key notions with a view to facilitate the implementation of the principle in Article 21 of the Oviedo Convention. The work of the ad-hoc group led in 2017 to the adoption by the DH-BIO of a Guide for the implementation of the Principle of Prohibition of Financial Gain with respect to the human body and its parts, as such, from living or deceased donors.

- Drafting Group for preparation of an Additional Protocol on the protection of human rights and dignity of persons with mental disorders with regard to involuntary placement and involuntary treatment (DH-BIO/PSY) set up in 2013. A public consultation was launched between 22 June 2015 and 15 November 2015 on the said Protocol as a working document. It aimed at eliciting comments from individuals and bodies/institutions from all the fields concerned. The comments received during the public consultation (DH-BIO/INF (2015)20) are being taken into account in the finalisation of the Additional Protocol.

- Drafting Group on Biobanks (DH-BIO/Biobanks) for the revision of Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin set up in 2015 following the Symposium on biobanks and research on biological materials of human origin, which objective was to provide a basis for the re-examination of Recommendation Rec(2006)4. The revised Recommendation was adopted by the DH-BIO at its 8th plenary meeting (December 2015). This Recommendation CM/Rec(2016)6, which follows the Recommendation (2006)4, was adopted by the Committee of Ministers on 11 May 2016.

C. Rapporteurs

Thematic rapporteurs are designated by the DH-BIO to facilitate co-ordination and progress in the related work during and between plenary meetings.

Rapporteur on public debate: Ms Tesi Aschan (Sweden)

Rapporteur on genetics and genomics, including genome editing: Dr Ingo Härtel (Germany)

Rapporteurs on intersex children: Dr Ritva Halila (Finland) and Prof. Constantinos Phellas (Cyprus)

Rapporteur on gender equality: Prof. Constantinos Phellas (Cyprus)

Rapporteur on predictivity, genetic testing and insurance (work finalised): Dr Doris Wolfslehner (Austria)

APPENDIX I Work of the CDBI (1992-2011)

A. Convention on Human Rights and Biomedicine and its Additional Protocols

The CDBI prepared the 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) setting out general principles and rules for the protection of the human being in the context of the development of biology and medicine. The Convention was adopted by the Committee of Ministers on 19 November 1996 and opened for signature on 4 April 1997 in Oviedo, Spain. The publication of the Explanatory Report to the Convention was authorised by the Committee of Ministers on 17 December 1996. The Convention (CETS No.164) and the Explanatory Report (ref. no. DIR/JUR (97) 5) are available from the Council of Europe Directorate General 1 – Human Rights and Rule of Law, Secretariat of the Committee on Bioethics (DH-BIO).

The CDBI also drew up a **first Additional Protocol on the Prohibition of Cloning Human Beings**. This Protocol (CETS No. 168) was adopted during the 101st Session of the Committee of Ministers, and opened for signature on 12 January 1998 in Paris.

The **second Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin was prepared by a Working Party⁴ on organ transplantation (CDBI-CO-GT1)**. The finalised draft Protocol was approved by the CDBI during its 18th meeting in June 2000 and adopted during the 109th Session of the Committee of Ministers (CETS No. 186). It was opened for signature on 24 January 2002 in Strasbourg.

The **third Additional Protocol was prepared by a Working Party on biomedical research (CDBI-CO-GT2)**. The finalised draft Protocol was approved by the CDBI during its 24th meeting in 20 June 2003. This Protocol (CETS No. 195) was adopted during the 890th meeting of the Committee of Ministers, at the level of their Deputies, and opened for signature on 25 January 2005 in Strasbourg.

The **fourth Additional Protocol concerning Genetic Testing for Health Purposes was prepared by a Group of Specialists on human genetics (CDBI-CO-GT4)**. The finalised draft Protocol was approved by the CDBI during its 32nd meeting on 8 June 2007. This Protocol (CETS No. 203) was adopted by the Committee of Ministers on 7 May 2008 and opened for signature on 27 November 2008.

The Convention foresees, with a view to developing its principles, the possibility of elaborating other Protocols on specific topics.

B. Recommendations, guidelines, reports

The following Working Parties/Groups of Specialists were responsible for preparing texts which were then referred to the CDBI for discussion and decision.

- **Working Party** responsible for the preparation of a draft Recommendation on the harmonisation of **medico-legal autopsy rules**. This Recommendation No. R (99) 3 was adopted by the Committee of Ministers on 2 February 1999.
- **Working Party on biotechnology (CDBI-Biotech)** set up in 2000 following the European Conference on ethical and legal questions raised by the developments in biotechnology and their consequences for human beings, animals and the environment. It was responsible for the preparation of a proposed framework for the future development of draft ethical and legal principles in the field of biotechnology.
- **Working Party on xenotransplantation (CDBI/CDSP-XENO)** set up under the joint authority of the CDBI and the European Health Committee (CDSP), responsible for the preparation of guidelines in this field and for making recommendations on public information. The finalised Recommendation on xenotransplantation was approved by the CDBI during its 22nd meeting in June 2002. Recommendation Rec (2003) 10 on xenotransplantation was adopted by the Committee of Ministers on 19 June 2003.

⁴ The denomination "Working Party" was replaced by "Group of Specialists" following Resolution (2011) 24 of the Committee of Ministers. Since 2012, the Committee on Bioethics (DH-BIO) has no more subordinate committees, but sets up small drafting groups on an ad hoc basis as part of its working methods.

- **Working Party on the protection of the human embryo and foetus (CDBI-CO-GT3)** responsible for the activities concerning the protection of the human embryo and foetus. The Working Party prepared a report on the protection of the human embryo *in vitro*, which was made public by the CDBI in June 2003.
- **Working Party on psychiatry and human rights (CDBI-PH)** responsible for the preparation of guidelines in this field. The finalised draft Recommendation concerning the protection of the human rights and dignity of persons with mental disorder was approved by the CDBI during its 26th meeting in March 2004. Recommendation Rec (2004) 10 concerning the protection of the human rights and dignity of persons with mental disorder was adopted by the Committee of Ministers on 22 September 2004.
- **Working Party on research on biological materials of human origin (CDBI-CO-GT2biomat)** entrusted with the preparation of a draft Recommendation on this subject. The finalised draft Recommendation was approved by the CDBI during its 29th meeting in October 2005. Recommendation Rec (2006) 4 on research on biological materials of human origin was adopted by the Committee of Ministers on 15 March 2006.
- **Group of Specialists** set up in 2007 with the task of preparing a draft **Guide for research ethics committee members**, which was adopted by the CDBI on 3 December 2010.
- **Working Party on predictivity and genetic testing in the field of insurance** set up in 2008 to prepare a consultation document with a view to a possible legal instrument.

APPENDIX II

List of Resolutions & Recommendations of the Committee of Ministers in the field of bioethics

- 1978 Resolution (78) 29 on the harmonisation of legislation of member States relating to removal, grafting and transplantation of human substances
- 1979 Recommendation R (79) 5 concerning international exchange and transportation of human substances
- 1981 Recommendation R (81) 1 on regulations for automated medical data banks
- 1983 Recommendation R (83) 2 on protection of persons suffering from mental disorders placed as involuntary patients
- 1984 Recommendation R (84) 16 concerning notification of work involving recombinant deoxyribonucleic acid (DNA)
- 1989 Recommendation R (89)2 on the protection of personal data used for employment purposes
- 1990 Recommendation R (90) 3 on medical research on human beings
- 1990 Recommendation R (90) 13 on prenatal genetic screening, prenatal genetic diagnosis and associated genetic counselling
- 1992 Recommendation R (92) 1 on the use of analysis of deoxyribonucleic acid (DNA) used within the framework of the criminal justice system
- 1992 Recommendation R (92) 3 on genetic testing and screening for health care purposes
- 1993 Recommendation R (93) 4 concerning clinical trials involving the use of components and fractionated products derived from human blood or plasma
- 1994 Recommendation R (94) 1 on human tissue banks
- 1994 Recommendation R (94) 11 on screening as a tool of preventive medicine
- 1997 Recommendation R (97) 5 on the protection of medical data
- 1997 Recommendation R (97) 15 on xenotransplantation
- 1998 Recommendation R (98) 7 concerning the ethical and organisational aspects of health care in prison
- 1999 Recommendation R (99) 3 on the harmonisation of medico-legal autopsy rules
- 1999 Recommendation R (99) 4 on principles concerning the legal protection of incapable adults
- 2001 Recommendation Rec (2001) 5 on the management of organ transplant waiting lists and waiting times
- 2002 Recommendation Rec (2002) 9 on the protection of personal data collected and processed for insurance purposes
- 2003 Recommendation Rec (2003) 10 on xenotransplantation
- 2003 Recommendation Rec (2003) 12 on organ donor registers
- 2003 Recommendation Rec (2003) 24 on the organisation of palliative care
- 2004 Recommendation Rec (2004) 7 on organ trafficking
- 2004 Recommendation Rec (2004) 8 on autologous cord blood banks
- 2004 Recommendation Rec (2004) 10 concerning the protection of the human rights and dignity of persons with mental disorder
- 2006 Recommendation Rec (2006) 4 on research on biological material of human origin
- 2007 Resolution ResAP (2007) 2 on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine
- 2008 Resolution on transplantation of kidneys from living donors who are not genetically related to the recipient
- 2008 Resolution on adult-to-adult living donor liver transplantation
- 2008 Resolution on donor responsibility and on limitation to donation of blood and blood components
- 2009 Recommendation REC (2009) 11 on principles concerning continuing powers of attorney and advance directives for incapacity
- 2010 Recommendation REC (2010) 6 on good governance in health systems
- 2012 Recommendation REC (2012) 8 on the implementation of good governance principles in health systems

- 2013 Resolution CM/RES (2013) 3 on sexual behaviours of blood donors that have an impact on transfusion safety
- 2013 Resolution CM/RES (2013) 55 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system
- 2013 Resolution CM/RES (2013) 56 on the development and optimisation of live kidney donation programmes
- 2015 Resolution CM/RES (2015) 10 on the role and training of critical care professionals in deceased donation
- 2016 Recommendation CM/Rec(2016)6 on research on biological materials of human origin
- 2016 Recommendation CM/Rec(2016)8 on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests

For other texts of the Council of Europe in the field of bioethics, including those by the Parliamentary Assembly, please refer to document DH-BIO/INF (2017)3, or see the website of the Bioethics Unit: www.coe.int/bioethics

APPENDIX III
COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

Resolution CM/Res(2011)24
on intergovernmental committees and subordinate bodies,
their terms of reference and working methods

*(Adopted by the Committee of Ministers on 9 November 2011
at the 1125th meeting of the Ministers' Deputies)*

The Committee of Ministers,

Having regard to Resolution Res(2005)47 on committees and subordinate bodies, their terms of reference and working methods;

Having regard to the decision taken by the Ministers' Deputies at their 1112th meeting (19 April 2011, item 1.6) on intergovernmental structures;

Having regard to Resolution CM/Res(2011)7 on Council of Europe conferences of specialised ministers;

Having regard to the Statutory Resolution CM/Res(2011)2 relating to the Congress of Local and Regional Authorities of the Council of Europe and the revised Charter appended thereto;

Having regard to Resolution Res(2003)8 on the participatory status for international non-governmental organisations with the Council of Europe;

Having regard to Statutory Resolution Res(93)26 on Observer Status;

Having regard to Resolution Res(2001)6 on access to Council of Europe documents;

Having regard to Recommendation Rec(81)6 of the Committee of Ministers to member states on the participation of women and men in an equitable proportion in committees and other bodies of the Council of Europe and to the Committee of Ministers' Declaration on Making gender equality a reality, adopted at the 119th Session of the Committee of Ministers of the Council of Europe (Madrid, 12 May 2009);

In pursuance of Articles 16 and 17 of the Council of Europe Statute,

Resolves as follows:

I. Scope of this resolution

1. This resolution shall apply to all intergovernmental committees and subordinate bodies set up by the Committee of Ministers, by virtue of Article 17 of the Council of Europe Statute.

2. If not provided otherwise, the rules set out in this resolution shall also apply *mutatis mutandis* to any committee created by the Committee of Ministers outside the scope of Article 17.

3. All references to the Secretary General in this resolution shall be subject to the relevant provisions of the Statute of the Council of Europe, the Staff Regulations and the rules on delegation of authority.

II. Categories of committees⁵

4. There shall be two categories of committees set up by the Committee of Ministers:

⁵ Unless specified otherwise, the term "committee" refers to steering and ad hoc committees and their subordinate bodies.

- a. *committees directly answerable to the Committee of Ministers*: steering committees with planning and steering functions and ad hoc committees with a more focused task; and
- b. *subordinate bodies* of steering or ad hoc committees, with specific and limited tasks.

III. Composition

A. Members

5. *Committees answerable to the Committee of Ministers*: they are composed of one representative of the highest possible rank in the relevant field designated by the government of each member state.⁶

6. *Subordinate bodies* answerable to steering or ad hoc committees: they are composed of representatives of all or of a limited number of member states of the highest possible rank in the relevant field designated by the governments of member states and/or of independent experts with established expertise in the relevant field. Where subordinate bodies are composed of a limited number of member states, due regard shall be given to geographical representation and periodic rotation of member states. Furthermore, they are open to the participation of representatives from other member states, at their own expense.

B. Participants

7. Participants shall take part in the meetings of committees with no right to vote nor defrayal of expenses unless otherwise indicated. They are:

- a. representatives of committees or other bodies of the Council of Europe engaged in related work, as well as the Parliamentary Assembly, the European Court of Human Rights, the Congress of Local and Regional Authorities of the Council of Europe, the Council of Europe Commissioner for Human Rights and the Conference of INGOs of the Council of Europe;

- b. representatives designated by states which have observer status with the Council of Europe, the European Union, intergovernmental organisations and any other entity, including social partners, authorised to participate in the meetings of steering and ad hoc committees by virtue of a resolution or decision of the Committee of Ministers.

C. Observers

8. Observers from states or organisations other than those referred to in paragraph 7.b above. They shall be admitted to steering committees, ad hoc committees and any subordinate body answerable to them in the following manner:

- a. as a general rule, upon their request to the Secretary General, observers are admitted, to steering and ad hoc committees or any subordinate body answerable to them, on the basis of a unanimous decision by that steering or ad hoc committee; in the event where unanimity is not reached, the matter may be referred to the Committee of Ministers at the request of two-thirds of the members of the committee concerned. The Committee of Ministers shall decide on the matter by a two-thirds majority of all the representatives entitled to sit on it;

- b. concerning special cases, such as the admission of non-member states without observer status to the Council of Europe, and any other case which may necessitate a political decision, the Secretary General shall refer the matter to the Committee of Ministers. This decision shall be taken by a two-thirds majority of all the representatives entitled to sit on it.

9. Observers shall have no right to vote nor defrayal of expenses.

IV. Terms of reference

10. By "terms of reference" shall be understood all directives relating to the activities of a committee subject to the present resolution.

⁶ Where necessary, a member state is entitled to designate more than one representative.

11. All committees and subordinate bodies shall have terms of reference.
12. Terms of reference of committees answerable to the Committee of Ministers shall be presented by the Secretary General and approved by the Committee of Ministers.
13. Terms of reference of subordinate bodies shall be presented by the Secretary General upon proposal by the parent committee, and approved by the Committee of Ministers.
14. All terms of reference shall be limited to a maximum period of two years in line with the biennial Programme and Budget of the Organisation, unless otherwise decided by the Committee of Ministers.
15. Terms of reference shall include:
 - a. name of committee;
 - b. category: steering committee, ad hoc committee or subordinate body;
 - c. reference to the relevant programme line/s of the Council of Europe Programme and Budget, including concrete and measurable expected results for which the committee is responsible;
 - d. where appropriate, its planning and advisory function;
 - e. where appropriate, terms of reference derived from a convention;
 - f. tasks and completion date;
 - g. specific qualifications of members;
 - h. composition of the committee: members, participants and observers and information concerning repayment of members' travelling and subsistence expenses by the Council of Europe, as set out in Appendix 2 to this resolution; and
 - i. working methods, including hearings and, if necessary and justified, proposals for consultants.
16. Terms of reference shall be accompanied by full information on their financial implications, detailing in particular, per committee, the operational budget and number of staff allocated.

V. Planning, monitoring and evaluation function of committees

17. Steering and ad hoc committees advise the Committee of Ministers and the Secretary General on the priorities and other matters with regard to their sectors, in particular on the relevance of activities in line with the priorities and criteria adopted by the Committee of Ministers.
18. The Secretariat shall inform members of committees and subordinate bodies of:
 - a. the institutional and regulatory framework of the Organisation, as set out in the Statute of the Council of Europe and other relevant texts including the present resolution;
 - b. programme line(s) under their responsibility and budgetary appropriations in the Programme and Budget of the Organisation;
 - c. results of monitoring mechanisms and procedures that may have an impact on their work while respecting applicable confidentiality rules;
 - d. the progress review report of the Programme and Budget so that they can examine and discuss it and report back on their respective parts;
 - e. relevant co-operation activities and activities in the field; and

f. relevant activities of other international organisations with a view to avoiding duplication and achieving synergies.

VI. Working methods

19. The functioning and operation of committees and subordinate bodies shall be governed by the Rules of Procedure set out in Appendix 1 to this resolution. Committees' work shall include relevant transversal perspectives in all areas of their work.

VII. Documents and meeting reports

20. The Secretary General shall be responsible for preparing and distributing documents to be discussed by the committees, as well as drafting the reports of their meetings, unless otherwise expressly provided for by the Committee of Ministers.

21. Committees shall prepare reports of their meetings. These reports shall include an evaluation of completed activities and a presentation of ongoing and planned work, together with the identification of its source and deadlines, as well as proposals for future activities and identification of activities that might be discontinued. These reports shall be made available, in both official languages, no later than one month after the last meeting day of the committee. Committees shall also adopt abridged meeting reports before the end of their meetings. Documents shall, where appropriate, contain an executive summary, action to be taken and resource implications.

VIII. Compendium of terms of reference

22. The Secretariat shall compile and keep up to date a "Compendium of terms of reference" containing:

- a. the present resolution and any subsequent amendments to it;
- b. Resolution Res(2004)25 on service contracts of consultants;
- c. the terms of reference of all intergovernmental committees and subordinate bodies;
- d. the terms of reference derived from conventions, or special statutes given to intergovernmental committees set up under them; and
- e. any other decision or message of the Committee of Ministers or the Secretary General relating to terms of reference;
- f. the information foreseen in paragraph 16.

IX. Convening of meetings

23. All meetings of committees and subordinate bodies shall be convened by the authority of the Secretary General by a single procedure in accordance with the authorisation given by the Committee of Ministers and with the general practices of good management. The Secretary General shall ensure that meetings are planned, convened and serviced as efficiently and economically as possible.

24. Convocations and preliminary draft agendas of meetings shall be circulated at least six weeks before the proposed date, except in cases of urgency, which shall be duly explained. Convocations shall specify the name of the committee, the place, date, opening time of the meeting, its duration, the subjects to be dealt with and the list of participants at the previous meeting. When appropriate, it shall contain an invitation to nominate a member, taking into account the relevant texts on participation of women and men in an equitable proportion in committees and other bodies of the Council of Europe and indicating the qualifications he or she should preferably possess.

25. For committees answerable to the Committee of Ministers, convocations shall be sent to nominees specified by the Permanent Representations with the Permanent Representations in copy. Nominations made by governments through Permanent Representations will remain valid until any change is notified or confirmed by them.

26. For subordinate bodies, convocations shall be sent as appropriate to nominees specified by Permanent Representations or by the parent committee or, in the absence of such a known nominee, to the Permanent Representations or to the Chair of the committee concerned respectively. Permanent Representations shall receive copies of convocations sent to designated members. Nominations made by governments through Permanent Representations will remain valid until any change is notified.

27. The Secretariat shall send the draft agenda, a provisional list of working documents and the documents themselves to the nominees, or in the absence of such a nomination, to the Permanent Representation concerned, at least 20 days before the meeting date. This documentation shall be made available to the Permanent Representations. Use should be made of information technology whenever possible.

28. The same arrangements shall apply *mutatis mutandis* to participants and observers.

X. Co-ordination

29. The Secretary General shall ensure that committees and subordinate bodies are informed about activities which may have implications for the execution of their respective terms of reference.

30. In order to ensure co-ordination between the Ministers' Deputies and committees answerable to the Committee of Ministers:

a. the Chairs of committees may be invited, whenever necessary, to take part in meetings of the Deputies' relevant Rapporteur Groups, Working Parties and Thematic Co-ordinators to discuss the evaluation of activities, present ongoing work and prospects for future activities, in line with the priorities of the Organisation;

b. the Chairs of the Deputies' relevant Rapporteur Groups, Working Parties and Thematic Co-ordinators may attend meetings of committees when it is deemed that this is of importance to the respective sector activity.

31. The Secretary General shall promptly inform committees of general guidelines issued by the Ministers' Deputies as regards the content, modalities of implementation and evaluation of the intergovernmental work.

XI. Review of the intergovernmental structure

32. A progress review on the intergovernmental structure will be carried out on a regular basis bearing in mind the reports referred to in paragraph 20 and the progress review report on the implementation of the Programme and Budget provided for by the Financial Regulations.

XII. Entry into force of this resolution

33. This resolution shall enter into force on 1 January 2012 and shall repeal and replace Resolution Res(2005)47.

Appendix 1 to Resolution CM/Res(2011)24

Rules of procedure for Council of Europe intergovernmental committees

Article 1 – Agenda

a. The Secretary General, in close consultation with the Chair, shall draw up the draft agenda which should be concrete, operational and result-oriented.

b. The agenda shall be adopted by the committee at the beginning of its meeting.

Article 2 – Documentation

Documents requiring a decision, whether originating from the Secretariat or from a member, shall be sent, in the official languages (cf. Article 6 below), to members at least three weeks before the start of the meeting at which the decision is to be taken. In exceptional cases, however, the committee may, if no member objects, consider a document submitted later. Maximum use should be made of information technology, including gathering together amendments and proposals, finalising texts and publishing decisions, provided in the latter cases that all the members of the committee have been properly informed in good time.

Article 3 – Privacy of meetings

Meetings shall not be held in public.

Article 4 – Hearings

Committees and subordinate bodies may organise hearings with international organisations, NGOs, research and academic institutions, experts, specialists, specialist organisations and professional organisations, in a position to contribute to their work, within the limits of available budgetary appropriations.

Article 5 – Quorum

There shall be a quorum if two-thirds of the members of the committee are present.

Article 6 – Official languages

- a. The official languages of the committee shall be those of the Council of Europe.
- b. In exceptional circumstances, the Secretary General may decide, in particular, in the case of steering and ad hoc committees, to provide for interpretation into one additional language other than the official languages, within the limits of available budgetary appropriations.
- c. A committee member may speak in a language other than the official languages, in which case he or she must herself/himself provide for interpretation into one of the official languages.
- d. Any document drafted in a language other than the official languages shall be translated into one of the official languages, the member from whom it originates being responsible for making the necessary arrangements.

Article 7 – Proposals

- a. Any proposal must be submitted in writing in one official language if a committee member so requests. In that case, it shall not be discussed until it has been circulated.
- b. Proposals made by participants and observers may be put to the vote if sponsored by a committee member.

Article 8 – Order of voting on proposals or amendments

- a. Where a number of proposals relate to the same subject, they shall be put to the vote in the order in which they were submitted. In case of doubt, the Chair shall decide.
- b. Where a proposal is the subject of an amendment, the amendment shall be put to the vote first. Where two or more amendments to the same proposal are presented, the committee shall vote first on whichever departs furthest in substance from the original proposal. It shall then vote on the next furthest removed from the original proposal, and so on until all the amendments have been put to the vote. However, where the acceptance of one amendment necessarily entails rejection of another, the latter shall not be put to the vote. The final vote shall then be taken on the proposal as amended or not amended. In case of doubt as to the order of priority, the Chair shall decide.
- c. Parts of a proposal or amendment may be put to the vote separately.

- d. In the case of proposals with financial implications, the most costly shall be put to the vote first.

Article 9 – Order of procedural motions

Procedural motions shall take precedence over all other proposals or motions except points of order. They shall be put to the vote in the following order:

- a. suspension of the sitting;
- b. adjournment of discussion on the item in hand; and
- c. postponement of a decision on the substance of a proposal until a specified date.

Article 10 – Reconsideration of a question

When a decision has been taken it is only re-examined if a member of the committee so requests, and if this request receives a two-thirds majority of the votes cast.

Article 11 – Voting

- a. Each member of the committee shall have one vote; however, where a government designates more than one member, only one of them is entitled to take part in the voting,
- b. Subject to any contrary provisions in these Rules, voting requires the quorum. The decisions of the steering committees are taken by a two-thirds majority of the votes cast.
- c. Except on procedural matters, other committees shall not take decisions by voting. They shall state their conclusions in the form of unanimous recommendations, or, if this proves impossible, they shall make a majority recommendation and indicate the dissenting opinions.
- d. Procedural matters shall be settled by a majority of the votes cast.
- e. Where the question arises as to whether or not a matter is procedural in nature, it may not be regarded as such unless the committee decides to that effect by a majority of two-thirds of the votes cast;
- f. For the purposes of these Rules, “votes cast” shall mean the votes of members cast for or against. Members abstaining shall be regarded as not having cast a vote.

Article 12 – Chair

- a. Every committee shall elect a Chair and Vice-Chair. However, the Chair of a subordinate body may be appointed by the steering or ad hoc committee to which it is answerable.
- b. The Chair shall conduct proceedings and sum up the conclusions whenever he or she thinks necessary. He or she may call to order a speaker who departs from the subject under discussion or from the committee’s terms of reference. The Chair shall retain the right to speak and to vote in her/his capacity as a member of the committee, except in cases where an additional expert from the same country has been appointed to sit on that committee.
- c. The Vice-Chair shall replace the Chair if the latter is absent or otherwise unable to preside the meeting. If the Vice-Chair is absent, the Chair shall be replaced by another member of the Bureau, appointed by the latter or, where there is no Bureau, by a member of the committee appointed by the committee.
- d. Election of the Chair and Vice-Chair shall require a two-thirds majority at the first ballot and a simple majority at the second ballot. In steering committees, the election shall be held by secret ballot, in other committees by a show of hands, unless a member of the committee requests a secret ballot.
- e. The term of office of the Chair and Vice-Chair shall be one year. It may be renewed once.

Article 13 – Bureau

a. Every steering and ad hoc committee may appoint a bureau consisting of the Chair, the Vice-Chair and a limited number of other members of the committee. The number of other members shall be specified in the committee's terms of reference. Any other committee may, if need be, appoint a bureau composed, normally, of not more than three members in addition to the Chair and Vice-Chair. The functions of the Bureau are:

- to assist the Chair in conducting the committee's business;
- to supervise the preparation of meetings at the committee's request;
- to ensure continuity between meetings as necessary;
- to execute other additional specific tasks delegated by its Committee.

b. No decision on substantive issues shall be taken by the Bureau on behalf of the committee. In exceptional cases and due to time constraint, the Bureau may have recourse to the tacit approval of all the members of the committee through electronic communication, in order to expedite procedure on decisions requested by the Committee of Ministers.

c. Other members of the Bureau shall be appointed in the same manner as the Chair and Vice-Chair. They shall be appointed immediately after the Chair and Vice-Chair in accordance with an equitable distribution of posts, taking into account in particular geographical distribution, gender balance and, where relevant, legal systems.

d. The term of office of such members shall correspond to the duration of the mandate of the committee and may be renewed once. However, a member may, on expiry of her/his second term, be appointed Chair or Vice-Chair. In order to ensure partial replacement of the Bureau each year, the first term of at least one such member shall be limited to one year.

e. A member elected to replace another whose term of office has not expired shall complete her/his predecessor's term. The same shall apply to the offices of Chair and Vice-Chair.

Article 14 – Working methods

a. Committees may appoint a rapporteur, a drafting committee or both.

b. Where necessary, in order to expedite the progress of their work, committees may entrust a rapporteur or a limited number of committee members with a specific task to be fulfilled by their next meeting, using primarily information technologies.

c. In exceptional cases, for specialised tasks that cannot be performed by a member of the committee or the Secretariat, committees may request the Secretary General to have recourse to consultants subject to the provisions of the relevant resolution and within the limits of budgetary appropriations.

d. Time- and cost-efficiency shall be a guiding principle for committee work, including best possible use of interactive technologies for networks and meetings.

e. Agenda items for information only shall be communicated to members in advance by electronic means allowing the committee to focus during its meeting on agenda items for decision.

Article 15 – Secretariat

a. The Secretary General shall provide the committee with the necessary staff, including the committee secretary, as well as with the administrative and other services it may require.

b. The Secretary General or her/his representative may at any time make an oral or written statement on any subject under discussion.

c. Committees may ask the Secretary General to prepare a report on any question relevant to their work.

Article 16 – Venue of meetings

- a. Committees shall normally be convened at the premises of the Council of Europe in Strasbourg.
- b. Exceptionally, the Secretary General may authorise, if there is no objection from the government of the state on whose territory it is intended to hold the meeting and if suitable technical facilities are available on-the-spot, to convene a committee elsewhere, in particular, in other Council of Europe premises, in accordance with the principles of sound management and within the resources available.

Article 17 – Revision

Any committee directly answerable to the Committee of Ministers may propose to the Committee of Ministers to amend these Rules or, in exceptional circumstances, to waive them in part.

Appendix 2 to Resolution CM/Res(2011)24

Payment of travelling and subsistence expenses

The travelling and subsistence expenses of one representative per member state participating in a steering and ad hoc committees shall be borne by the Council of Europe unless otherwise indicated in the respective terms of reference,⁷ within the limits of budgetary appropriations.

The travelling and subsistence expenses of either all or only a limited number of members of subordinate bodies, as indicated in their respective terms of reference shall be borne by the Council of Europe, within the limits of budgetary appropriations.

⁷ For example, where the terms of reference provide for reimbursement of the expenses of an additional member for the country whose representative has been elected Chair and in special cases set out in the terms of reference.