Strasbourg, 25 February 2025

CDBIO/INF (2025) 1

STEERING COMMITTEE FOR HUMAN RIGHTS IN THE FIELDS OF BIOMEDICINE AND HEALTH (CDBIO)

Information document concerning the CDBIO

Secretariat memorandum prepared by the Human Rights and Biomedicine Division Directorate of Social Rights, Health and Environment

I. INTRODUCTION

Set up in 1949, the Council of Europe is an intergovernmental organisation which fosters political, legal, and cultural cooperation between its 46 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 its 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 Alain Berset (Switzerland).

The Committee of Ministers comprises the Ministers of Foreign Affairs of the 46 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 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 entry 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 entry 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 entry into force on 1 May 2006), the additional Protocol on Biomedical Research (adopted by the Committee of Ministers on 30 June 2004 and entry into force on 1 September 2007), and the additional Protocol concerning Genetic Testing for Health Purposes (adopted by the Committee of Ministers on 7 May 2008 and entry into force on 1 July 2018).

In 2012, the Steering Committee on Bioethics (CDBI) became the Committee on Bioethics (DH-BIO) and was a subordinate body of the Steering Committee for Human Rights (CDDH), except for the tasks assigned to the Steering Committee on Bioethics with regard to the Convention on Human Rights and Biomedicine.

In 2022, the Committee on Bioethics (DH-BIO) has become a Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO).

II. **TERMS OF REFERENCE**

STEERING COMMITTEE FOR HUMAN RIGHTS IN THE FIELDS OF BIOMEDICINE AND HEALTH

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(2021)3 on intergovernmental committees and subordinate bodies, their terms of reference and working methods.

Category: Steering Committee

Duration: 1 January 2024 - 31 December 20271

Programme: Advancing social justice, good health and a sustainable environment

Sub-programme: Health and human rights

MAIN TASKS

Under the authority of the Committee of Ministers, and bearing in mind the Council of Europe legal standards, as well as the relevant case law of the European Court of Human Rights, the CDBIO carries out the work assigned to the Steering Committee in Bioethics by the Convention on the protection of human rights and the dignity of human beings with regards to the applications of biology and medicine (Convention on Human Rights and Biomedicine): conducts the intergovernmental work on human rights protection in the fields of biomedicine, as well as health; in particular with regard to issues raised by the Covid-19 pandemic and taking into account the lessons to be learnt from the health crisis and advises the Committee of Ministers on all questions within its fields of competence. In particular, the CDBIO is instructed to:

- take due account of the Reykjavik Declaration²[8] in conducting its activities and submit i. proposals for its implementation as appropriate;
- ii. take account of the relevant key findings and challenges set out in the Secretary General's 2023 Report on the state of democracy, human rights and rule of law "An Invitation to Recommit to the Values and Standards of the Council of Europe";
- promote equitable access to health care, patient rights, protection of persons in vulnerable iii. situations and citizen participation in the healthcare and biomedical research policies and, where appropriate, prepare relevant guidelines and other tools (reference tools, implementation guides), in accordance with the principles laid down in the Convention on Human Rights and Biomedicine:
- iν. assess ethical and legal challenges raised by scientific and technological developments, as well as by the evolution of practices, in the fields of biomedicine and health;
- contribute to raising awareness and facilitating the implementation of the principles laid down ٧. in the Convention on Human Rights and Biomedicine and its additional protocols, taking also into account the outcome of co-operation activities in the relevant fields:
- vi. carry out the regular re-examination foreseen in the Convention on Human Rights and Biomedicine and its additional protocols;
- develop further the principles laid down in the Convention on Human Rights and Biomedicine. vii. as appropriate, also in the light of the relevant case law of the European Convention on Human Rights:
- co-operate with the relevant intergovernmental bodies and organisations in particular with a viii. view to promoting consistency between normative texts;
- raise-awareness about Council of Europe standards and tools in its field of competence in ix. the member States and beyond, through the neighbourhood policy and in other international and global fora where relevant:

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¹These terms of reference are approved for the first biennial period 2024-2025. For the second biennial period 2026-2027, they are approved on a provisional basis, subject to confirmation upon the adoption of the budget for 2026-2027.
² Reykjavík Declaration - United around our values.

- hold regular exchange of views in order to evaluate its activities and advise the Committee of х. Ministers and the Secretary General on future priorities in its sector including possible new activities and those that might be discontinued;
- take due account of the following mainstreamed perspectives in the performance of its tasks: xi. gender, youth, children's rights, rights of persons with disabilities, and Roma and Traveller³[9] issues;
- where relevant, contribute to strengthening meaningful engagement with civil society xii. organisations and national human rights institutions in its work;
- xiii. 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 conventions for which it has been given responsibility⁴ and report back to the Committee of Ministers;
- contribute to the achievement of, and review progress towards, the UN 2030 Agenda for xiv. Sustainable Development, in particular with regards to Goal 3: Good health and well-being, Goal 5: Gender equality, Goal 10: Reduced inequalities and Goal 16: Peace, justice and strong institutions;
- where relevant, take account of, and propose effective responses to, the challenges posed in XV. its field of competence by the Russian Federation's war of aggression against Ukraine.

Main deliverables

Under the authority of the Committee of Ministers, the CDBIO is instructed to complete these deliverables, within the following deadlines:

	Category	Priority	Deadline
	▼	▼	▼
Online Guide of good practice for the participation of children in decision making processes on matters relating to their health in non-official languages	А	2	31/12/2024
2. Report on artificial intelligence applications in healthcare	А	2	31/12/2024
3. Report on promoting dialogue amongst the public, practitioners and policy makers for the purpose of the development of regulations on genomics medicine	А	2	31/12/2024
4. Draft Recommendation promoting the use of voluntary measures in mental health care services	А	1	31/12/2024
5. Report on the case law of the European Court of Human Rights relevant to mental health	А	1	31/12/2024
6. Horizon scanning conference	С	1	31/12/2024
7. Report on equitable access to innovative treatments and technologies in healthcare systems	А	3	31/12/2025
8. Youth forum on bioethics ⁵	Α	1	31/12/2025
9. Final report of the Strategic Action Plan on Human Rights and Technologies in Biomedicine 2020-2025	С	1	31/12/2025

³ The term "Roma and Travellers" is used at the Council of Europe to encompass the wide diversity of the groups covered by the work of the Council of Europe in this field: on the one hand a) Roma, Sinti/Manush, Calé, Kaale, Romanichals, Boyash/Rudari; b) Balkan Egyptians (Egyptians and Ashkali); c) Eastern groups (Dom, Lom and Abdal); and, on the other hand, groups such as Travellers, Yenish, and the populations designated under the administrative term "Gens du voyage", as well as persons who identify themselves as Gypsies. The present is an explanatory footnote, not a definition of Roma and/or Travellers.

⁴ Cf. relevant decisions of the Committee of Ministers (<u>CM/Del/Dec(2013)1168/10.2</u>) and list of Conventions in document <u>CM(2023)132</u>.

⁵ Subject to the availability of extrabudgetary resources.

10.Draft Strategic Action Plan on Human Right in Biomedicine 2026-2029	С	1	31/12/2025
11.Interpretative guide to adapting the existing human rights framework to neurotechnologies	С	1	30/06/2026
12.Report following the examination of the additional protocol concerning genetic testing	В	2	30/06/2026
13.Report following the re-examination of the additional protocol concerning biomedical research	В	2	31/12/2027
14.Report following the re-examination of Recommendation <u>CM/Rec(2016)6</u> on research of biological materials of human origins	В	3	30/12/2027

Key

A: deliverable under preparation (2022-2023 terms of reference or Committee of Ministers' decision) or deliverable foreseen in the terms of reference provisionally approved for 2024-2025 and reviewed where relevant in the framework of the preparation of the draft Programme and Budget 2024-2027

B: review of implementation/re-examination foreseen by the recommendation/protocol/convention

C: newly proposed deliverable

COMPOSITION ▼

Members

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, in particular legal, medical and scientific aspects, including in relation to emerging technologies and to the functioning of their health system, and able to consider these from a human rights perspective.

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 <u>CM/Del/Dec(2013)1168/10.2</u> 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;
- Congress of Local and Regional Authorities of the Council of Europe;
- European Court of Human Rights;
- Commissioner for Human Rights of the Council of Europe;
- Conference of INGOs 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);
- Conference of the Parties of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime Committee);
- Steering Committee for Human Rights (CDDH);
- Steering Committee on the Rights of the Child (CDENF);
- European Committee on Legal Co-operation (CDCJ);
- Committee on Transplantation of Organs and Tissues (CD-P-TO);

- Committee on Blood Transfusion (CD-P-TS):
- 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 (one or more representatives, including, as appropriate, the European Union Agency for Fundamental Rights (FRA));
- Observer States to the Council of Europe: Canada, Holy See, Japan, Mexico, United States of America;
- Other international organisations (WHO, UNESCO, United Nations Office of the High Commissioner for Human Rights, OECD and European Science Foundation (ESF)).

Observers

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

- Australia, Israel;
- the Conference of European Churches (KEK);
- European Network of National Human Rights Institutions (ENNHRI).

Observer status may be requested in accordance with Article 8 of <u>Resolution CM/Res(2021)3</u> on intergovernmental committees and subordinate bodies, their terms of reference and working methods.

Working methods

The rules of procedure of the Committee are governed by <u>Resolution CM/Res(2021)3</u> on intergovernmental committees and subordinate bodies, their terms of reference and working methods.

	Plenary meetings ▼			Bureau meetings ▼		
	Members incl. Chair	Meetings per year	Days per meeting	Members	Meetings per year	Days per meeting
2024	47	2	4	7	2	2
2025	47	2	4	7	2	2
2026	47	2	4	7	2	2
2027	47	2	4	7	2	2

The CDBIO will appoint from amongst its members up to 5 Rapporteurs on mainstreamed perspectives, including a Gender Equality Rapporteur.

Subject to the agenda, the chairs of its subordinate structures may be invited to attend CDBIO Bureau and/or plenary meetings. The CDBIO will hold regular exchanges of views with the Steering Committee for Human (CDDH).

III. MEMBERSHIP

The governments of the 46 member States⁶ may appoint experts. Such members are entitled to vote (1 vote per delegation) on matters arising within the CDBIO. 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 Steering Committee for the Rights of the Child (CDENF), the European Committee on Legal Co-operation (CDCJ), the Commissioner for Human Rights, the

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⁶ 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, San Marino, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, North Macedonia, Turkey, Ukraine, United Kingdom.

Conference of INGOs 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), UN Office of the High Commissioner fo Human Rights, OECD (Organization for Economic Co-operation and Development), WHO (World Health Organization), the European Science Foundation and the CEC (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 (2021) 3 on intergovernmental committees and subordinate bodies, their terms of reference and working methods, see Appendix II) the CDBIO elected:

- Tomas Dolezal (Czechia), Chair (elected in November 2024)
- Damaris Carnal (Switzerland), Vice-Chair (elected in November 2024)
- Anne Forus (Norway), member of the Bureau (re-elected in November 2024)
- Luisa Borgia (San Marino), member of the Bureau (re-elected in November 2024)
- Andréas Valentin (Austria), member of the Bureau (re-elected in November 2024)
- Sanne Van Weezel (The Netherlands), member of the Bureau (elected in November 2023)
- Iuliia Davydova (Ukraine), member of the Bureau (elected in November 2024)

V. SECRETARIAT

The Secretariat prepares necessary documentation prior to meetings of the CDBIO 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 CDBIO and 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 (2021) 3, Article 15 b). Initiation of consensus or compromise within the meetings is one of the main functions of the Secretariat.

VI. MEETINGS

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

Resolution (2021) 3 of the Committee of Ministers (adopted by the Committee of Ministers on 12 May 2021 at the 1404th 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 CDBIO.

VII. PARLIAMENTARY ASSEMBLY

The Parliamentary Assembly is the deliberative body of the Council of Europe and is composed of 306 representatives (and the same number of substitutes) appointed by the 46 member States' national parliaments. The Parliamentary Assembly has been represented in the intergovernmental committees responsible for bioethics activities since 1990 (the CAHBI, the CDBI, the DH-BIO, and then the CDBIO) 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 CDBIO

A. Work of the CDBIO

a) The main work in 2025 concerns:

Under the Governance pilar of the SAP:

 Presentation of the report on the impact of AI on the patient-doctor relationship at a conference on AI enabled healthcare and human rights, to be held on 21 May 2025, in Helsinki, in cooperation with the Finish authorities;

Under the Equity pilar of the Strategic Action Plan on human rights and technologies in biomedicine (2020-2025) (SAP):

• Finalisation of a white paper on equitable and timely access to appropriate innovative treatments and technologies in healthcare systems;

Under the Integrity pilar of the SAP:

- Presentation of the Guide on children's participation in decisions about their health in nonofficial languages, at the mid term conference of the Strategy for the rights of the child, in Strasbourg, on 4 April 2025;
- Finalisation of the related child friendly materials;
- Translation of the Guide on children's participation in decisions about their health in non-official languages.
- Finalisation of a new strategic action plan 2026-2030
- Launching of a new HELP course on human rights in Imental healthcare

b) The main work in 2024 concerns:

Under the Equity pilar of the Strategic Action Plan on human rights and technologies in biomedicine (2020-2025) (SAP):

 Progress in the preparation of a white paper on equitable and timely access to appropriate innovative treatments and technologies in healthcare systems;

Under the Governance pilar of the SAP:

- Finalisation of the report on the impact of AI on the patient-doctor relationship;
 - o The report was finalised in June 2024

Under the Cooperation and communication pilar of the SAP:

• Preparation of the CDBIO strategy on the integration of a youth perspective;

Under the Integrity pilar of the SAP:

• Translation of the Guide on children's participation in decisions about their health in non-official languages, jointly developed by the CDBIO and the CDENF, and the development of related child-friendly material;

- The Guide was translated in Armenian, Hungarian, Polish, Spanish, Romanian, Latvian, Lithuanian
- Finalisation of the draft Recommendation on the respect for autonomy in mental healthcare;
 - The draft Recommendation was approved in November 2024 and sent to the Committee of Ministers with a view to its adoption.
- Preparation of a new strategic action plan 2026-2030.

c) The main work in 2023 concerned:

Under the Equity pilar of the Strategic Action Plan on human rights and technologies in biomedicine (2020-2025) (SAP):

 Progress in the work on equitable access to innovative treatments and technologies in healthcare systems;

Under the Governance pilar of the SAP:

- The preparation of a report on the impact of AI on the doctor-patient relationship;
- The preparation of the report of the workshop on promoting dialogue on genomic medicine;

Under the Integrity pilar of the SAP:

- The finalisation of the draft Guide on children participation in decision making process on matters relevant to their health, jointly with the Steering Committee for the Rights of the Child (CDENF);
- The drafting of a recommendation for the promotion of voluntary measures in mental healthcare service:
- The publication of an analysis of the case law of the European Court of Human rights relevant to mental health;
- The finalisation of the report of the seminar on early intervention on intersex children;

The preparation of the mid-term report of the SAP;

The preparation of an overview of the legal framework and practices in COE member states relevant to medically assisted procreation;

The preparation of an overview of legislation relevant to patients' rights.

d) The main work in 2022 concerned:

Under the Equity pilar of the Strategic Action Plan on human rights and technologies in biomedicine (2020-2025) (SAP):

- The finalisation and approval of a draft recommendation on equitable access to medicinal products and medical equipment in a situation of shortage;
- The first steps in the work on equitable access to innovative treatments and technologies in healthcare systems;
- The finalisation and adoption of a guide to health literacy contributing to trust building and equitable access to healthcare.

Under the Governance pilar of the SAP:

- The finalisation of the re-examination process of Article 13 of the Oviedo Convention on intervention on the human genome in the light of the development of gene editing technologies, with the publication of its conclusion and clarification of the provisions;
- The publication of a consultant report on the impact of AI on the doctor-patient relationship;
- The publication of the report of the round table on neurotechnologies and human rights coorganised with OECD in November 2021
- The organisation of the workshop on promoting dialogue on genomic medicine

Under the Integrity pilar of the SAP:

• Consultations of stakeholders and children on the draft guide on children participation in decision making process on matters relevant to their health, jointly with the Steering Committee for the Rights of the Child (CDENF);

- The organisation of a seminar on relevant legislation and good practices with regard to early intervention on intersex children;
- The development of an outline of a draft recommendation for the promotion of voluntary measures in mental healthcare service.

B. Work of the DH-BIO

a) The main work of DH-BIO in 2021 concerned:

In the framework of the implementation of the Strategic Action Plan on human rights and technologies in biomedicine, the preparation, by consultant experts, of a report on "Health literacy for equitable access to health care for priority groups – towards a Guide to policy, strategy and service design" and, in turn, the setting up of a drafting group to prepare a guide to health literacy.

In the context of the COVID-19 pandemic, a webinar on COVID-19 and public debate – lessons learned and preparedness.

The finalisation of a statement on COVID-19 and vaccines aiming to ensure equitable equitable access to vaccination during the current and future pandemics.

The finalisation of a statement on human rights considerations relevant to "vaccine pass" and other similar documents:

The implementation of the Guide to public debate on human rights and biomedicine, including its dissemination and translation into non-official languages.

The start of the work on ensuring equitable access to treatment and equipment in a context of scarce resources.

The start of a work on children participation in decision-making process on matters relevant to their health carried out jointly with the Steering Committee on the Rights of the Child and aiming at the development of a guide.

The continuation of a work on genome editing to provide clarifications on the scope of Article 13 with regard to research and to the notion of therapeutic, diagnosis and preventive purposes.

A round table on "human rights and neurotechnologies: do we need new rights?" organised jointly with the OECD in November 2021.

b) The main work of DH-BIO in 2020 concerned:

The launch and implementation of the Guide to public debate on human rights and biomedicine, including its translation into numerous languages and its dissemination.

The launch and implementation of the Strategic Action Plan on human rights and technologies in biomedicine (2020-2025), including the preparation of an expert report on gender equality in biomedicine by Professor Ina Wagner entitled "Human rights in biomedicine: Integrating a gender equality perspective".

In the context of the COVID-19 pandemic, the organisation of webinars on (i) promoting health literacy in the context of a pandemic: relevance and challenges, and (ii) COVID-19 testing - key human rights and ethical concerns.

The start of the work on ensuring equitable and timely access to appropriate innovative traeatments and technologies in healthcare, taking into account the COVID-19 pandemic and the ethical issues it raises.

C. <u>Drafting Groups responsible for the preparation of texts</u>

a) Currently active Drafting Groups

• Drafting Group on the integration of a youth perspective

The Drafting Group has been entrusted by the CDBIO to prepare a strategy on the integration of a youth perspective in the Committee.

• Drafting Group on equitable and timely access to appropriate innovative treatments and technologies in healthcare

The Drafting Group has been entrusted by the CDBIO to prepare a white paper equitable and timely access to appropriate innovative treatments and technologies in healthcare

Drafting Group on AI in biomedical field

The Drafting Group has been entrusted by the CDBIO to prepare a report on the impact of AI on patient doctor relationship.

Preparatory Group for the horizon scanning exercise

To provide a basis for the development of the new strategic action plan, the Group has been entrusted with the task of:

- developing a horizon scanning questionnaire to be addressed to national ethics committees and human rights institutions;
- organising a horizon scanning event with high level experts and thought leaders

b) Previous Drafting Groups

Drafting Group on children participation in decision making process (joint drafting group with CDENF)

The Drafting Group has been entrusted by the CDBIO to to prepare a Guide on children participation in decision-making process in matters regarding their health.

Drafting Group to develop a guide on health literacy

The Drafting Group was entrusted by the CDBIO to prepare a guide to health literacy for equitable access to health care, especially for persons in vulnerable situations.

Drafting Group on equity of access to treatment and equipment in a context of scarce resources

The Drafting Group was entrusted by the CDBIO to prepare a draft instrument on equitable access to scarce healthcare resources.

Drafting Group on genome editing

The Drafting Group was entrusted by the CDBIO with the task of proposing elements of clarifications on the scope of the provisions of Article 13 of the Oviedo Convention with regard to research as well as on the notion of "therapeutic, diagnostic and preventive purposes".

Drafting Group on equity of access to vaccines

The Drafting Group was entrusted with drafting responsibility for the elaboration of a statement anchored in the scope of Article 3 of the Oviedo Convention while focusing on equity of access to vaccines during the current and future pandemics. The aim of the Statement was to promote fair access to vaccination, considering that some persons are systematically disadvantaged in accessing healthcare. The statement aims to add value to the work undertaken by other organisations (e.g. WHO and EU) and to take advantage of the collaboration of EDQM and MEDICRIME.

• Drafting Group for the development of a Strategic Action Plan

The Drafting Group was tasked with developing a Strategic Action Plan aimed at defining the main axes and objectives of its work over the coming years, as appropriate, in cooperation with other committees and/or intergovernmental organizations, to address the main human rights issues raised by developments in the biomedical field.

Ad hoc Group on public debate

Following the conference on emerging technologies and human rights, the Ad hoc Group was tasked with developing a practical guide to facilitate public debate, particularly in the field of emerging technologies. The aim of the guide was to promote public debate and consultation on fundamental bioethical questions raised by developments in biology and medicine, in accordance with Article 28 of the Oviedo Convention.

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 are 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 adhoc 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) were taken into account in the finalisation of the Additional Protocol. At its 2nd plenary meeting (2-4 November 2022), the CDBIO agreed to send the draft additional protocol to the Committee of Ministers with a view to its adoption.

D. Rapporteurs

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

Rapporteur on public debate: Tesi Aschan (Sweden)

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

Rapporteur on gender equality: Iuliia Davydova (Ukraine) Rapporteur on youth: Mark Bale (United Kingdom)

Rapporteur on neurotechnologies: Anne Forus (Norway)

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 I – Human Rights and Rule of Law, Secretariat of the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO).

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 Party⁷ 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

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⁷ The denomination "Working Party" was replaced by "Group of Specialists" following Resolution (2011) 24 of the Committee of Ministers. Since 2022, the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) has no more subordinate committees, but sets up small drafting groups on an ad hoc basis as part of its working methods.

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.

- 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

COUNCIL OF EUROPE COMMITTEE OF MINISTERS

Resolution CM/Res(2021)3 on intergovernmental committees and subordinate bodies, their terms of reference and working methods

(Adopted by the Committee of Ministers on 12 May 2021 at the 1404th meeting of the Ministers' Deputies)

The Committee of Ministers,

Having regard to Resolution <u>CM/Res(2011)24</u> on committees and subordinate bodies, their terms of reference and working methods;

Having regard to the decisions taken by the Ministers' Deputies at their 1386th meeting (21 October 2020, item 11.5) and at their 1395th meeting (10 February 2021);

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

Having regard to the Statutory Resolution <u>CM/Res(2020)1</u> relating to the Congress of Local and Regional Authorities of the Council of Europe and the revised Charter appended thereto;

Having regard to Resolution <u>CM/Res(2016)3</u> 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);

Having regard to Resolution Res(2004)25 on service contracts of consultants;

Seeking to complement the rich exchanges allowed by physical meetings, especially plenary meetings, with the flexibility allowed by online meetings.

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 committees8

- 4. There shall be two categories of committees set up by the Committee of Ministers:
- 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.⁹
- 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. When deciding on the composition of subordinate bodies composed of a limited number of member States and/or independent experts, due regard shall be given by the parent committee to geographical representation and, where relevant, different legal systems, and periodic rotation of member States. Furthermore, they are open to the participation of representatives, including from Permanent Representations, 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:

⁸ Unless specified otherwise, the term "committee" refers to steering and ad hoc committees and their subordinate bodies.

⁹ Where necessary, a member State is entitled to designate more than one representative.

- 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;
- c. by the same majority, the Committee of Ministers may also decide on the admission of observers when adopting the terms of reference of the committee concerned.
- 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.
- 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 no longer than the corresponding Programme and Budget cycle of the Organisation. Terms of reference may be adjusted as necessary in the light of the mid-term review.
- 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 2022 and shall repeal and replace Resolution CM/Res(2011)24.

Appendix 1 to Resolution CM/Res(2021)3

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

- a. 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.
- b. Maximum use should be made of information technology, including between meetings. This includes for the purpose of gathering together amendments, comments and proposals, finalising texts and taking decisions, and publishing decisions provided in the latter cases that all the members of the committee have been properly informed in good time. When taking decisions by written procedure or electronic means, every effort should be made to reach a consensus.
- c. In accordance with the principle of transparency established by Resolution Res(2001)6 on access to Council of Europe documents, the documentation of committees, including notably meeting reports and adopted texts, shall be published unless a committee decides, for a specified reason, that it is necessary to classify a certain document or category of documents. Documents shall be published once any classification expires. Documents of committees and subordinate bodies shall be made available to Permanent Representations and all participants and observers of meetings on an equal basis with committee members.

Article 3 - Privacy of meetings

Meetings shall not be held in public. The Secretariat shall ensure a secured conduct of meetings, including in respect to electronic voting, in accordance with all applicable rules.

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, and independent experts shall not have the right to vote.
- 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. In the case of a vote by written procedure, the Secretariat shall transmit to members, on the Chair's instruction, the draft decision to be voted upon together with a voting form indicating the deadline by which members must ensure that their vote reaches the Secretariat of the committee. In the case of a vote by secret ballot, the Secretariat shall ensure the secrecy of the vote.
- g. 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 of members entitled to vote at the first ballot, a simple majority of members entitled to vote at the second ballot and the highest number of votes at the third 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. The Bureau shall not function as a drafting committee, but may occasionally be given limited drafting tasks. 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. The provisions of this resolution shall apply *mutatis mutandis* to the functioning of a drafting committee.
- 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 resolution Res(2004)25¹⁰ and within the limits of budgetary appropriations.
- d. Time- and cost-efficiency shall be a guiding principle for committee work. Respecting the principles of this resolution, the committee shall prioritise best possible use of digital technologies including for meetings and written consultations.
- 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.

¹⁰ In order to identify the most suitable consultants, the Secretary General should when appropriate consult members of relevant committees, national authorities including the Permanent Representations, professional associations and academic bodies (Res(2004)25, Article 9).

b. When it is not possible to convene plenary meetings of steering and ad hoc committees in a single location, they may be held by videoconference. Other meetings may also be held when appropriate with the use of digital technologies.

The proposal to hold a plenary meeting by videoconference shall be made by the Chair, in consultation with the Bureau, where applicable, or by the Secretary General, and approved by the committee, subject to the availability of the necessary budgetary resources.

Remote attendance of members at a meeting shall be treated as presence in person for the purposes of the Rules of Procedure, for all proceedings such as quorum, participation in discussions and voting.

c. 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(2021)3

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, 11 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.

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¹¹ 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 of the Committee and in special cases set out in the terms of reference.