COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Strasbourg, 14 June 2022 CDBIO / RAP 1

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

1st meeting

31 May – 3 June 2022

Hybrid

Report

I. Adoption of the agenda

1. The Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) held its 1st meeting from 31 May to 3 June 2022.

2. Ms Ritva Halila (SF), CDBIO Chair, opened the meeting and welcomed the new members if the Committee. The list of participants appears in Appendix I to this report.

3. The agenda is adopted. It appears in Appendix II to this report.

4. Mr Christophe Poirel, Human Rights Director, DGI, in an opening address, referred to the recent developments in the Organisation. He underlined also the responsibilities attached to steering committees and, finally informed about the latest decisions of the Committee of Ministers in the context of the examination of the draft Additional Protocol concerning the protection of human rights and dignity of persons with regard to involuntary placement and involuntary treatment within mental healthcare services.

II. Equitable access to scarce medical treatment and equipment

5. The Chair, Ms Ritva Halila, recalled this work's background and objective. She underlined the importance of the comments to be formulated by delegations with a view to the approval of the draft Recommendation in November 2022, at the 2nd plenary meeting, and its presentation to the Committee of Ministers at the beginning of 2023.

6. The Chair of the Drafting Group, Tomáš Doležal, briefly summarised the work and presented the draft recommendation (purpose and scope, key features, and added value). Tomáš Doležal recalled that the drafting group organised a targeted stakeholder consultation with international organizations, patients, and healthcare professionals.

7. Delegations were invited to make general comments on the draft Recommendation, the coherence with its objectives, and if there was anything unnecessary and/or missing.

8. Delegations expressed general support, welcoming the comprehensive and well-refined draft Recommendation. Ms Anne Kaiser, from the office of the Special Representative of the Secretary General on Migration and Refugees welcomed the text and the support it will provide to their work.

9. Delegations raised questions and observations on the scope, and other aspects related to the context of application (i.e., conventional/contingency/emergency care), and the level to which the Recommendation is addressed (individual and/or collective).

10. The importance of putting in place strategies for shortage prevention was recalled.

11. One delegation asked about possible mechanisms for monitoring the implementation of the Recommendation at the national level. Several examples were discussed.

12. The Chair of the Drafting Group recalled the mandate received. The Drafting Group did not focus on specific public health emergencies. It addressed the issue of how to ensure equitable access, whatever the root cause of the shortage, while considering art. 3 of the Oviedo Convention. The complementary of this work with other organisation’s work was recognised by stakeholders involved in the consultation, such as the EMA.

13. Mr Kristof Van Assche, Consultant for the Secretariat, presented two questions related to the substantial principles for ensuring equitable access for the individuals in need (Chapter II) and reminded delegations that Chapter III (procedural aspects) and Chapter IV (prevention and mitigation) contain elements more addressed to authorities.

14. Based on the suggestions received during the discussion, the Chair of the Drafting Group presented a document, prepared with the support of the Consultant and the Secretariat, containing alternative proposals for formulating the substantial principles included in Chapter II. He recalled that the drafting group made proposals, but it was for delegations to decide and stressed the need for them to indicate their choices and, where appropriate, send written proposals.

15. It was agreed to organise a consultation meeting with delegations concerned on 20 September 2022, in Paris, on the occasion of the Bureau meeting, to discuss in particular the wording of the scope and the section on criteria for priorisation.

16. **Delegations were invited to send any written comments on the draft Recommendation by 20 June 2022.**

III. Genome editing technologies

17. The Chair of the Drafting Group, Ms Anne Forus (N), referred to the decision taken by the Committee on Bioethics (DH-BIO) at its 18th meeting (1-4 June 2021), which considered that "Taking into account the technical and scientific aspects of these developments as well as the ethical issues they raise, the conditions were not met for a modification of the provisions of Article 13. However, it agreed on the need to provide clarifications, in particular on the terms "preventive, diagnostic and therapeutic" and to avoid misinterpretation of the applicability of this provision to "research"."

18. When presenting the proposals, she underlined the agreement within the Group, namely that:

- in addition to sperm and oocytes reference to embryo and precursors were to be added;
- basic research was covered as long as it is in compliance with the purpose limitations laid down in the article. The Group acknowledged that certain research could involve the creation of embryo but agreed that this was not in the scope of its work.

19. The Secretariat specified that the format in which the proposals were presented is in line with the objective set for the introduction of the clarification as an addendum to the Explanatory report in relation to Article 13 of the Oviedo Convention.

20. One delegation asked whether basic research of any kind was covered. It was pointed out that the provision operated within the scope of the Oviedo Convention. It was also underlined in this context that the drafters mainly focused on modifications of cells to be used in human being and cells which have the potential of becoming a human being. Furthermore, a member of the Drafting Group indicated that the latter was content that, when it comes to basic research, the three purposes were broad enough to cover not only what was directly relevant to them but also what "could lead to".

21. Subject to small editorial modifications in the last paragraph (i.e. "such disease" in the last part of the last sentence), the proposals were supported by delegations. One delegation however indicated that it would abstain.

22. **Delegations were invited to inform the Secretariat, by 20 June 2022, whether they have any objection to the clarifications being placed in an addendum to the explanatory report to the Oviedo Convention.**

23. In the absence of objection by that date, the clarifications will be considered as agreed. The conclusions of the re-examination process of Article 13 presenting the clarifications will then be inserted as an addendum to the Explanatory Report to the Oviedo Convention and will be sent to the Committee of Ministers for specific information.

IV. Children's participation in decision-making on matters relevant to their health

24. Mr Joost Van Haelst, Co-Chair of the Drafting Group for the CDENF, underlined the fruitful cooperation between the two steering committees. In this context, he referred to the new Strategy for the Rights of the Child and identified namely the following possible topics on which this cooperation with CDBIO could be further developed:
    - Fostering children access to quality mental health care services
    - Follow up to the seminar on early intervention on intersex children

25. Ms Ritva Halila, Co-Chair of the Drafting Group for the CDBIO, presented the draft guide. On this occasion she expressed her thanks to Ms Natalia Zaytseva, from the Secretariat, for the quality of her work in supporting the drafting group.

26. One delegation indicated that it would have some suggestions for clarification and modification concerning other forms of participation. But this did not call into question the content of the document which it supported.

27. The representative of the PACE referred to the works undertaken by the PACE in relation to children participation and the proposal made to designate a rapporteur on this topic. He informed the CDBIO about the current report on the impact of Covid-19 on the mental health of children and young adults. He expressed support for the work undertaken jointly by the CDBIO and the CDENF.

28. Delegations agreed that the draft responds to the objectives set for this work.

I. Background

29. One delegation underlined the need to take into account children who will never reach capacity, not because of age but due to disability.

30. Another delegation suggested including an example of inappropriate practice, namely of "undue inducement".

31. The need to involve children irrespective of whether they can or cannot give consent for age or other reasons was underlined. It was also suggested not to link the provision of information to ability to give consent.

32. The lack of reference to the provisions of the Oviedo Convention relevant to consent to research participation was noted.

II. Fulfilling children's right to participation in health care

33. The need was underlined to clarify the responsibility for providing explanation on the reason why another decision that the one reflecting the wish of the child has been taken and whether it needs to be document.

34. The Secretariat invited delegations to send more examples on individual participation in decision-making process.

35. One delegation supported by another one, stressed the need to refer the necessary resources to build trust and develop child friendly materials.

36. Delegations were invited to liaise with the delegation of their respective country in the CDENF about the draft Guide.

37. **Delegations were invited to send their possible comments on the draft in writing by 20 June 2022.**

38. Furthermore**, delegations were invited to check the reference to national legislation made in the appendix and send possible corrections where necessary by 20 June 2022.**

39. The importance for the Guide to include examples of good practices was underlined and **Delegations were invited to send such examples as soon as possible and in any case by 2 September 2022.**

40. A video prepared by the European network of excellence for paediatric research (TEDDY) in the context of this joint work undertaken by CDBIO and CDENF, was presented which aimed at raising awareness on the importance of children participation in decision making process on matters relevant to their health.

V. Health literacy

41. The Chair of the Drafting Group, Ms Assunta Morresi (I), presented the revised draft guide with focus on equitable access for all people who may be affected by the consequences of individual decisions affecting health, including those in vulnerable situations, as well as the people around them, such as caregivers.

42. In this connection, there was emphasis on building sustainable trust in health systems, by facilitating people's knowledge and management of health-related risks.

43. Reference was made to the actions, good practice and tools referred to in the draft Guide which pertain to health literacy challenges both for individuals and health systems, namely access to valid health information, access to appropriate care, as well as communication between individuals, health professionals and health authorities, shared decision-making regarding treatments and care, and access to digital spaces to understand and use health services.

44. Delegations expressed general support for the draft Guide as a practical tool to assist decision-makers, health providers and health professionals in promoting access to healthcare on an equitable basis. They underlined the need for everyone to understand, appraise, and apply health information to make free and informed decisions.

45. One delegation underlined in particular, the need for health professionals to communicate to patients in clear and simple terms the findings of biomedical research.

46. Delegations also welcomed reference to more good practice examples in the guide, especially those pertaining to actions in the CDBIO Strategic Action Plan on human rights and technologies in biomedicine (2020-2025).

47. **With a view to finalisation and adoption of the draft guide at its next plenary, CDBIO delegations were invited to send the Secretariat by 20 June 2022, any specific comments and/or good practice examples or tools to be referred to in the draft Guide.**

VI. Artificial intelligence

48. The Secretariat informed the CDBIO of the launch, on 7 June 2022, of the report of Mr Brent Mittelstadt, consultant expert, on the impact of AI systems regarding the doctor-patient relationship, which focuses on six themes: (1) Inequality in access to high quality healthcare; (2) Transparency to health professionals and patients; (3) Risk of social bias in AI systems; (4) Dilution of the patient's account of well-being; (5) Risk of automation bias, de-skilling, and displaced liability; and (6) Impact on the right to privacy. The Chair of the CDBIO welcomed

the report noting that it will provide an important source of input for the CDBIO's work in this field.

49. The CDBIO was informed about the work of the Committee on Artificial Intelligence (CAI) which has been tasked with elaborating an appropriate legal framework on the development, design and application of artificial intelligence. This work includes transversal work with other intergovernmental committees.

50. Welcoming the opportunity to communicate and cooperate with the CAI, the CDBIO agreed to invite the CAI to be represented in its plenary meetings.

51. As regards the setting-up of the Drafting Group on AI in healthcare, the Chair of the CDBIO thanked delegations for having replied to the call for expressions of interest. The CDBIO agreed to the list of proposed members, which is to include a representative of the CAI.

52. The Chair of the CDBIO recalled that the Drafting group on AI in healthcare would start its work in Autumn 2022 with a view to preparing a report on the impact of AI systems in the doctor-patient relationship, to be finalised by 2024.

53. To support its work on AI in healthcare, the Secretariat informed the CDBIO of its intention to open a call for secondments. **Delegations are thereby invited to contact the Secretariat at the earliest opportunity to explore secondment opportunities for this activity**.

VII. Promoting public dialogue on genomic medicine

54. The CDBIO was informed that the workshop will be held online on 10 November 2022.

55. The Secretariat presented the draft concept and programme of the workshop with emphasis on the processes and stakeholders (e.g. biobanks) needed to integrate and embed public dialogue in the development and regulation of genomic medicine.

56. CDBIO delegations supported the approach of the Preparatory group and agreed on the programme and conceptual framing for the workshop, welcoming the structure of the panel sessions, suggested speakers and its emphasis on different stakeholder perspectives, such as those of young people.

57. Reference was made to the need for public dialogue on the risks associated with the findings of biomedical research (e.g. polygenic scoring for cancer) and on the needs regarding direct-to-consumer access to genetic testing. This prompted one delegation to call for public dialogues to include a sober description of the field of genomics in order to fully discuss and understand its prospects and implications for people's lives.

58. In addition to those already referred to in the draft programme, **CDBIO delegations were invited to suggest other speakers, including young people from diverse backgrounds, who could actively participate in the workshop and to send them to the Secretariat at the latest by 30 June 2022.**

VIII. Working method

a. Responsibilities of the CDBIO with regard to the Committee of Ministers as steering committee

59. The Secretariat recalled the mid-term report to be sent to the Committee of Ministers, foreseen in the Strategic Action Plan (SAP) for 2023. The report should contain "a review of progress in respect of the objectives and actions in the SAP, and an assessment of its ongoing relevance."

60. Delegations agreed to entrust the Bureau with the task of preparing proposals for the preparation of this mid-term report, as well as possible new priorities to be considered for the next quadrennium.

b. Priorities in the light of recent developments

61. The delegations welcome the message and suggestions made by Ms Leyla Kayacik, Special Representative of the Secretary General for Migration and Refugees (SRSGMR), for future activities relevant to migrants, refugees and health. The fruitful cooperation with the office of the SRSGMR in particular in the activities relevant to equity under the SAP was underlined.

62. Delegations then exchanged with Ms Anne Kayser, Representative of the Office of the SRSGGME.

63. Underlining the current situation in Ukraine, they agreed on the importance of health-related issues in migrants and refugees which had already been identified as a major issue in the context of the preparation of the SAP.

64. The Representative of Ukraine thanked delegations who have sent her information on existing measures to support in particular women in post trauma situations. She referred to a newly created center to address those situations. The Chair of the CDBIO invited her to send more information on this center to be shared with delegations. Any relevant measure taken in member states or initiative taken within the Council of Europe could also be shared.

65. Consideration will be given to the possibility of a declaration from the CDBIO on these issues. The Bureau was entrusted with the task or preparing a draft to be considered at the next plenary meeting.

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66. The delegations were reminded about the two documents to be published in 2023 in accordance with the term of reference of the CDBIO:

- An overview of the national legislation on the protection and promotion of patients' rights (users of the health system)
- Overview of the legal framework and practices in the member States relevant to medically assisted procreation (MAP)

67. **Delegations were invited to check their replies to the questionnaire on MAP** to ensure that they are up to date and, where appropriate to send to the Secretariat the changes necessary **by 2 September 2022**.

68. When it comes to patient rights, it was acknowledged that the subject was very broad.

69. Delegations agree to entrust the Bureau with the task of reflecting on the best approach(es) and developing possible questionnaire(s) to collect the relevant information, with a view to a decision at the 2nd plenary meeting in November 2022.

c. Classification of documents

70. At the last meeting of the DH-BIO**,** Delegations agreed, in principle, on changing the approach concerning the status of documents which, from now on, will be a priori public except when decided otherwise by the Committee. The Bureau had been entrusted with the task of presenting a table with the status of the different types of documents prepared for and by the CDBIO.

71. **Delegations were invited to indicate by 20 June 2022 whether they have any objection to the proposal made by the Bureau on the classification of documents.** In this absence of objection by that date, the classification will be considered as agreed.

IX. Neurotechnologies: report of the rapporteurs to the round table held on 9 November 2021

72. Prof. Siobhan O'Sullivan (IRL), General Rapporteur for the round table co-organised with the OECD on 9 November 2021, presented the main elements of the report on the round table prepared together with the three other rapporteurs and soon to be finalised. Her presentation appears in appendix III to this report.

73. She concluded with three possible avenues for actions that could be considered as a follow up to the round table, some of which could be carried out in cooperation with the OECD and UNESCO:

- Public awareness/Public dialogue: reflecting on how to include the public, including private actors, in the dialogue with possible cooperation with OECD on the basis of Principle 5 of its Recommendation on Responsible Innovation in Neurotechnology.
- Sharing of best practices in minimising risks, which could be carried out in cooperation with UNESCO, as well as OECD
- Adaptative interpretation guidelines of existing human rights with regard to neurotechnologies: how to use existing human rights framework for the protection of individuals with regard to the applications of neurotechnologies.
  In relation to the latter, she underlined that these technologies would not necessarily require different framework, but this may not be the case of future technologies. Rather than regulating the technologies she suggested regulating their applications.

74. One delegation raised the issue of applications outside biomedicine. In reply, reference was made to the relevant work carried out by OECD.

75. Ms Anne Forus (N), also member of the International Bioethics Committee (IBC) and its Bureau, indicated that she will bring the discussion at the level of UNESCO. She referred to the relevant IBC report. The Secretariat indicated that the issue will also be raised at the UN Interagency Committee on Bioethics (UNIACB) in which the CoE is an associated member, with a view to closer cooperation with the organisations concerned which are also members of the UNIACB.

76. Delegations congratulated the General Rapporteur for the quality of the work achieved in cooperation with the other rapporteurs. They agreed for the report to be published accompanied by a communique highlighting the main conclusions of the round table, to be finalized at the next plenary meeting.

IX. In agreement with the Committee of Ministers' decision, preparation of a draft Recommendation to promote voluntary measures in mental healthcare

77. Mr Daniele Cangemi, Head of the CoE Department for Human rights, Justice and Legal Co-operation, standards setting activities, presented briefly the recent decision of the Committee of Ministers providing for complementary measures for the protection of autonomy and promotion of human rights in mental health, reflecting a comprehensive approach of the human rights issues in this field. He underlined in this context the very clear and strong appreciation of the work achieved by the CDBIO on a very complex matter, expressed during the discussion in the CM.

78. When it comes to the report of the relevant case law of the ECtHR, an existing report prepared by the Research Division of the Court will be updated. The compendium on good practices

promoting voluntary measures was already published. However, it would be important to continue updating it with new examples of relevant practices. The preparation of a draft recommendation promoting the use of voluntary measures in mental healthcare services was a new task with which the CDBIO was now entrusted.

79. One delegation underlined the resources implications of this new work.

80. Another delegation stressed the reasonable approach taken by the CM, which acknowledged the work already achieved by the DH-BIO and gave a mandate to continue working on this topic. She underlined that the Committee of Ministers had been sensitive to the difficulties related to this topic and wished to put emphasis on the protection of the autonomy of the persons and on the basic principle of primacy of voluntary measures. It was important for this new instrument to be as strong as possible and to provide for a form of monitoring of its implementation in the member states. The CDBIO could, for example, be in charge of following the implementation of the recommendation every three years for example. When the work will be finished, this comprehensive package to protect human rights in mental healthcare services will clearly demonstrate the primacy of voluntary measures and the principle of autonomy and self-determination. This would hopefully address any misunderstanding as to the position of the Conseil de l'Europe on the protection of autonomy and human rights of persons in mental healthcare services.

81. Taking into account the work already achieved which would provide a strong basis for such recommendation, Delegations agreed to entrust the Bureau, assisted by the Secretariat and a consultant, with the drafting of a draft Recommendation to be submitted to the CDBIO.

82. The possibility of a seconded person could be considered to reinforce the Secretariat for this new work with which the CDBIO has been entrusted by the Committee of Ministers.

X. Dates of the next meetings

83. The date of 2-4 November 2022 was confirmed for the 2nd plenary meeting of the CDBIO to be held in presential, subject possible evolution of the public health situation.

84. The dates considered for the 3rd meeting (9-12 May or 6-9 June 2023) will need to be confirmed.

XI. Other business

a. PACE Recommendation 2227 (2022) – "Deinstitutionalisation of persons with disabilities"

85. The Delegations agreed with the comments prepared by the Secretariat, with the introduction of a new paragraph referring to relevant work carried out by the CDBIO for the promotion of autonomy and protection of persons in vulnerable situations, including persons with disabilities.

b. Cooperation activities

86. Ms Meri Katvalyan, project officer for the cooperation project on human rights and biomedicine in Armenia, informed the CDBIO about the achievements and future activities considered in the framework of the Armenian Action Plan. Her presentation appears in appendix IV to this report.

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87. The Chair briefly referred to a request she received from the CD-P-TO Chair and Vice Chair as a follow up to the Guide on prohibition of financial gain, who were invited to provide some clarifications with a view to the consideration of the request by the CBDIO.

Appendix I
List of participants

MEMBERS / *MEMBRES*

	ALBANIA / *ALBANIE*	Awaiting nomination / *Nomination en attente*
KUDO	**ANDORRA** / *ANDORRE*	**Mr David PÉREZ SURRIBAS** President of the National Committee of bioethics
COE	**ARMENIA** / *ARMENIE*	**Ms Anna MKRTUMYAN** Head of the Legal Department Ministry of Health
	AUSTRIA / *AUTRICHE*	**Dr Isabelle HASSLER** **Apologised/Excusée** Federal Chancellery of Austria / Co-ordination Science, Research, Technology, Education, Social issues, Health Secretariat of the Austrian Bioethics Commission
KUDO		**Mr Stefan SCHWAB** Judge Ministry of Justice
KUDO	**AZERBAIJAN** / *AZERBAÏDJAN*	**Dr Ismayil S ZULFUGAROV** Head of Proteomics Lab Institute of Molecular Biology and Biotechnologies of the Azerbaijan National Academy of Sciences
COE		**Ms Gulnara BALAKISHIYEVA** PhD in Molecular biology Science Secretary of Azerbaijan National Committee on Bioethics Leading Researcher at Department of Fundamental Institute of Molecular Biology and Biotechnology
COE	**BELGIUM** / *BELGIQUE*	**Mr Paul COSYNS** Vice-président de Comité consultatif de Bioéthique
COE	**BOSNIA AND HERZEGOVINA** / *BOSNIE-HERZÉGOVINE*	**Ms Dunja PEJOVIC** Coordinator of the Regional Health Development Center for Mental Health in SEE Ministry of Civil Affairs
COE	**BULGARIA** / *BULGARIE*	**Ms Vihra MILANOVA** Head of Psychiatric Clinic Alexandrovska University Hospital
	CROATIA / *CROATIE*	**Dr Vanja NIKOLAC** **Apologised/Excusée** Head of Service, Service for blood, tissues and cells inspection Ministry of Health
KUDO	**CYPRUS** / *CHYPRE*	**Prof. Constantinos N. PHELLAS** Chair of the Cyprus National Bioethics Committee University of Nicosia

COE KUDO	**CZECH REPUBLIC /** *REPUBLIQUE TCHEQUE*	**Doc. JUDr. Tomáš DOLEŽAL** Ph.D., LL.M., Head of the Department of Private Law and Head of the Research Unit for Medical Law and Bioethics Czech Academy of Science, Institute of State and Law **Ms doc. PhDr. Ing. Hana KONEČNÁ** Ph.D., Jihočeská univerzita v Českých Budějovicích Zdravotně sociální fakulta, Katedra klinických a preklinických oborů
COE	**DENMARK /** *DANEMARK*	**Ms Berit DEA HVOLBY** Head of Section Ministry of Health
COE	**ESTONIA /** *ESTONIE*	**Dr Aime KEIS** Vicechair of the National Committee on Bioethics and Human Research University of Tartu
COE COE COE	**FINLAND /** *FINLANDE*	**Prof. Ritva HALILA** Docent, Senior Medical Officer Ministry of Social Affairs and Health **Ms Maija MIETTINEN** Ministry of Social Affairs and Health **Ms Mia SPOLANDER** Legal Officer Unit for Human Rights Courts and Conventions, Legal Service Ministry for Foreign Affairs
COE KUDO COE COE COE	**FRANCE**	**Mr Kamyar ASSARI** Consultant juridique Sous-direction des droits de l'Homme Direction des affaires juridiques Ministère de l'Europe et des Affaires étrangères **Dr Mélodie BERNAUX** Directrice de projets Délégation ministérielle au numérique en santé (DNS) Ministère des Solidarités et de la Santé **Mme Lucie BOZEC** Chargée de mission greffe Bureau bioéthique, éléments et produits du corps humain (PP4) Direction générale de la Santé (DGS) Ministère de la Santé et de la Prévention **Dr Fadia DIB** Médecin chargée de la procréation, embryologie et génétique humaine Bureau bioéthique, éléments et produits du corps humain (PP4) Direction générale de la Santé (DGS) Ministère de la Santé et de la Prévention **Mme Guilaine GANRY** Rédactrice Bureau du droit des personnes et de la famille Sous-direction du droit civil Direction des affaires civiles et du sceau (DACS) Ministère de la Justice

KUDO		**Dr Jacques MONTAGUT** Ancien membre du CCNE
	GEORGIA / *GÉORGIE*	**Prof. Givi JAVASHVILI** **Apologised/Excusé** Head of Family Medicine Department Tbilisi State Medical University Chairman of the National Council on Bioethics
COE KUDO COE COE COE	**GERMANY** / *ALLEMAGNE*	**Prof. Dr. Elmar DOPPELFELD** Honorary Chair of the "Permanent Working Party of Research Ethics Committees in Germany Inc." **Mr Carlo GRIMM** Division 611 Federal Ministry of Education and Research **Dr Ingo HÄRTEL** Division 316 Federal Ministry of Health **Prof. Dr. Dr. Thomas HEINEMANN** Philosophical-Theological University of Vallendar (PTHV) **Dr Judith MENTGEN** Head of Division III B 6 German Federal Ministry of Justice and Consumer Protection
KUDO	**GREECE** / *GRECE*	**Prof. Andreas KARABINIS** Intensivist, Professor of Emergency Medicine Athens Medical School National and Kapodistrian University of Athens
COE	**HUNGARY** / *HONGRIE*	**Prof. Ernö BÁCSY** MD, PhD, DSc, Medical Research Council of Hungary **Dr Tamás KARDON** **Apologised/Excusé** Associate professor, Secretary of the Scientific and Research Ethics Committee of the Hungarian Medical Research Council
	ICELAND / *ISLANDE*	**Mr Rögnvaldur G. GUNNARSSON** **Apologised/Excusé** Legal Advisor Ministry of Welfare **Ms Kristín Ninja GUDMUNDSDÓTTIR** **Apologised/Excusée** Legal Advisor Ministry of Health
COE	**IRELAND** / *IRLANDE*	**Dr Siobhan O'SULLIVAN** Chief Bioethics Officer An Roinn Sláinte Department of Health Teach Hawkins
KUDO KUDO	**ITALY** / *ITALIE*	**Prof. Assunta MORRESI** Prof. Associato di Chimica Fisica, Dipartimento di Chimica, Biologia e Biotecnologi Università degli Studi di Perugia **Prof. Laura PALAZZANI** Lumsa, Facoltà di giurisprudenza Roma

	LATVIA / *LETTONIE*	**Dr Vents SĪLIS** **Apologised/Excusé** Assistant Professor at Riga Stradins University Department of Humanities
	LIECHTENSTEIN	Awaiting nomination / *Nomination en attente*
KUDO	**LITHUANIA** / *LITUANIE*	**Dr Asta ČEKANAUSKAITĖ** Director of Lithuanian Bioethics Committee
	LUXEMBOURG	**Ms Julie-Suzanne BAUSCH** **Apologised/Excusée** Présidente de la Commission nationale d'éthique
COE	**MALTA** / *MALTE*	**Prof. Pierre MALLIA** Professor of Family Medicine, Bioethics & Patients' Rights, Chairperson, National Health Ethics Committee, Dept. of Health, Chairperson, Bioethics Consultative Committee Ministry of Health Coordinator, Bioethics Research Programme, Univ. of Malta, President, Malta College of Family Doctors
	REPUBLIC OF MOLDOVA / *RÉPUBLIQUE DE MOLDOVA*	**Mr Ion PRISACARU** **Apologised/Excusé** Secretary of State Ministry of Health **Mr Maxim DONICI** **Apologised/Excusé** Head of the Legal Service Ministry of Health
KUDO	**MONACO**	**Dr Thomas ALTHAUS**
COE	**MONTENEGRO** / *MONTÉNÉGRO*	**Prof. Dr Olivera MILJANOVIC** MD, PhD, Faculty of Medicine - University of Montenegro Director of Centre for Medical Genetics and Immunology Clinical Centre of Montenegro
COE KUDO	**NETHERLANDS** / *PAYS-BAS*	**Mr Harrie STORMS** Ministry of Health, Welfare and Sports **Ms Sanne VAN WEEZEL** Ministry of Health, Welfare and Sports
	NORTH MACEDONIA / *MACÉDOINE DU NORD*	**Ms Olgica VASILEVSKA** **Apologised/Excusée** Senior Counselor, Directorate for Multilateral Relations and Security Cooperation, Sector for Council of Europe, OSCE and other European Organizations Ministry of Foreign Affairs
COE	**NORWAY** / *NORVEGE*	**Ms Anne FORUS** Senior Adviser, ph.d, Biotechnology and health legislation department Division of specialised health care services Norwegian Directorate of Health
KUDO	**POLAND** / *POLOGNE*	**Ms Mariola GROCHULSKA** Département des droits de l'homme Ministère de la Justice
KUDO	**PORTUGAL**	**Prof. Jorge SOARES** Conseiller au Conseil National d'Ethique pour les Sciences de la Vie

COE KUDO	**ROMANIA** / *ROUMANIE*	**Mr Gheorghe BORCEAN** Président de l'Ordre des Médecins et Prof. Ass. à l'Université de Médecine et Pharmacie " Victor Babes" de Timisoara Vice-President of the Romanian College of Physicians Spitalul Municipal Caransebes **Ms Beatrice Gabriela IOAN** Associate Professor President of the Bioethics Commission of the Romanian College of Physicians Institutul de Medicina Legala
COE	**SAN MARINO** / *SAINT-MARIN*	**Dr Luisa BORGIA** President of the National Bioethics Committee
COE	**SERBIA** / *SERBIE*	**Prof. Dr Zvonko MAGIC** Head of the Institute for Medical Research in the MMA (Military Medical Academy), professor of the human genetics at the Medical Faculty and Cochairmen of the National Committee for bioethics of UNESCO Commission of Serbia Serbian Academy of Sciences and Arts
KUDO	**SLOVAKIA** / *SLOVAQUIE*	**Prof. Jozef GLASA** Institute of Pharmacology and Clinical Pharmacology, Institute of Health Care Ethics, Slovak Medical University in Bratislava; Institute of Medical Ethics and Bioethics n.f.; Ethics Committee (NEC) Ministry of Health
	SLOVENIA / *SLOVÉNIE*	**Prof. Marjeta TERČELJ ZORMAN** **Apologised/Excusée** Dr.Med.
COE	**SPAIN** / *ESPAGNE*	**Prof. Carlos M. ROMEO – CASABONA** Professor of Penal Law, Head Inter-University Chair in Law and the Human Genome
COE	**SWEDEN** / *SUÈDE*	**Ms Tesi ASCHAN** Legal Adviser The National Board of Health and Welfare, Socialstyrelsen
	SWITZERLAND / *SUISSE*	**Prof. Dr. Rodrigo RODRIGUEZ** **Apologised/Excusé** Département fédéral de justice et police DFJP Office fédéral de la Justice OFJ, Domaine de direction Droit privé
KUDO KUDO KUDO	**TÜRKIYE**/ *TÜRKIYE*	**Ms Ayşenur ÇOBAN** Assistant Expert Ministry of Family and Social Services **Ms Tuna İLBARS** Unit Coordinator Department of Blood and Blood Products **Directorate General of Health Services** Ministry of Health **Mr Ahmet Metin GÖKLER** Justice Counsellor Permanent Representation of the Republic of Türkiye

COE	**UKRAINE**	**Ms Iuliia DAVYDOVA** Professor, Head of High-Risk Pregnancy Department Institute of Pediatrics, Obstetrics and Gynecology, member of Local Bioethics Committee
COE KUDO	**UNITED KINGDOM /** *ROYAUME-UNI*	**Dr Mark BALE** Deputy Director Health Science & Bioethics Division Department of Health **Dr Pete MILLS** Assistant Director Nuffield Council on Bioethics

PARTICIPANTS / *PARTICIPANTS*

KUDO KUDO KUDO	**PARLIAMENTARY ASSEMBLY /** *ASSEMBLÉE PARLEMENTAIRE*	**Ms de BRUIJN WEZEMAN** Rapporteur on the deinstitutionalisation of people with disabilities **Mr Jean-Pierre GRIN** Conseiller national (Suisse) **Mr Olivier FRANÇAIS** Conseiller aux Etats
	CDCJ	**Prof. Dr. Rodrigo RODRIGUEZ** **Apologised/Excusé** Département fédéral de justice et police DF Office fédéral de la Justice OFJ Domaine de direction Droit privé
KUDO	**CDENF**	**Mr Joost VAN HAELST** Member of CDENF Co-Chair of the Drafting Group for the Guide on children participation in decision-making process on matters relevant to their health

OTHER PARTICIPANTS / *AUTRES PARTICIPANTS*

	EUROPEAN UNION / ***UNION EUROPEENNE***	Awaiting nomination / *Nomination en attente*
	EUROPEAN COMMISSION / *COMMISSION EUROPEENNE*	**Dr Jim DRATWA** **Apologised/Excusé** Head of Ethics and Head of the EGE Secretariat Member of the Bureau of European Policy Advisers (BEPA) European Commission
	CONFERENCE OF INGOS / *CONFERENCE DES OINGS*	**Mr Frank Ulrich MONTGOMERY** **Apologised/Excusé** Standing Committee of European Doctors (CPME) **Ms Ruth ALLEN** **Apologised/Excusée** International Federation of Social Workers (IFSW)
KUDO	**CANADA**	**Mr Peter MONETTE** Health Canada
KUDO	**HOLY SEE /** *SAINT-SIEGE*	**Mgr Jacques SUAUDEAU** Cure Saint Bruno Voiron

COE	**JAPAN** / *JAPON*	**Mr Tetsushi HIRANO** Chargé de mission
COE KUDO COE	**MEXICO** / *MEXIQUE*	**Dr Patricio J. SANTILLAN DOHERTY** National Commissioner of Bioethics **Mr Gustavo Fernando OLAIZ BARRAGAN** Deputy Director on Public Policy and Bioethics National Commission of Bioethics **Ms Eva PIZANO CEJKA** Adjointe à l'Observateur Permanent / Première Secrétaire
	USA / *ETATS-UNIS D'AMERIQUE*	Awaiting nomination / *Nomination en attente*
	UNESCO	**Mr Irakli KHODELI** **Apologised/Excusé** Section de la bioéthique Division de l'éthique des sciences et des technologies
	OECD / *OCDE*	**Mr David WINICKOFF** **Apologised/Excusé** STI/STP
	WHO / *OMS*	**Dr Andreas REIS** **Apologised/Excusé** Technical Officer HIS/KER Cluster of Health Systems and Innovation **Dr Katherine LITTLER** **Apologised/Excusée** Global Health Ethics, Health Systems and Innovation Cluster

OBSERVERS / *OBSERVATEURS*

KUDO	**CONFERENCE OF EUROPEAN CHURCHES (CEC)** / *CONFERENCE DES EGLISES EUROPEENNES (CEC)*	**Prof Dr. Julija VIDOVIC** Membre du Groupe de travail

CONSULTANTS / *CONSULTANTS*

BELGIUM / *BELGIQUE* COE	**Dr Kristof VAN ASSCHE** Consultant in Equitable access to scarce healthcare resource
DENMARK / *DANEMARK* KUDO	**Dr Kristine SØRENSEN** Consultant in Health literacy
FINLAND / *FINLANDE* KUDO	**Dr Leena PAAKKARI** Consultant in Health literacy
ITALY / *ITALIE* KUDO	**Dr Annagrazia ALTAVILLA** Consultant in Children participation

SECRETARIAT / *SECRETARIAT*

PARLIAMENTARY ASSEMBLY / *ASSEMBLÉE PARLEMENTAIRE*	
KUDO	**Ms Tanja KLEINSORGE** Head of Secretariat Committee on Social Affairs, Health and Sustainable Development
COE	**Ms Anita GHOLAMI** Committee on Social Affairs, Health and Sustainable Development
KUDO	**Ms Yulia PERERVA** Committee on Social Affairs, Health and Sustainable Development
OFFICE OF THE COMMISSIONER FOR HUMAN RIGHTS / *BUREAU DU COMMISSAIRE AUX DROITS DE L'HOMME*	**Ms Patricia OTVOS** **Apologised/Excusée** Adviser
OFFICE OF THE SPECIAL REPRESENTATIVE OF THE SECRETARY GENERAL ON MIGRATION AND REFUGEES / *BUREAU DE LA REPRESENTANTE SPECIALE AUPRES DE LA SECRETAIRE GENERALE SUR LES MIGRATIONS ET LES REFUGIES*	**Ms Anne KAYSER** Administrator
COMMITTEE ON ARTIFICIAL INTELLIGENCE / *COMITE SUR L'INTELLIGENCE ARTIFICIELLE* **(CAI)**	**Mr Kristian BARTHOLIN** Secretary
STEERING COMMITTEE ON ANTI DISCRIMINATION, DIVERSITY AND INCLUSION / *COMITE DIRECTEUR SUR L'ANTI-DISCRIMINATION, LA DIVERSITE ET L'INCLUSION* **(CDADI)**	**Mr Wolfram BECHTEL** Secretary
SEXUAL ORIENTATION AND GENDER IDENTITY UNIT / *UNITE ORIENTATION SEXUELLE ET IDENTITE DE GENRE* **(SOGI)**	**Ms Eleni TSETSEKOU** Head of Unit
EUROPEAN COMMITTEE FOR THE PREVENTION OF TORTURE AND INHUMAN OR DEGRADING TREATMENT OR	**Mr Michael NEURAUTER** **Apologised/Excusé** Head of Division

PUNISHMENT : COMITE EUROPEEN POUR LA PREVENTION DE LA TORTURE ET DES PEINES OU TRAITEMENTS INHUMAINS OU DEGRADANTS **(CPT)**	
COMMITTEE OF THE CONVENTION FOR THE PROTECTION OF INDIVIDUALS WITH REGARD TO AUTOMATIC PROCESSING OF PERSONAL DATA / *COMITÉ CONSULTATIF DE LA CONVENTION POUR LA PROTECTION DES PERSONNES À L'ÉGARD DU TRAITEMENT AUTOMATISÉ DES DONNÉES A CARACTÈRE PERSONNEL (***T-PD)**	**Ms Isabelle SERVOZ-GALLUCCI** **Apologised/Excusée** Secretary
STEERING COMMITTEE FOR THE RIGHTS OF THE CHILD / *COMITE DIRECTEUR POUR LES DROITS DE L'ENFANT* **(CDENF)**	**Ms Katrin UERPMANN** Secretary
EUROPEAN COMMITTEE ON BLOOD TRANSFUSION / *COMITE EUROPEEN (ACCORD PARTIEL) SUR LA TRANSFUSION SANGUINE* **(CD-P-TS)**	**Mr Richard FORDE** **Apologised/Excusé** Secretary
EUROPEAN COMMITTEE ON ORGAN TRANSPLANTATION / *COMITE EUROPEEN SUR LA TRANSPLANTATION D'ORGANES* **(CD-P-TO)**	**Ms Marta LOPEZ-FRAGA** **Apologised/Excusée** Secretary
DIRECTORATE GENERAL HUMAN RIGHTS AND RULE OF LAW / *DIRECTIONGENERALE DES DROITS DE L'HOMME ET ETAT DE DROIT*	**Mr Christophe POIREL** Director, Human Rights Directorate **Mr Daniele CANGEMI** Head of Department
HUMAN RIGHTS, JUSTICE AND LEGAL COOPERATION, STANDARD SETTING ACTIVITIES DEPARTMENT - HUMAN RIGHTS AND BIOMEDICINE DIVISION / *SERVICE DES ACTIVITES NORMATIVES EN MATIERE DE DROITS DE L'HOMME, JUSTICE ET*	**Ms Laurence LWOFF** Secretary of the CDBIO / *Secrétaire du CDBIO* Tel: +33 (0) 388 41 22 68, Email: laurence.lwoff@coe.int **Mr Lee HIBBARD** Administrator / *Administrateur* Tel: +33 (0) 388 41 31 04, Email: lee.hibbard@coe.int **Mr Lorenzo MONTRASIO** Administrator / *Administrateur* Tel: +33 (0) 390 21 61 87, Email: Lorenzo.montrasio@coe.int

COOPERATION JURIDIQUE - DIVISION DES DROITS DE L'HOMME ET DE LA BIOMEDECINE	**Ms Natalia ZAYTSEVA** Administrator / *Administratrice* Tel: +33 (0) 390 21 62 51, Email: Natalia.zaytseva@coe.int **Ms Catherine FORNE** Assistant / *Assistante* Tel: +33 (0) 388 41 22 20, Email: catherine.forne@coe.int **Ms Laura HENNINGER** Assistant / *Assistante* Tel: +33 (0) 388 41 30 05, Email: laura.henninger@coe.int **Ms Tatiana WINTER** Assistant / *Assistante* Tel: +33 (0) 388 41 33 67, Email: tatiana.winter@coe.int **Ms Marianthi GKAKOU** Trainee / *Stagiaire* (Greece/*Grèce*)
THE INTERPRETING, TRAVEL, EVENTS AND MULTIMEDIA DEPARTMENT (ITEM) / *LE SERVICE DE L'INTERPRETATION, DES VOYAGES, DES EVENEMENTS ET DU MULTIMEDIA (ITEM)*	**Ms Chloé CHENETIER** **Mr Luke TILDEN** **Ms Amanda BEDDOWS -LARIVIERE**

Appendix II
Agenda

Tuesday 31 May 2022 (9.30 – 17.00)	
Seminar on "Early intervention on intersex children – Promoting children rights"	
Wednesday 1 June 2022 (10.00- 12.30 / 14.00 - 16.30)	
10.00	**Opening Address by Christophe Poirel, Director, DGI - Human Rights Directorate**
10.15-10.45	**1. Adoption of the draft agenda** ○ New CBIO members invited to introduce themselves ○ Reminder about the main decisions to be taken during the meeting
10.45-12.30	**2. Equitable access to scarce healthcare resources** *Objectives:* ○ *Examination of the draft Recommendation on equitable access to scarce medical treatment and equipment, with a view to its approval at the 2nd plenary meeting (2-4 November 2022)* ○ *Examination of preliminary draft elements for the Explanatory Memorandum* The delegations are invited to make: ▪ **General comments** on the draft: - Does the draft Recommendation meet its objective? i.e. ensuring that priorities in accessing scarce health resources are set consistently and with respect for human dignity and the protection of human rights. - Is there anything in the draft Recommendation which you consider unnecessary and/or missing? ▪ Comment on the **following specific issues**: - Are age and disability to be considered grounds in the priority-setting for the allocation of scarce resources? - To what extent, in the priority-setting between individuals in need of scarce resources, specific attention needs to be paid to those who are systematically disadvantaged in relation to health? *(NB: SAP timeline: Recommendation to be finalised and approved in November 2022)*

14.00-15.00	**3. Genome editing technologies** *(where necessary to continue on Friday 3 June)* *Objective*: ○ *Examination of the draft clarifications on the terms of Article 13 with a view to their finalisation*
15.00-16.30	**4. Children's participation in decision-making on matters relevant to their health** *Objectives:* ○ *Examination of the draft guide with a view to give guidance to the Drafting Group* ○ *Presentation of the video prepared by TEDDY's network to raise awareness on children participation in decision making process* *(NB: SAP timeline: Guide to be finalised and adopted by CDENF and CDBIO in 2023, where possible in June)*
Thursday 2 June 2022 (10.00-12.30 / 14.00-16.30)	
10.00-11.30	**8. Working method** a. Responsibilities of the CDBIO with regard to the Committee of Ministers as steering committee b. Priorities in the light of recent developments Intervention by the new representative of the Secretary General on Migration and Refugees, Ms Leyla Kayacik c. Classification of documents
11.30-12.00	**6. Artificial intelligence** *Objective:* ○ *Setting up the drafting group in charge of preparing the report on AI and its impact in medicine, in particular on patient-doctor relationship* *(NB: SAP timeline: Report to be finalised in 2024)*
12.00-12.30	**13. Other business** a. PACE Recommendation 2227 (2022) – "Deinstitutionalisation of persons with disabilities" for opinion: preparation of comments for the Committee of Ministers b. Cooperation activities c. SAP: Update methodology and timeframe for the priority actions planned revised in the light of the priorities agreed

14.00-15.00	**9. Neurotechnologies** *Objective:* ○ *Presentation of the report by the General Rapporteur of the Round Table co-organised with OECD, on 9 November 2021, and early exchange with delegations on possible follow up*
15.00-16.30	**5. Health literacy** *Objective:* ○ *Examination of the draft Guide, with a view to its finalisation at the 2nd plenary meeting (2-4 November 2022) for adoption* The delegations are invited: - to make: ○ General comments on the guide: Does the guide meet its objective i.e. a guide to health literacy for all, including persons in vulnerable situations, to empower them to access health care of appropriate quality on an equitable basis with other groups in society ○ Specific comments on the guide: Is there anything in the guide which you consider unnecessary and/or missing? - to suggest good practices and tools to enrich the guide (for example as regards shared decision making, and communication between individuals, health professionals and health authorities) – would you have good practice that illustrates themes of importance (such as genomic medicine, caregivers, health misinformation/disinformation)? *(NB: SAP timeline: Guide to be finalised in November 2022)*
Friday 3 June 2022 (10.00- 12.30)	
10.00-10.30	**10. In agreement with the Committee of Ministers' decision, preparation of a draft Recommendation to promote voluntary measures in mental healthcare** *Objective*: ○ *Agreement on the working method for the preparation of the draft Recommendation*
10.30-11.00	**7. Promoting public dialogue on genomic medicine** *Objective:* ○ *Examination of the draft programme of the workshop to be held on 10 November 2022, with a view to its validation*
11.00-11.45	**3. Genome editing technologies** *(where necessary)* *Objective*: ○ *Examination of the draft clarifications on the terms of Article 13 with a view to their finalisation*

11.45-12.15	**11. Decisions taken by the CDBIO at its 1st meeting** ○ *Approval of the Abridged meeting report which includes the decisions*
12.15-12.30	**12. Dates of the next meetings** ○ *2nd meeting of the CDBIO: 2-4 November 2022* ○ *3rd meeting of the CDBIO: 9-12 May / 6-9 June 2023*

POINTS TO BE DEALT WITH IN WRITING

	**14. Developments in the field of bioethics** Delegations, including observers, are invited to send information in writing. a. Developments in member states and other states b. Developments in the field of bioethics in international organisations c. Developments in other Council of Europe bodies d. Developments at the European Court of Human Rights
	**15. Chart of signatures and ratifications of the Convention on Human Rights and Biomedicine, the Protocol on the Prohibition of Cloning Human Beings, the Protocol concerning Transplantation of Organs and Tissues of Human Origin, the Protocol concerning Biomedical Research and the Protocol concerning Genetic Testing for Health Purpose**
	**16. Cooperation with other committees** a. European Committee on Organ Transplantation (CD-P-TO) b. European Committee on Blood Transfusion (CD-P-TS) c. Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD) d. Steering Committee for the Rights of the Child (CDENF) e. Steering Committee for Legal Cooperation (CDCJ)

Appendix III
Presentation from Prof. Siobhan O'Sullivan

Neurotech
Neurorights CD-BIO

Appendix IV
Presentation from Ms Meri Katvalyan

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