

Strasbourg, 17 November 2021

DH-BIO / Abr RAP 19 Rev

**COMMITTEE ON BIOETHICS
(DH-BIO)**

19th meeting

2-4 November 2021

Kudo

Abridged report

I. Adoption of the agenda

1. The Committee on Bioethics (DH-BIO) held its 19th meeting online from 2 to 4 November 2021.
2. The Chair, Ms Ritva Halila (SF) opened the meeting and welcomed the new members of 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. The Chair thanked M. Daniele Cangemi, new Head of the Human Rights, Justice and legal Co-operation, Standards Settings activities Department for his participation. In his address, M. Cangemi congratulated the Committee for its responsiveness in the context of the Covid-19 pandemic. Furthermore, he underlined the transversal approach adopted in the majority of the works carried out by the Committee as illustrated by the round table on human rights and neurotechnologies to be co-organised with the OECD on 9 November. He referred to the important links established with the CDDH and the mutual wish to maintain them if, as proposed, the committee on bioethics, starting in 2022, becomes a steering committee. In this regard, he recalled the specific role of steering committees in advising the Committee of Ministers as well as the Secretary General on priorities in their sector including possible new activities and those which might be discontinued. This strategical role is particularly important in the current context and may lead to consider specific measures including in its working method to fulfil that role. He ensured the committee about the continuous support of the Secretariat in its work.

II. Collection of examples of good practices aiming at promoting voluntary measures in mental health care

5. Dr Piers Gooding (Australia), consultant, made a presentation on the updated Compendium on good practices aiming at promoting voluntary measures in mental health care containing comments and additions received from delegations after the 18th DH-BIO Plenary meeting in June 2021. Delegations congratulated Dr Gooding for the work completed.
6. The updated web version of the draft Compendium was also presented to the Committee by the Secretariat.
7. Delegations expressed wide support for the work carried out and agreed on the publication of the Compendium and its dissemination (including in non-official languages).
8. Considering that the compendium provides a good starting point, one delegation suggested drafting a recommendation or another instrument on promoting the use of voluntary and non-coercive measures in mental healthcare services. Delegations considered that such an instrument, in addition to the Additional Protocol, would reaffirm the message that voluntary measures are the primary rule and that involuntary measures are accepted only as a last resort and remain an exception. **Delegations are invited to send their remarks on this proposal [Document DH-BIO(2021)30] by 1 December 2021.**

III. Additional Protocol concerning the protection of human rights and dignity of persons with regard to involuntary placement and involuntary treatment within mental health care services

9. Following a thorough drafting process and extensive consultations, the delegations agree by 31 votes in favour, 1 against and 7 abstentions, to present the draft Additional Protocol to the Committee of Ministers. In accordance with this procedural decision, the draft Additional Protocol will be sent to the Committee of Ministers with a view to a decision.

10. After the vote the delegation from Finland made the following statement:
*“In the understanding of the Government of Finland, this vote is of purely procedural nature. This is not a vote on the adoption of the text of the draft additional protocol. In our understanding, this committee voted solely on the transfer of the draft text to the Committee of Ministers for decision.
This delegation voted in favour of the transfer, because we see that in the current circumstances, this committee cannot move forward without further guidance from the Committee of Ministers.
We believe that the draft additional protocol would provide necessary legal safeguards to the persons in involuntary placement and involuntary treatment in mental healthcare services, and better protect their rights. However, we cannot disregard the extensive criticism this draft has been subjected to.
Therefore, we would like to clarify that this vote does not, in any way, indicate the Government’s forthcoming position in the Committee of Ministers’ decision-making procedures nor mean the approval of the text of the draft additional protocol as it stands now.”*
11. Three other delegations expressed similar positions with regard to this vote.
12. The delegations agreed with the limited editorial changes made to the Explanatory Report in the light of comments made by two delegations. The text of the finalised Explanatory report will be sent to the Committee of Ministers together with the draft Additional Protocol. It was reminded that the Explanatory Report is prepared under the responsibility of the Secretariat and will be not subject to a decision at the level of the Committee of Ministers.
13. The representative of the PACE recalled the opposition expressed with regard to the draft Additional Protocol. The representatives of the European Disability Forum (EDF) and of the European Association of Service Providers for Persons with Disability (EASPD) also reiterated their position against the draft Protocol.

IV. Health literacy

14. Ambassador Stefanek, Special Representative of the Secretary General for Migration and Refugees presented his mandate and the Action Plan on Protecting Vulnerable persons in the context of migration and Asylum in Europe (2021 – 2025), underlining intersecting points with the work of the DH-BIO. He welcomed the offer to contribute the ongoing work of the DH-BIO in the fields of health literacy and access to treatment and equipment in a time of scarcity.
15. The Chair of the DH-BIO thanked Ambassador Stefanek for his presentation and congratulated him on the achievements of his mandate, especially the visibility brought to the Council of Europe’s work in protecting migrants and asylum seekers in Europe.
16. The Chair of the Drafting Group on health literacy, Assunta Morresi (I), presented the strategic objective and specific action concerning the preparation of a guide to health literacy for equitable access to healthcare. Consultant expert, Leena Paakkari (SF), presented the draft outline for the guide, underlining the intention of the drafting group to address all policymakers from across government agencies and authorities, not just healthcare. She also provided further information on the format and main features of the guide.
17. The Chair of the DH-BIO welcomed the progress of the drafting group and thanked the speakers for their presentations. She underlined the need for good practices to underpin the guide on health literacy and the desire for the drafting group to organise a targeted consultation on the preliminary draft guide, in early 2022. This was welcomed by delegations.

18. **DH-BIO delegations were invited to provide to the Secretariat at the latest by 1 December 2021:**

- **good practices examples of health literacy,**
- **any other written comments on the draft outline.**

V. Genome editing technologies

19. Anne Forus (N), Chair of the Drafting Group on genome editing recalled that the Committee at its 18th meeting had agreed to:

- Set up a drafting group to provide clarifications on the terms “preventive, diagnostic and therapeutic” and to avoid misinterpretation of the applicability of this provision to “research”.
- Publish the following communiqué:
“In accordance with its statement on gene editing technology adopted in December 2015 and its Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025); the Committee on Bioethics (DH-BIO) examined Article 13 of the Oviedo Convention in the light of developments in human genome editing. Taking into account the technical and scientific aspects of these developments as well as the ethical issues they raise, it considered that 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”.”

20. The Chair of the Drafting Group then presented the outcome of the discussions at the first meeting of the Drafting Group which focused namely on the scope of the work with which the Group had been entrusted. The few comments made by delegations will be taken into account by the Drafting Group.

21. **The delegations were invited to send to the Secretariat at the latest by Monday 29 November 2021, definitions of the terms “diagnostic”, “therapeutic” and “preventive” which exist at national level.** This invitation is also addressed to other intergovernmental organisations working in related fields, such as WHO.

VI. Children’s participation in decision-making on matters relevant to their health

22. The Secretariat has informed the Committee about the progress done with regard to the development of the Guide on children’s participation in the decision-making process on matters regarding their health as it is foreseen by the Strategic Action Plan.

23. The first meeting of the joint Drafting Group of the DH-BIO and CDENF is scheduled on 29 November 2021. The Secretariat introduced the composition of the group, as well as presented the timeline of the work ahead, including video production activity (“by children for children”) and children consultation process.

24. Delegations expressed general support for the planned approach of the work to be undertaken.

25. The Chair of the DH-BIO agreed to co-chair the drafting group together with the co-chair of the CDENF.

VII. Equitable access to scarce healthcare resources

26. Tomas Dolezal (CZ), Chair of the Drafting Group recalled the objectives of the work and presented the current structure of the preliminary draft guidelines and its key messages. He also presented the proposal to organise a targeted consultation on the preliminary draft guidelines in early 2022 in order for revised draft guidelines to be presented to the DH-BIO at its 20th plenary meeting.
27. Delegations welcomed the progress of the drafting group and the proposals. However, they suggested keeping the title in line with the original mandate of the work.
28. It was noted that it is essential to keep the draft instrument balanced between the need to provide practical details and the need to remain realistic, taking into account existing differences between the CoE member states, including in resources availability.
29. Several Delegations considered that making the guidelines a recommendation would increase the relevance and impact of this work. A decision will be taken at a later stage taking into consideration also the need to be timely in providing guidance to member states in the light of COVID19.
30. **Delegations were invited to provide at the latest by 1 December 2021:**
 - **Written comments on the preliminary draft guidelines, and**
 - **Suggestions of possible stakeholders to be contacted as part of the targeted consultation planned by the Drafting Group (e.g., international organisations, professional and patient organisations).**

VIII. Early intervention in intersex children

31. The Secretariat presented a concept note on the organisation of the seminar on relevant legislation and practices for the promotion of children rights with regard to early intervention on intersex children, identifying the following primary objectives of the event:
 - Raising awareness on ethical and human rights/children rights issues raised by early intervention on intersex children
 - Identifying legislation and sharing practices promoting children rights:
 - Examples of areas concerned
 - Training
 - Decision making process regarding early interventions
 - Accompanying/supporting measures
32. It was proposed to hold an in-person event at the Council of Europe on 31 May 2022, first day of the next plenary Session of the DH-BIO, in cooperation with CDEF and Sexual Orientation and Gender Identity Unit.
33. This was followed by an exchange of views among delegations and support of the concept note proposed.
34. Four delegations expressed their interest to become members of the preparatory group to organise the seminar. Two delegations formulated proposals concerning the seminar.
35. **All delegations are invited to share information regarding existing practices on early intervention on intersex children in their countries, as well as relevant contacts of potential speakers for the seminar before 20 December 2021.**

IX. Artificial intelligence

36. Brent Mittelstadt (UK), consultant, presented the draft study on AI in healthcare, its impact on the doctor-patient relationship, and how certain principles of the Oviedo Convention might be challenged (Appendix III).
37. Delegations expressed their general support for the work done and raised several issues to be considered by the consultant expert in the finalisation of his work. These included (i) bias in AI training datasets which are not representative of the context and diversity of patients, as well as automation bias in AI processes; (ii) reliance on AI in healthcare settings and the devaluation and/or displacement of healthcare professionals, prompting a call for a review of education and training of medical professionals; (iii) the right to privacy and the protection of personal data when AI identifies new correlations and findings attributable to individuals but which are not shared with them, and (iv) patient safety when AI is deployed, including the distribution of responsibility and liability in cases of medical error (e.g. when adjusting a patient's medication). In addressing such issues, reference was made to strengthening the composition of national and local ethics committees to include more diverse technical profiles with expertise in AI.
38. The Chair of the DH-BIO thanked Brent Mittelstadt and **invited delegations to send any written comments on the draft study to the Secretariat, at the latest by 1 December 2021.**
39. As regards membership of the new drafting group on AI, the Chair noted the expression of interest of one delegation. **She invited all other delegations to express interest in joining the group to the Secretariat, at the latest by 1 December 2021.**

X. Promoting dialogue on genomic medicine

40. Referring to the draft introductory note, the Chair of the Preparatory Group, Mélodie Bernaux (F), provided information on the results of its first meeting with reference to the context and framing of the action, the aims of which are to inter alia promote a common understanding of genomic medicine, to highlight the stakes at play, to identify good practice examples and to propose a way forward for the DH-BIO.
41. The Chair of the DH-BIO thanked the chair and members of the Preparatory Group for their work so far and **invited delegations to send to the Secretariat, at the latest by 1 December 2021, their replies to the following stocktaking questions and proposed structure for the workshop:**

Stocktaking questions:

- **Does public dialogue on genomic medicine exist in your country? If so, who are the stakeholders, what tensions do they raise, and what are the consequences in shaping any regulation?**

Proposed workshop sessions:

- **Introductory session on public dialogue concerning the collection and sharing of genomic data and its governance, and on the right to know or not to know the results of genomic testing.**
- **Second session (roundtable) concerning the different stakeholders involved in the articulation of public dialogue on genomic medicine – who are they, why do they matter and how to make their engagement count.**
- **Third session (roundtable) on the role played by the public in the development and regulation on genomic medicine.**

XI. Election to the Bureau

42. Ritva Halila (SF), Chair, and Siobhan O’Sullivan (IRL), Vice-Chair, were re-elected by acclamation for a new mandate of one year. Tomas Dolezal (CZ) was re-elected by acclamation to the Bureau, for a new mandate of two years.

XII. Decisions taken by the DH-BIO at its 19th meeting

43. In agreement with the delegations, the finalised list of decisions taken at the meeting is sent to the members of the Committee inviting them to comment by Monday 8 November at 14.00. Decisions are approved as no comments are received by the agreed deadline.

XIII. Dates of the next meetings

44. The DH-BIO agreed on the following dates for the next plenary meetings:
- 20th plenary meeting: 31 May-3 June 2022
 - 21st plenary meeting: 15-18 November 2022 [alternative 7-10 November 2022] (tbc)

XIV. Other business

a. Classification of documents

45. Delegations agreed, in principle, on changing the approach concerning the status of documents which, from now on, will be a priori public except for decisions by the Committee. The Secretariat will prepare a list of the different types of documents for discussion at the Bureau.

b. Round table on neurotechnologies

46. The Secretariat reported on progress regarding the organisation of the Round Table on human rights issues raised by the application of neurotechnologies, co-organised with the OECD with the participation of UNESCO, underlying the high number of existing registrations, and encouraging delegations to register for the event and to disseminate information about it.

c. Cooperation activities

47. The Secretariat briefly presented the main achievements of the cooperation project on the “Protection of Human Rights in biomedicine” in Armenia, including analyses of Armenian legislation corresponding with the main principles enshrined in the Oviedo Convention, work on the development of legislation for the establishment of an ethical committee and a code of ethics in Armenia, diagnostic study on human rights issues in emergency situations in Armenia including public health and humanitarian crises, as well as several launches of HELP courses on bioethics. The Project has applied for its extension in 2022.

d. Terms of reference proposal (2022-2025)

48. Delegations were informed about progress achieved in the examination of the draft terms of reference (ToR) for 2022 – 2025 which provides for a modification of the status of the Committee to become a steering committee.

e. Prohibition of financial gain

49. A delegation drew the attention of other delegations on issues raised in recommendations of the European society for human reproduction and embryology concerning gamete donations, with regard to the principle of prohibition of financial gain. It was recalled that this principle is addressed in the guide adopted by the DH-BIO, as well as by the CD-P-TO.

Appendix I
List of participants

MEMBERS / MEMBRES

ALBANIA / ALBANIE	Awaiting nomination / <i>Nomination en attente</i>
ANDORRA / ANDORRE	Mr David PÉREZ SURRIBAS apologised/excusé President of the National Committee of bioethics Ms Sansa NEUS VIVES
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 Mr Stefan SCHWAB Judge Ministry of Justice
AZERBAIJAN / AZERBAÏDJAN	Dr Ismayil S ZULFUGAROV Head of Proteomics Lab Institute of Molecular Biology and Biotechnologies of the Azerbaijan National Academy of Sciences
BELGIUM / BELGIQUE	Mr Paul COSYNS Vice-président de Comité consultatif de Bioéthique
BOSNIA AND HERZEGOVINA / BOSNIE-HERZÉGOVINE	Mr Dalibor PEJOVIC apologised/excusé Head of Unit for Statistics and Analytical Affairs and Reporting in Health Department for Health Ms Dunja ŠMITRAN apologised/excusée Ministry of Civil Affairs
BULGARIA / BULGARIE	Ms Sylvia TOMOVA apologised/excusée Chief Legal Advisor Legal Directorate Ministry of Health
CROATIA / CROATIE	Dr Vanja NIKOLAC apologised/excusée Head of Service, Service for blood, tissues and cells inspection Ministry of Health
CYPRUS / CHYPRE	Prof. Constantinos N. PHELLAS Chair of the Cyprus National Bioethics Committee University of Nicosia

CZECH REPUBLIC / REPUBLIQUE TCHEQUE	<p>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</p> <p>Ms doc. PhDr. Ing. Hana KONEČNÁ Ph.D., Jihočeská univerzita v Českých Budějovicích Zdravotně sociální fakulta, Katedra klinických a preklinických oborů</p>
DENMARK / DANEMARK	<p>Ms Cecilie KALTOFT AUGUSTINUS apologised/excusée Head of Section Ministry of Health</p> <p>Tuesday 2 November Ms Nina FJORD FROMBERG Danish Ministry of Health</p> <p>Wednesday 3 November Ms Anne Cathrine BOLLERUP Danish Patient Safety Authority</p> <p>Thursday 4 November Mr Lars PETERSEN Danish Ministry of Health</p>
ESTONIA / ESTONIE	<p>Dr Aime KEIS Assistant, Chief lecturer of medical ethics Faculty of Medicine University of Tartu</p>
FINLAND / FINLANDE	<p>Prof. Ritva HALILA Docent, Senior Medical Officer Ministry of Social Affairs and Health</p> <p>Ms Maija MIETTINEN Ministry of Social Affairs and Health</p> <p>Ms Mia SPOLANDER Legal Officer Unit for Human Rights Courts and Conventions, Legal Service Ministry for Foreign Affairs</p>
FRANCE	<p>Dr Mélodie BERNAUX Bureau bioéthique, produits et éléments du corps humain, de la politique des produits de santé et de la qualité des pratiques et des soins Ministère des solidarités et de la santé</p> <p>Ms Lucie BOZEC Bureau bioéthique, produits et éléments du corps humain, de la politique des produits de santé et de la qualité des pratiques et des soins Ministère des solidarités et de la santé</p> <p>Dr Jacques MONTAGUT Ancien membre du CCNE</p>

	<p>Mr Kamyar ASSARI Direction des affaires juridiques Sous-direction des droits de l'Homme Ministère de l'Europe et des affaires étrangères</p> <p>Mr Etienne MAKHLOUFI Stagiaire au Ministère de la Santé</p>
GEORGIA / GÉORGIE	<p>Prof. Givi JAVASHVILI Head of Family Medicine Department Tbilisi State Medical University Chairman of the National Council on Bioethics</p>
GERMANY / ALLEMAGNE	<p>Prof. Dr. Elmar DOPPELFELD Honorary Chair of the "Permanent Working Party of Research Ethics Committees in Germany Inc."</p> <p>Mr Carlo GRIMM Division 611 Federal Ministry of Education and Research</p> <p>Dr Ingo HÄRTEL Division 316 Federal Ministry of Health</p> <p>Prof. Dr. Dr. Thomas HEINEMANN Philosophical-Theological University of Vallendar (PTHV)</p> <p>Dr Judith MENTGEN Head of Division III B 6 German Federal Ministry of Justice and Consumer Protection</p>
GREECE / GRECE	<p>Prof. Andreas KARABINIS Intensivist, Professor of Emergency Medicine Athens Medical School National and Kapodistrian University of Athens</p>
HUNGARY / HONGRIE	<p>Prof. Ernő BÁCSY MD, PhD, DSc, Medical Research Council of Hungary</p>
ICELAND / ISLANDE	<p>Mr Rögnvaldur G. GUNNARSSON Legal Advisor Ministry of Welfare</p> <p>Ms Thorunn STEINSDOTTIR Legal Advisor Ministry of Welfare</p>
IRELAND / IRLANDE	<p>Dr Siobhan O'SULLIVAN Chief Bioethics Officer An Roinn Sláinte Department of Health Teach Hawkins</p>

ITALY / ITALIE	<p>Prof. Assunta MORRESI Prof. Associato di Chimica Fisica, Dipartimento di Chimica, Biologia e Biotecnologi Università degli Studi di Perugia</p> <p>Prof. Laura PALAZZANI Lumsa, Facoltà di giurisprudenza Roma</p>
LATVIA / LETTONIE	<p>Dr Vents SĪLIS Assistant Professor at Riga Stradins University Department of Humanities</p>
LIECHTENSTEIN	Awaiting nomination / <i>Nomination en attente</i>
LITHUANIA / LITUANIE	<p>Dr Asta ČEKANAUSKAITĖ Director of Lithuanian Bioethics Committee</p>
LUXEMBOURG	<p>Ms Julie-Suzanne BAUSCH Présidente de la Commission nationale d'éthique</p>
MALTA / MALTE	<p>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</p>
REPUBLIC OF MOLDOVA / RÉPUBLIQUE DE MOLDOVA	<p>Ms Rodica GRAMMA Associate Professor State University of Medicine and Pharmacy (USMF)</p>
MONACO	<p>Mr Xavier RAUSCHER Administrateur Juridique Service du droit International, des droits de l'homme et des libertés fondamentales</p>
MONTENEGRO / MONTÉNÉGRO	<p>Ms Olivera MILJANOVIC Prim. doc., Director Centre for Medical Genetics and Immunology Medical Centre of Montenegro</p>
NETHERLANDS / PAYS-BAS	<p>Mr Harrie STORMS Ministry of Health, Welfare and Sports</p> <p>Ms Sanne VAN WEEZEL Ministry of Health, Welfare and Sports</p>
NORTH MACEDONIA / MACÉDOINE DU NORD	<p>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</p>

NORWAY / NORVEGE	<p>Ms Anne FORUS Senior Adviser, ph.d, Biotechnology and health legislation department Division of specialised health care services Norwegian Directorate of Health</p> <p>Ms Vårin HELLEVIK Department of Specialized Mental health care and Addiction Treatment Norwegian Directorate of Health</p>
POLAND / POLOGNE	<p>Ms Mariola GROCHULSKA Département des droits de l'homme Ministère de la Justice</p>
PORTUGAL	<p>Prof. Jorge SOARES Président du Conseil National d'Ethique pour les Sciences de la Vie</p>
ROMANIA / ROUMANIE	<p>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</p> <p>Mrs Beatrice Gabriela IOAN Associate Professor President of the Bioethics Commission of the Romanian College of Physicians Institutul de Medicina Legala</p>
RUSSIAN FEDERATION / FÉDÉRATION DE RUSSIE	<p>Ms Lyalya GABBASOVA Assistant to the Minister Ministry of Health</p> <p>Ms Leyla NAMAZOVA-BARANOVA</p> <p>Ms Daria KHUKHREVA Ministry of Health</p> <p>Ms Olga OPANASENKO Counsellor Department of the Humanitarian Cooperation and Human Rights Ministry of Foreign Affairs</p>
SAN MARINO / SAINT-MARIN	<p>Dr Luisa BORGIA President of the National Bioethics Committee</p>
SERBIA / SERBIE	<p>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</p>

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 Dr.Med.
SPAIN / ESPAGNE	Ms Concepción MARTIN ARRIBAS Subdirección General de Investigación en Terapia Celular y Medicina Regenerativa Instituto de Salud Carlos III – ISCIII Prof. Carlos M. ROMEO – CASABONA Professor of Penal Law, Head Inter-University Chair in Law and the Human Genome
SWEDEN / SUÈDE	Ms Tesi ASCHAN Legal Adviser The National Board of Health and Welfare, Socialstyrelsen
SWITZERLAND / SUISSE	Prof. Dr. Rodrigo RODRIGUEZ Département fédéral de justice et police DFJP Office fédéral de la Justice OFJ, Domaine de direction Droit privé Ms Nina SCHERRER Wissenschaftliche Mitarbeiterin Sektion Forschung am Menschen, Eidgenössisches Departement des Innern EDI, Bundesamt für Gesundheit BAG, DB Öffentliche Gesundheit, Abteilung Biomediz
TURKEY / TURQUIE	Prof. Ergun ÖZSUNAY apologised/excused Professor of Civil Comparative Law and EU Private law Istanbul Culture University, Faculty of Law Ms Tuna İLBARS apologised/excused Unit Coordinator Department of Blood and Blood Products Directorate General of Health Services Ministry of Health
UKRAINE	Ms Iuliia DAVYDOVA Professor, Head of High-Risk Pregnancy Department Institute of Pediatrics, Obstetrics and Gynecology, member of Local Bioethics Committee Prof. Olesya HULCHYI Vice-Rector Shupyk National Medical Academy of Postgraduate Education
UNITED KINGDOM / ROYAUME-UNI	Dr Mark BALE Deputy Director Health Science & Bioethics Division Department of Health

	<p>Dr Pete MILLS Assistant Director Nuffield Council on Bioethics</p>
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PARTICIPANTS / PARTICIPANTS

<p>PARLIAMENTARY ASSEMBLY / ASSEMBLÉE PARLEMENTAIRE</p>	<p>Ms de BRUIJN WEZEMAN Rapporteur on the deinstitutionalisation of people with disabilities</p> <p>Ms Anita GHOLAMI Committee on Social Affairs, Health and Sustainable Development</p> <p>Mr Jean-Pierre GRIN Conseiller national (Suisse)</p> <p>Ms Dana KARANJAC apologised/excusée Committee on Culture, Science, Education and Media</p> <p>Ms Tanja KLEINSORGE Head of Secretariat Committee on Social Affairs, Health and Sustainable Development</p>
<p>OFFICE OF THE COMMISSIONER FOR HUMAN RIGHTS / BUREAU DU COMMISSAIRE AUX DROITS DE L'HOMME</p>	<p>Mr Hasan BERMEK Adviser</p>
<p>SRSG'S OFFICE / BUREAU DU RSSG</p>	<p>Mr Drahoslav ŠTEFANEK Special representative of the Secretary General for migration and refugees / Représentant spécial de la Secrétaire Générale sur les migrations et les réfugiés</p> <p>Mr Vedran IAN-KJELDEN Senior Programme Officer</p> <p>Mr Benoit OLRV Trainee</p>
<p>CDCJ</p>	<p>Prof. Dr. Rodrigo RODRIGUEZ Département fédéral de justice et police DF Office fédéral de la Justice OFJ Domaine de direction Droit privé</p>
<p>CPT</p>	<p>Mr Michael NEURAUTER apologised/excusé Head of Division of the Secretariat of CPT</p>
<p>T-PD</p>	<p>Awaiting nomination / <i>Nomination en attente</i></p>
<p>CDENF</p>	<p>Ms Katrin UERPMANN apologised/excusée Secretary of the Steering Committee for the Rights of the Child</p>

CD-P-TS	Awaiting nomination / <i>Nomination en attente</i>	
CD-P-TO	Ms Marta LOPEZ-FRAGA Secretary	apologised/excusée

OTHER PARTICIPANTS / AUTRES PARTICIPANTS

EUROPEAN UNION / UNION EUROPEENNE	Awaiting nomination / <i>Nomination en attente</i>	
EUROPEAN COMMISSION / COMMISSION EUROPEENNE	Dr Jim DRATWA Head of Ethics and Head of the EGE Secretariat Member of the Bureau of European Policy Advisers (BEPA) European Commission Ms Mariann KARCZA	
CONFERENCE OF INGOS / CONFERENCE DES OINGS	Mr Miguel CABRAL	apologised/excusé
CANADA	Awaiting nomination / <i>Nomination en attente</i>	
HOLY SEE / SAINT-SIEGE	Mgr Jacques SUAUDEAU	
JAPAN / JAPON	Awaiting nomination / <i>Nomination en attente</i>	
MEXICO / MEXIQUE	Ms Berenice CRUZ MAYA Directrice du Développement Institutionnel à la Commission Nationale de Bioéthique Mr Gustavo Fernando OLAIZ BARRAGAN Sous-directeur des Politiques Publiques et de Bioéthique à la Commission Nationale de Bioéthique Mr Eden GONZALEZ Commission Nationale de Bioéthique	
USA / ETATS-UNIS D'AMERIQUE	Awaiting nomination / <i>Nomination en attente</i>	
UNESCO	Ms Dafna FEINHOLZ KLIP Section de la bioéthique Division de l'éthique des sciences et des technologies	apologised/excusée
OECD / OCDE	Mr David WINICKOFF STI/STP Ms Laura KREILING	apologised/excusé apologised/excusée
WHO / OMS	Dr Andreas REIS Technical Officer HIS/KER Cluster of Health Systems and Innovation	

	Dr Katherine LITTLER Global Health Ethics, Health Systems and Innovation Cluster
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OBSERVERS / OBSERVATEURS

BELARUS / BELARUS	<p><u>Mr Andrei BABCHANOK</u> <u>Head of Legal Department</u> <u>Ministry of Health</u></p> <p><u>Ms Tatyana DOKUKINA</u> <u>Deputy Director for Science of the Republican Scientific and Practical Center for Mental Health</u></p> <p>Ms Valerya SOKOLCHIK Dean of the Department of Public Health and Healthcare Management Belarusian Medical Academy of Post-Graduate Education</p>
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<p>THE INTERPRETING, TRAVEL, EVENTS AND MULTIMEDIA DEPARTMENT (ITEM) / LE SERVICE DE L'INTERPRETATION, DES VOYAGES, DES EVENEMENTS ET DU MULTIMEDIA (ITEM)</p>	<p>Ms Amanda BEDDOWS Interpreter / <i>Interprète</i></p> <p>Mr Jean-Jacques PEDUSSAUD Interpreter / <i>Interprète</i></p> <p>Ms Corinne McGEORGE (2/11) Interpreter / <i>Interprète</i></p> <p>Mr Jan KROTKI (3-4/11) Interpreter / <i>Interprète</i></p>

Appendix II
Agenda

Tuesday 2 November 2021 (9.30-13.00)

09.30-09.50	<p>1. Adoption of the draft agenda</p> <ul style="list-style-type: none"> ○ New DH-BIO members invited to introduce themselves ○ Reminder about the main decisions to be taken during the meeting
09.50-10.30	<p>2. Collection of examples of good practices aiming at promoting voluntary measures in mental health care</p> <p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ <i>Presentation of the compendium by Dr Piers Gooding (Australia), Consultant, and its online version</i> ○ Decision: <i>Agreement on the publication of the compendium and its dissemination (including in non-official languages)</i>
10.30-11.30	<p>3. Protocol concerning the protection of human rights and dignity of persons with regard to involuntary placement and involuntary treatment within mental health care services</p> <p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ Decision <i>to present the draft Additional Protocol to the Committee of Ministers with a view to a decision</i> <i>Following a comprehensive drafting process and a thorough and extensive consultation process, it is proposed that the draft additional protocol (doc. DH-BIO(2019)20 REV4) be presented to the Committee of Ministers for decision. Delegations will be asked to indicate if they are in agreement with this proposal and will be invited to register their electronic vote as yes, no or abstain</i> ○ <i>Examination of the draft Explanatory Report with a view to its finalisation by the Secretariat</i>
11.30-13.00	<p>4. Health literacy</p> <p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ <i>Presentation by Mr Stefanek, Special Representative of the Secretary General for migration and refugees, on the relevance of the subject for the Action Plan on Protecting Vulnerable persons in the context of migration and Asylum in Europe (2021 – 2025)</i> ○ <i>Presentation of the work of the Drafting group by its Chair, Assunta Morresi (IT), as well as Leena Paakkari (consultant)</i> ○ <i>Exchange with delegations on the draft outline with a view to providing any guidance to the Drafting Group</i> <p><i>(NB: SAP timeline: Guide to be finalised in November 2022)</i></p>




Wednesday 3 November 2021 (9.30-13.00)

09.30-10.30	<p>5. Genome editing technologies</p> <p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ <i>Presentation by Anne Forus (NO), Chair of the Drafting Group, on the progress made by the Drafting Group</i> ○ <i>Exchange with delegations with a view to give possible guidance to the Drafting Group</i>
10.30-10.50	<p>6. Children's participation in the decision-making process on matters regarding their health</p> <p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ <i>Overview of the ongoing work by the Secretariat</i> <p><i>(NB: SAP timeline: Guide to be finalised in Autumn 2022)</i></p>
10.50-12.00	<p>7. Equitable access to scarce healthcare resources</p> <p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ <i>Presentation by Tomas Dolezal (CZ), Chair of the Drafting Group, of preliminary draft guidelines on equitable access to scarce healthcare resources</i> ○ <i>Exchange with delegations on the document with a view to give guidance to the Drafting Group, including the methodology foreseen by the Group</i> <p><i>(NB: SAP timeline: Draft instrument to be finalised by End of 2022)</i></p>
12.00-12.30	<p>14. Other business</p> <ol style="list-style-type: none"> a. Classification of documents: reconsideration of the current practices in accordance with the CM Recommendation b. Round table on neurotechnologies jointly organised with OECD, to be held on 9 November 2021 c. Cooperation activities <ul style="list-style-type: none"> - Armenia Action Plan d. Terms of reference proposal (2022-2025) – Information CM discussion with a view to the adoption of the budget and programme of activities e. SAP: Updated methodology and time frame for the priority actions planned
12.30-12.45	<p>13. Dates of the next meetings</p> <ul style="list-style-type: none"> ○ <i>20th meeting of the DH-BIO: 31 May-3 June 2022</i> ○ <i>21st meeting of the DH-BIO: proposal 15 -18 November 2022</i>

Thursday 4 November 2021 (9.30-13.00)

09.30-10.15	<p>8. Early intervention on intersex children</p> <p>Objectives:</p> <ul style="list-style-type: none">○ Presentation of the draft concept note○ Exchange with delegations on the draft○ Setting up of an organisation group for the seminar: call for expression of interest <p>(NB: SAP timeline: Seminar to be held on 31 May 2022)</p>
10.15-11.15	<p>9. Artificial intelligence</p> <p>Objectives:</p> <ul style="list-style-type: none">○ Presentation of the draft study prepared Prof. Brent Mittelstadt (UK), Consultant○ Exchange with the delegations with a view to the finalisation of the report○ Setting up of a Drafting group to prepare a report: call for expression of interest <p>(NB: SAP timeline: Report to be finalised in 2024)</p>
11.15-12.00	<p>10. Promoting dialogue on genomic medicine</p> <p>Objectives:</p> <ul style="list-style-type: none">○ Presentation of the draft introductory note by the Chair of the Preparatory Group, including approach proposed for the preparation of the workshop○ Exchange with delegations on the draft introductory note <p>(NB: SAP timeline: Workshop to be held in November 2022)</p>
12.00-12.15	<p>11. Bureau elections</p> <p>Objectives: Election of Chair and Vice-Chair as well as one Bureau member</p> <ul style="list-style-type: none">○ Chair and Vice-Chair first term of one year is coming to an end: both are re-eligible for another term of one year○ Bureau member: JUDr. Tomáš Dolezal (Czech Republic) first term of two years comes to an end: re-eligible for another term of two years
12.15-13.00	<p>12. Decisions taken by the DH-BIO at its 19th meeting</p> <ul style="list-style-type: none">○ Approval of the list of decisions

POINTS TO BE DEALT WITH IN WRITING

	<p>15. Developments in the field of bioethics</p> <p>Delegations, including observers, are invited to send information in writing.</p> <ol style="list-style-type: none">Developments in member states and other statesDevelopments in the field of bioethics in international organisationsDevelopments in other Council of Europe bodiesDevelopments at the European Court of Human Rights
	<p>16. 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</p>
	<p>17. Cooperation with other committees</p> <ol style="list-style-type: none">European Committee on Organ Transplantation (CD-P-TO)European Committee on Blood Transfusion (CD-P-TS)Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)Steering Committee for the Rights of the Child (CDENF)Steering Committee for Legal Cooperation (CDCJ)