COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Strasbourg, 20 May 2015 **DH-BIO/ abr RAP 7**

COMMITTEE ON BIOETHICS

(DH-BIO)

7th MEETING
Strasbourg, 4-7 May 2015

ABRIDGED REPORT

Adoption of the agenda

1. The Committee on Bioethics (DH-BIO) held its 7th meeting in Strasbourg from 4 to 7 May 2015. The agenda of the meeting and the list of participants appear in Appendix I and Appendix II to this abridged report.

2. On 4-5 May, the Conference on Emerging Technologies and Human Rights was held under the auspices of the Belgian Chairmanship of the Committee of Ministers of the Council of Europe. The programme of the conference appears in Appendix III to this abridged report. The video recording of the conference is available on line: www.coe.int/bioethics.

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 Purposes

3. The DH-BIO took note of the information sent in written form on the current process towards signature and/or ratification of the Oviedo Convention and/or its Additional Protocols in some member or observer states.

Developments in the field of bioethics

4. The DH-BIO took note of the developments in the field of bioethics within the member states, as well as in international organisations. It was also informed of the relevant developments in other Council of Europe bodies.

Predictivity, genetic testing and insurance

5. The Committee examined the draft Recommendation prepared by the Rapporteur, in cooperation with the Secretariat, in the light of the comments received by delegations. Some minor editorial changes were agreed.

6. Two delegations informed the Committee that they would only be able to provide possible comments after the meeting.

7. **Delegations were invited to send their possible comments on the draft Recommendation as well as the draft explanatory memorandum in writing by 1 July 2015.**

8. In the light of the comments received, the Rapporteur, in cooperation with the Secretariat, will prepare a revised version of the Draft Recommendation to be examined by the DH-BIO for finalisation at its 8th plenary meeting and its subsequent submission to the CDDH. With a view to the latter and the examination of the text by the CDDH, delegations were invited to contact the delegates to CDDH and to provide relevant information about the draft Recommendation.

Re-examination of Recommendation (2006) 4 on research on biological materials of human origin

9. The Committee examined the draft revised Recommendation as modified by the Drafting Group in the light of the comments received during the public consultation carried out in March-August 2014 and taking into account the opinion from the T-PD.

10. **The delegations made a number of comments, that they were invited to submit in written form as well as possible complementary comments, where appropriate accompanied by drafting proposals by 1 July 2015.**

11. **Delegations were also invited to make comments on the elements for the Explanatory Memorandum by 1 July 2015.**

12. The Drafting Group was entrusted with the task of preparing a revised version of the draft Recommendation in the light of the comments from delegations, to be examined by the DH-BIO

at its 8th plenary meeting (December 2015) with a view to its approval and subsequent presentation to the Committee of Ministers for adoption.

13. The Secretariat was entrusted with the task of preparing a revised draft Explanatory Memorandum in the light of the comments from delegations, to be presented to the DH-BIO 8th plenary meeting (December 2015).

Additional Protocol on the protection of the human rights and dignity of persons with mental disorders with regard to involuntary placement and involuntary treatment

14. The Committee examined the preliminary draft Additional Protocol as modified by the Drafting Group in the light of the comments made by delegations at its 6th meeting (12-14 November 2014). A number of changes were made to the text.

15. The DH-BIO agreed to launch an open public consultation process on the revised draft Additional Protocol as a working document. A request for comments would be specifically sent, to the Council of Europe Committee of Experts on the Rights of People with Disabilities (DECS-RPD), the Conference of International Non-Governmental Organisations and the Commissioner for Human Rights, as well as to the Office of the High Commissioner for Human Rights of the United Nations and the Fundamental Rights Agency of the European Union.

16. National delegations may also wish to send specific requests to relevant experts, bodies, organisations at national level (ensuring, where necessary, translation into one of the two official languages i.e. English or French, of any comments received).

17. The consultation would be held from June to mid-November 2015. The Secretariat was entrusted with preparing the cover letter in cooperation with the Chair of the Drafting Group and of the DH-BIO.

DEBRA

18. The DH-BIO was informed that, at the request of Serbian authorities, a bilateral seminar will be organised in the second part of 2015, on emerging technologies in particular in the field of genetics.

Working methods and future activities

Follow up to the Conference on emerging technologies and human rights

19. Following the Conference held on 4-5 May 2015, the Bureau was entrusted with the task of making proposal(s) to the DH-BIO on the approach to be followed for the preparation of the White Paper based on the outcome of the conference.

Terms of reference

20. The DH-BIO examined its draft terms of reference for the 2016-2017 biennium prepared on the basis of the activity proposals for that period agreed at its 6th plenary meeting (12-14 November 2014). It agreed to insert a reference to emerging technologies under the expertise of the members, and to include the Council of Europe Commissioner for Human Rights and Conference of International Non-Governmental Organisations in the list of participants invited to send a representative(s).

21. The draft ToR as revised (see Appendix IV) were approved and will now be submitted to the CDDH with a view to its examination at its next plenary meeting (17-19 June 2015).

Other business

Follow up to the Statement on the prohibition of financial gain

22. The Committee took note that a “horizon scanning meeting” on the prohibition of financial gain had taken place in Paris on 16 December 2014, as a follow up to the Declaration adopted in May 2014 by the DH-BIO and CD-P-TO on the prohibition of any form of commercialisation of human organs. The experts invited had acknowledged that challenges to the principle of Article

21 (prohibition of financial gain) should be addressed. The need to have more clarity on the definitions of key terms, such as “payment”, “incentives” and “compensation” was in particular underlined as a priority issue.

23. The DH-BIO agreed with the Bureau on the relevance of the issues raised, which relate directly to one of the fundamental principles of the Oviedo Convention. It supported the proposal from the Bureau to give priority to the clarification on definitions of relevant terms as underlined at the meeting.

24. To that end and so as to benefit from possible existing work, **delegations were invited to provide information by 1 July 2015, on any possible work undertaken at national level about the framing of the notions of “compensation”, “payment" and “incentives” and other terms relevant to the principle of non commercialisation of the human body and its parts, as such.**

25. The Bureau will then make possible concrete proposal(s) for action which could include the possibility of establishing a drafting group to develop elements of clarification on the definition of relevant terms, in which other relevant committees and organisations could be invited to participate in particular, CD-P-TO, CD-P-TS, WHO and the European Commission.

Cooperation with other Committees

26. The Chair of the DH-BIO will send a letter to the newly elected Chair of the CD-P-TO proposing to meet her with a view to discuss way(s) to ensure efficient cooperation on any future project.

HELP programme

27. **In view of developing an outline for a specific course on bioethical principles in the framework of the European Programme for Human Rights Education of Legal Professionals (HELP), delegations were invited to send relevant national case law (where possible with an internet reference) on bioethical issues by 20 September 2015.**

28. The aim of this exercise is to identify specific areas which are of particular relevance for legal professionals such as judges, public prosecutors and lawyers. It was thus not required to provide a detailed analysis of the legal reasoning used by domestic courts, but rather information on the type of questions on bioethical issues arising in legal practice.

Seminar on the case law of the European Court of Human Rights relevant to bioethical issues

29. The DH-BIO supported the proposal to organize, by the end of 2016 beginning of 2017, a seminar on the case law of the European Court of Human Rights relevant to bioethics as part of the preparation of the Conference to be held in 2017, on the occasion of the 20th anniversary of the Oviedo Convention.

30. A rapporteur, in cooperation with the Secretariat and the Bureau of the DH-BIO, will be in charge of the preparation of the seminar. **DH-BIO members who would be interested by this task were invited to inform the Secretariat.**

Direct to consumer genetic testing

31. Given its heavy workload for 2015, the DH-BIO decided to postpone the organisation of an international round table on direct to consumer genetic testing initially foreseen in the second part of the year. It also agreed to reconsider its scope which might need to be broadened in the light of the outcome of the Conference on Emerging Technologies and Human Rights.

Re-examination of the Additional Protocol concerning Biomedical Research

32. In accordance with Article 35 of the Additional Protocol concerning Biomedical Research, the latter should have been re-examined in 2012. However, at its 1st meeting (19 – 22 June 2012), the DH-BIO considered that “a re-examination of the Protocol would be premature at this stage. In the light of the imminent review of Recommendation Rec (2006) 4 on research on biological materials of human origin, the Committee had agreed to postpone the re-examination of the Protocol and to reconsider it in three years i.e. 2015.” Accordingly, the point will be on the agenda of the 8th plenary meeting.

Gene editing

33. The DH-BIO referred to the ethical implications raised by the possible applications on human embryo and germline of a new technology (CrisprCas9) making it possible more easily and precisely to modify genetic characteristics and to the recent public debate on these issues. Reference was made, in this context, to the principles laid down in Article 13 of the Oviedo Convention applicable to interventions on the human genome.

34. **Delegations were invited to send, by 15 June 2015, information on the situation in their countries as regards the use of this technology i.e. CRISPR-Cas9, in particular with a view to the possible modification of the genetic characteristics of an embryo or germline, in the light of Article 13 of the Oviedo Convention.**

Other topical issues

35. The DH-BIO held a short discussion on two new issues identified by respectively in the context of the preparation of the next Council of Europe Strategy for the Rights of the Child (2016-2019), and by a delegation, which raised important ethical questions: (i) Transgender and intersex children, and (ii) Gender aesthetic surgery.

36. **Delegations were invited to provide information on possible current work undertaken at national level with regard to both of these matters by 1 July 2015.**

Dates of the next meetings

37. The DH-BIO agreed on the following dates for its next meetings:

- 8th meeting of the DH-BIO: 1-4 December 2015
- 9th meeting of the DH-BIO: 31 May-3 June 2016 (alternative 17-20 May 2016)

38. The DH-BIO took note that the Bureau would hold its next meeting on 12-14 October 2015, which would include a joint session with the Biobanks Drafting Group, as well as a specific session devoted to the follow up to the Conference on Emerging Technologies and Human Rights.

APPENDIX I

Agenda

4 May 2015 (9.00 – 18.00) - 5 May 2015 (9.00 - 13.00)

"EMERGING TECHNOLOGIES AND HUMAN RIGHTS"

International conference

Items for information, without decision required by the DH-BIO, are indicated by the following symbol: 

1. Adoption of the agenda

2. 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 Purposes

3. Developments in the field of bioethics

Delegations, including observers, are invited to send information **in writing**.

a. Developments in the field of bioethics in member states and other states
b. Developments in the field of bioethics in international organisations
c. Developments in the field of bioethics in other Council of Europe bodies
d. Developments in the field of bioethics at the European Court of Human Rights

4. Predictivity, genetic testing and insurance

- Presentation of:

- the revised draft Recommendation on the processing for insurance purposes of personal health-related data, in particular data resulting from genetic tests;
- the draft Explanatory Memorandum to the Recommendation.

- Early exchange on the revised drafts:

Delegations will be invited to indicate any possible remaining difficulties with the draft Recommendation. Indicative vote may be considered with a view to the finalisation of the draft Recommendation at the 8th plenary meeting (1-4 December 2015) and its subsequent presentation to the CDDH for approval.

5. Re-examination of Recommendation (2006) 4 on research on biological materials of human origin

Examination of the draft Recommendation revised in the light of the comments received during the public consultation, as well as the opinion of the T-PD with a view to its approval at the 8th plenary meeting (1-4 December 2015) and subsequent presentation to the Committee of Ministers for adoption.

6. Additional Protocol on the protection of the human rights and dignity of persons with mental disorders with regard to involuntary placement and involuntary treatment

- Examination of the draft Additional Protocol revised by the Drafting Group in the light of the comments made by delegations.
- Decision on the proposal of the Bureau to launch consultations on the draft Additional Protocol as a working document.

7. Cooperation programme (DEBRA)

- Information on the Conference on Emerging Technologies to be held in Belgrade, Serbia in the 2nd half of 2015, in cooperation with the Serbian authorities.
- Delegations wishing to organise DEBRA activities in 2016 are invited to send their written request by 10 November 2015 at the latest.

8. Working methods and future activities of the DH-BIO

- Follow up to the Conference on "Emerging Technologies and Human Rights"
- Biennium 2016 – 2017: Draft Terms of Reference of the DH-BIO

9. Relations with other international bodies

10. Dates of the next meetings

Dates proposed:
8th meeting of the DH-BIO: 1-4 December 2015
9th meeting of the DH-BIO: 31 May – 3 June 2016 / 17 – 20 May 2016

11. Other business

a. Follow up to the Statement on prohibition of financial gain under Article 21

b. Cooperation with other Committees

i) Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)

ii) Ad hoc Committee on Data Protection (CAHDATA)

iii) European Committee on Organ Transplantation (CD-P-TO)
- Follow up to the Declaration on the Prohibition of any form of commercialisation of human organs

iv) European Committee on Blood Transfusion (CD-P-TS)

12. Decisions taken by the DH-BIO at its 7th meeting

Approval of the list of decisions.

APPENDIX II

List of participants

MEMBER STATES / ETATS MEMBRES

Albania/Albanie - **apologised/excusé**

Andorra/Andorre – Mr Pere PASTOR VILANOVA, Juge, Cour Suprême de Justice, Avda de Tarragona, AD 500 Andorra la Vella, Andorra

Armenia/Arménie – Mr Igor MADOYAN, Phd, President of National Center of Bioethics, n.24, ave Sayat-Nova, apt. 14, entrance 1, 0001 YEREVAN

Austria/Autriche – Dr Renate FALLY-KAUSEK, Medical Officer, Federal Ministry of Health, Department III/8– Health of children and young people, gender aspects, nutrition, Radetzkystrasse 2, A-1030 WIEN

Dr. Doris WOLFSLEHNER, Head of the division "Bioethics" at the Federal Chancellery of the Republic of Austria, Ballhausplatz 2, 1014 Wien

Dr. Peter BARTH, Oberstaatsanwalt, Abteilungsleiter-Stellvertreter in der Zivilrechtssektion, 1070 Wien, Museumstraße 7,Wien **apologised/excusé**

Azerbaijan/Azerbaïdjan – Dr Alamadar MAMMADOV CHARKAZ (PhD), Head of lab Structure and Expression of Genome of FPBP of Institute Botany of ANAS, 3. AZ1073, Baku, 40 Badamdar highway, Institute of Botany

Belgium/Belgique – Mme Régine WILMOTTE, Juriste au sein de la direction générale des Etablissements de Soins du Service public fédéral « Santé publique », Place Victor Horta 40, boite 10, 1060 Bruxelles

Bosnia and Herzegovina/Bosnie-Herzégovine – Dr. Serifa GODINJAK, Head of Department for European Integration and International Cooperation, Sector for Health, Ministry of Civil Affairs, Trg BiH 1, 71000 Sarajevo, Bosnia and Herzegovina

Bulgaria/Bulgarie – Ms Sylvia TOMOVA, Ministry of Health, Legal Directorate, Chief Legal Advisor, Place St Nedelia 5, Sofia 1000

Croatia/Croatie – Dr. Vanja NIKOLAC, Head of Service, Service for blood, tissues and cells inspection, Ministry of Health, Ksaver 200a, 10 000 Zagreb, Croatia

Cyprus/Chypre – Mrs Rena PETRIDOU-VRAHIMI, Attorney of the Republic of Cyprus, Office of the Attorney General of the Republic of Cyprus, Appeli Street n° 1, 1403 NICOSIA **apologised/excusée**

Czech Republic/République Tchèque – Pr. Pavel MARTASEK, Professor of Medicine, Expert on Genetics, Dept. of Pediatrics, Center for Applied Genomics, 1st School of Medicine, Charles University, Ke Karlovu 2, Building D /2nd floor, 128 08 PRAGUE 2

Denmark/Danemark – Mrs Birgitta WINKLER, Special Advisor, Hospital Policy, Ministry of Health, 6, Holbergsgade, DK-1057 Copenhagen K

Estonia/Estonie – Prof Hele EVERAUS, Head of the Clinic, Haematology and Oncology Clinic, Tartu University, Tartu University Hospital, Puusepa 8, 51014 Tartu

Finland/Finlande – Ritva HALILA, M.D., Ph.D., Senior Medical Officer, National Advisory Board on Social Affairs and Health Care (ETENE), Ministry of Social Affairs and Health, P.O. Box 33, FI-00230 Government

Mia SPOLANDER, Legal Officer, Ministry for Foreign Affairs, Unit for Human Rights Courts and Conventions (OIK-40), P.O. Box 411, (Laivastokatu 22), 00023 Valtioneuvosto **apologised/excusée**

France - M. Rodolphe FERAL, Sous-direction des droits de l'homme, Direction des affaires juridiques, Ministère des affaires étrangères et européennes, 57, bd des Invalides, 75700 Paris

Mme Isabelle ERNY, Attachée principale d'administration centrale, Ministère de la Santé, Direction Générale de la Santé, Secrétariat Général, Division droit, éthique et appui juridique, 14 avenue Duquesne, 75350 PARIS 07 SP

Dr Jacques MONTAGUT, Directeur de l'IFREARES, 20 route de Revel, 31400 TOULOUSE

Tania JEWCZUK, Magistrat, Bureau du droit des personnes et de la famille, Direction des affaires civiles et du sceau, Ministère de la Justice

Georgia/Géorgie – Dr Givi JAVASHVILI, Head of Family Medicine Department, State Medical Academy of Georgia, Chairman of the National Council on Bioethics, 29 I. Chachavadze Avenue, 0179 TBILISI

Germany/Allemagne – Mrs Andrea MITTELSTÄDT, Federal Ministry of Justice and Consumer Protection, Division III B 2, Mohrenstraße 37, D-10117 Berlin

Prof. Elmar DOPPELFELD, Honorary Chair of the Permanent Working Party of Research Ethics Committees in Germany Inc., Lenaustraße 15, D-50858 Köln

Prof. Thomas HEINEMANN, Philosophical-Theological University of Vallendar (PTHV), Pallottistraße 3, D-56179 Vallendar

Dr. Ingo HÄRTEL, Federal Ministry of Health, Division 313, Friedrichstraße 108, D-10117 Berlin

Dr. Daniela von BUBNOFF, Federal Ministry of Education and Research, Division 612, Friedrichstraße 130 B, D-10117 Berlin

Dr. Mareike MEIER, Federal Ministry of Justice and Consumer Protection, Division III B 2, Mohrenstraße 37, D-10117 Berlin

Greece/Grèce – Dr Stamatia GARANIS-PAPADATOS, Lecturer, National School of Public Health, 196 Alexandras Avenue, 11521 Athens

Hungary/Hongrie - Prof. Ernö BÁCSY, MD, PhD, DSc, advisor of the Presidency, Medical Research Council of Hungary (ETT), H-1051 Budapest, Arany János utca 6-8

Iceland/Islande – Asa Thorhildur THORDARDOTTIR, Legal Advisor, Ministry of Welfare, Hafnarhúsinu við Tryggvagötu, 101 Reykjavík

Ireland/Irlande – Paul IVORY, Bioethics Officer, CMO's Office, Department of Health, Hawkins Street, Dublin 2

Ms Angela O'FLOINN, Dept of Health, Hawking House, Dublin 2 **apologised/excusée**

Dr. Siobhán O'SULLIVAN, Chief Bioethics Officer, Dept. of Health, Hawkins House, Dublin **apologised/excusée**

Italy/Italie - Laura PALAZZANI, Lumsa, Facoltà di giurisprudenza, via Pompeo Magno 22, 00192 Roma **apologised/excusée**

Prof. Assunta MORRESI, Prof. Associato di Chimica Fisica, Dipartimento di Chimica, Biologia e Biotecnologie, Università degli Studi di Perugia, V. Elce di Sotto, 8, 06123 PERUGIA

Latvia/Lettonie – Dr.Vents SĪLIS, Assistant Professor at Riga Stradins University, Department of Humanities, Dzirciema street 16, Riga, LV- 1007

Liechtenstein **apologised/excusé**

Lithuania/Lituanie – Dr Eugenijus GEFENAS, Chairman of Lithuanian Bioethics Committee, Associate Professor at Vilnius University, Lithuanian Bioethics Committee, Vilnius str.33, LT-2001 VILNIUS

Ms Jurate SEREPKAITE, Chief specialist, Lithuanian Bioethics Committee, Vilnius str. 33, LT-2001, Vilnius **apologised/excusée**

Luxembourg – Mr Jean-Paul HARPES, membre du Comité National d'Ethique de la Recherche, 119, Val des Bons Malades, L-2121 Luxembourg **apologised/excusé**

Mr Jean-Claude MILMEISTER, Chargé d'études, Diplômé en biologie et en bioéthique, Commission Consultative Nationale d'Éthique pour les Sciences de la Vie et de la Santé (C.N.E.), 18-20, montée de la Pétrusse, L-2327 Luxembourg

Mr Mike SCHWEBAG, Attaché de Gouvernement 1er en rang, Ministère de la Santé, Allée Marconi - Villa Louvigny, 2423 Luxembourg **apologised/excusé**

Malta/Malte -

Republic of Moldova/République de Moldova – Rodica GRAMMA, MD, PhD, associate professor, School of Public Health Management, Director of Department of International Relations and European Integration of the State University of Medicine and Pharmacy "Nicolae Testemitanu", Chisinau

Lucia TURCAN, Assistant Professor, PhD., The State University of Medicines and Pharmacy "Nicolae Testemitanu", Clinical Pharmacology Department, Chisinau, Republic of Moldova **apologised/excusée**

Monaco - **apologised/excusé**

Montenegro/Monténégro – Ms Olivera MILJANOVIC, Prim. doc., Director of the Centre for Medical Genetics and Immunology, Medical Centre of Montenegro, Krusevac bb, 81000 Podgorica

Netherlands/Pays-Bas – Ms. Joyce BROUWERS-VERSTAPPEN, (Senior) Beleidsmedewerker, Afdeling Ethiek, directie Publieke Gezondheid, Ministry of Health, Welfare and Sport, Parnassusplein 5, The Hague

Norway/Norvège – Mrs Anne FORUS, Senior Adviser, ph.d, Biotechnology and health legislation department, Division of specialised health care services, Norwegian Directorate of Health, P.O.Box 7000, St Olavs plass, N-0130 Oslo

Camilla Closs WALMANN, Senior Adviser, Department for Biotechnology and Health Law, Norwegian Directorate of Health, P.O.Box 7000 St Olavs plass, N-0130 Oslo

Ms Vårin Kathrin HELLEVIK, Senior Adviser, Department for Mental Health Care Services, Division of Specialist Health Care Services, Norwegian Directorate of Health, P.O. Box 7000 St Olavs Plass, N-0130 Oslo

Poland/Pologne – Ms Mariola GROCHULSKA, Département des droits de l'homme, Ministère de la Justice, Al. Ujazdowskie 11, 00-950 WARSAW

Portugal - Prof. Miguel OLIVEIRA DA SILVA, Conselho Nacional de Ética para as Ciências da Vida Av. D. Carlos I, nº 146, 2º Esq, 1200-651, Lisboa **apologised/excusé**

Romania/Roumanie – Mr. Gheorghe BORCEAN, Vice-President of the Romanian College of Physicians, Spitalul Municipal Caransebes, str. Gradinilor nr. 36ª, CARANSEBES, jud. CARAS-SEVERIN 325400

Mrs Beatrice Gabriela IOAN, Associate Professor, President of the Bioethics Commission of the Romanian College of Physicians, Institutul de Medicina Legala, str. Bunavestire nr. 4, IASI

Russia/Russie – Mr Boris YUDIN, Director, Institute of Human Studies, Russian Academy of Sciences, Volkhonka 14, MOSCOW 119992

San Marino/Saint-Marin - Dr. Luisa BORGIA, Vice-President of the National Ethics Committee, Contrada Le Grazie, n.3, 62029 Tolentino (MC), Italia

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, 11000 Belgrade

Slovakia/Slovaquie – Assoc. Prof. Jozef GLASA, MD, PhD, PhD; Institute of Pharmacology and Clinical Pharmacology, Slovak Medical University; National Reference Centre for Management of Chronic Hepatitis; Institute of Medical Ethics and Bioethics n.f.*; Ethics Committee, Ministry of Health SR; Limbová 12, 83303 Bratislava

Slovenia/Slovénie – Urh GROSELJ, MD,MA, University Children's Hospital, University Medical Center Ljubljana, Bohoriceva 20, 1000 Ljubljana

Dr. Božidar VOLJČ, Institute for Transfusion Medicine, Slajmerjeva 6, Ljubljana 1000 **apologised/excusé**

Spain/Espagne – Mª Concepción MARTIN ARRIBAS, Subdirección General de Investigación en Terapia Celular y Medicina Regenerativa – Instituto de Salud Carlos III – ISCIII, Avda. Monforte de Lemos 5, 28029 Madrid

Carlos ALONSO BEDATE, Centro de Biología Molecular, Member of the National Committee for Bioethics, C/ Alberto Aguilera, 21. 28015 Madrid

Prof. Carlos M. ROMEO – CASABONA, Professor of Penal Law, Head, Inter-University Chair in Law and the Human Genome, Avda. de las Universidades 24; 48007 BILBAO

Javier ARIAS-DIAZ, Associate Professor of Surgery, Subdireccion de Terapia Celular y Medicina Regenerativa, Instituto de Salud Carlos III, Sinesio Delgato 4, 28029 Madrid

Sweden/Suède – Mrs Tesi ASCHAN, Legal Adviser, The National Board of Health and Welfare, Socialstyrelsen, 106 30 Stockholm

Switzerland/Suisse – Dr Martin GÖTZ, Office fédérale de la santé publique, Division Biomédecine, collaborateur scientifique, Seilerstrasse 8, 3003 Bern

Rodrigo RODRIGUEZ, Prof. dr en droit, avocat, Conseiller scientifique, Départément fédéral de justice et police DFJP, Office fédéral de la Justice OFJ, Domaine de direction Droit privé, Bundesrain 20, 3003 Bern

Mme Nadine KELLER, Collaboratrice scientifique, Département fédéral de l'intérieur – DFI, Office fédéral de la santé publique – OFSP, Section Sécurité biologique et génétique humaine, Seilerstrasse 8, 3003 Berne **apologised/excusée**

Ms. Rahel MÜLLER, avocate, Collaboratrice scientifique, Département fédéral de justice et police DFJP, Office fédéral de la justice OFJ, Domaine de direction de Droit privé, Gestion, état-major, Bundesrain 20, 3003 Berne **apologised/excusée**

"The Former Yugoslav Republic of Macedonia"/"l'ex-République yougoslave de Macédoine" – **apologised/excusé**

Turkey/Turquie – Prof. Ergun ÖZSUNAY, Professor of Civil, Comparative Law and EU Private law, Istanbul Culture University, Faculty of Law, İstiklal cad. 245, Tunca Apt. Daire 7, 34430 ISTANBUL
Ukraine - Prof Zoreslava SHKIRYAK-NYZHNYK, Vice-president of Bioethics Committee of National Academy of Medical Sciences, Chief of the Department of Family Health Problems, Academy of Postgraduate Education, Institute of Paediatrics, Obstetrics and Gynaecology, Mayborody str., 8, 04050 KYIV

United Kingdom/Royaume-Uni - Dr Mark BALE, Deputy Director, Health Science & Bioethics Division, Department of Health, Richmond House, Whitehall, London SW1A 2NS

Peter MILLS, Assistant Director, Nuffield Council on Bioethics, 28 Bedford Square, London WC1B 3JS

Melanie PEFFER, Health Science & Bioethics Division, Department of Health, Richmond House, Whitehall, London SW1A 2NS

INVITED EXPERTS / EXPERTS INVITES

Prof. Elaine GADD, Honorary Professor, School of Law, Queen Mary University of London, Fox Court, 14 Gray's Inn Road, London, WC1X 8HN

Dr. Kristof van ASSCHE, Postdoctoral researcher at Bioethics Institute Ghent, Ghent University, Belgium, Blandijnberg 2, 9000 Gent, Belgium

PARTICIPANTS

CDCJ - M. Francesco CRISAFULLI, Chair of the CDCJ, Magistrat, Tribunal de Rome, Via Fezzan 41 00199 Roma, Italy

CDDH – Mme Brigitte KONZ, Juge de Paix directrice, Cité judiciaire, Plateau du St Esprit, Bâtiment JP - L-1475 Luxembourg

CD-P-TS – Dr. Guy RAUTMANN, Secretary of the European Committee on Blood Transfusion (CD-P-TS), European Directorate for the Quality of Medicines and HealthCare, Department of Biological Standardisation and OMCL Network **apologised/excusé**

CD-P-TO – Ms Marta LOPEZ FRAGA, Secretary of the CD-P-TO **apologised/excusée**

T-PD – Mme Sophie KWASNY, Secretary of the T-PD **apologised/excusée**

PARLIAMENTARY ASSEMBLY/ASSEMBLÉE PARLEMENTAIRE – Ms/Mme Guguli MAGRADZE, Member of the Committee on Social Affairs, Health and Sustainable Development/Membre de la Commission des questions sociales, de la santé et du développement durable, Member of the Parliament of Georgia

Ayşegül ELVERIŞ, Co-Secretary to the Committee on Social Affairs, Health and Sustainable Development, Parliamentary Assembly of the Council of Europe, F-67075 Strasbourg Cedex

Dana KARANJAC, Committee on Culture, Science, Education and Media **apologised/excusée**

OTHER PARTICIPANTS / AUTRES PARTICIPANTS

EUROPEAN COMMISSION/COMMISSION EUROPEENNE – Mr Lino PAULA, European Research Area, Ethics and Gender Unit, Directorate-General for Research and Innovation, Office SDME 3/14, B-1049 Brussels, Belgium **apologised/excusé**

Dr Maurizio SALVI, Senior scientist, Ethics of science and new technologies, Joint Research Centre (JRC), B-1049 Brussels/Belgium, rue du Champ de Mars 21 - CDMA 6/112 **apologised/excusé**

Dr Jim DRATWA, Head of Ethics and Head of the EGE Secretariat, Member of the Bureau of European Policy Advisers (BEPA), European Commission, Rue de la Loi 200 Wetsraat, BERL 8/358, B-1049 Brussels

Canada – Dr. Peter MONETTE, Manager of Bioethics, Department of Health Canada, Science Policy Directorate, Strategic Policy Branch, Health Canada, Brooke Claxton Building, 70 promenade Colombine Driveway, Tunney's Pasture, Ottawa, Ontario K1A 0K9 , Postal Locator: 0909C **apologised/excusé**

Holy See/Saint-Siège – Mgr. Jacques SUAUDEAU, Cure Saint Bruno, 5 Place Saint Bruno, 38500 Voiron, France

Japan/Japon – Mr Takaaki SHINTAKU, Consul, Attorney Consulat Général du Japon à Strasbourg, 20, place des Halles, 67000 STRASBOURG **apologised/excusé**

Mexico/Mexique – Dr. Manuel H Ruiz de CHÁVEZ, President of the National Academy of Medicine of Mexico, President of The Council of the National Commission of Bioethics, Carretera Picacho-Ajusco No. 154, piso 6°, Col. Jardines de la Montaña. C.P. 14210, Del. Tlalpan, Mexico, D. F, Mexico

USA/Etats-Unis d'Amérique – **apologised/excusé**

UNESCO – Ms Ângela MELO, Director, Division of Ethics, Youth and Sport, 1, rue Miollis, 750735 Paris cedex 15, France **apologised/excusée**

Mrs. Dafna FEINHOLZ KLIP, Section de la bioéthique, Division de l'éthique des sciences et des technologies, UNESCO, 1 rue Miollis, 75732 PARIS CEDEX 15

OECD/OCDE – Mr Ken GUY, Head of the Science and Technology Policy Division, Directorate for Science, Technology and Innovation **apologised/excusé**

World Health Organisation/Organisation Mondiale de la Santé (WHO/OMS) – Dr Abha SAXENA (MD), Coordinator, Global Health Ethics, Secretary, Research Ethics Review Committee (ERC), HIS/KER, Cluster of Health Systems and Innovation, World Health Organization, 20, Avenue Appia, CH- 1211, Geneva 27, Switzerland

Dr Andreas REIS, Technical Officer, HIS/KER, Cluster of Health Systems and Innovation, World Health Organization, 20, Avenue Appia, CH- 1211, Geneva 27, Switzerland **apologised/excusé**

Permanent representation of Mexico/Représentation permanente du Mexique – M. Santiago OÑATE LABORDE, Permanent Observer

OBSERVERS / OBSERVATEURS

Australia - Samantha ROBERTSON, Executive Director, Research Translation, National Health and Medical Research Council (NHMRC), Postal Address: National Health and Medical Research Council, GPO Box 1421, Canberra ACT 2601, Australia **apologised/excusée**

Israel/Israël – Dr Ilana SCHMIDT-HOPFELD, Department of Science Teaching, Weizmann Institute of Science, 200 Herzl St., REHOVOT 76100, Israel **apologised/excusée**

Professeur Michel REVEL, Weizmann Institute, Department of Molecular Genetics, Brasil House, 5 REHOVOT 76100, Israel **apologised/excusé**

European Science Foundation/Fondation Européenne de la Science (ESF) – Dr Maria Manuela NOGUEIRA, Senior Science Officer, European Science Foundation, 1 quai Lezay-Marnésia, BP 90015, 67080 Strasbourg cedex, France **apologised/excusée**

Prof. Isabel VARELA-NIETO, Instituto Investigaciones Biomédicas "Alberto Sols", Neurobiology of Hearing Group, Arturo Duperier 4, 28029 Madrid, Spain **appologised/excusée**

KEK – Conference of European Churches/Conférence des Eglises Européennes – Pasteur Richard FISCHER, Secrétaire Exécutif de la Conférence des Eglises européennes, 8, rue du Fossé des Treize, 67000 Strasbourg

SECRETARIAT

Bioethics Unit
Unité de la Bioéthique

Ms Laurence LWOFF, Secretary of the DH-BIO / Secrétaire du DH-BIO, Tel: +33 (0) 388 41 22 68, Email: laurence.lwoff@coe.int

Mr Ramon PRIETO SUAREZ, Administrator / Administrateur, Tel: +33 (0) 388 41 29 93, Email: ramon.prieto-suarez@coe.int

Ms Katrin UERPMANN, Administrator / Administratrice, Tel: +33 (0) 390 41 43 25, Email: Katrin.UERPMANN@coe.int

Ms Anneli TÖRRÖNEN, Administrator / Administratrice, Tel: +33 (0)388 41 38 41, E-mail: anneli.torronen@coe.int

Ms Tatiana WINTER, Assistant / Assistante, Tel: +33 (0) 388 41 33 67, Email: tatiana.winter@coe.int

Ms Catherine FORNÉ, Assistant / Assistante, Tel: +33 (0) 388 41 22 20, Email: catherine.forne@coe.int

INTERPRETERS / INTERPRETES

Sarah ADLINGTON
Amanda BEDDOWS
Shéhérazade HOYER
Sylvie BOUX

APPENDIX III

Programme of the conference

4 MAY 2015

9.00 – 9.30 **OPENING**

Ms Gabriella Battaini-Dragoni, Deputy Secretary General of the Council of Europe

Ambassador Dirk Van Eeckhout, Permanent Representative of Belgium to the Council of Europe

Ms Liliane Maury Pasquier, Chair of the Sub-Committee on Public Health of the Parliamentary Assembly of the Council of Europe (PACE)

9.30 – 11.00 **SESSION 1 – INTRODUCTION**

Chair: *Dr Anne Forus (Norway), Chair of the Preparatory Group for the Conference*

- **Objectives and approach of the Conference**
  Dr Anne Forus, Chair of the Preparatory Group for the Conference
- **Driving force for developments**
  Prof. Andy Stirling (United Kingdom), Science Policy Research Unit, University of Sussex
- **Presentation of the background studies**
  – "From Bio to NBIC convergence – From Medical Practice to Daily Life"
  Dr Rinie van Est and **Dr Dirk Stemerding** (Netherlands), Rathenau Institut
  – "Report on ethical issues raised by emerging sciences and technologies"
  Prof. Roger Strand and **Prof. Matthias Kaiser** (Norway), Centre for the Study of Sciences and Humanities, Bergen University

Questions and clarification

11.00 – 11.30 BREAK

11.30 – 13.00 **SESSION 2 – TECHNOLOGY, INTERVENTION AND CONTROL OF INDIVIDUALS**

Rapporteur: *Dr Michael Fuchs, Germany*
Chairs: *Prof. Dr. Paul A.J.M. Boon (Belgium), Director of the Institute for Neuroscience, Ghent University Hospital*
Prof. Zvonko Magic (Serbia), member of the Bureau of the Committee on Bioethics (DH-BIO)

- **Introductory presentation: what is at stake?**
  Prof. Dr. Hub Zwart (Netherlands), Radboud University Nijmegen - Faculty of Science
- **Ethical and societal perspectives**
  Prof. Jean-Noël Missa (Belgium), Co-director of the Interdisciplinary Research Centre in Bioethics, Université libre de Bruxelles, member of the Belgium National Consultative Committee of Bioethics
- **Human rights challenges**
  Prof. Dominique Thouvenin (France), Chair «Health Law and Ethics» Research Center «Law, Science and Technology» Paris 1 Panthéon Sorbonne

Discussion

13.00 – 14.30 LUNCH BREAK

14.30 – 16.00 **SESSION 3 – DATA COLLECTING AND PROCESSING - NEW DIMENSIONS**

Rapporteurs: *Mr Hugh Whittall, United Kingdom ; Mr Gérard Lommel, Luxembourg, Bureau of the Consultative Committee of the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (T-PD)*
Chairs: *Prof. Damir Marjanović (Bosnia and Herzegovina), International Burch University, Sarajevo*
Prof. Mariachiara Tallacchini (Italy), Università Cattolica del Sacro Cuore

- **Introductory presentation: what is at stake?**
  Dr Péter Kimpián (Hungary), Head of International Affairs and Public Relations Department, Hungarian Authority for Data Protection and Freedom of Information
- **Ethical and societal perspectives**
  Prof. Dr. Peter Dabrock (Germany), Chair of Systematic Theology (Ethics) at the Department of Theology, University Erlangen-Nuremberg, Member of the European Group on Ethics in Science and New Technologies (EGE)
- **Human rights challenges**
  Prof. Yann Joly (Canada), Research Director, Centre of Genomics and Policy, McGill University, Montreal

Discussion

16.00 – 16.30 BREAK

16.30 – 18.00 **SESSION 4 – EQUITY OF ACCESS**

Rapporteur: *Prof. Laura Palazzani, Italy*
Chairs: *Ms Liliane Maury Pasquier, Chair of the Sub-Committee on Public Health of the Parliamentary Assembly of the Council of Europe (PACE)*
Prof. Pavel Tishchenko (Russian Federation), Russian Academy of sciences

- **Introductory presentation: what is at stake?**
  Prof. Jan Helge Solbakk (Norway), Institute of Health and Society, Centre for Medical Ethics, Faculty of medicine, Oslo
- **Ethical and societal perspectives**
  Prof. Stefano Semplici (Italy), Chair of the International Bioethics Committee of UNESCO
- **Human rights challenges**
  Dr Yolanda Gómez-Sánchez (Spain), Professor of Constitutional Law National University for distance learning, Madrid

Discussion

5 MAY 2015

9.00 – 10.30 — **SESSION 5 – GOVERNANCE**

Rapporteur: *Dr André Gazsó, Austria*

Chairs: *Prof. Beatrice Ioan (Romania), Vice Chair of the Committee on Bioethics (DH-BIO)*

Prof. Stefano Semplici (Italy), Chair of the International Bioethics Committee of UNESCO

- **Introductory presentation: Overview of existing governance systems and available tools**
  Prof. Sheila Jasanoff (USA), Pforzheimer Professor of Science and Technology Studies, Harvard Kennedy School, Harvard University
- **Are existing governance systems challenged by emerging technologies and their convergence?**
  Prof. Herman Nys (Belgium), Director of the Centre for Biomedical Ethics and Law, Leuven University, Member of the European Group on Ethics in Science and New Technologies
- **How and who can respond: priority actions and possible models?**
  Prof. Sheila Jasanoff (USA) and **Prof. Herman Nys** (Belgium)

Discussion

10.30 – 11.30 — **ROUND TABLE: Priority human rights challenges arising from emerging technologies**

Participants: *Prof. Dr. Peter Dabrock (Germany), Dr Yolanda Gómez-Sánchez (Spain), Prof. Sheila Jasanoff (USA), Prof. Yann Joly (Canada), Prof. Matthias Kaiser (Norway), Dr Péter Kimpián (Hungary), Prof. Jean-Noël Missa (Belgium), Prof. Herman Nys (Belgium), Prof. Stefano Semplici (Italy), Prof. Jan Helge Solbakk (Norway), Dr Dirk Stemerding (Netherlands), Prof. Roger Strand (Norway), Prof. Dominique Thouvenin (France), Dr Rinie van Est (Netherlands), Prof. Dr. Hub Zwart (Netherlands)*

Moderator: *Dr Doris Wolfslehner (Austria), member of the Bureau of the Committee on Bioethics (DH-BIO)*

11.30 – 12.00 — BREAK

12.00 – 13.00 — **SESSION 6 – CONCLUSIONS**

Chairs: *Dr Mark Bale (United Kingdom), Chair of the Committee on Bioethics (DH-BIO)*

Ms Brigitte Konz (Luxembourg), Vice-Chair of the Steering Committee for Human Rights (CDDH)

- **Joint presentation by the rapporteurs of the sessions**

CLOSING

- **Mr Jean-Yves Le Déaut,** General Rapporteur on science and technology impact assessment of the Committee on Culture, Science, Education and Media of the Parliamentary Assembly of the Council of Europe (PACE)
- **Dr Mark Bale,** Chair of Committee on Bioethics (DH-BIO)

APPENDIX IV

Terms of reference

Committee on Bioethics (DH-BIO)

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

Type of committee: Subordinate body

Terms of reference valid from: **1 January 2016 until 31 December 2017**

Main tasks
Under the authority of the Committee of Ministers, the DH-BIO shall carry out the tasks assigned to the Steering Committee on Bioethics (CDBI) by the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. Under the supervision of the Steering Committee for Human Rights (CDDH), the DH-BIO will conduct intergovernmental work on the protection of human rights in the field of biomedicine assigned to it by the Committee of Ministers. The DH-BIO will in particular: (i) conduct regular re-examinations foreseen in the Convention and its Additional Protocols; (ii) develop further the principles laid down in the Convention on Human Rights and Biomedicine, as appropriate; (iii) contribute to raising awareness and facilitating the implementation of these principles; (iv) assess ethical and legal challenges raised by developments in the biomedical field; (v) co-operate with the European Union and relevant intergovernmental bodies, in particular with a view to promoting consistency between the normative texts; (vi) in accordance with decisions CM/Del/Dec(2013)1168/10.2 of the Committee of Ministers, carry out, at regular intervals, within the limits of the available resources and bearing in mind its priorities, an examination of some or all of the conventions[1] for which it has been given responsibility and report back to the Committee of Ministers.
Pillar/Sector/Programme
Pillar: Human Rights **Sector:** Ensuring Social Rights **Programme:** Bioethics
Expected results
(i) Subject to the carrying out of consultations on a draft text, an additional protocol on the protection of the human rights and dignity of persons with mental disorders with regards to involuntary treatment and involuntary placement is finalised. (ii) On the basis of the outcome of the International Conference on Emerging Technologies and Human Rights, a White Paper is prepared on challenges for human rights raised by emerging technologies and their convergence. (iii) The Additional Protocol concerning Biomedical Research is re-examined and where appropriate, revised. (iv) Contribution is made to the re-examination of Recommendation (97) 5 on the protection of medical data carried out by the T-PD. (v) Support is provided to possible work on prenatal sex selection undertaken by the CDDH in cooperation with the Gender Equality Commission. (vi) A survey on the Oviedo Convention – impact, relevance and challenges – is finalised. (vii) An International Conference for the 20th anniversary of the Oviedo Convention is organised.

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

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

Participants:

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

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

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

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

Observers:

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

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

Working methods

Meetings:

48 members, 2 meetings in 2016, 4 days
48 members, 2 meetings in 2017, 4 days

Bureau

7 members, 2 meetings in 2016, 2 days
7 members, 2 meetings in 2017, 2 days

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

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

[2] European Directorate for the Quality of Medicines and Healthcare.

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

Appendix 1 - **Relevant decision of the Committee of Ministers and list of Conventions**

CM/Del/Dec(2013)1168/10.2 (Review of Council of Europe conventions – Report by the Secretary General)

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

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

- draw the attention of member States to the relevant conventions;

- where necessary, identify any operational problems or obstacles to ratification of the relevant conventions, and draw the attention of member States to reservations which impact substantively on the effectiveness of their implementation;

- encourage States to regularly examine the possibility and/or desirability of becoming a Party to new Council of Europe conventions;

- assess the necessity or advisability of drafting amendments or additional protocols to the conventions for which they have been given responsibility or drafting supplementary conventions;

- and to report back to the Committee of Ministers;

***

DH-BIO	
164	Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine
168	Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings
186	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin
195	Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research
203	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes