COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Strasbourg, 15 December 2015 **DH-BIO/ abr RAP 8**

COMMITTEE ON BIOETHICS

(DH-BIO)

8th MEETING
Strasbourg, 1-4 December 2015

ABRIDGED REPORT

I. Adoption of the agenda

1. The Committee on Bioethics (DH-BIO) held its 8th meeting in Strasbourg from 1 to 4 December 2015. The agenda of the meeting and the list of participants appear in Appendix I and Appendix II to this abridged report.

II. 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

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

III. Developments in the field of bioethics

3. 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.

IV. Predictivity, genetic testing and insurance

4. The DH-BIO examined the draft Recommendation on the processing, for insurance purposes, of personal health-related data, in particular data resulting from genetic tests, revised in the light of the comments made by delegations.

5. It agreed to modify the title to read: “Recommendation on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests”. Some editorial changes are also made to the draft Explanatory Memorandum on the basis of proposals by delegations.

6. **The DH-BIO unanimously agreed to submit the draft Recommendation, as finalised, to the Steering Committee for Human Rights (CDDH), recommending the CDDH to approve it and to send it to the Committee of Ministers with a view to its adoption**. The text of the draft Recommendation as finalized appears in Appendix III to this abridged report.

7. Furthermore, the DH-BIO took note of the content of the draft Explanatory Memorandum prepared under the responsibility of the Secretariat.

8. The DH-BIO agreed to de-restrict the documents containing the draft Recommendation and its draft Explanatory Memorandum.

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

9. The DH-BIO examined the draft Recommendation on research on biological materials of human origin revised in the light of the comments made by delegations.

10. Editorial changes were made to the draft Recommendation, as well as to its draft Explanatory Memorandum on the basis of proposals by delegations.

11. The DH-BIO **approved the draft Recommendation as revised, by unanimity of the votes cast (with 4 abstentions) and agreed to submit it to the Committee of Ministers with a view to its adoption.** One delegation expressed reservations with regard to certain provisions of three Articles. The text of the draft Recommendation as approved appears in the Addendum to this abridged report. This Recommendation is intended, once adopted, to replace Rec(2006)4 on research on biological materials of human origin.

12. The DH-BIO took note of the draft Explanatory Memorandum prepared under the responsibility of the Secretariat. This text appears in the Addendum to this abridged report.

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

13. The Secretariat gave a presentation highlighting the main comments which had been received during the public consultation on the draft Additional Protocol carried out from 22 June to 15 November 2015. In the light of these comments, the DH-BIO considered important to reflect on the possible way(s) forward on this topic.

14. In this respect, it was decided that questions would be sent to delegations and to the members of the Drafting Group inviting them to reflect on the possible options that could be considered for the work undertaken on the rights of persons with mental disorder subject to involuntary measures.

15. **Delegations were invited to send their replies to these questions by 29 February 2016.** The replies would be examined by the Bureau, with a view to a discussion at the 9th plenary meeting on possible ways to pursue work in this area.

VII. DEBRA

16. The DH-BIO was informed that a seminar on "Ethical Aspects of Emerging Technologies and Genomics" had taken place in Belgrade on 20 November 2015, which had recommended ratification by Serbia of the Additional Protocols concerning Biomedical Research and concerning Genetic Testing for Health Purposes. The proceedings of the seminar would be made available at a later stage.

17. The DH-BIO took note of the request of the Armenian authorities for a bilateral seminar to be organised in the second part of 2016, on issues around medical treatment in end-of-life situations.

VIII. Emerging technologies

18. The DH-BIO agreed with the proposal of the Bureau to set up a strategic group as a follow-up to the conference on "Emerging technologies and human rights" held on 4-5 May 2015, under the auspices of the Belgian Chairmanship of the Committee of Ministers. The strategic group would be focusing on the outputs of the conference and would consider related initiatives that could be taken at the Council of Europe and, where appropriate, that might be more relevant for other international organisations.

19. The group will be chaired by the Chair of the DH-BIO and will include the Chair of the Preparatory group for the Conference, as well as three of its rapporteurs and two other members of the DH-BIO who had expressed their interest in joining the group. **Other delegations willing to participate in this group were invited to do so as soon as possible and in any case by 10 December 2015.** The first meeting of the group will take place in Paris on 17 December 2015.

IX. Follow-up to the statement on prohibition of financial gain

20. The DH-BIO agreed to set up an ad hoc group as a follow-up to the statement on the prohibition of any form of commercialisation of human organs (adopted by the DH-BIO and the CD-P-TO in May 2014, and subsequently adopted at its level by the Committee of Ministers on 9 July 2014).

21. The group would be entrusted with the task of preparing proposals for clarification of key notions with a view to facilitate the implementation of the principle in Article 21 of the Oviedo Convention.

22. The DH-BIO accepted the offer of Ms Doris Wolfslehner (Austria), member of the Bureau, to chair this ad hoc group. The group would be composed of representatives of DH-BIO (or expert proposed by DH-BIO delegations), as well as from other relevant CoE committees namely the CD-P-TO and CD-P-TS. WHO and the European Commission would be invited to participate in the meetings of the ad hoc group.

23. **Delegations interested in becoming a member of this ad hoc group or to propose an expert to participate in its work were invited to inform the Secretariat by 18 December 2015.**

X. Re-examination of the Additional Protocol concerning Biomedical Research

24. In accordance with its Article 35, the Additional Protocol concerning Biomedical Research shall be re-examined within 5 years of its entry into force. However, in 2012, the DH-BIO considered that a re-examination of the Protocol would be premature and agreed to postpone the re-examination process to 2015.

25. **The DH-BIO considered that there was no development which required changes to be made to the provisions of the Protocol at this stage and agreed to close the re-examination process**. This could be reconsidered where appropriate, after the conference to be organised for the 20th anniversary of the Oviedo Convention, which would examine the relevance and challenges of its principles.

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

26. Mr Philippe Boillat, Director General, Directorate General of Human Rights and Rule of Law, addressed the DH-BIO. In his speech, he made reference to the last report of the Secretary General on the State of Democracy, Human Rights and the Rule of Law in Europe presented in May 2015, and underlined the relevant elements therein for the DH-BIO. He stressed in this context the importance of an integrated approach between intergovernmental, cooperation and information/training activities.

Seminar on the jurisprudence of the ECtHR

27. The rapporteur for the preparation of the seminar presented an outline proposal for the seminar on the international case-law on human rights in the biomedical field. This seminar will be organised in the context of the preparation of the conference to be held at the end of 2017 on the occasion of the 20th anniversary of the Oviedo Convention. Delegations welcomed the approach taken and entrusted the rapporteur and the Secretariat with the task of revising and further developing the program and of identifying possible speakers in coordination with the Bureau.

28. It was agreed that the Seminar would be held on the first day of the 10th plenary meeting.

XII. Election of a Chair and a Vice-Chair

29. The DH-BIO re-elected by acclamation Mr Mark Bale (United Kingdom), Chair of the DH-BIO, and Dr Beatrice Ioan (Romania), Vice-Chair, for a second term of office of one year.

XIII. Other business

a. Genome editing

30. Taking into account recent developments concerning human genome editing, as well as the recent debate on this issue organised by the Committee on Social Affairs, Health and Sustainable Development of the PACE, the **DH-BIO unanimously adopted a statement on genome editing technologies** (see Appendix IV to this abridged report). In this statement, **the DH-BIO:**

- **recalled the reference principles laid down in the Convention on Human Rights and Biomedicine (Oviedo Convention) applicable to interventions on the human genome;**

- **declared that, as part of its mandate, it will examine the ethical and legal challenges raised by these emerging genome editing technologies, in the light of the principles laid down in the Oviedo Convention.**

31. Delegations were invited to disseminate the statement to any relevant persons or institutions at national level.

b. HELP and Bioethics

32. The Secretariat presented the "HELP and Bioethics" project, consisting in the elaboration of a course on core principles of Human Rights in biomedicine, intended for legal and health professionals from all member States. Subject to appropriate funding, the development of the course would start in 2016.

33. With a view to the development of the course, as well as of possible other training activities in the future, **each delegation was invited to send to the Secretariat by 15 January 2016, the name and CV of up to five experts in the field of law and/or in the biomedical field**. Experts should have experience in training in bioethical issues, should be able to draft and speak in English and have computer skills.

c. Cooperation with other Committees

34. The DH-BIO was informed that in its process of reexamination of Rec(97)5 on the protection of medical data, the T-PD intended to consult the delegations to the DH-BIO on a draft revised text at the end of April 2016 for comments by the end of May. It was agreed that this point would be on the agenda of the 9th meeting, with a view to preparing a contribution by the DH-BIO to the T-PD on the basis of the comments that will be sent by delegations before the meeting.

35. The DH-BIO considered it would be important to articulate ways of ensuring efficient cooperation with the CD-P-TO, given the significant number of areas of common interest. The recent videoconference between the chairs of both committees provided a good basis to that end.

d. Surrogacy

36. In the light of recent developments in this field as well as the work currently being carried out at the PACE, the DH-BIO agreed to update the questionnaire of 2005 on medically assisted procreation with some additional questions on surrogacy. Following suggestions made by some delegations, the Secretariat will revise the list of additional questions and will send the revised questionnaire to delegations.

37. **Delegations were invited to update their previous replies to the questions and reply to the new questions on surrogacy by 29 March 2016**. The replies would then be compiled and presented to the 9th plenary meeting of the DH-BIO.

e. Transgender and intersex children

38. The DH-BIO was informed that issues around transgender and intersex children were included in the new Strategy for the Rights of the Child 2016-2021. The DH-BIO agreed to contribute to possible activities which might be undertaken by other Council of Europe committees in this area.

39. The Secretariat informed the DH-BIO that an expert study might be commissioned to take stock of the existing provisions relevant to the protection of children rights in the biomedical field in Council of Europe texts, with a view to identifying possible areas for future activities.

f. Aesthetic genital surgery

40. Delegations were invited to submit further information on possible development at national level to address this topic.

XIV. Dates of the next meetings

41. The DH-BIO agreed on the following dates for its next meetings:
    - 9th meeting of the DH-BIO: 31 May-2 June 2016
    - 10th meeting of the DH-BIO: 5-8 December 2016
      Date agreed after consultation with the CDDH with a view to facilitate participation of CDDH delegations in the seminar on the international case law in bioethics to be held on the first day of the meeting.

42. The DH-BIO took note that the Bureau would hold its next meeting on 4-6 April 2016.

APPENDIX I

Agenda of the 8th meeting of the DH-BIO

LIST OF ITEMS

1. Adoption of the draft 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
4. Predictivity, genetic testing and insurance
5. Re-examination of Recommendation (2006)4 on research on biological materials of human origin
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
7. Cooperation programme (DEBRA)
8. Emerging technologies
9. Follow-up to the Statement on prohibition of financial gain
10. Re-examination of the Additional Protocol concerning Biomedical Research
11. Working methods and future activities of the DH-BIO
12. Elections of the Chair and Vice-Chair
13. Relations with other international bodies
14. Dates of the next meetings
15. Other business
16. Decisions taken by the DH-BIO at its 8th meeting

TUESDAY 1 DECEMBER MORNING (9.30 – 13.00)	
	1. Adoption of the draft 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
	**13. Relations with other international bodies**
	**7. Cooperation programme (DEBRA)**
	**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**
	15 d. Gene editing • Examination of the draft statement proposed by the Bureau with a view to its finalisation
	11. Working methods and future activities of the DH-BIO • Address by Mr P. Boillat, Director General of Human Rights and Rule of Law
	5. Re-examination of Recommendation (2006)4 on research on biological materials of human origin • Examination of the revised draft Recommendation on research on biological materials of human origin with a view to its **approval and subsequent submission to the Committee of Ministers**

TUESDAY 1 DECEMBER MORNING (9.30 – 13.00)	
	• Examination of the revised draft Explanatory Memorandum • Approval of the draft Recommendation
WEDNESDAY 2 DECEMBER MORNING (where necessary, 9.00-13.00)	
	5. Re-examination of Recommendation (2006)4 on research on biological materials of human origin
WEDNESDAY 2 DECEMBER AFTERNOON (14.30 – 18.00)	
	8. Emerging technologies Examination of the proposal from the Bureau on the approach to be taken with a view to the elaboration of a white paper based on the outcome of the Conference held in May 2015 **with a view to a decision**.
	9. Follow-up to the Statement on prohibition of financial gain Examination of the proposal from the Bureau on the follow up to the Statement on prohibition of financial gain **with a view to a decision.**
	10. Re-examination of the Additional Protocol concerning Biomedical Research At its 1st meeting (19-22 June 2012), taking into account the revision of Rec(2006)4, the DH-BIO agreed to postpone the re-examination of the Protocol and to reconsider it in 2015.
	11. Working methods and future activities of the DH-BIO • Seminar on the jurisprudence of the ECtHR relevant to bioethical issues - Presentation of a proposal for an outline • Biennium 2016 – 2017: Terms of Reference of the DH-BIO
THURSDAY 3 DECEMBER MORNING (9.00-13.00)	
	4. Predictivity, genetic testing and insurance • Examination of the revised draft Recommendation on the processing for insurance purposes of personal health-related data, in particular data resulting from genetic tests, **with a view to its finalisation** and subsequent submission to the CDDH; • Examination of the revised draft Explanatory Memorandum to the Recommendation.
THURSDAY 3 DECEMBER AFTERNOON (14.30-18.00)	
	4. Predictivity, genetic testing and insurance (where necessary)
	15. Other business a. European Programme for Human Rights Education of Legal Professionals (HELP)

TUESDAY 1 DECEMBER MORNING (9.30 – 13.00)	
	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) European Committee on Organ Transplantation (CD-P-TO) iii) European Committee on Blood Transfusion (CD-P-TS) c. Surrogacy. Possible update of the questionnaire of 2005 on Medically Assisted Procreation (MAP) d. Transgender and intersex children e. Gender aesthetic surgery
FRIDAY 4 DECEMBER MORNING (9.00-13.00)	
	12. Elections of the Chair and Vice-Chair
	5. Re-examination of Recommendation (2006)4 on research on biological materials of human origin **Approval** of the draft Recommendation on research on biological materials of human origin with a view to its presentation to the Committee of Ministers for adoption
	14. Dates of the next meetings Dates proposed: 9th meeting of the DH-BIO: 31 May – 3 June 2016 / (17 – 20 May 2016) 10th meeting of the DH-BIO: December 2016
	16. Decisions taken by the DH-BIO at its 8th meeting **Approval** of the list of decisions

APPENDIX II
List of participants

MEMBER STATES / ETATS MEMBRES

Albania/Albanie - **apologised/excusé**

Andorra/Andorre – Mme Imma RODRIGUEZ, Carrer Pau Casals 2, 3r 1a. AD 500-ANDORRA LA VELLA

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

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

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, Belgique

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 **apologised/excusée**

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

Cyprus/Chypre – **apologised/excusé**

Czech Republic/République Tchèque – Prof. 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 – Ms Sofie Skou SANDAGER, Head of Section, Ministry of Justice, Slotsholmsgade 10, 1216 København K, Denmark

Ms Kirstine F. HINDSBERGER, Ministry of Health, 6, Holbergsgade, DK-1057 Copenhagen K **apologised/excusée**

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

Finland/Finlande – Katja KUUPPELOMÄKI, Legal Officer, Unit for Human Rights Courts and Conventions Legal Service, inistry for Foreign Affairs of Finland, P.O.Box 411,FI-00023 Government

Anneli TÖRRONEN, Ministry of Social Affairs and Health, P.O. Box 33, FI- 00023 Government

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
apologised/excusée

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, Finland
apologised/excusée

France - 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

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

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

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, Hungary

Iceland/Islande – Ms. Thorunn STEINSDOTTIR, Legal Advisor, Ministry of Welfare, Hafnarhúsinu við Tryggvagötu, 101 Reykjavik

Ireland/Irlande – Dr. Siobhán O'SULLIVAN, Chief Bioethics Officer, Dept. of Health, Hawkins House, Dublin 2, Ireland

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

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

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 (IT)
apologised/excusée

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

Luxembourg – 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 **apologised/excusé**

Mr Mike SCHWEBAG, Médiateur Santé, Service national d'information et de médiation santé, 73, rue Adolphe Fischer (4e étage), L-1520 Luxembourg **apologised/excusé**

Malta/Malte - Mme Mary Anne CIAPPARA, B. Pharm., M. Phil. Pharmacist, Hon. Secretary, Bioethics Consultative Committee, Palazzo Castellania, 15 Merchant Street, VALLETA

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, Republic of Moldova

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 **apologised/excusée**

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, Norway

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, Norway **apologised/excusé**

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, Portugal **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, Serbia

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, Slovak Republic

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

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, Spain

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, Spain

Prof. Javier ARIAS-DIAZ, Full Professor of Surgery, Department of Surgery, Complutense University – San Carlos Clinic Hospital, 28040, Madrid, Spain

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 **apologised/excusé**

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 **apologised/excusé**

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

INVITED EXPERTS / EXPERTS INVITES

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 **apologised/excusé**

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

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**

Mr Bruno BIONI, study visitor

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

OTHER PARTICIPANTS / AUTRES PARTICIPANTS

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, Rue de la Loi 200 Wetsraat, BERL 8/358, B-1049 Brussels **apologised/excusé**

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, 67 000 STRASBOURG **apologised/excusé**

Mexico/Mexique – Dr. Manuel H Ruiz de Chávez, President of the Council of the National Comission of Bioethics. Calz. Arenal No. 134, Col. Arenal-Tepepan, Deleg. Tlalpan, Mexico D. F., Mexico

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

UNESCO – 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 **apologised/excusé**

Mr Tee Wee ANG, Permanent Secretariat, UN Inter-Agency Committee on Bioethics, UNESCO, 1 rue Miollis, 75732 PARIS CEDEX

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 **apologised/excusée**

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 Denmark/Représentation permanente du Danemark – Mr Thomas SAND KIRK, Deputy Permanent Representative, Permanent Representation of Denmark to the Council of Europe

Permanent representation of Mexico/Représentation permanente du Mexique – Mr 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 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
Sylvie BOUX
Shéhérazade HOYER

APPENDIX III

Draft Recommendation on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests
as finalised by the DH-BIO at its 8th meeting

Preamble

Chapter I
General provisions

Chapter II
Processing of health-related personal data

Chapter III
Specific provisions on genetic tests

Chapter IV
Provisions on risk assessment

Chapter V
Social importance of coverage for certain risks

Chapter VI
Mediation, consultation and monitoring

Preamble

I. The Committee of Ministers, under the terms of Article 15(b) of the Statute of the Council of Europe,

II. Considering that the aim of the Council of Europe is to achieve a greater unity between its members, in particular through harmonising laws on matters of common interest;

III. Recalling the principles laid down in

- the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine ("the Convention on Human Rights and Biomedicine") (ETS No. 164) and in
- the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108);

IV. Taking into consideration

- Recommendation (2002)9 on the Protection of Personal Data collected and processed for Insurance Purposes;
- Recommendation (97)5 on the Protection of Medical Data;

as well as the European Social Charter and the European Code of Social Security;

V. Bearing in mind the significant expansion of private insurance contracts covering risks related to an individual's health, physical integrity, age or death;

VI. Considering the sensitive nature of the personal health-related data processed in these contracts;

VII. Taking into account developments in the field of genetics, in particular the prospects of obtaining data more and more easily on the genetic characteristics of individuals, the analysis of which may be particularly complex;

VIII. Bearing in mind the risks of an incorrect or excessive interpretation of these data regarding the state of health of the persons concerned in the – sometimes very distant – future;

IX. Convinced of the social importance in each country of appropriate cover of certain risks related to health, physical integrity, age or death;

X. While recognising the insurer's legitimate interest in assessing the level of risk presented by the insured person;

XI. Aware of the role that voluntary private insurance can play in supplementing (and occasionally replacing) cover of these risks by the social security scheme or other public or compulsory insurance;

XII. Convinced, moreover, of the social importance, which varies from country to country, of cover of risks related to death, insofar as insurance may be a precondition for access to certain financial services;

XIII. Emphasising the need to strike a fair balance between the constraints relating to the nature of the private insurance contract, the protection of the individual interests of the insured persons and consideration of the social importance of certain risks;

XIV. Considering the need for member States to take appropriate measures to ensure respect for the fundamental rights of insured persons in regard to private insurance contracts relating to a person's health, physical integrity, age or death; to provide a regulatory or convention-based framework for the processing for insurance purposes of health-related personal data, in particular predictive data whether or not of a genetic nature, and to promote the insurability of individuals presenting a higher health risk, especially with regard to the social importance of coverage for certain risks;

XV. Considering that obtaining these results may in certain cases require legislation or regulations, whereas in other cases dialogue between the insurers, patient and consumer representatives, health professionals, the competent authorities and other relevant stakeholders may produce satisfactory results;

XVI. RECOMMENDS that the governments of member States implement the provisions of this Recommendation.

Chapter I - General provisions

Object

1. Member States should take appropriate measures to ensure respect for fundamental rights of persons, without discrimination, in the context of the insurance contracts covered by this Recommendation.

Scope

2. This Recommendation applies to personal and group insurance contracts with the objective to insure the risks linked to a person's health, physical integrity, age or death.

3. None of the proposed measures of this Recommendation should be interpreted as limiting or otherwise affecting the possibility for any member State to grant the insured person a wider measure of protection.

Definitions

4. For the purpose of this Recommendation:

- "insured person" refers to the individual whose risks are covered by the contract, whether in the process of being drawn up or concluded;
- "insurer" refers to both insurance and re-insurance companies;
- "third party" is any natural or legal person other than the insured person or the insurer;
- "examination" includes any non-genetic or genetic test;
- "genetic test" refers to a test involving analysis of biological samples of human origin, aiming at identifying the genetic characteristics of a person which are inherited or acquired during early prenatal development;
- "health-related personal data" refer to all personal data related to the health of an individual;
- "processing of personal data" means any operation or set of operations which is performed upon personal data.

Chapter II - Processing of health-related personal data

Principle 1 – Insurers should justify the processing of health-related personal data.

5. Health-related personal data should only be processed for insurance purposes subject to the following conditions:

- the processing purpose has been specified and the relevance of the data has been duly justified;
- the quality and validity of the data are in accordance with the generally accepted scientific and clinical standards;

- data resulting from a predictive examination have a high positive predictive value; and

- processing is duly justified in accordance with the principle of proportionality in relation to the nature and importance of the risk in question.

6. Health-related data from family members of the insured person should not be processed for insurance purposes, unless specifically authorised by law. If so, the criteria laid down in paragraph 5 and the restriction laid down in paragraph 17 have to be respected.

7. The processing for insurance purposes of health-related personal data obtained in the public domain, such as on social media or internet fora, should not be permitted to calculate risks or premiums.

8. The processing for insurance purposes of health-related personal data obtained in a research context involving the insured person should not be permitted.

9. Questions posed by the insurer should be clear, intelligible, direct, objective and precise. Insurers should provide easy access to a contact person, having the requisite competence and experience, to address any difficulties of understanding in regard to the documents for the collection of health-related personal data.

Principle 2 – Insurers should not process personal health-related data without the consent of the insured person.

10. Health-related personal data should not be processed for insurance purposes without the insured person's free, express and informed, written consent.

11. Health-related personal data should in principle be collected from the insured person by the insurer. The transmission of health-related personal data by a third party should be made subject to the insured person's consent.

Principle 3 – Insurers should have adequate safeguards for the storage of health-related personal data.

12. Insurers should not store health-related personal data which is no longer necessary for the accomplishment of the purpose for which it was collected. They should, in particular, not store health-related personal data if an application for insurance has been rejected; or if the contract has expired and claims can no longer be made. An exemption can be made if further storage is required by law.

13. Insurers should adopt internal regulations to protect the security and confidentiality of the insured person's health-related data. In particular, health-related personal data should be stored with limited access separately from other data and data kept for statistical purposes should be anonymised.

14. Internal and external audit procedures should be put in place for adequate control of the processing of health-related personal data in regard to security and confidentiality.

Chapter III - Specific provisions on genetic tests

Principle 4 – Insurers should not require genetic tests for insurance purposes.

15. In accordance with the principle laid down in Article 12 of the Convention on Human Rights and Biomedicine, predictive genetic tests must not be carried out for insurance purposes.

16. Existing predictive data resulting from genetic tests should not be processed for insurance purposes unless specifically authorised by law. If so, their processing should only be allowed after independent assessment of conformity with the criteria laid down in Paragraph 5 by type of test used and with regard to a particular risk to be insured.

17. Existing data from genetic tests from family members of the insured person should not be processed for insurance purposes.

Chapter IV - Provisions on risk assessment

Principle 5 – Insurers should take account of new scientific knowledge.

18. Insurers should regularly update their actuarial bases in line with relevant new scientific knowledge.

19. On request of the insured person, the insurer should provide relevant information and justification to that person regarding the calculation of the premium, any additional premium or any total or partial exclusion from insurance.

Chapter V – Social importance of coverage for certain risks

Principle 6 – Member States should facilitate risks coverage that is socially important.

20. Member States should recognise the social importance of coverage for certain risks and should, where appropriate, take measures to facilitate affordable access to insurance coverage for persons presenting an increased health-related risk.

Chapter VI - Mediation, consultation and monitoring

Principle 7 – Member States should ensure adequate mediation, consultation and monitoring.

Mediation in disputes between insured persons and insurers

21. Member States should ensure that mediation procedures be set up, where they do not exist**,** to ensure fair and objective settlement of individual disputes between insured persons and insurers. Insurers should inform all insured persons about the existence of these mediation procedures.

Collective consultation between parties

22. Member States should promote consultation between insurers, patient and consumer representatives, health professionals and the competent authorities, to ensure a well-balanced relationship between the parties and increase transparency vis-à-vis the public.

Monitoring of practices

23. Member States should ensure independent monitoring of practices in the insurance field in order to evaluate compliance with the principles laid down in this Recommendation.

APPENDIX IV

Statement on genome editing technologies
adopted by the DH-BIO at its 8th meeting

- The development of new genome editing technologies, such as CRISPR-Cas9, has given rise to important reaction in particular within the scientific community. Gene modification methods are not new and have been used for several decades playing an essential role in biomedical research. The new genome editing technologies have made possible simple and precise modifications in a wide variety of species.

- There is strong support for the better understanding of the causes of diseases and for future treatment and these technologies have considerable potential for research in this field and to improve human health. However, the application of genome editing technologies to human gametes or embryos raises many ethical, social and safety issues, particularly from any modification of the human genome which could be passed on to future generations.

- These developments have led eminent experts and institutions within and outside the biomedical field worldwide to call for an in-depth analysis of potential risks of genome editing and for international and regional debate on its implications for the human being.

- In this context, the Committee on Bioethics (DH-BIO), representing 47 European states, wishes to recall the work carried out at the level of the Council of Europe on developments in the biomedical field and its implications for human being, and to underline the relevance of the framework provided by the Convention on Human Rights and Biomedicine (ETS N° 164, 1997), hereinafter referred to as "the Oviedo Convention" – the only international legally binding instrument addressing human rights in the biomedical field.

- The Convention represents the outcome of an in-depth discussion at European level, on developments in the biomedical field, in particular in the field of genetics. This work was guided by the acknowledgement of the positive perspectives of genetic modification with the development of knowledge of the human genome; but also by the greater possibility to intervene on and control genetic characteristics of human beings, raising concern about possible misuse and abuses, in particular the intentional modification of human genome so as to produce individuals or groups endowed with particular characteristics and required qualities.

- Article 13[1] of the Oviedo Convention addresses these concerns about genetic enhancement or germline genetic engineering by limiting the purposes of any intervention on the human genome, including in the field of research, to prevention, diagnosis or therapy. Furthermore, it prohibits any intervention with the aim of introducing a modification in the genome of any descendants.

- These expectations and concerns remain both very relevant today with regard to those new genome editing technologies.

The Committee on Bioethics (DH-BIO):

- **is convinced that the Oviedo Convention provides principles that could be used as reference for the debate called for at international level on the**

[1] Article 13 - Interventions on the human genome
An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

fundamental questions raised by these recent technological developments; and recalls that the need for such debates was foreseen by the Convention in its Article 28[2];

- **agrees, as part of its mandate, to examine the ethical and legal challenges raised by these emerging genome editing technologies, in the light of the principles laid down in the Oviedo Convention.**

[2] Article 28 – Public debate
Parties to this Convention shall see to it that the fundamental questions raised by the developments in biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.