



International

Dialogue

On

Bioethics

- European Commission -

Brussels, 19 February 2009

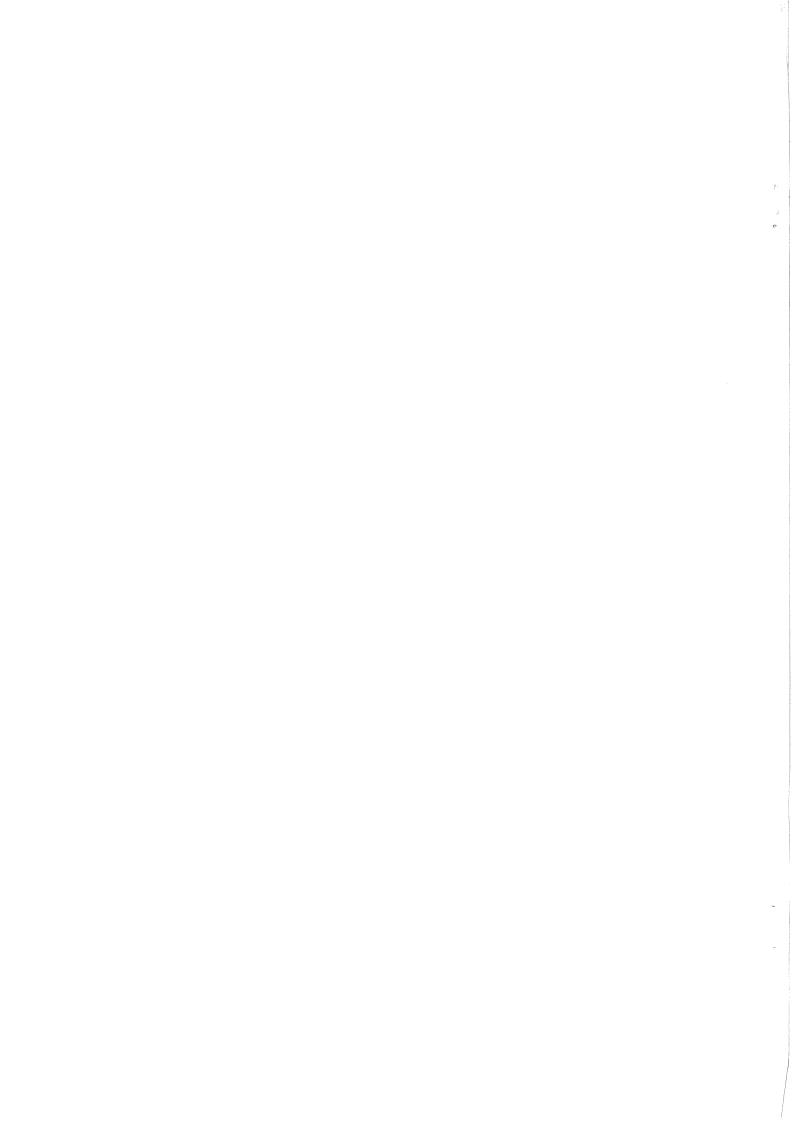


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INTRODUCTION

The International Dialogue on Bioethics

The sheer size of the European Union in economic, trade and financial terms makes it a world player. The EU has a web of bilateral and multilateral agreements covering most countries and regions of the globe. The biggest trader and home to the world's second currency, the EU also spends one billion euro a month in assistance projects in all five continents. Handling the Union's external relations is literally a global responsibility. To expand and deepen relations with other countries and regions, the EU holds regular summit meetings with its main partners, like the United States of America, Japan, Canada and, more recently, Russia and India, as well as regional dialogues with countries in the Mediterranean, the Middle East, Asia and Latin America. Although at the beginning these relationships focused mainly on trade issues, they have expanded over the years to cover investment, economic cooperation, finance, energy, science and technology and environmental protection as well as political matters such as international crime and human rights.

1. EU political developments

At the latest European Council on December 13 2007, the Heads of State and Government of the EU agreed to sign the EU Reform Treaty in Lisbon. The ratification process is ongoing.

The Reform Treaty clearly identifies a set of European values, such as human dignity, freedom, democracy, protection of human rights, pluralism, non-discrimination, tolerance, justice, solidarity and gender equality. These values are enshrined in the European Charter of fundamental rights endorsed by the Presidents of the three EU Institutions (Council, Commission and European Parliament) on December 12 and will form the cornerstone of the design and implementation of EU policies on areas spanning research to security, immigration to energy and climate change.

The Reform Treaty also reinforces the role of the EU in the international policy arena, a role that already embraces a number of EU policy sectors from the economy and global trade (think of the new version of the Lisbon Agenda and globalisation), to research (the European Research Area and the international aspect of research), energy and climate change (think of the role of the EU in the debate on a post-Kyoto agreement), security and immigration. Europe is a global player in a multi-polar world with all its inherent complexity and difficulty.

The idea that Europe is a community of values with a key role to play in international affairs is behind the Commission's drive to concentrate its work on global discussions on research and innovation, science and technology, respecting its powers and the institutional role of different international organisations. Bioethics is a key issue in these discussions.

This ambitious policy strategy was reflected in the 2008 EC work programme. The Commission has focused on delivering core policies for the globalisation agenda, fully aware that "internal and external policy goals are intertwined as never before, underpinning the need for a modern and integrated vision on how to project, promote and protect Europe's interests and values successfully".

The Commission's 2008 pipeline of work included several examples of international action.

The Commission has explored new avenues for implementing the Millennium Development Goals. The European Union has a unique status on the international stage and among the donor community. It is the world's largest donor, as it accounts for 60% of the world's official development assistance. The European Commission manages more than a fifth of EU development aid, with the European Community's aid budget amounting to €8.5 billion in 2007. This assistance is provided to more than 160 countries, territories or organisations worldwide to fight poverty and promote economic development and democracy. The ultimate objective of EU policy is to give people in less advanced countries control over their own development. This is why EU priorities aim to attack the sources of their vulnerability: ensuring better food and clean water; improving access to education, healthcare, employment, land and social services; providing better infrastructure and a better environment. EU initiatives aim to eradicate diseases and provide access to cheap medicines to combat scourges like HIV/AIDS. The EU also seeks to cut the debt burden on poor countries.

The Commission has moved ahead with its Global Europe agenda, continuing to press for a WTO trade agreement and at the same time working on an ambitious set of bilateral negotiations. 2008 was the first year of the Economic Partnership Agreements and the 10th European Development Fund. New resources and a new focus on aid effectiveness and complementarity will play a fundamental part in development policy, using the deeper relationship now forged with ACP partners. The completion of the Doha Development Agenda will remain a high priority as one of the best ways to bring new market opportunities to EU business, foster development and limit protectionism worldwide. At the same time, the EU will continue to advance and, if possible, close ongoing bilateral trade negotiations. Cementing relationships with developing countries is based on the delivery of the Millennium Development Goals and building alliances with them on global issues which often affect them the most severely, such as energy and food security, climate change and migration. The Commission will continue to progress the relationships it has forged with developing countries.

The Commission's work in the area of humanitarian assistance has continued to focus on preparing, launching, negotiating and concluding agreements with several third countries. But development assistance is not just about providing clean water and surfaced roads, it is also about helping developing countries improve their trade performance by giving them better access to the EU market. This should enable them to develop and strengthen their external trade and thereby reap the benefits of globalisation. This is why the EU's development strategy also focuses on helping poor countries improve their infrastructure, develop their productive potential and make their public administration and institutions more efficient. With this support, some will be able to grasp trade opportunities and secure more inward investment to broaden their economic base. This is essential in enabling countries to integrate into the global economy and achieve sustainable growth and development.

The Commission has actively responded to political developments across the globe and continues working for *stabilisation and reconstruction* in the Middle East, partly through its role in the Quartet and as major donor in the region, as well as in Africa and South Asia.

The Commission has also sought to enhance the transatlantic partnership, a crucial cornerstone of Europe's external relations and which was given a new political push by the adoption at the last EU-US summit of a framework for advancing transatlantic economic integration.

This is just a list of the priorities of the EC in 2008, an ambitious plan of the EU, which was consolidated in the EC work plan for 2009. In 2009, the Commission will continue to build long-

term relationships with key partners. Under the European Neighbourhood Policy, the Commission will develop ideas to help strike the right balance between enhancing economic and political relationships with its neighbours as a whole and the need to tailor relationships to different regions and different partners.

The examples above illustrate that fundamental values will be central to EU policy and legislation and that the EC intends to put an unprecedented focus on its work on international affairs. Science and technology are no exception, and the global dimension of bioethics will be key.

2. What does the Commission do in the field of bioethics?

BEPA is the Commission department that has horizontal responsibility for ethics. Work in the field of bioethics and ethics of science can be summarised under the following four headings:

- 1. Policy Design/Legislative Proposals
- 2. Structuring the pan-European debate on bioethics
- 3. Research Funding
- 4. Networking.

Policy Design/Legislative Proposals

Bioethics feature strongly in a host of <u>Community policies</u>. Examples of relevant policies include the Science and Society Action Plan, the Action Plan on Life Sciences and Technology and the Nanotechnology Action Plan.

Issues of bioethics in <u>legislation</u> come up in a host of policy areas, such as clinical trials, patents, data protection, research (FP), medicinal products for human use, animals used for experimental and other scientific purposes and animal welfare.

Structuring the pan-European debate on bioethics

In order to build expertise on bioethics, in 1991 the Commission set up the European Group on Ethics in Science and New Technologies (EGE), an independent group, with the mandate to advise the Commission on ethical questions relating to science and new technologies, either at the request of the Commission or on its own initiative. The Group is composed of 15 members, selected by the President following an open call for applicants.

Following President Barroso's requests, in 2006-2007 the EGE issued opinions on (1) Ethical aspects of nanomedicine, (2) The ethics review of FP7 human embryonic stem cells projects, (3) Ethical aspects of animal cloning for food supply (4) Ethics of modern developments in agriculture technologies and it is currently working on an opinion on ethics of synthetic biology.

An inter-services group on ethics and EU policies was established on October 10 2006, chaired by BEPA (Dr Salvi is Chair of the Inter-Service Group). The platform serves to rationalise and coordinate Commission work on bioethics and the ethics of science and new technologies. In 2006-2008, the platform discussed a number of Commission initiatives, such as: Animal cloning for food market, Radio Frequency Identification Devices: ethical and policy issues, Scientific Integrity, Ethics of Nanomedicine, Privacy Enhancing Technologies, Data Profiling and Personal Data Matching and Towards a European Union — Africa Strategic Partnership, Ethics, Research and Globalisation.

Research Funding

Since the 4th EU Framework Programme for research, a research programme on bioethics, the Commission has financed pan-European interdisciplinary research into the ethics of science and

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bioethics. Under FP7 this research effort was underpinned by financial support for ethics, governance, human rights and democracy research projects under the Science, Economy and Society research programme.

DG Research, with the help of external independent experts, also conducts an <u>ethical review</u> to ascertain that Commission-funded research proposals involving issues of major significance on bioethics are ethically sound (e.g. use of human biological material, involvement of vulnerable people in research activities, such as children and the elderly, use of non-human primates etc.).

Networking

The Commission finances <u>pan-European debates</u> on bioethics and <u>networking</u> between relevant bioethics bodies. Examples of networking activities promoted and supported by the Commission include:

- a) The Forum of National Ethics Councils (NEC Forum) established in 2003 by DG Research and clustering the National Ethics Committees of the 27 Member States. It now involves all 27 Member States.
- b) The European Network of Research Ethics Committees (EUREC), which consists of almost all national associations of research ethics committees in Europe and is also managed by DG Research.

The Commission organises <u>public consultations</u> and <u>conferences</u> on issues of major significance of bioethics, which is an example of how it promotes debates.

In addition, the Commission participates on behalf of the European Community in a number of international fora dealing with bioethical issues, including fora in the Council of Europe. Financial support to bioethics initiatives carried out by international organisations (for example Unesco and Council of Europe in 2008) is also provided from the EC.

4. Conclusions

During its term of office, the Commission has sought to enable the European Union to respond effectively to globalisation. In a globalised world, the objectives and challenges identified above must be addressed through dialogue, tolerance and mutual respect of socio-cultural identity.

The European Charter of fundamental values shows that, although Europe is multicultural, it shares common values that are intimately linked to the EU's identity. This common ground underpins the European approach to implementing policies based on respect for human rights, ethics, pluralism and the participatory processes, conducive to public acceptance and democracy. But this implies open debate, mutual respect and tolerance, which are key to the EU's efforts, action and initiatives at European and international level.

The international dialogue on bioethics is designed to facilitate links, synergy and action between stakeholders at global level on the ethics of science and technology. Inclusiveness and transparency are the main principles upon which this initiative is proposed.

Maurizio SALVI, PhD Bureau of European Policy Advisors -BEPA, Secretary of the International Dialogue

REMIT OF THE EC INTERNATIONAL DIALOGUE

The international dialogue on ethics of science and new technologies intends to achieve the following goals:

- To cluster Chairs of National Ethics Councils or equivalent bodies from different regions of the world.
- To allow a better exchange of information and communication between the above mentioned bodies.

The international dialogue will be chaired by the President of the European Group on Ethics of science and new technologies (EGE) and the Chair of the NEC of the EU Member States having the Council Presidency.

The international dialogue will be financed by the European Commission (Bureau of European Policy Advisors –BEPA). The Commission will provide its Secretariat. The international dialogue should meet on annual basis, preferably in Brussels.

The First Secretary General of the international dialogue will be Mr Salvi (BEPA, Head EGE Secretariat).

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The European Group on Ethics in Science and New Technologies (EGE)

The European Group on Ethics in Science and New Technologies (EGE) is an independent, pluralist and multidisciplinary body which advises the European Commission on ethical questions relating to sciences and new technologies, either at the request of the Commission or on its own initiative. The European Parliament and the European Council may draw the Commission's attention to questions which they consider to be of major ethical importance.

The EGE is composed by 15 Members that participate in their personal capacities and are asked to advise the Commission independently from any outside influence. In order to face the ethical issues that are arising with the rapid advances in science and technology, the Members represent a broader range of professional competences in different disciples such as, inter alia, biology and genetics, medicine, pharmacology, agricultural sciences, ICT, law, ethics, philosophy, and theology.

The identification and selection of the EGE Members is made on the basis of an open call for expressions of interest published in the Web.

The EGE issues Opinions after hearings and discussions with the main experts of the fields. For every full Opinion to be issued by the Group, a public roundtable is held before the Opinion is adopted, to which representatives of the Institutions of the European Union, experts of the fields, parties representing different interests, including NGOs, patients and consumer organizations and industrial stakeholders, are invited to participate in the debate.

EGE Opinions and publications are available at:

http://ec.europa.eu/european group ethics/avis/index en.htm

Details on EGE activities are available at:

http://ec.europa.eu/european group ethics/activities/index en.htm

EGE remit and composition are published at:

http://ec.europa.eu/european group ethics/mandate/index en.htm

Members of the EGE - 2005 - 2009

Prof. Emmanuel AGIUS, Professor of Moral Philosophy and Moral Theology, Faculty of Theology, University of Malta

Prof. Diána BÁNÁTI, Professor of Food Safety, Director General of the Central Food Research Institute, Hungary

Prof. Francesco BUSNELLI, Professor of Civil Law, Professor at Scuola Superiore di Studi Universitari e di Perfezionamento S. Anna of Pisa, Italy

Dr. Anne CAMBON-THOMSEN, Research Director, CNRS, Head of a Research Team on Genetics and Public Health, Inserm U558, Toulouse, France

Prof. Rafael CAPURRO, Information Ethics, University of Media, Stuttgart, Germany

Prof. Inez de BEAUFORT, Professor of Health Care Ethics, Erasmus Medical Centre, Rotterdam, The Netherlands

Prof. Jozef GLASA, Professor of Clinical Pharmacology & Therapeutics, Hepatology and Medical Ethics/Bioethics at the Slovak Medical University in Bratislava, Slovak Republic

Prof. Hille HAKER, Professor of Moral Theology and Social Ethics, Goethe University, Frankfurt, Germany

Prof. Göran HERMERÉN, Professor of Medical Ethics, Faculty of medicine, Lund University, Sweden (Chairman)

Prof. Julian KINDERLERER, Professor of Intellectual Property Law, University of Cape Town, Professor of Biotechnology & Society, University of Technology, Delft, The Netherlands, Chair, Task Group on Public Perception of Biotechnology, European Federation of Biotechnology, Former Director, Sheffield Institute of Biotechnology Law and Ethics

Prof. Krzysztof MARCZEWSKI, Chef Supervisor of the Department of Nephrology, Endocrinology and Metabolic Disease, Pope John Paul II Regional Hospital Zamość, Head of the Department of Medical Ethics, Skubiszewski Medical University of Lublin, Poland

Ms Paula MARTINHO DA SILVA, Lawyer, President of the National Council of Ethics for the Science of Life, Portugal (Vice-Chairman)

Prof. Linda NIELSEN, Professor of Law, University of Copenhagen, Denmark

Prof. Pere PUIGDOMENÈCH, Research Professor of CSIC, Director of the Plant Molecular Genetics Laboratory, CSIC-IRIA, Barcelona, Spain.

Prof. Günter VIRT, Professor of Moral Theology, University of Vienna, Austria

ARGENTINA

NEC Name: National Committee of Ethics in Science and Technology (Comité Nacional de Ética en la Ciencia y la Tecnología – CECTE)

1.	Year o	f establishment of NEC
	2001	
	Remit	of NEC
	1.	Studies controversial issues related to research ethics and the ethical implications
		of policies and regulations involving all areas scientific research and new
		technologies.
	2.	Identifies ethical questions raised by new advances in science and technology and
		addresses topics of scientific responsibility for larger social concerns.
	3.	Receives requests for studies and recommendations from different governmental
		bodies, public and private institutions and individuals.
	4.	Elaborates recommendations and reports based on the critical transdisciplinary
		analysis of the best available evidence and in the light of relevant ethical principles.
	5.	Appoints experts from different disciplines to produce discussion papers on the
		state of art of the issues under study.
	6.	Promotes regional and international cooperation in research ethics on questions of
		ethical relevance.
	Comp	osition of NEC
	Total 1	number: 11
	Multid	isciplinary team of experienced experts including:
	1.	Exact, natural, biomedical, social sciences, and humanities researchers
	2.	Experts in law
		-
4.	List of	the last three NEC's opinions
	1.	Conflicts of interest in small scientific communities
	2.	Scientific knowledge and ethics in environmental issues
	3.	Access to scientific knowledge in the public domain

5.	List of the next two future topics covered by NEC's opinions
	 Codes of responsible research conduct in Nanosciences and Technologies Ethics of research involving animals
6.	Chairperson
	Otilia Vainstok
7.	Contact details
	Contact person: Prof. Alfredo Stolarz Comité Nacional de Ética en la Ciencia y la Tecnología Ministerio de Ciencia, Tecnología e Innovación Productiva Ecuador 873 4º piso - (C1214ACM) Buenos Aires, República Argentina cecte@mincyt.gov.ar http://www.cecte.gov.ar

AUSTRALIA

NEC Name: Australian Health Ethics Committee

1.	Year of establishment of NEC
1.	1 ear of establishment of NEC
	1992
2.	Remit of NEC
	(a) to advise the Council on ethical issues relating to health; and
	(b) to develop and give the Council human research guidelines under subsection 10(2);
	and
	(c) any other functions conferred on the Committee in writing by the Minister after
	consulting the CEO, namely:
	1. develop and give the Council guidelines for the conduct of health research involving
	humans, additional to those required for function (b) above;
	2. promote ethical conduct in health and medical research involving humans;
	3. support and facilitate the work of institutions and of human research ethics committees
	in the oversight of health and medical research;
	4. foster community debate, and consult with relevant stakeholders on ethical issues in
	health, and health and medical research;
	5. provide advice to Council on ethical issues in health research and medical research;
	6. monitor international developments in ethical issues relating to health and health and
	medical research involving humans, and liaise with relevant international organisations and
	individuals.
3.	Composition of NEC
	* the Chair;
	* a person with knowledge of the ethics of medical research;
	* a person who has expertise in law;
	* a person who has expertise in philosophy;
	* a person who has expertise in religion;
	* a person who has experience in medical research;
	* a person who has experience in public health research;
	* a person who has experience in social science research;
	* a person who has experience in clinical medical practice;
	* a person who has experience in nursing or allied health practices; * a person with knowledge of the regulation of the medical profession;
	a person with knowledge of the regulation of the medical profession,

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	* a person with understanding of health consumer issues; * a person with understanding of the concerns of people with a disability; and * no more than 2 other persons with expertise relevant to the functions of the Committee.
4.	List of the last three NEC's opinions
	1. Ethical Guidelines for the Care of People in Post-Coma Unresponsiveness (Vegetative State) or a Minimally Responsive State, June 2008.
	2. Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice
	and Research, March, 2007
	3. National Statement on Ethical Conduct in Human Research, March, 2007
5.	List of the next two future topics covered by NEC's opinions
	 Commercialisation of human tissue Ethical issues in chronic illness and transition to palliative care
6.	Chairperson and Secretariat
	Chair:
	Professor Colin J. H. Thomson
	Secretariat:
	Health and Research Ethics Section
	National Health and Medical Research Council
7.	Contact details
	Australian Health Ethics Committee
	NHMRC
	GPO Box 1421
	Canberra ACT 2601, Australia

BRAZIL

NEC Name: National Committee on Research Ethics

1.	Year of establishment of NEC
	1996
	1990
2.	Remit of NEC
	National Health Council of the Health Ministry
3.	Composition of NEC
J.	Composition of type
	13 titulaires (5 médecins, 2 représentants des sujets de recherche, 2 infirmiers, 1 dentiste, 1
	philosophe, 1 assistant social e 1 administrateur.
	13 suppléants.
4.	List of the last three NEC's opinions
4.	List of the last three NEC's opinions
	1. Évaluation de 864 projets em 2008
	2. Directrices éthiques spécifiques pour de nouveaux médicaments pour la recherche
	avec des indigènes et en génétique.
	3. Recherches multicentres et Banque de Données
5.	List of the next two future topics covered by NEC's opinions
	1. Brazilian Platform for research Plateforme Brazil for research with human beings
	2. Evaluation of the Comitês (600) of Ethics of the Institutions
6.	Chairperson and Secretariat
	President: Gysélle Saddi Tannous
	Secretary: Fátima Pianta
	l

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7.	Contact details
	conep@saude.gov.br
	<u>coneplasadae.govisi</u>

CANADA

NEC Name: Canadian Institutes of Health Research - Ethics Portfolio

1.	Year of establishment of NEC
	2001
2.	Remit of NEC
۷.	Refill of NEC
	In the area of Ethics, CIHR is mandated by Parliament to:
	- promote, assist and undertake health research that meets the highest standards of
	ethics
	- foster the discussion of ethical issues and the application of ethical principles to
	health research.
3.	Composition of NEC
	Gemponden er rage
	The CIHR Ethics Portfolio consists of three major entities, each complementary to each
	other:
	- Standing Committee on Ethics (14 members)
	- Institute Advisory Board Ethics Designates (one for each of the 13 Institutes)
	- Ethics Office (9 members)
4.	List of the last three NEC's policy files
	1. CIHR Procedure for Handling Cases of Non-Compliance
	2. Privacy Best Practices
	3. Guidelines for Health Research Involving Aboriginal People
5.	List of the next two future topics covered by NEC's opinions
	1. Partnership with the for-profit private sector: Guidance document
	2. Best Practices for Research Involving Children

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6.	Chairperson and Secretariat
	Dr. Harvey Chochinov, Standing Committee on Ethics Dr. Ray Saginur, Institute Advisory Board Ethics Designate Dr. Geneviève Dubois-Flynn, Ethics Office
7.	Contact details
	Geneviève Dubois-Flynn, PhD, A/Director, Ethics Office
	160 Elgin Street - Ottawa, Ontario K1A 0W9 - Canada
	Phone: (613) 954-1801 - E-mail address: <u>Genevieve.Dubois-Flynn@cihr-irsc.gc.ca</u>
	Website: www.cihr.ca

CHINA

NEC Name: Ethics Committee, Ministry of Health, China

1.	Year of establishment of NEC
	2000
2.	Remit of NEC
	In 1988 a national committee on biomedical research involving human subjects was established by Ministry of Health, China. Its function is to review protocols sponsored by the Ministry of Health. In March 2000 National Ethics Committee was set up by the Ministry of Health to provide policy counselling and regulatory recommendations.
3.	Composition of NEC
	The first term: 13 members
	5 medical professionals
	3 public health/health administration experts
	3 ethicists/philosophers
	1 lawyer
	1 medical publisher.
	Second term: 17 members
	Ethicists/philosophers 6
	Public health/health administration experts 5
	Medical professionals 3
	Lawyers 2
	Medical publisher 1
4.	List of the last three NEC's opinions
	 Regulation on Ethical Reviews of Biomedical Research Involving Human Subjects Ethical Principles and Regulatory Recommendations on Stem Cell Research
	3. Regulations on Assisted Reproductive Technologies

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5.	List of the next two future topics covered by NEC's opinions
	 Ethical Guidance on Clinical Application of Stem Cell Research Ethical Guidance on Medical Publications
6.	Chairperson and Secretariat
	President, Qi Guoming Vice-President, Qiu Renzong Secretariat: Wu Peixin
7.	Contact details
	Qi Guoming: guomingqi2003@yahoo.com.cn Qiu Renzong: rzq@chianphs.org
	Wu Peixin: wpxin@hotmail.com

EGYPT

NEC Name: National Bioethics Committee in Egypt

1.	Year of establishment of NEC
	1994
2.	Remit of NEC
	Ministerial Decree
3.	Composition of NEC Forty participants
	Physicians, Scientists, Lawyers, Economics, Religions Leaders
4.	List of the last three NEC's opinions
	 Electronics Safety ethics Ethics and utilization of stem cells Ethics in Dealing with deformed babaies
5.	List of the next two future topics covered by NEC's opinions
	To be decided as 2009 plan
6.	Chairperson and Secretariat
	Chair Prof. I.C. Badran Vice president Prof. H. El Hadidi Secretary prof. Sayed Seif
7.	Contact details
	Dar El Shefa St. Garden City Cairo Egypt
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INDIA

NEC Name: The Central ethics committee on Human Research (CECHR).

Year of establishment of NEC 1996
Remit of NEC
The Central Ethics Committee on Human Research (CECHR) is the National Ethics Committee with secretariat at Bioethics Cell in Indian Council of Medical Research (ICMR) Headquarters Office, New Delhi, India. It is a referral body for the Ministry of Health and Family Welfare as well as other Ministries under Govt. of India for all Bioethics related activities.
In addition, the Council also has an Institutional Ethics Committee which reviews the projects generated by ICMR Headquarters scientists. It is also proposed that this committee may review proposals from WHO-SEARO. The secretariat of the Council's IEC is also with the Bioethics Cell at Indian Council of Medical Research, New Delhi. Bioethics Cell coordinates all activities related to ethical issues pertaining to bio-medical research on humans and animals in India. Bioethics cell performs following activities:
Opinions on bioethics issues at national level
Formulating Ethical Guidelines
Education / Training in bioethics
Consultation on issues related to Bioethics and functioning of Institutional Ethics Committees
Maintaining database for Bioethics Resources
Co-coordinating International Collaboration on bioethics
Organizing Seminars/Symposia related to Bioethics
• Survey of Institutional Ethics Committees to examine the functioning of ethics committees.
• Conducting training of the trainers to monitor ethics committees which are selected on the basis of the above survey (with a view to increase understanding) of the existing status of ethics committee functioning.
Composition of NEC
 Dr. M.S. Valiathan, Cardiac Surgeon and National Professor, Academy of Higher Education, Manipal

	 Dr. S.S. Agarwal, Human Geneticist, Lucknow Dr. Sandip Basu, Immunolgoist, National Institute of Immunology, New Delhi Dr. Yesudian, Social Scientist, Tata Institute of Social Sciences, Mumbai Dr. V. I. Mathan, Clinical Epidemiologist, Vellore Dr. G. Padmanabhan, Basic Scientist and Former Director, Indian Institute of Sciences, Bangalore Dr. Lalji Singh, Molecular Biologist and Director, Cellular and Molecular Biology, Hyderabad Dr. Mira Shiva M.D. Coordinator, Initiative for Health Equity & Society Director, Diverse Women for Diversity, New Delhi Dr. Vasantha Muthuswamy,
4.	List of the last three NEC's opinions
	 Burden of disease due to HIV/AIDS –Estimation of prevalence of HIV collectively in 6 selected Indian States. Phase I trial of Leishmania Vaccine Phase I trial of 2 HIV Vaccines in Pune and TRC
5.	List of future topics covered by NEC's opinions
	 HPV Preventive vaccine in young adolescent girls Aerosol measles vaccines trial HIV and TB combined trial
6.	Chairperson and Secretariat
	Chairman: Dr. M.S. Valiathan, Central Ethics Committee on Human Research (CECHR), Indian Council of Medical Research, New Delhi
7.	Contact details
	Dr. Vijay Kumar, Scientist F/Deputy Director General (Sr. Grade) & Member Secretary, Institutional Ethics Committee, Indian Council of Medical Research AIIMS Campus, Ansari Nagar, New Delhi -110029. Email: kumarv@icmr.org.in

INDONESIA

NEC Name: National Bioethics Commission (Komisi Bioetika Nasional = KBN)

1.	Year of establishment of NEC
	17 th of September 2004
2.	Remit of NEC
	National scope/level (Indonesia), Budget around US \$ 89.000,-
3.	Composition of NEC
	1 (one) chairperson3 (three) vice chairpersons1 (one) principal secretary who is also the head of KBN's secretariat.
4.	List of the last three NEC's opinions
5.	 standpoint on stem cells experiment/research standpoint on genetic resources standpoint on the important of bioethics education List of the next two future topics covered by NEC's opinions discussion on cloning therapeutic research sustainability of biodiversity, biosphere & environment
6.	Chairperson and Secretariat
	Chairperson: Prof. Dr. Umar Anggara Jenie (2004-2008), the new chairperson will be elected at the end of February 2009.
	Secretariat: National Bioethics Commission (Komisi Bioetika Nasional = KBN), Sasana Widya Sarwono Building 2 nd floor, LIPI, Jl. Gatot Subroto no. 10, Jakarta 12190, Indonesia

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7.	Contact details
	Dr. Amru H. Nazif, Principal Secretary of KBN
	email: amru96@cbn.net.id

JAPAN

NEC Name: Japan has two national bodies:

- (1) Expert Panel on Bioethics, Council for Science and Technology Policy (CSTP), Cabinet office (general advisory body on bioethical issues)
- (2) Bioethics and Biosafety Commission, Council for Science and Technology, Ministry of Education, Culture, Sports, Science and Technology (MEXT) (advisory body on research ethics)

1.	Year of establishment of NEC
	(1) 2001 (First established in 1997 as Bioethics Committee, in the Council for Science and Technology, Science and Technology Agency)
r	(2) 2001
2.	Remit of NEC
	 (1) - Investigation and study relating to bioethics in response to rapid development of life science. - Advisory function for the MEXT and other ministries.
	 (2) Deliberation of important matters of bioethics and biosafety Preparation of regulatory frameworks including laws and guidelines in relevant subjects Review of the research protocols of embryonic stem cell research in accordance with the relevant guidelines
3.	Composition of NEC
	(1) Current composition: 23 members (8 CSTP executive members and 15 expert members, including biologists, medical scientists, sociologist, lawyers, journalists (no prescribed number of expert members and areas of expertise)
	(2) Current composition: 20 members, including biologists, medical scientists, lawyers, bioethicists, philosophers(no prescribed number of members and areas of expertise)
4.	List of the last three NEC's opinions
	 Advice on "The Guidelines for Derivation and Utilization of Human Embryonic Stem Cells" (November 2008) Report on "Amendment of the Guidelines for Derivation and Utilization of Human Embryonic Stem Cells" (March 2007) Report on "The Basic Conceptual Approach Relating to Handling of Human Embryos" (July 2004)

 Report on the creation of human gamete cells from embryonic stem cells, induced pluripotent stem cells and somatic stem cells (February 2009) Report on the utilization of human somatic cell nuclear transfer embryos for the purpose of therapeutic cloning research (February 2008) Report on the role of institutional review board (March 2003) List of the next two future topics covered by NEC's opinions
 Draft amendments to the relevant guidelines concerning the utilization of human somatic cell nuclear transfer cells for the purpose of therapeutic cloning research Creation of human gamete cells from embryonic stem cells, induced pluripotent stem cells and somatic stem cells
 Creation of human fertilised embryos for the purpose of the research on assisted reproduction technology Review of the Guidelines for Derivation and Utilization of Human Embryonic Stem Cells
Chairperson and Secretariat
 (1) Chairperson: Masuo AIZAWA Secretariat: Life Science Group, CSTP, Cabinet Office (2) Chairperson: Takehiko SASAZUKI Secretariat: Office for Bioethics and Biosafety, Research Promotion Bureau, Ministry of Education, Culture, Sports, Science and Technology
Contact details
(1) mailto:g.life@cao.go.jp (2) mailto: ethics@mext.go.jp

MEXICO

NEC Name: Comisión Nacional de Bioética (National Commission of Bioethics)

1. Year of establishment of NEC

07 September 2005 as a deconcentrated body of the Ministry of Health. It exists before, since 1992, but with less responsibilities, budget and autonomy.

2. Remit of NEC

In 2005, the National Commission of Bioethics was established by a presidential decree as deconcentrated body of the Ministry of Health. Members of the Council are appointed by the Minister of Health, the rest of the team, the operative structure, can't be remove or appointed, they access through civil professional service and posted are publicly advertised. People have to pass exams and interviews.

3. Composition of NEC

Council

Six members honorary. Appointed by the minister of heath

President: Four years term. Currently: Physician: Former minister of health and Dean of the National University (UNAM).

Six members: two years term. Multidisciplinary, plural and gender balanced.

Two physicians, One Psychologist, two Philosophers, a lawyer. Three men and three women. Balance in bioethical perspectives.

Commission

The operative structure of the Commission is composed currently by 11 members, but will have 32 in total. Administrative, support and technical personnel. With a Executive Director and to directors: Operative and Planning and Academic Development. The departments we have are: Research Ethics Committees, Bioethics Committees, Bioethics Commissions for Federal States, Public Policies, Genomics, Training and Education, Scientific, Evaluation.

	We have a Centre for Bioethics Knowledge.
	The above posts are occupied on the basis of civil service, so posts are publicly advertised.
4.	List of the last three NEC's opinions
	Our work is more oriented to build a bioethical infrastructure and culture and not issuing reports. But we have produce some opinions and/or material
	 On abortion. On Euthanasia
5.	List of future topics covered by NEC's opinions
	 Access to benefits when the research is over. Debate on cloning at UN Bioethics and Social Science.
6.	Chairperson and Secretariat
	President of the council: Dr. Guillermo Soberón Acevedo Executive Director of the Commission and Executive Secretary of the Council: Dr Dafna Feinholz Klip
7.	Contact details
	Dafna Feinholz Klip: dradafnasalud@gmail.com or dafna.feinholz@gmail.com Cc to Verónica Huacuja: vhbioetica@yahoo.com.mx

Pan-African Bioethics Initiative (PABIN)

PABIN: Pan African Bioethics Initiative and COPAB: Pan African Bioethics Congress

Year of establishment of NEC

PABIN: Pan African Bioethics Initiative (2001) COPAB: Pan African Bioethics Congress (2008)

2. Remit of NEC

PABIN is an African Forum for discussion on bioethical issues for experts and researchers, created by CBS: Cameroon Bioethics Society and other African and international institutions and experts (TDR / WHO). The four (4) PABIN meetings focused on clinical trials in Africa.

COPAB is an African Forum for consultation, dialogue and guidance on social issues related to Ethics and Bioethics, under the auspices of the African Union. COPAB has been proposed in the framework of the implementation of Resolution AHG/Res.254 (XXXII) adopted by the OAU Bioethics Summit at the Conference of Heads of States and Governments at the 32nd African Summit of the OAU in Yaounde in July 1996. The Institution of reference of COPAB is the African Union. COPAB is an advisory body to the Ethics and Bioethics for the African Union, African States, African Civil Society and International Cooperation. Therefore, from COPAB must come the twenty members of the African Advisory Ethics Committee (2AEC). The role of the 2AEC is to issue opinions and conduct studies in various areas of the field of bioethics. To do so it must rely on the Scientific Commission of COPAB. This Commission includes experts and delegates from institutions (including PABIN for example) working in major ethical issues of research and the ethical dilemmas and gathered as much as possible within African platforms, for example:

- 1. African Platform on the Ethics of Clinical Trials and Evaluation of Guidelines for Health Research
- 2. African Platform on Good Clinical Practice
- 3. African Platform on Health and Human Rights in prison
- 4. African Platform on research on GMOs, toxic waste and climate change
- 5. African Platform on genital mutilation, female genital mutilation in particular
- 6. African Platform on Biosafety standards
- African Platform on the values of start and end of life.

3. Composition of NEC

Composition of PABIN

According to the latest updated membership in October 2008 for the preparation of its General Assembly, PABIN currently has about fifty members coming from about twelve (12) African countries, out of the fifty-three (53) countries that include the African continent and a national chapter in six (6) African countries (Cameroon, Ethiopia, Ghana, Nigeria, Tanzania, Zambia).

Composition of COPAB

Composition of the General Assembly

- 1. Delegates of technical institutions ie the Scientific Committee of COPAB (Delegation / country + continental coordination)
 - Research Institutions (53)
 - National Advisory Ethics Committees and Associations of Ethics (53)
- 2. Delegates of the Pan African Institutions
 - African Union Commission
 - Pan African Parliament
 - United Nations Economic Commission for Africa
 - African Commission on Human Rights
- 3. Delegates of African States
 - Government (53)
 - Parliament (53)
- 4. Delegates of the African Civil Society
 - FBO (Delegation / country + continental coordination)
 - Professional of Health, the Bar, Education, (Delegation/country + continental coordination)
- 4. List of the last three NEC's opinions

PABIN is not worked on this activity.

Regarding COPAB, its creation was implemented in May 2008 in Yaounde, Cameroon, through the organization of the 1st Pan African Bioethics Congress, promoted by CBS (Cameroon Bioethics Society) with the support of the African Union Commission, the United Nations Economic for Africa, the Pan African Parliament.

The African Advisory Ethics Committee, which is responsible for issuing opinions on behalf of COPAB, will officially assume his duties in favour of the hosting of the 2nd edition of COPAB in Yaounde from 19 to 21 April 2010.

5. List of the next two future topics covered by NEC's opinions

Each platform of the Scientific Commission of COPAB is requested to develop opinions and recommendations to the attention of the 2AEC.

Part of the agenda of the 2nd edition of COPAB will be the study of the African Convention on Bioethics, to be proposed to the Assembly of the African Union (Conference of Heads of State and Government).

6. Chairperson and Secretariat

Acting Chairperson of PABIN: Prof. Pierre Effa, Douala, Cameroon Secretariat: Dr Abraham Aseffa, Addis Ababa, Ethiopia

Chairperson of the Follow-up Committee of COPAB: Prof. Pierre Effa Secretariat of the Follow-up Committee of COPAB: M. Gervais N. Atahouet, Cotonou, Benin

7. Contact details

PABIN

Secretariat: Dr Abraham Aseffa

Addis Ababa, Ethiopia Email: <u>aseffaa2@yahoo.com</u>

COPAB

Public Health and Bioethics Researh Centre (CERB)

Cameroon Bioethics Society (CBS)

Building of « Pharmacie de l'Harmonie », Bonamoussadi Road, Akwa Nord Tel +237 33 40 95 45 / +237 77 76 75 19, POB 490 Douala – Cameroon

Email: effapierre@yahoo.fr, cerbcbs@yahoo.fr

Brussels, 19/02/2009

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PHILIPPINES

NEC Name: Philippine Health Research Ethics Board

1.	Year of establishment of NEC	
1.	1. Teat of Combining of 1120	
	1984, reorganized into the PHI	REB in 2006
2.	Remit of NEC	
	Health Research, both in the p	ublic and private sector
3.	Composition of NEC	
.	Gompoulou of Financia	
	Dr. Marita VT Reyes	Prof. Leonardo de Castro
	Dr. Angeles Tan-Alora	Dr. Ma. Arlissa Aguiluz
	Dr. Cecilia Tomas	Fr. Romeo Intengan
	Dr. Ma. CarmenTolabing	Dr. Albert Rebosa
	Dr. Jaime Montoya	Ms. Crispinita Valdez
	Dr. Elizabeth Ventura	Dr. Gilbert Hoggang
	Mr. Abdulrahim M. Bagundan	g
4.	List of the last three NEC's op.	inions
	·	
	Not applicable	
5.	List of the next two future topi	cs covered by NEC's opinions
	Not applicable	
	тчос аррпсавіс	
6.	Chairperson and Secretariat	
	Philippine Council for Health I	Research and Development serves as the Secretariat, with
		Director sitting on the Board ex-oficio
L	1	

7.	Contact details
	Philippine Health Research Ethics Board, PCHRD, DOST
	Gen. Santos Ave., Bicutan, Taguig, Metro Manila

RUSSIA

NEC Name: Russian Committee on Bioethics (RCB)

1.	Year of establishment of NEC
	2006
2.	Remit of NEC
	Adoption of expert opinions, recommendations and statements on ethical, legal, scientific and social problems arising in biomedical research projects and technologies; participation in drafting of Russian laws on issues related with bioethics; monitoring of compliance with international and national norms in scientific research and health-care practice; furtherance of the ratification of international bioethical instruments by Russia; identification and analysis of new tendencies in development of bioethical norms as well as international practices in the field. RCB is responsible for contacts with domestic and foreign scientific and educational institutions, with nongovernmental and public organizations which are active in the field of bioethics
3.	Composition of NEC
J.	RCB includes 34 members (chairperson, four vice-chairpersons, two secretaries), who are experts in biology, medicine, law, philosophy. Two of them are currently deputies of the State Duma (Russian Parliament)
4.	List of the last three NEC's opinions
	 Opinion on euthanasia Opinion on the Russian Law forbidding cloning of humans Position of the RCB in relation to signing by Russia the Convention on Bioethics of the Council of Europe
5.	List of the next two future topics covered by NEC's opinions
	Russian law on transplantology of human organs and tissues

	2. Ethical and legal norms in the field of research on human stem cells
6.	Chairperson and Secretariat
	Chairperson – Prof. Rem V. Petrov (biology and medicine);
	Vice-Chairpersons – Prof. Yuriy M. Lopukhin (medicine), Prof. Yuriy D. Sergeev (law),
	Prof. Konstantin G. Skryabin (biology), Prof Boris G. Yudin (philosophy);
	Secretaries – PhD Larissa P. Kiyashchenko (philosophy), Nataliya G. Stepanova (biology)
7.	Contact details
	Post address: Institute of Philosophy, Room 206, Volkhonka, 14
	Moscow, 119992, Russia
	e-mail: byudin@yandex.ru
	website: bioethics.ru

SOUTH AFRICA

NEC Name: National Health Research Ethics Council

1.	Year o	f establishment of NEC
	2005	
	Remit	of NEC
	1.	Determine guidelines for functioning of health research ethics committees
	2.	Register and audit health research ethics committees
	3.	Set norms and standards for conducting research on humans and animals,
		including norms and standards for conducting clinical trials
	4.	Adjudicate complaints about the functioning of health research ethics committees
	'	and hear any complaint by a researcher who believes that he or she has been
		discriminated against by a health research ethics committee
	5.	Refer to the relevant statutory health professional council matters involving the
		violation or potential violation of an ethical or professional rule by a health care
		provider
	6.	Institute such disciplinary action as may be prescribed against any person found to
		be in violation of any norms and standards, or guidelines, set for the conducting of
		research in terms of this Act
	7.	Advise the national department and provincial departments on any ethical issues
		concerning research
	Comp	osition of NEC
Total number: 14 Multidisciplinary team of experienced experts including:		
	1.	Research Ethics Committee Members
	2.	Community representative
	1	Ethicists Legally qualified individuals
		Clinicians
	6.	Researchers
	7.	Scientists
	8.	Pharmaceutical Industry representative
	9.	Veterinary Scientist

4.	List of the last three NEC's opinions	
	1. Ethics in Health Research: Principles, Structures and Processes	
	2. Guidelines for Good Clinical Practice in Research in South Africa	
	3. Registration of Research Ethics Committees	
5.	List of the next two future topics covered by NEC's opinions	
	1. Accreditation of Research Ethics Committees	
	2. Education and Training of Research Ethics Committees	
6.	Chairperson and Secretariat	
	Professor Danie du Toit: Chairperson	
	Professor Amaboo Dhai: Co-Chairperson	
	Dr Lindiwe Makhubalo: Head – Secretariat	
	NB. The Chairperson, Co-Chair and Head-Secretariat constitute the NHREC EXCO	
7.	Contact details	
	Chairperson: dutoitd@tut.ac.za	
	Co-Chairperson: amaboo.dhai@wits.ac.za	
	Head – Secretariat: <u>makubl@health.gov.za</u>	

USA

NEC Name: The President's Council on Bioethics

1.	Year of establishment of NEC
1.	Teat of establishment of type
	By executive order of the President, November 2001
	(due to expire: September 2009)
2.	Remit of NEC
	The Council's primary function is to advise the President of the USA on ethical issues
	generated by advances in biomedicine and biotechnology; its secondaryalbeit very
	importantfunctions are to educate the public, provide a forum for national discussion of
	bioethical questions and issues, and collaborate internationally on the analysis and
	resolution of bioethical problems.
	resolution of blockment problems.
3.	Composition of NEC
<i>J</i> .	Composition of IVEC
	Eighteen (18) members, including the chairman:
	Edmund D. Pellegrino, M.D. (chairman)
	Georgetown University Medical Center
	Floyd E. Bloom, M.D. The Scripps Research Institute
	Benjamin S. Carson, M.D.
	Johns Hopkins Medical Institutions
	Rebecca S. Dresser, J.D., M.S.
	Washington University
	Nicholas N. Eberstadt, Ph.D.
	American Enterprise Institute
	Jean Bethke Elshtain, Ph.D.
	University of Chicago
	Daniel W. Foster, M.D.
	University of Texas, Southwestern Medical School
	Michael S. Gazzaniga, Ph.D.
	Dartmouth College
	Robert P. George, J.D., D.Phil
	Princeton University
	Alfonso Gómez-Lobo, Dr. Phil.
	Georgetown University
	William B. Hurlbut, M.D.
	Stanford University Donald W. Landry, M.D., Ph.D.

	Columbia University
	Peter A. Lawler, Ph.D. Berry College Paul McHugh, M.D. Johns Hopkins Hospital Gilbert C. Meilaender, Ph.D. Valparaiso University Janet D. Rowley, M.D. The University of Chicago Diana J. Schaub, Ph.D. Loyola College Carl E. Schneider, J.D. University of Michigan
4.	List of the last three NEC's opinions
	 Controversies in the Determination of Death, electronically published January 13, 2009 The Changing Moral Focus of Newborn Screening, electronically published November 24, 2008 Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics, published March 2008
5.	List of the next two future topics covered by NEC's opinions
	 Health Care and the Common Good (to be published in February 2009) Organ Transplantation: An Ethical Inquiry (to be published in March 2009)
6.	Chairperson and Secretariat
	Chairman: Edmund D. Pellegrino, M.D.
	Executive Director: F. Daniel (Dan) Davis, Ph.D.
7.	Contact details
	Address: 1425 New York Avenue, N.W., Suite C100, Washington, D.C. 20005

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NATIONAL

ETHICS

COUNCILS

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AUSTRIA

NEC Name: Austrian Bioethics Commission

1.	Year of establishment of NEC
	2001
2.	Remit of NEC
	The Austrian Bioethics Commission consists of up to 25 experts representing the fields of medicine, genetics, sociology, law, philosophy and theology. The Commission provides a forum for interdisciplinary discourse on human medicine and human biology. Its members are appointed by the Federal Chancellor for a period of two years. Meetings are convened monthly between October and July in Vienna.
	The Austrian Bioethics Commission is an independent, self-organising body. It puts great emphasis on publicising its work in order to stimulate public discussion on ethical questions, and cooperates with comparable institutions in the European Union and international bodies in the field of Bioethics.
	The Secretariat of the Austrian Bioethics Commission is at the Austrian Federal Chancellery.
3.	Composition of NEC

Dr. Christiane DRUML (Chair), Medical University of Vienna, Ethics-Commission UnivProf Dr Günther PÖLTNER (Deputy Chair), Vienna University, Institut for Philosophy

UnivProf Dr Christine MANNHALTER (Deputy Chair), Medical University of Vienna, Clinical Institute for Medical and Chemical Diagnostics

Univ.Prof. Dr. Helmut FUCHS, University of Vienna, Faculty of Law, Department of Criminal Law and Criminology

UnivProf Dr Richard GREIL, <u>Medical University of Salzburg, Internal Medicine III</u>, <u>Oncology</u>

UnivProf Dr. Karin GUTIÉRREZ-LOBOS, Medical University of Vienna, Department of Psychiatry

UnivProf Dr. Markus HENGSTSCHLÄGER, Medical University of Vienna, Medical Genetics

UnivProf DDr Josef ISENSEE, University of Bonn, Faculty of Law, <u>Institute for Public Law</u>

UnivProf. Dr. Dr. h.c. Peter KAMPITS, Vienna University, Faculty of Philosophy and Educational Sciences

Prim. Dr. Ludwig KASPAR, Directorate for Cooperation of institutions of the Vienna Health System with the EU

UnivProf DDr Christian KOPETZKI, Vienna University, Faculty of Law, <u>Institute for Public Law/Medicine Law</u>

UnivProf Dr. Ursula KÖLLER, Hietzing Hospital, Institute for Laboratory Medicine UnivProf Dr Ulrich KÖRTNER, <u>Vienna University</u>, Faculty of Protestant Theology, <u>Institute for Systematic Protestant Theology</u>

UnivProf Dr Gerhard LUF, Vienna University, Faculty of Law, Institute for Philosophy and Theory of Law

UnivDoz DDr Barbara MAIER, <u>Medical University of Salzburg</u>, <u>Gynaecology</u>, <u>IVF</u> <u>Laboratov Salzburg</u>

UnivProf Dr Johannes G. MERAN, M.A., Barmherzige Brüder Hospital, Internal Medicine

UnivProf Dr. Daniela PRAYER, Medical University of Vienna, Department of Radiology UnivProf Dr. Anita RIEDER, Medical University of Vienna, Institute for Social Medicine, Center for Public Health

UnivProf Dr. Marianne SPRINGER-KREMSER, Medical University of Vienna, Department of Psychoanalysis and Psychotherapy

UnivProf DDr. Michaela STRASSER, University Salzburg, Department for Social Sciences and Economics

UnivProf Dr Günter VIRT, Vienna University, Faculty of Catholic Theology Dr. Klaus VOGET, President of the Austrian national Council of Disabled Persons UnivProf Dr Ina WAGNER, <u>Vienna University of Technology</u>, <u>Institute of Design and Assessment of Technology</u>

UnivProf Dr. Ernst WOLNER, Medical University of Vienna, Department of Surgery, UnivProf Dr Kurt ZATLOUKAL, Medical University of Graz, Institute of Pathology

4.	List of the last three NEC's opinions
	 Recommendations with Gender Reference for Ethics Committees and Clinical Studies und Opinion of the Bioethics Commission (PDF 67 kB), 15th November 2008
	2. Cord Blood Banking (PDF 91 kB) Ruling of the Bioethics Commission, 19 May 2008
	3. Nanotechnology, a Catalogue of Ethical Problems and Recommendations (PDF 36 kB) Ruling of the Bioethics Commission of 13 June 2007
5.	List of future topics covered by NEC's opinions
	 hESC Research assistive technologies research integrity
6.	Chairperson and Secretariat
	Acting Chair: Christian DRUML Head of Secretariat: Doris WOLFSLEHNER

7.	Contact details
	Austrian Bioethics Commission Federal Chancellery Ballhausplatz 2
	A-1010 Wien Tel.: ++43/1/53115-2987 Fax: ++43/1/53209-2987
	mailto:doris.wolfslehner@bka.gv.at www.bundeskanzleramt.at/bioethik/ www.bundeskanzleramt.at/bioethics

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BELGIUM

NEC Name: the Belgian Advisory Committee on Bioethics

1	V f blish most of NEC	
1.	Year of establishment of NEC	
	The 13 th January 1996	
2.	Remit of NEC	
	 To provide advice on the problems raised by research and research applications in the fields of biology, medicine and health care; these problems are studied from the ethical, social and legal points of view, particularly from the angle of the respect for human rights; To inform the public and the authorities about these problems. 	
3.	Composition of NEC	
	26 Members appointed by means of the Royal Decree of 29 May 2000 conferred in the Council of Ministers	
	Sixteen leading figures from academia, recommended by the various university councils - 8 French-speaking members: - 8 Dutch-speaking members	
	Six practising doctors of medicine recommended by the National Council of the Medical Association - 3 French-speaking physicians - 3 Dutch-speaking physicians	
	Two lawyers recommended by the National Council of the Bar - 1 French-speaking lawyer - 1 Dutch-speaking lawyer	
	Two magistrates from the magistrature - 1 French-speaking magistrate - 1 Dutch-speaking magistrate	
	9 Members recommended by the King and by the executive authorities of the three Communities and the United Assembly of the Joint Commission for Community Matters: 2 members recommended by the King	

- 2 members recommended by the executive authorities of the Flemish Community
- 2 members recommended by the executive authorities of the French-language Community
- 1 member recommended by the executive authorities of the German-language Community
- 2 members recommended by the executive authorities of the United Assembly of the Joint Commission for Community Matters
- i.e. 35 ordinary members with the right to vote. Each ordinary member has an alternate, who is appointed according to the same procedure.
- 8 Members participating in the work of the Committee in an advisory capacity:
- 1 representative of the federal Minister of Justice
- 1 representative of the federal Minister responsible for science policy
- 1 representative of the federal Minister responsible for public health
- 1 representative of the Femish Community
- 1 representative of the French-language Community
- 1 representative of the German-language Community
- 2 representatives of the Joint Commission for Community Matters
- i.e. 8 members attending in an advisory capacity.

In total 43 members.

When composing the Committee, attention is paid to a *balanced representation* of the various ideological and philosophical movements, to a balanced number of men and women and to an equal number of Dutch- and French-speaking members. The same applies to a balance between members from academia and the medical professions and those from the philosophical, legal and life science communities.

- 4. List of the last three NEC's opinions
 - 1. Opinion Nr. 42 of 16 April 2007 on umbilical cord blood banks
 - 2. Opinion No. 43 of 10 December 2007 concerning the problem of whether or not human body parts should be commercialised
 - 3. Opinion No. 44 of 23 June 2008 concerning the inhibition of growth of very severely mentally handicapped children
- 5. List of the next two future topics covered by NEC's opinions
 - 1. Biobank for research use
 - 2. Pandemic
- 6. Chairperson and Secretariat
 - Jeanine-Anne Stiennon, Vice-Chairwoman and Chairwoman- 21 april 2005 20 april 2006
 - Paul Devroey, Vice-Chairman and Chairman- 21 april 2008 20 april 2009

	 Michel Dupuis, Vice-Chairman and Chairman - 21 april 2007 - 20 april 2008 Paul Schotsmans, Vice-Chairman and Chairman - 21 april 2006 - 20 april 2007
	Lieven Dejager, Responsible for coordination Monique Bosson, Responsible for Information
7.	Contact details
	Monique Bosson Phone number: 00.32.2.525.09.07 Mail: bioeth-info@health.fgov.be

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CYPRUS

NEC Name: THE CYRPUS NATIONAL BIOETHICS COMMITTEE

1.	Year of establishment of NEC
	2001
2.	Remit of NEC
	The Committee's mission is the constant monitoring, survey, systematic analysis and evaluation of the issues and problems that relate to the scientific research, progress and implementation of the sciences of biotechnology, biology, medicine, genetics and pharmaceutics as well as to the human intervention on the biological procedure and the human genotype and the investigation of their moral, deontological, social, humanistic and legal dimensions.
	Also the Committee is responsible for the bioethical assessment and approval of research protocols relating to biomedical research on human beings and their biological substances, clinical trials on Medicinal Products for human use, and, medical devices applied on human beings.
3.	Composition of NEC
	The CNBC has 13 members, including the chairperson. The members represent different professions and disciplines, and are appointed by the Council of Ministers of the Republic of Cyprus for a term of office of four years. According to the provisions of the legislation, at least four members must emerge from the humanities and social sciences sector; four members must emerge from the area of medical and biological sciences, and four members from the area of any other science or profession or who are distinguished in any area of activity for their contribution.
4.	List of the last three NEC's opinions
	1. Opinion on palliative care
	2. Opinion on genetically modified organisms

	3. Opinion on prenuptial test for thalassaemia before the conclusion of a civil wedding
5.	List of the next two future topics covered by NEC's opinions
	Biobanks Operational Guidelines of research ethics committees
6.	Chairperson and Secretariat
	Chairperson: Mrs. Rena Vrahimi-Petridou Secretariat : Mrs. Yiota Nicolaou
7.	Contact details
	Tel: +357 22899227, + 35722889103 Fax: +357 22665080 Email: repetridou@law.gov.cy Website: www.bioethics.gov.cy

CZECH REPUBLIC

NEC Name: Bioethics Committee (of Research and Development Council at the Czech Government)

1.	Year of establishment of NEC
	2006 - on the base of the law 227/2006 Coll., without legal base since 1997
2.	Remit of NEC
	Biomedical research, including human embryonic stem cell research
3.	Composition of NEC
	14 members
4.	List of the last three NEC's opinions
	1. 2. 3.
5.	List of the next two future topics covered by NEC's opinions
	1. 2.
6.	Chairperson and Secretariat
	Vice Chair Dr. Josef Kuře (currently acting Chair; Chairperson will be nominated soon)
7.	Contact details
	Dr. Josef Kuře UCB Komenského nam. 2 66243 Brno Czech Republic jkure@med.muni.cz Tel. +420549494913 Fax +420549497935

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DENMARK

NEC Name: The Danish Council of Ethics

1.	Year of establishment of NEC
	1987
2.	Remit of NEC
	The Council gives advice and information to the Danish Parliament, the public authorities and the public in general on the ethical issues related to the development in biotechnologies pertaining to human beings, nature, the environment and foodstuffs. Furthermore, the Council deals with the general development in the health care system.
3.	Composition of NEC
	The Council consists of 17 members; a mixture of experts and laymen with publicly substantiated knowledge of the ethical, cultural and social questions of importance to the work of the Council. Equal numbers of both sexes (8 men and 9 women or vice versa). Appointed for a period of three years. May accept reappointment once. Nomination of the 17 members 9 members are appointed by the Committee in the Parliament 4 members are appointed by the Minister of Health and Prevention 1 member is appointed by the Minister of Environment 1 member is appointed by the Minister of Food, Agriculture and Fisheries 1 member is appointed by the Minister of Science, Technology and Innovation 1 member is appointed by the Minister of Economic and Business Affairs
4.	List of the last three NEC's opinions
	 Statement on Organ Donation (December, 2008) (in Danish. Will be translated to English) The Ethical Challenge – virtual Dilemma Game (Facebook), (May, 2008) (in Danish only) Statement on Ethical Aspects of Chimaera Research (October, 2007) (in Danish and English)
5.	List of future topics covered by NEC's opinions
	1. Embryo diagnostics 2. Climate change, foodstuffs, and ethics 3. Medical optimization 4. The Ethics of Health Care Prevention
6.	Chairperson and Secretariat
	The Council Mr. Peder Agger, MSc, Professor (Ecology) – Chairman Mrs. Lotte Hvas, MD, general practitioner – Vice-Chairman The Secretariat Mrs. Lise Wied Kirkegaard, MA, Head of Secretariat Nine employees.

7.	Contact details
	The Danish Council of Ethics Ravnsborggade 2-4, 4 th Floor DK-2200 Copenhagen N Denmark Phone: +45 35 37 58 33 E-mail, the Secretariat: info@etiskraad.dk Mr. Peder Agger: pa@ruc.dk
:	Mrs. Lise Wied Kirkegaard: lwk@etiskraad.dk
OHOUSE STATES	

ESTONIA

NEC Name: ESTONIAN COUNCIL ON BIOETHICS

	TY C IF I CATEC
1.	Year of establishment of NEC
	1998
	1996
2.	Remit of NEC
	NEC is coordinating and advisory body at the Ministry of Social Affairs
3.	Composition of NEC
	13 members of NEC are appointed by the Minister of Social Affairs for 3 years
	They represent various medical specialities, ethics and law. One place is reserved for a
	member of the Estonian Parliament (Riigikogu).
4.	List of the last NEC's opinions
	1. Data protection in medicine
	2. Ethical aspects of the central digital health record
5.	List of the next two future topics covered by NEC's opinions
	1. Surrogate motherhood
	2. End of life and suicide
6.	Chairperson and Secretariat
0.	Champerson and Consuming
	Chairperson: Prof. Hele Everaus, MD, PhD, oncologist
	Seretary: Kristi Lõuk, philosopher
7.	Contact details
'	
	Chairperson: hele.everaus@kliinikum.ee
	Secretary: kristi.louk@ut.ee
L	

International Dialogue on Bioethics

FINLAND

NEC Name: The Sub-Committee on Medical Research Ethics

1.	Year of establishment of NEC
	1999
2.	Remit of NEC
	Sub-Committee on Medical Research Ethics According to the Medical Research Act (488/1999, amended 295/2004) the independent Ethics Committees are responsible for ethical pre-evaluation of medical research and their amendments. The Sub-Committee on Medical Research Ethics (TUKIJA) evaluates the ethical aspects of international multi-centre trials on Medicinal Products. It can also delegate that duty to the Hospital District Ethics Committee. As a national Research Ethics Committee TUKIJA also supports the Ethics Committees of Hospital Districts in fundamental ethical issues concerning medical or other health care research and assists in arranging training on these issues. A research proposal, which has been given a negative opinion by a local Ethics Committee, can be sent to TUKIJA for revaluation. TUKIJA is nominated by Ministry of Social Affairs and Health for four years mandate.
3.	Composition of NEC
	Chairman: Professor Heikki Ruskoaho, M.D., Ph.D., Molecular Pharmacology, University of Oulu Vice Chairman: Professor Helena Kääriäinen, MD, Docent, Specialist in Medical Genetics, National Institute for Health and Welfare Members: Professor Kari Kivistö, Clinical Pharmacology & Toxicology, University of Tampere Professor Tapani Keränen MD, Specialist in Neurology and Clinical Pharmacology, University of Kuopio Professor Elina Hemminki MD, Docent, Epidemiology, National Institute for Health and Welfare Professor Markku Koskenvuo, Epidemiology, University of Helsinki Docent Katriina Aalto-Setälä MD, Specialist in Internal Medicine and Cardiology, University of Tampere Docent Kristian Läksy, MD, Psychiatry, University Hospital of Oulu Docent Maija Pohjavuori MD, Specialist in Paediatrics and Neonatology, University Hospital of Helsinki Researcher Helena Siipi, Philosophy and Ethics, University of Turku Managing Director Eija Orpana, ML, MBA, legality questions, Finnish Student Health Service Ministerial Adviser Mervi Kattelus LLM, legality questions, Ministry of Social Affairs and Health Teacher Mervi Matero, layperson, City of Helsinki Education Department

4.	List of the last three NEC's opinions (regulations and guidance)
	1. The financial disquisitions related to medical research proposals
	2. Recommendation on informing the research subjects on ionizing radiation
	3. Report on Children in Medical Research
5.	List of the next two future topics covered by NEC's opinions
	Report on national legislation on human databanks
	2. Recommendations on Informed Consent Forms
6.	Chairperson and Secretariat
	Acting Chair: Prof Heikki Ruskoaho
	Executive Secretary: Senior Officer Outi Konttinen
7.	Contact details
	The Sub-Committee on Medical Research Ethics (TUKIJA)
	Ministry of Social Affairs and Health
	P.O.BOX 33 (Kirkkokatu 14, Helsinki)
	FIN-00023 Government, Finland
	Email: etene@stm.fi
	Internet: http://www.etene.org/tukija/index.shtml

FRANCE

NEC Name: French National Ethics Advisory Committee for Life Sciences and Health

1.	Year of establishment of NEC
	1983
2.	Remit of NEC
	To give opinions on ethical problems and societal issues raised by progress in the fields of biology, medicine and health.
3.	Composition of NEC
	40 members, including:
	5 personalities belonging to the main philosophical and spiritual families;
	19 personalities chosen for their qualification and interest in ethical problems;
	15 personalities from the field of research.
4.	List of the last three NEC's opinions
	1. Opinion n° 103 : On ethics and childhood deafness: considerations on
	information regarding systematic neonatal screening and on medical management
	of deaf children (12/2007)
	2. Opinion n° 104 : On the 'Personal Medical Record' and the computerisation of
	health-related data. (2008)
	3. Opinion n° 105 : On questions for the States General on Bioethics. (2008)
5.	List of the next two future topics covered by NEC's opinions
	Ethical questions raised by a possible influenza pandemic
	2. Palliative care

6.	Chairperson and Secretariat
	Chairperson: Pr Alain Grimfeld Secretariat: Marie-Hélène Mouneyrat
7.	Contact details
	contact@comite-ethique.fr
	www.ccne-ethique.fr

GERMANY

NEC Name: Deutscher Ethikrat (German Ethics Council)

1.	Year of establishment of NEC
	The German Ethics Council was established in 2008, substituting the National Ethics
	Council, which was in place since 2001
2.	Remit of NEC
	Following the Ethics Council Act of 16 July 2007, the German Ethics Council shall pursue
	the questions of ethics, society, science, medicine and law and the probale consequences
	for the individual and society that result in connection with research and development, in
	particular in the field of the life sciences and their applications to humanity.
	Its duties shall include but not be limited to the following:
	1. informing the public and encouraging discussion in society, engaging the various social
	groups;
	2. preparing opinions and recommendations for political and legislative action;
	3. cooperation with national ethics councils and comparable institutions of other states
	and of international organisations.
3.	Composition of NEC
	26 members:
	13 members nominated by the German Parliament
	13 members nominated by the German Government
4.	List of the last three NEC's opinions
	The German Ethics Council has not published any opinions yet, since it was only
	established in 2008.
5.	List of the next two future topics covered by NEC's opinions

	1. Anonymous Birth 2. Biobanks
6.	Chairperson and Secretariat
	Chairperson: Prof. Dr. Edzard Schmidt-Jortzig
	Head of office: Dr. Joachim Vetter
7.	Contact details
	German Ethics Council
	Jaegerstrasse 22/23
***************************************	10117 Berlin
	Phone: +49 30 20370 424
	Fax: +49 30 20370 252
i i	E-mail: <u>kontakt@ethilrat.org</u>
	Internet: www.ethikrat.org

GREECE

NEC Name:

1.	Year of establishment of NEC
1.	Tear of establishment of NEC
	1999
2.	Remit of NEC
	The Hellenic National Bioethics Commission is an independent advisory body of experts that examines ethical questions raised by the advances of the biological sciences and issues recommendations addressed to the relevant public authorities. The Commission functions under the umbrella of the General Secretariat of the Government and its mission is to highlight the interaction of life sciences and contemporary social values. More specifically the Commission: (a) investigates the ethical, social and legal aspects that arise from scientific advances in biology, biotechnology, medicine and genetics, (b) outlines, in collaboration with the respective ministries, proposals of public policy and provides specific recommendations on related issues, (c) collaborates with international organizations and related bodies and represents Greece to international fora, and (d) informs the public on issues related to biotechnological advances and the impact of their applications promoting public awareness and dialogue. The Commission has also the responsibility to co-ordinate other relevant committees at a national level.
3.	Composition of NEC
	George Maniatis, Emeritus Professor of General Biology, University of Patras Savas Agouridis, Emeritus Professor of Theology, University of Athens Myrto Dragona-Monachou, Emeritus Professor of Philosophy, University of Athens Costas B. Krimbas, Member of the Academy of Athens, Professor Honoris causa of Genetics, Agricultural University of Athens and Emeritus Professor of History and Philosophy of Biology, University of Athens Dimitris Roupakias, Professor of Plant Breeding, University of Thessaloniki Pavlos Sourlas, Professor of Philosophy of Law, University of Athens Constantinos Tsoukalas, Emeritus Professor of Sociology, University of Athens John Vlahoyiannis, Professor of Medicine and Nephrology, University of Patras
4.	List of the last three NEC's opinions

	 Research ethics in the biological sciences (June 2008) Use of Genetic Data in Private Insurance (January 2008) Prenatal and Preimplantation Diagnosis and Embryo Treatment (April 2007)
5.	List of the next two future topics covered by NEC's opinions 1. Environmental Ethics: Ethics of the conservation of Biodiversity 2. Enhancement
6.	Chairperson and Secretariat Acting Chair: Prof George Maniatis Head of Secretariat: Marianna Dracopoulou
7.	Hellenic National Bioethics Commission Evelpidon 47 113 62 Athens Greece e-mail: secretariat@bioethics.gr URL: www.bioethics.gr

HUNGARY

NEC Name: Health Science Council, Scientific and Research Ethics Commission

1.	Year of establishment of NEC
	1989
2.	Remit of NEC
2.	The main task of our Commission is review research protocols on national level.
3.	Composition of NEC
	1 president 1 vice president 1 secretary 31 members (4 bioethicists, 1 journalist, 2 priests, 1 nurse, 1 biologist, 22 physicians).
4.	List of the last three NEC's opinions
	The main task of our Commission is review research protocols on national level. The commission participated in the preparation of the following regulations: 1. Stem cell research. 2. Regulation of biobanks. 3. Regulation and data protection of human genetics research.
5.	List of the next two future topics covered by NEC's opinions
6.	Chairperson and Secretariat
	Prof. Zoltán Papp president Prof. László Vécsei vice president. Dr. László Szőnyi secretary
7.	Contact details
	szolasz@gyer1.sote.hu

Inte	ernational Dialogue on Bioethics	Brussels, 19/02/2009	

IRELAND

NEC Name: Irish Council for Bioethics

1.	Year of establishment of NEC
	2002
2.	Remit of NEC
	 To identify and interpret the ethical questions raised by biomedicine in order to respond to, and anticipate, questions of substantive concern. To investigate and report on such questions in the interests of promoting public understanding, informed discussion and education. In light of the outcome of its work, to stimulate discussion through conferences, workshops, lectures, published reports and where appropriate suggest guidelines.
3.	Composition of NEC
	The Council currently has 14 members (maximum of 15 permitted), its membership is multidisciplinary with members coming from backgrounds as diverse as medicine, law, science, philosophy, theology and journalism. Members are invited to join the Council by virtue of their personal expertise, distinction and authority, and not as representatives of particular bodies or professions. Members are appointed for a period of three years.
4.	List of the last three NEC's opinions
	 Ethical, Scientific and Legal Issues Concerning Stem Cell Research Is it time for Advance Care Directives? Opinion 2007 Genetically Modified Crops, Threat or Opportunity for Ireland?
5.	List of the next two future topics covered by NEC's opinions
	 Biometrics Research Governance
6.	Chairperson and Secretariat
	Chairperson: Dr. Dolores Dooley

	Secretariat: Dr. Siobhán O'Sullivan, Ms. Emily DeGrae, Mr. Paul Ivory
7.	Contact details
	Tel: +353 1 4773217 Fax: +353 1 4029590 e-mail: info@bioethics.ie

ITALY

NEC Name: Comitato Nazionale per la Bioetica

1. Year of establishment of NEC The Italian Bioethics Committee was established by a decree signed by the President of the Council of Ministers on 28 March 1990 2. Remit of NEC The tasks are the following: to express opinions and suggest solutions, also for the purpose of preparing legislative acts, to address the ethical and legal problems that may emerge as a result of the progress of research and the emergence of possible new applications of clinical interest, taking into account the safeguarding of fundamental human rights and human dignity and the other values as expressed in the Constitutional Charter and in the international instruments supported by Italy; to propose solutions for the functions of control over both the safeguarding of human and environmental security in the production of biological material and the protection from all risk of all patients treated with products produced by genetic engineering or who are subjected to gene therapy; to promote the drawing up of codes of conduct for practitioners operating in the various sectors concerned and to encourage the proper informing of public opinion. 3. Composition of NEC The members of the CNB are 26: professors of medicine, biology, genetics, philosophy, history, law, bioethics and biolaw Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Roberto Colombo, Bruno Dallapiccola, Antonio Da Re, Maria Luisa Di Pietro, Emma Fattorini, Carlo Flamigni, Romano Forleo, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Aldo Isidori, Claudia Mancina, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, , Alberto Piazza, Vittorio Possenti, Rodolfo Proietti, Lucetta Scaraffia, Monica Toraldo di Francia, Giancarlo Umani Ronchi, Grazia Zuffa

4.

List of the last three NEC's opinions

5.	Drug experimentation on women Informed refusal and renouncement to healthcare in the patient-physician relationship Premature infants List of the next two future topics covered by NEC's opinions
	 Hybrid and Chimeras Ethics and neurosciences
6.	Chairperson and Secretariat
	The President: Prof. Francesco Paolo Casavola; Honorary presidents: Proff. Giovanni Berlinguer, Adriano Bompiani, Francesco D'Agostino, Rita Levi Montalcini, Adriano Ossicini; Vice presidents: Proff. Lorenzo D'Avack, Riccardo Di Segni, Luca Marini, Laura Palazzani secretariat coordinator: Dott.ssa Emira Aloe Spiriti; scientific secretariat: Grazia M. De Maria, Stefano Marcucci, Daniela Marrani; Marcella Marcelli administrative coordinator: Dott.ssa Agnese Camilli administrative secretariat: Delia Amari, Lorella Autizi, Maria Paglia, Anna Piermarini, Stefano Tedesco.
7.	Contact details
	Comitato Nazionale per la Bioetica Via della Mercede, 96 - 00187 Roma – Italia <u>cnbioetica@palazzochigi.it</u>

LATVIA

NEC Name: Central Medical Ethics Committee of Latvia

1.	Year of establishment of NEC
	1998
2.	Remit of NEC
	Committee is independent non profit organization. Committee meets once per month, if necessary more often. The mission of the Ethics Committee is to ensure that from a scientific ethical point of view biomedical research projects are carried out in a responsible manner, and that the rights, safety and wellbeing of subjects participating in a biomedical research project are protected, while at the same time creating the possibility of developing new, valuable knowledge. Committee participates in preparing documents and regulations on bioethics; solves actual problems in bioethics; participates in developing of teaching of bioethics, consults different organizations' on bioethics, collaborates with institutions which are interested in development of bioethics in Latvia and other countries.
3.	Composition of NEC
3.	Central Medical Ethics Committee of Latvia consists of 12 members:. Representatives from: Ministry of Health, Academy of Sciences, University of Medicine, Biro of Human rights, State institute of experimental and clinical medicine, Association of nurses, Association of pharmaceutics, Association of disabled, Association of retired, of religion, of Association of physicians, of Association of professional organizations' of medical personal. Committee is set up in 1998 by Cabinet of Ministers. Personalities are approved by Cabinet of Ministers.
4.	List of the last three NEC's opinions

	Taking into account that Committee is without any budget, we are not preparing written opinions.
5.	Chairperson and Secretariat
	Acting Chair: Prof.Aivars Lejnieks Secretary general: Laima Rudze
7.	Contact details
	Central Medical Ethics Committee of Latvia Cēsu 31/6 3 rd floor, 323 room Riga. LV 1012, Latvia Tel. +371 7043776 e-mail laima.rudze@voava.gov.lv

LITHUANIA

NEC Name: Lithuanian Bioethics Committee

1.	Year of establishment of NEC
	1995
2.	Remit of NEC
	Lithuanian Bioethics Committee takes responsibility for these two broad areas of activities:
	1. to inform and educate the biomedical community and general public on moral
	dilemmas arising in the context of modern health care.
	2.to protect patients' rights in the fields of biomedical research and clinical practice as well
	as to coordinate the ethical review of research protocols in Lithuania.
2	Composition of NEC
3.	Composition of NEC
	Lithuanian Bioethics Committee consists of a Secretariat and the Council. The Council of
	Committee is a multidisciplinary body representing different professional backgrounds,
	such as life sciences, humanities, law. 16 members of the Council are appointed by the
	Minister of Health.
4.	List of the last three NEC's opinions
	The Committee has been mainly involved in presenting its opinions to different
	governmental institutions as well as to the Parliament related to different bioethical issues
	(therefore they are not published):
	In 2007 Lithuanian Bioethics Committee has issued an opinion on the draft Law on Disposal of Human Remains;
	2. In 2008 the Committee has issued an opinion on the draft Law on Protection of
	Life in the Prenatal Phase and
	3. on the draft Law on Medically Assisted Reproduction.

5.	List of the next two future topics covered by NEC's opinions
	1. Peculiarities of the biomedical research undertaken on cadavers
	2. Publicity of information related to biomedical research
6.	Chairperson and Secretariat
	Chairperson: Eugenijus Gefenas
	Secretariat: Asta Cekanauskaitė, Ingrida Narusyte-Daugeliene, Egle Japertiene
7.	Contact details
	Web-site: http://bioetika.sam.lt
	Contact Person: Eugenijus Gefenas, Asta Cekanauskaite, Ingrida Narusyte-Daugeliene
	Address: Didzioji str. 22, LT-01128 Vilnius, Lithuania
	Phone: +370 5 2124565
	Fax: +370 5 260 8640
	Email: lbek@sam.lt

LUXEMBOURG

NEC Name: Commission consultative nationale d'éthique pour les sciences de la vie et de la santé

1.	Year of establishment of NEC
	Established in1988, functional since 1989
2.	Remit of NEC
	The mission of the National Ethics Commission consists in the study, either on its own initiative or at the request of the Government, of the ethical aspects of various issues raised in the field of health and life sciences and of the ways and means to implement them.
3.	Composition of NEC
	The National Ethics Commission is composed of 15 members including a chairman and a vice-chairman. According to its statutes, members are appointed by the Government for renewable term of five years.
4.	List of the last three NEC's opinions
	 Avis 19: Bref Avis sur le projet de loi n° 5448 relatif aux tissus et cellules humains utilisés à des fins thérapeutiques. Avis 20: Les limites de l'accès aux soins de santé au Grand-Duché de Luxembourg Avis 21: Le diagnostic de la mort en rapport avec le don d'organes. La pénurie de greffons.
5.	List of future topics covered by NEC's opinions
	Avis 22 concernant la législation relative aux adoptions et la problématique de l'accouchement anonyme (in progress)
6.	Chairperson and Secretariat
	Chairman: Paul Kremer Chargé d'études: Jean-Claude Milmeister
7.	Contact details
	Commission Nationale d'Ethique

Brussels, 19/02/2009

2, Circuit de la Foire Internationale L-1347 Luxembourg

MALTA

NEC Name: Bioethics Consultative Committee, Malta

1.	Year of establishment of NEC
	1989
2.	Remit of NEC
	 To offer an opinion regarding any bioethical issues To advice the Minister on such matters to sustain and encourage open discussion on bioethical issues
3.	Composition of NEC
	A multidisciplinary body with 13 members led by a Chairperson. Members come from medical, pharmacy, nursing, legal, ethical, and philosophical backgrounds and are appointed by the Minister on their own individual merit and capabilities.
4.	List of the last NEC's opinions
	 Medically Assisted Procreation Stem cell research Advanced Therapy Medical Products Organ donation and transplantation
5.	List of the next two future topics covered by NEC's opinions 1. Organ donation from anencephalic newborn infants 2. Opinion on draft embryo protection Act
6.	Chairperson and Secretariat

	Chairperson: Dr Michael Asciak, MD, MPhil
	Hon Secretary. Ms MaryAnne Ciappara, BPharm, MPhil.
7.	Contact details
	Bioethics Consultative Committee
	c/oPalazzo Castellania
	15 Merchants Street,
	Valletta

NETHERLANDS

NEC Name: Standing Committee on Medical Ethics and Health Law

1.	Year of establishment of NEC
	1977
2.	Remit of NEC
	The committee functions as an internal review board for all of the Health Council's reports dealing with normatively laden subjects. It also has an 'early warning' function and as such it draws up its own reports. The committee participates in several international networks of National Ethics Committees.
3.	Composition of NEC
4	Prof dr JA Knottnerus (chairperson) Prof mr JKM Gevers (vice-chairperson) Prof dr mr J Legemaate Dr WLM Kramer Prof mr AC Hendriks Prof dr DL Willems Prof dr GA den Hartogh Prof dr GRPTM Grol Prof dr RPTM Grol Prof dr GRJ de Groot Dr GCML Page-Christiaens Prof dr ir FE van Leeuwen Prof dr MA Verkerk Dr MR den Hartog-van Ter Tholen, (advisor) dr TME Smith-Mets Prof dr mr JCJ Dute Prof dr ir H Jochemsen Staff: dr mr CJ van de Klippe, mr LF Stultiëns, dr H Wijsbek.
4.	List of the last three NEC's opinions
	 Considerations pertaining to neonatal life termination Should blood donors be tested for Variant Creutzfeldt-Jacob disease? Confidence in responsible care? The effects of performance indicators and moral issues associated with their use.
5.	List of the next two future topics covered by NEC's opinions

	 Foetal therapy (ethical and legal aspects) Industry sponsored research
6.	Chairperson and Secretariat
	Chairperson: Prof dr Andre Knottnerus Secretariat: Dr Hanneke van de Klippe Dr Henri Wijsbek
7.	Contact details Health Council of the Netherlands PO Box 16052 NL 2500 The Hague E mail: h.w.j.m.wijsbek@gr.nl

POLAND

NEC Name: Bioethics Commission, Ministry of Health

1.	Year of establishment
	2001
2.	Remit of NEC and activities
	There is no formal NEC in Poland, the Comission is dealing with ethical aspects of health research.
	Legal basis of its creation:
	functions on the basis of Art. 29 item 5 of the law of December 5, 1996 (Journal of Law of 2002 No. 2, pos. 204, and No. 76, pos. 691), appointed by the Minister of Health on January 17, 2001 (regulation of the Minister of Health of July 24, 2001, regarding the appointment of and rules of procedure of a Bioethics Appeals Commission - Journal of Regulations of the Minister of Health No. 8, pos. 47, and No. 134, pos. 81 - as well as the regulation of the Minister of Health of June 28, 2002, regarding the appointment of an Bioethics Appeals Commission - Journal of Regulations of the Ministry of Health of 2002 No. 7, pos. 35
	Rules of procedure:
	the regulation of the Minister of Health and Social Welfare of May 11, 1999 (Journal of Laws No. 47, pos. 480) concerning the particular rules of appointing and funding as well as the procedure of bioethics committees,
	Considering appeals against decisions of the bioethics committees of the regional chambers of physicians, institutions of higher medical education, as well as institutions of higher education with departments of medicine, and also medical research and development institutions, hereinafter "bioethics committees",
	Cooperating with bioethics committees, organizing meetings and training for the members of bioethics committees
	The comission also answers specific questions related to health research (clinical trials, experimental therapy, etc.) originating within the Ministry of Health and directed to it from outside.
	Organization of international conferences
3.	Composition

D.Barnas, licentiate in nursery Dr P.Bilinski (internal medicine, endocrinology, public health) The rev.professor W.Boloz, (bioethics, ethics, moral theology) Prof.A.Chybicka (pediatrics, haematology, oncology) Prof.R.S.Debski (on-gyn, endocrinology) Prof.A.Gorski (internal medicine, clinical immunology, bioethics) Prof.emeritus Z.S.Herman (internal medicine, pharmacology) Prof. R.Krajewski (neurosurgery) Prof. D.E.Moska (pharmacy) Dr J.A.Piatkiewicz (internal medicine) Prof.emeritus S.Puzynski (psychiatry) Prof.emeritus T.Tolloczko (surgery) Administration: W.Walawska List of the last three NEC's opinions 4. The ethics of intellectual property rights and patents - 2004 http://www.iitd.pan.wroc.pl/events/patents.html The responsible conduct of research - 2005 http://www.iitd.pan.wroc.pl/events/RCR.html The Ethics of Research in Emergency Medicine - 2006 http://www.iitd.pan.wroc.pl/events/EmergMed.html List of future topics covered by NEC's opinions 5. Qualifications of lead investigators in clinical trials (the commission recommends higher requirements than those currently existing, including specialty or subspecialty boards, and a doctorate). Number of projects concurrently directed by one investigator - the commission recommends introducing rules preventing concurrent directing of multiple projects (such rules exist in non-clinical research). Chairperson and Secretariat 6.

	Chair: Prof.A.Gorski Secretary: Prof. R.Krajewski Administration: W.Walawska.
7.	Contact details
	Ministry of Health Department of Science and Higher Education ul. Miodowa 15 00-952 Warszawa tel. (0-22) 634-94-00, 634-94-65, 831-15-53 fax. (0-22) 634-9465 e-mail: agorski@ikp.pl dep-nk@mz.gov.pl

PORTUGAL

NEC Name: National Council of Ethics for the Life Sciences (CNEV)

<u> </u>	V C Lish CNEC
1.	Year of establishment of NEC
	1990
2.	Remit of NEC
	The National Council of Ethics for the Life Sciences (CNEV) is an independent body created in 1990 by Law n° 14/90 of the 9 th of June for the purpose of " analyzing systematically the moral problems which arise out of scientific progress in the fields of biology, medicine or general health care". The CNEV defines itself as national, independent, pluralist and consultative.
3.	Composition of NEC
	President Paula Martinho da Silva
	Paula Martinno da Silva
	Council Members designed by Parliament
	Angostinho Almeida Santos
	Antonio Vaz Carneiro
	Jorge Sequeiros
	Miguel Oliveira da Silva
	Rui Lopes Nunes
	Salvador Massano Cardoso
	Council Members designated by Government
	João Lobo Antunes – Health Care
	José de Oliveira Ascensão – Superior Science and High Learning
	José Pedro Ramos Ascensão – Youth
	Marta Mendonça – Justice
	Michel Renaud – Education
	Council Members designated by other entities
	Daniel Serrão – Lisbon Academy of Sciences
	Fernando Regateiro – Science and Technology Foundation
	Jorge Biscala – Nationwide organisations representing bioethics –related activities
	Jorge Soares – Legal Higher Council of Forensic Medicine
	Pedro Fevereiro – Biologists' Association
	Maria do Céru Patrão Neves – Council of Deans of Portuguese Universities
	Maria Fernanda Henriques – Commission for the Equality and Rights of Women
	Pedro Nunes – Medical Association

	Rita Amaral Cabral – Bar Association
	Assessor for the President: Ana Sofia Carvalho
	Secretary: Cíntia Águas
4.	List of the last three NEC's opinions
-T.	56/CNEV/2008 – Opinion on Direct Marketing of Genetic Test to the Public 55/CNEV/2008 – Opinion on the Draft Bill on the Legal Regime of Quality and Safety Relating to the Donation, Procurement, Testing, Processing, Preservation, Storage, Distribution and Application of Tissues and Cells of Human Origin.
	53/CNEV/2007 – Opinion on Draft Bills N° 126/X (which establishes the Principles of Scientific Research in Stem Cells and the Use in Embryos), and N° 376/X (which establishes the Legal System for the Use of Stem Cells, for Research Purposes and the Therapeutic Applications).
5.	List of the next two future topics covered by NEC's opinions
	NEC will start a new mandate very soon.
6.	Chairperson and Secretariat
	Chairperson : Paula Martinho da Silva Executive Secretary: Cíntia Águas
7.	Contact details
	Conselho Nacional de ùEtica para as Ciências da Vida Presidência do Conselho de Ministros Rua Professor Gomes Teixeira, Ed PCM – 4° 1399-022 Liboa Tel: +351 213 927 316 Fax: +351 213 927 629 www.cnec.gov.pt cintia.aguas@sg.pcm.gov.pt

ROMANIA

NEC Name: Bioethics Committee (attached to College of Physicians)

1.	Year of establishment of NEC
	2000
2.	Remit of NEC
3.	Composition of NEC
	1 President
	1 Vice president
	1 Secretary
	3 Members (all appointed by the president)
4	The Calabara NECLATT
4.	List of the last three NEC's opinions
	1. Medical mistakes in clinical practice: creation of a mediation tool between patients
	and physicians in litigation or involved malpraxis complaint
	2. Explicit consent and presumed consent in transplantation
	3. Ethical issues related to GMOs acceptance
5.	List of the next two future topics covered by NEC's opinions
J.	List of the next two future topies covered by 1420 3 0 pinions
	1. Develop guidelines for informed consent in different medical domains
	2. Develop guidelines for stem cell research
6.	Chairperson and Secretariat
	Beatrice Ioan
	Cristina Gavrilovici
7.	Contact details
1.	Contact details

ioanbml@yahoo.com
cristina gavrilovici@yahoo.com

SLOVAKIA

NEC Name: Etická komisia Ministerstva zdravotníctva Slovenskej republiky

1.	Year of establishment of NEC
	1990
2.	Remit of NEC
	to advise the minister, departments of the ministry of health, and if asked, also other ministries and high level state institutions, on ethical issues of health care and biomedical research (details given in the Statutes issued by the minister of health)
3.	Composition of NEC
	13 regular members (professions*: 9 physicians, 2 scientists – genetics, biology, 2 theologians) 1 extraordinary member 1 secretary
	* some members have dual professional competencies, e.g. medicine/bioethics, biology/ethics, medicine/theology, medicine/biochemistry.
4.	List of the last NEC's opinions
	1. Umbilical cord blood banking (2008)
5.	List of the next two future topics covered by NEC's opinions
	 Rejection of life sustaining treatment (blood transfusion) by a patient High cost therapies
6.	Chairperson and Secretariat
	Mr. Peter Križan, MD, PhD. – chairperson e-mail: <u>peter.krizan@erudis.sk</u>
	Mr. Peter Valúch, MA – administrative secretary

	e-mail: peter.valuch@health.gov.sk
7.	Contact details
	Mailing address:
	Etická komisia Ministerstva zdravotníctva SR
	Limbová 2
	837 52 Bratislava, Slovak Republic
	e-mail: <u>peter.valuch@health.gov.sk</u>

SLOVENIA

NEC Name: National Medical Ethics Committee of Slovenia

1.	Year of establishment of NEC
	1995 (as a successor of an older Committee est. in 1979)
2.	Remit of NEC
11 i i i i i i i i i i i i i i i i i i	Preparing opinions on ethical issues in biomedicine and health care upon requests by the Parliament, Government Ministries, various bodies and institutions as well as individuals.
	Ethical review of biomedical research projects.
3.	Composition of NEC
	13 members: 7 practising or retired physicians, a clinical psychologist, a sociologist, a lawyer, a theologian, a medical deontologist, a lay person.
4.	List of the last three NEC's opinions
	 Patient's right to posthumous confidentiality Right to refuse life-saving medical procedures Conscientious objection
5.	List of the next two future topics covered by NEC's opinions
	Palliative sedation Advance directives and continuing power of attorney
6.	Chairperson and Secretariat
	Prof. Joze Trontelj, Chair Tone Zakelj, Vice-Chair
7.	Contact details
	joze.trontelj@kclj.si
	tone.zakelj@kclj.si
	mailing address: National Medical Ethics Committee, University Medical Center Zaloška 2 , SI-1525 Ljubljana

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SPAIN

NEC Name: Comité de Bioética de España (Bioethics Committee of Spain)

T 1	VCLU-LCNEC
1.	Year of establishment of NEC
	O at a large 2000
	October 2008
	(created by Law 14/2007, 3 rd July, on Biomedical Research, art. 77 ff.)
2.	Remit of NEC
	a) To issue reports, proposals and recommendations for the state and autonomous public powers in matters with relevant ethical implications.
	b) To issue reports, proposals and recommendations on matters that the Committee considers relevant related with the ethical and social implications of Biomedicine and the Health Sciences.
	c) To establish the general principles for the drafting of good practices codes for scientific research that shall be developed by the Research Ethics Committees.
	d) Represent Spain in the supranational and international forums and organisations that deal with Bioethics.
	e) Draft an annual memory of activities.
	f) Any others that are attributed in the regulations that develop this Law.
3.	Composition of NEC
	Members:
	Carlos Alonso-Bedate
	Carmen Ayuso-Gercía
	Jordi Camí-Morell
	María Casado-González
	Yolanda Gómez-Sánchez
	César Loris-Pablo
	José Antonio Martín-Pallín
	César Nombela-Cano
	Marcelo Palacios-Alonso
	Carlos María Romeo-Casabona
	Pablo Simón-Lorda
	Tire Call 1 and NIECL addition
4.	List of the last three NEC's opinions

5.	List of the future topics covered by NEC's opinions
	Seven opinions, reports and guidelines are under preparation by the Committee. The related issues will be made public in the next weeks.
6.	Chairperson and Secretariat
	Chair: Victoria Camps
	Secretary: Joaquin Arenas (External to the Committee: no right to vote).
7.	Contact details
	(Temporary address) (Website under construction) Comité de Bioética de España Instituto de Salud Carlos III C/ Sinesio Delgado, 6 Pabellón - 5 28029 - Madrid

SWEDEN

NEC Name: The Swedish National Council on Medical Ethics

1.	Year of establishment of NEC		
	The Council has been operational since 1986.		
2.	Remit of NEC		
	The National Council on Medical Ethics is an advisory body to the Swedish government on ethical issues raised by scientific and technological advances in biomedicine. The Council constitutes a forum for the exchange of information and ideas and promotes discussion on new medical research and applications. The Council deals with questions that have been referred to it or issues identified by the Council itself.		
	Administratively, the Council is a committee/working group established by the government and affiliated to the Government Offices where its secretariat is located.		
Members of the Council represent the seven political parties of the Swedish parliamer agencies and interest groups working with various aspects of health and medical care. I three-year term and are appointed by the Minister of Health, based on nomination political parties, agencies and interest groups. The expert members represent medic philosophy. They are appointed based on professional expertise and recognition. The 21 members.			
	Special experts are often invited to hearings and seminars with the Council. The discussions may result in an official statement of opinion, which is most frequently addressed to the Ministry of Health and Social Affairs. The Council meets on a monthly basis. It organizes annually a one-day conference open to health professionals and others with an interest in medical ethics as well as hearings and seminars on current topics, often in collaboration with for example the Swedish Advisory Board on Gene Technology, the Swedish Research Council, and the Swedish Society of Medicine.		
3.	Composition of NEC		
	Council members as of 1 januari 2009 Daniel Tarschys (chair) Prof Political Science Ann Arleklo MP Leif Carlson former MP Sven-Olov Edvinsson Senior Physician Anders Henriksson County Council Commissioner Tuulikki Koivunen Bylund Dean of Uppsala Cathedral Elina Linna MP Chatrine Pålsson Ahlgren MP Barbro Westerholm MP		

	Lars Berge-Kleber Repr. of The Swedish Disability Federation					
-	Daniel Brattgård Hospital Chaplain					
	Marianne Granath Repr. of The Swedish Association of Local Authorities and Regions					
	Göran Hermerén Prof. emeritus of Medical Ethics Karin Johannisson Prof. of History of Science and Ideas Christina Kärvinge Repr. of the National Board of Health and Welfare Nicla Lawrence Medical Ethics Repr. of the Society of Medicine					
	Niels Lynöe Prof. of Medical Ethics, Repr. of the Society of Medicine					
	Lisbeth Löpare Johansson Repr. of The Swedish Association of Health Professionals					
	Lena Rehnberg Repr. of the Ministry of Health and Social Affairs					
	Nils-Eric Sahlin Prof. of Medical Ethics					
	Jan Wahlström Prof. emeritus of Clinical Genetics					
	Expert in Medical Law (temporarily vacant)					
4.	List of the last three NEC's opinions					
	1. Human/animal mixes in research (December 2008)					
	2. Decisions at the end of life (November 2008)					
	3. Health care for asylum seekers and hidden refugees (March 2008)					
	o, Treman cure for any runn occurre and running of the control of					
5.	List of the next two future topics covered by NEC's opinions					
	1. Priority setting in health care					
	2. (Future methods in prenatal diagnostics or 'Neuroethics')					
6.	Chairperson and Secretariat					
	Acting Chair: Prof. Daniel Tarschys					
	Head of Secretariat: Erik Forsse					
	Council secretary: Lotta Eriksson					
7.	Contact details					
	Statens Medicinsk-etiska råd					
	National Council on Medical Ethics					
	103 33 Stockholm					
	Sweden					
	e-mail: smer@social.ministry.se					
	URL: www.smer.se					

UNITED KINGDOM

NEC Name: Nuffield Council on Bioethics

1.	Year of establishment of NEC
	1991
2.	Remit of NEC
	The Nuffield Council on Bioethics examines ethical issues raised by new developments in biology and medicine, with a view to providing independent advice to policy makers and stimulating debate in bioethics.
	The Council is an independent body funded jointly by the Nuffield Foundation, the Medical Research Council and the Wellcome Trust.
	The Council's terms of reference require it:
	 to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern; to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body; in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.
3.	Composition of NEC

Professor Albert Weale FBA (Chair)

Professor of Government at the University of Essex

Professor Peter Smith CBE FMedSci (Deputy Chair)

Professor, Infectious Disease Epidemiology Unit

London School of Hygiene and Tropical Medicine

Professor Steve Brown FMedSci

Director of the MRC Mammalian Genetics Unit at Harwell

Professor Roger Brownsword

Professor of Law at the Centre for Medical Law and Ethics, King's College London

Professor Robin Gill

Michael Ramsey Chair of Modern Theology at the University of Kent

Professor Sian Harding FAHA

Professor of Cardiac Pharmacology at the NHLI, Faculty of Medicine, Imperial College London

Professor Peter Harper

University Research Professor in Human Genetics at Cardiff University

Professor Ray Hill FMedSci

Business Development Advisor at Imperial College London

Professor Søren Holm

Professorial Fellow in Bioethics at Cardiff Law School

Professor Christopher Hood FBA

Gladstone Professor of Government and Fellow of All Souls College Oxford and Director of the ESRC's Public Services Research Programme

Professor Tony Hope

Professor of Medical Ethics at the University of Oxford

Mr Anatole Kaletsky

Associate Editor of The Times

Dr Rhona Knight FRCGP

General Practitioner and Senior Clinical Educator at the University of Leicester

Professor Graeme Laurie FRSE

Professor of Medical Jurisprudence at the University of Edinburgh

Dr Tim Lewens

Lecturer in the Department of History and Philosophy of Science at the University of Cambridge

Professor Ottoline Leyser CBE FRS

Professor of Plant Developmental Genetics at the University of York

Professor Anneke Lucassen

Professor in Clinical Genetics and Honorary Consultant in Clinical Genetics at the University of Southampton

Professor Alison Murdoch FRCOG

Professor of Reproductive Medicine, consultant gynaecologist and Head of the NHS Newcastle Fertility Centre at Life

Dr Bronwyn Parry

Reader in Geography at Queen Mary, University of London

Professor Hugh Perry FMedSci

Professor of Experimental Neuropathology at the University of Southampton and Director of the Southampton Neuroscience Group

Professor Nikolas Rose

James Martin White Professor of Sociology at the London School of Economics and Political Science

Professor Jonathan Wolff

Professor of Philosophy at University College London

4. List of the last three NEC's opinions

	 Critical care decisions in fetal and neonatal medicine (November 2006) The forensic use of bioinformation Public Health: ethical issues
5.	List of the next two future topics covered by NEC's opinions 1. Dementia 2. Personalised Healthcare
6.	Chairperson and Secretariat Chair: Prof Albert Weale Head of Secretariat: Hugh Whittall
7.	Nuffield Council on Bioethics 28 Bedford Square London WC1B 3JS UK e-mail: cperkins@nuffieldbioethics.org URL: www.nuffieldbioethics.org

Brussels, 19/02/2009

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LITHUANIA Lithuanian Bioethics Committee		Ms. Ingrida NARUSYTE- DAUGELIENE
LUXEMBOURG	Commission consultative nationale d'étique	Mr. Jean-Claude MILMEISTER

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	pour les sciences de la vie et de la santé	
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