



XV NEC Forum meeting

3-4 March

International Dialogue on Bioethics

Madrid 2010

4-5 March



Wednesday, 3 March 2010

Morning Session

10.00 - EGE NEC joint session:

13.00 Theme; Institutional role of the advisory Ethics bodies

- Opening and Welcome

José Jerónimo Navas Palacios

Director del Instituto de Salud Carlos III

Peteris Zilgalvis

Head of Unit, Governance and Ethics, DG Research, European Commission

Maurizio Salvi

Head of EGE Secretariat, Bureau of European Policy Advisers, European Commission

- The Role of the EGE within the EU Institutional setting

Goran Hermeren - President EGE

- Overview of role/remit of NECs in the EU

Michael Fuchs - Bonn University

- NEC as a Council of Minister advisory body

Paul Schotsmans- Belgian Advisory Committee on Bioethics

- NEC as a Parliament advisory body

Kristiane Weber-Hassemer - German Ethics Council

13.00 - Lunch

14.30



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Afternoon Session

NEC FORUM

Theme: ethics deliberation and international clinical trials

14.30 - Opening Speeches

14.50

Victoria Camps

Comité de Bioética de España, President

Peteris Zilgalvis

Head of Unit, Governance and Ethics, DG Research, European. Commission

14.50 - What Ethics frame?

18.00

Chair: Pablo Simón Lorda
Comité de Bioética de España

14.50 - Ethics councils. When to deliberate is mandatory

15.10

Diego Gracia

*Professor of history of Medicine in Universidad
Complutense de Madrid.*

15.10 - Short comments and questions from NEC panel:

15.20

Laura Palazzani, Italian National Bioethics Committee

Peter Križan, Slovak National Ethics Committee

15.20 - General discusión

15.30

**15.30 - Are the so called "classical" bioethics principles in the
15.50 developed countries still valid?**

John Harris

*Research Director University of Manchester Institute of
Science, Ethics and Innovation*

15.50 - Short comments and questions from NEC panel;

16.00

Hugh Whittall, Nuffield Council

*Jean Claude Ameisen, French National Consultative Ethics
Committee on Health and Life Sciences*

16.00 - General discusión

16.15



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6.15 - Coffee Break
16.45

16.45 - Round table:
18.00 Collaborative Biomedical research and development: interaction between academia and the private and public sectors

Chair: César Nombela
Comité de Bioética de España

16.45 - Introduction by Carlos Alonso - Comité de Bioética de
17.05 España
"The triple helix for a global health"

Short reactions from representative of

- Private sector: José Félix Olalla, Sanofi Aventis
- Public Sector: François Hirsch, INSERM, F
- NEC representative: Dick Willems, Centre for Ethics and Health, NL

- General discussion

18:15 Cocktail

Thursday, 4 March 2010

Morning Session

09.30 - **NEC FORUM (continued)**
13.00

Clinical trials and ethics; Current regulatory approaches

Chair: Yolanda Gómez
Comité de Bioética de España

09.30 - EU Clinical trials legislation
09.50 Stefan Fuehring - DG ENTR, European Commission

Health/Consumer Policy



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- 09.50 – EC ethics review
10.10 Dorian Karatzas, DG RTD, European Commission
Igidovos *Research and Technological Development*
- 10.10 - US legislation
10.30 Daniel Davies, Georgetown University
- 10.30 - Discussion
11.00
- 11.00 - Coffee Break**
- 11.30 Ethics Review and Clinical trials regulation: experiences and future challenges**
- Chair: Carlos Romeo Casabona
Comité de Bioética de España
- 11.30 - Perspectives from Austria
11.50 Christiane Druml - Austrian Bioethics Commission
- 11.50 - Clinical trials and the public sector
12.10 François Hirsch - INSERM, France
- 12.10 - Perspectives from the Netherlands
12.30 Dick Willems and Alies Struijs - Centre for Health & Ethics,
NL
- 12.30 - Discusión
13.00



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13.00 - 13.10 Closing of the meeting

Closing words by Victoria Camps, Comité de Bioética de España,

**Invitation to the next NEC Forum meeting by Paul Schotsmans, Belgian
Advisory Committee on Bioethics**

**Closing words by Peteris Zilgalvis, Head of Unit, Governance and Ethics,
DG Research, European Commission**

END NEC FORUM

13:10 – 14:30 Lunch



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International Dialogue on Bioethics

The role of ethics in international biomedical research

A conference organised by the European Commission's Bureau of European Policy Advisers (BEPA)

PRELIMINARY PROGRAMME

Thursday, 4 March 2010

Chair President of EGE: Prof Göran Hermerén

14.30 – **Welcome**

15.00 President of EGE: Prof Göran Hermerén
President ES NEC: Ms Victoria Camps (EU Council Rotation Presidency)
Director del Instituto de Salud Carlos III : José Jerónimo Navas Palacios

15.15 – **Key note: "EU as a community of values"**

15.30 Mr Margaritis Schinas, Principal Adviser, Deputy Head of BEPA

15.30 – **Key note: "Equity, solidarity and global governance"**

16.00 Sir Michael Marmot, Director International Institute for Society and Health

15.45 – **Debate**

16.20

16.20 – **How to handle conflict between international regulatory regimes?**

- 17.30
- Prof Qiu Renzong, China (SARS) (10 min)
 - Ms Cathy Tansey, Canada (SARS) (10 min)
 - Prof Manuel Ruiz de Chavez, Mexico (swine flu) (10 min)

- Debate (30 min)

17.30- **Coffee break**

18.00

18.00- **International initiatives**

- 19.00
- CoE, Ms Laurence Lwoff (10 min)
 - Unesco, Ms Dafna Feinholz (10 min)
 - WHO, Ms Marie Charlotte Bousseau (10 min)

- Debate (30 min)



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- 19.00- **Key note: "Ethics and EU"**
19.15 Mr Antoniõ Fernando Correia de Campos, European Parliament's Scientific Technology Options Assessment commission (STOA)
20.30 Official Dinner

Friday, 5 March 2010

Chair President ES NEC: Ms Victoria Camps

- 09.30 – **Ethics review and biomedical research in emerging and developing countries - case studies**
10.40

- Prof Danie Du Toit, South Africa (10 min)
- Prof Leonardo De Castro, The Philippines (10 min)
- Prof Christian de Paul de Barchifontaine, Brazil (10 min)
- Prof Boris Yudin, Russia (10 min)
- Prof Anggara Umar Jenie, Indonesia (10 min)
- Prof Vijay Kumar, India (10 min)
- Ms Otilia Vainstock, Argentine (10 min)

- 10.40 – Debate (30 min)
11.10

- 11.10 – Coffee break
11.30

- 11.30 – **What ethics frame for a global governance of biomedical research?**
12.50

- Prof Ibrahim Badran, Egypt (10 min)
- Prof Ryuichi Ida, Japan (10 min)
- Dr Timothy Dyke, Australia (10 min)
- Prof Chifumbe Chintu, PABIN (10 min)

- Debate (30 min)

- 12.50 – **Closing ceremony**
13.00

- President of EGE: Prof Göran Hermerén
- President ES NEC: Ms Victoria Camps → *public awareness*
- IBD Secretary: Mr Maurizio Salvi → *Next steps = reinforces the Dialogue. web page*

- 13.00- Lunch
14.30