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2011

Ethics and biomedical research in the EU -

Activities of the Directorate General Research and Innovation

European Commission
DG Research and Innovation
Directorate B: European Research Area
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**The views expressed are those of the speaker and do not necessarily reflect the official opinion of the European Commission*





EU Policy and values

- The Heads of State and Government of the EU signed the [Lisbon Treaty](#) on December 13, 2007. The Treaty is in force as of 1-12-09.
- The **Lisbon Treaty** inter alia indicates a set of [European Values](#), such as human dignity, freedom, democracy, human rights protection, pluralism, non-discrimination, tolerance, justice, solidarity and gender equality. The values above are stated in the [European Charter of fundamental rights](#) that has been [proclaimed by the Presidents of the 3 EU Institutions](#) (Council, Commission and European Parliament) on **December 12, 2007**.
- Respect for [free and informed consent](#) in biomedicine and for the [protection of personal data](#) are explicitly mentioned in the European Charter of fundamental rights



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These values underpin EU legislation and policies in the area of biomedical research, and imply high ethics standards for research and innovation in the EU.

High ethics standards are important also because they add to the quality of research and innovation:

- They promote research integrity and a better alignment of research with social needs and expectations.
- They support the societal uptake of the new products, processes and services that are the result of scientific research, because high ethical standards generally merit public trust.



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Ethics Activities with regard to biomedical research at DG Research and Innovation



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EC Ethics Review



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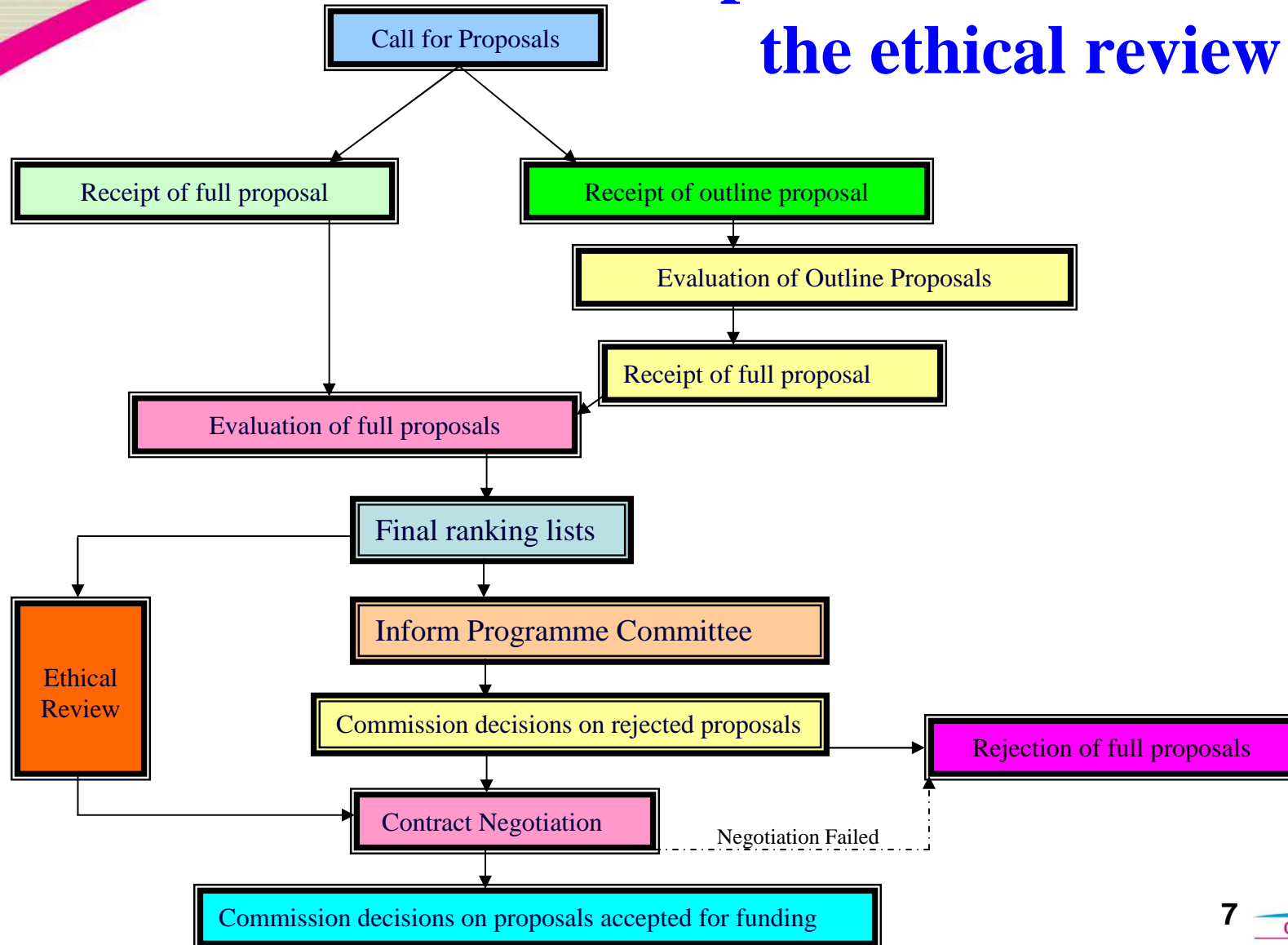
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EC Ethics Review

- An integral component of the research proposal evaluation procedure undertaken by the European Commission.
- A legal requirement under FP7:
ensure that all research activities are conducted in accordance with fundamental ethical principles (Article 6 , FP Decision).



EC evaluation procedure including the ethical review





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EC Ethics Review

The ethics review is conducted by independent panels:

- variety of disciplines with a reasonable balance of scientific and non-scientific members.
- geographical and gender balanced
- composition depending on the nature of the proposals under review.



EC Ethics Review

- In particular, the Ethical Review Panel discusses the following elements:
 - The **awareness** of the applicants on the **social impact** of the research they propose
 - Whether the relevant **European Directives, international Conventions/Declarations** are applied
 - Whether the consortium is seeking the **approval of relevant local ethics committees.**



EC Ethics Review - Audit

- 'the Ethical Review report may indicate the need to organise a follow-up review at a later stage of the project' (Rules for submission of proposals)
- Main aim is to check
 - whether all potential ethical issues have been taken into consideration and there is compliance with relevant regulations and FP7 ethical guidelines
 - Are the ethical issues periodically reviewed at the management level, are the correct actions taken to manage the risks?
 - Are the ethical requirements mentioned within the contract successfully implemented (e.g. informed consent forms or sheets, legal authorisations, etc)
 - Quality of the deliverables related to Ethics



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EC 'Support Actions' focusing on capacity building, infrastructures, networking, exchange of best practice



- ❖ European Group on Ethics (EGE)
 - *Independent, multidisciplinary advisory body to the President of the European Commission*

- ❖ Forum of National Ethics Councils (NEC Forum)
 - *An independent informal platform for exchange of best practices in the field of ethics and science*
 - <http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1305>

- ❖ European Network of Research Ethics Committees (EURECNET)
 - *network of national networks and associations of Research Ethics Committees (RECs) in Europe*
 - <http://www.eurecnet.org/index.html>



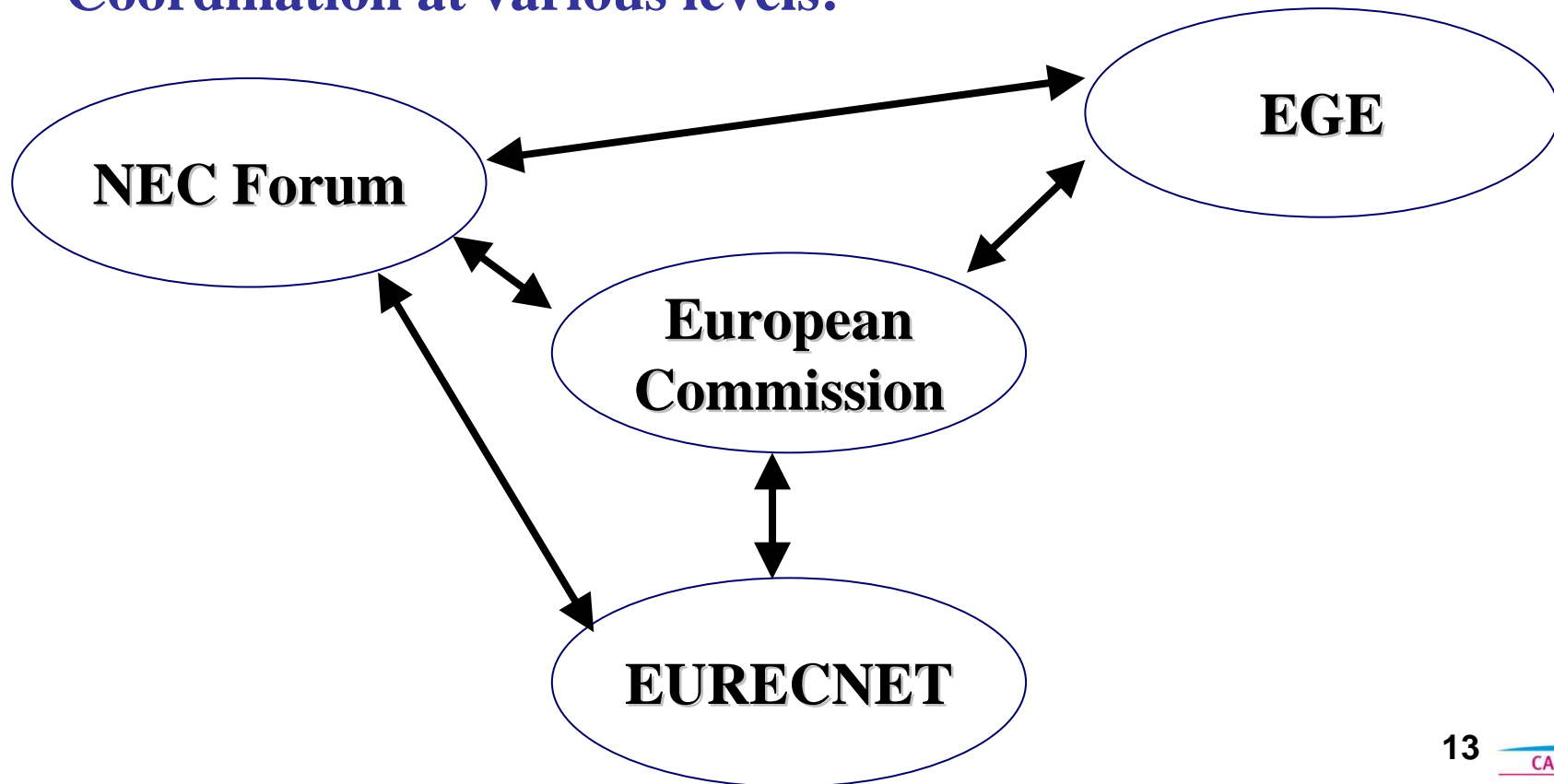
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Ethics Activities by the EC

A robust ethics infrastructure in the European Research Area (ERA)

Coordination at various levels:





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Supporting infrastructures and exchange of best practise:

- Forum of National Ethics Councils (NEC Forum)

***11th NEC Forum
27-28 Feb 2008
Brdo, Slovenia***





❖ Other Specific `Support Actions`, e.g.:

- EC-UNESCO Conference '[Joint Action for Capacity Building in Bioethics](#)', Mexico City, November 2009
- [Textbook on Ethics in Research \(2010\)](#)
<http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1362>
- Expert group on Biobanks (2011/2012), collaborating with the Council of Europe





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Thank you for your attention

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