The European Commission as a Partner of International Cooperation in Research Ethics

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The objectives and activities of the Governance and Ethics Unit

- The Governance and Ethics Unit deals with European and international governance aspects linked to risks and ethics in research.

- One of the Unit’s tasks is to analyse, through ethics reviews, whether the values - enounced in the European Charter of Fundamental Rights - are respected in the research activities funded by the European Commission.
The objectives and activities of the Governance and Ethics Unit

1. Ethics Reviews

- One of the objectives of EC Ethics reviews consists in ensuring that Community research conducted in partner countries complies with fundamental ethical principles.
- Seventh Framework Programme (Decision N° 1982/2006/EC), Article 6 (1§):

« All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles. »
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1. Ethics Reviews

FP6 Research Proposals undergoing EC ethics reviews in 2006

- 90% Other
- 10% Proposals involving developing countries
The objectives and activities of the Governance and Ethics Unit

1. Ethics Reviews

Sensitive ethical issues raised by FP6 research proposals undergoing ethics reviews in 2006

- Adult healthy volunteers in CT: 11%
- Children in CT: 15%
- Data Protection and Benefit Sharing: 25%
- Informed Consent: 31%
- Intrusive nature of the study: 18%
The objectives and activities of the Governance and Ethics Unit

2. Capacity-building projects in research ethics

Why support capacity-building in partner countries?

- Both partners can learn, the EC and the countries in question. Some partner countries show a need of "ethics capacities" when they are asked to review international research activities: problems of sustainability or lack of coordination may exist but in other cases examples of best practice are present.

- **It is of primary interest to** foster ethics structures in partner countries when this is needed, in order to enable them to participate in international research relevant to their needs and **to undertake their own ethics review** of research proposals.
The objectives and activities of the Governance and Ethics Unit

2. Capacity-building projects in research ethics

Objectives

- Through EU-funded research projects, it is possible to build capacities in research ethics by sharing knowledge and best practices in the field of ethics, including between partner countries themselves.

- The long term objective is to strengthen the capacity of ethics committees in implementing international ethics guidelines and their own national requirements, and to promote their active participation in the international debate on research ethics as our equal partners.
The objectives and activities of the Governance and Ethics Unit

2. Capacity-building projects in research ethics

Description of key research projects

- Several "Governance and Ethics" collaboration projects with developing countries and emerging economies were financed through FP6:

→ ex. EULABOR, BIONET, EDCEP, GENBENEFIT, NEBRA, GLOBAL FORUM ON BIOETHICS IN RESEARCH
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**EULABOR** (European and Latin America Ethical Regulations Systems of Biomedical Research: Comparative Analysis of its Pertinence and Application for Human Subject Protection)

- EULABOR is the first European and Latin American network on ethics regulation of biomedical research.

- This project is supported by the European Commission (budget: 289 270, 00 €) in FP6 – 2004 – Science and Society –, and coordinated by Inserm.
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**EULABOR**

1) OBJECTIVES

- EULABOR aims to evaluate the systems of ethics regulation of biomedical research involving human subjects, considering their pertinence and consequences in the context of socio-economic conditions and cultures in Argentina, Brazil, Chile, Mexico, France, Germany and Spain.

- The ultimate objective is to propose new perspectives to deal with ethical issues of biomedical research.
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EULABOR

2) ACTIONS

- EULABOR will propose training programs for different audiences to give them some insight in the ethical dimension of research.

- It will discuss tools to improve the awareness of the public and stakeholders on ethical issues, taking into account the differences between Northern and Southern countries.
After a global and comparative analysis of the ethics regulation systems of biomedical research in the countries under study, EULABOR performed in 2006 an identification of the major common problematic issues of these systems.

The common problematic issues are structured in 3 areas:
- **Foundations & disruption** of the ethics regulation system
- **Interest & conflicts** in the framework of techno biomedical science
- **Civil society**, empowerment, citizenship & research ethics
For instance, EULABOR shows great differences between the countries concerning the application of the two pillars of ethics regulation: informed consent and research ethics committees.

- **in Europe**: the information to the patients, the collection of informed consent and its evaluation by ethics committees are a legal-administrative steps

- **in Chile, Mexico and Argentina**: the ethics committees suffer a lack of administrative and political support
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EULABOR

4) COMMENTS FROM MEMBERS

- According to the Inserm’s research and coordinator of EULABOR, this project is “the first step to the ethical approach in biomedical research, combining on one hand the plurality and sharing national experiences, and on the other, the respect of common values”.

- According to one member of the EULABOR’s advisory board, “the clinical research presently is organised in an international network, and in this context, it is necessary to establish bridges between different cultural ethics approach to better protect the persons involved in clinical trials”.

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**BIONET**

- BIONET is a Coordinated Action Project, funded by the European Commission under FP6.
- BIONET is a 21-partner European-Chinese collaboration on ethical governance in the life sciences.
- This network will work to undertake research, training, workshops and conferences, together with the production of relevant materials and documentation, on the ethical governance of research in the life sciences and biomedicine within and between China and European countries.
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1) OBJECTIVES

- Two cultures working together to tackle some of the most challenging issues in biomedical research ethics, such as the latest developments in reproductive medicine, genomics, biobanking, and stem cell research.

- Its special focus was on questions of informed consent and ethical review boards in assisted reproductive technologies and biomedical research.
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2) ACTIONS

- Within BIONET, the New Ethical Expert Group will work towards guidelines for best practice in ethical governance of collaborative research between China and Europe, foster mutual understanding and provide opportunities to learn from each other.

- The group works on the assumption that an exchange process can provide better solutions for both sides.
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3) COMMENTS FROM MEMBERS

■ “Communication, based on listening to the concerns of others in different cultural contexts, is a seed from which ethics can grow. It is itself an ethical act.

■ “Though bioethics emerged a little late in China, in recent years our government has made great efforts to develop bioethics working with scholars in related fields. Now with the support of the government and efforts of scholars, we have seen how bioethics has really provided guidance in biomedical research and practice”.
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**EDCEP** (European and Developing Countries Ethics Partnership)

- EDCEP is a **Specific Support Action**, funded by the European Commission under FP6 (budget: 200,000 €).
- The aim of the project is to **develop capacity in research ethics review** related to **clinical research in developing countries**.
- The project is coordinated from the University of Bergen, Norway, in collaboration with the Centre for Science, Society and Citizenship in Rome, Italy as a partner.
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1) OBJECTIVES

- This project will develop capacity in research ethics review related to clinical research in developing countries, through two specific main objectives:
  
  ➔ It will increase capacity for ethics review among researchers in key developing countries which will be involved in the European and Developing Country Clinical Trials Partnership. These researchers will provide needed ethics expertise necessary for the success of this new EU initiative.
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**EDCEP**

2) ACTIONS

- The project will organize **two training and capacity building workshops** in several developing countries.
- Through these workshops the **necessary infrastructure and networks** will be prepared which will have the needed ethics review capacity for the recently launched European and Developing Countries Clinical Trials Partnership (EDCTP).
- The final workshop will develop an **agenda for a sustainable ethics partnership** which can be utilized by the EDCTP.
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**GENBENEFIT**

( Genomics and Benefit Sharing with Developing Countries: from biodiversity to Human Genomics)

- A three-year policy-development project that started in September 2006, establishing a research network between France, Lithuania, the UK, India, South Africa and the Philippines.

- Total Budget: 548 639 euros
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**GENBENEFIT**

1) OBJECTIVES

- Advance knowledge and ethical insight into existing benefit sharing frameworks with regard to human genetic resources.
- Explore paradigmatic international case studies to identify ethical concerns and possible solutions.
- Create an international network of experts and stakeholders on benefit sharing from human and non-human areas to explore synergies.
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Promote future policy developments by developing an “ethics health check” prerequisite for benefit sharing agreements involving vulnerable groups and communities in the context of human genetic resources.

Contributes to international dialogue on ethical principles.
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2) PARTICIPANTS

- University of Central Lancaster, UK
- University of the Witwatersrand, Johannesburg, South Africa
- Research and Information System for Developing Countries, New Delhi, India
- Assistance Publique-Hopitaux de Paris - Centre d'Etique Clinique Cochin, Paris, France
- Vilniaus Universitetas, Lithuania
- University of the Philippines, Diliman, The Philippines
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**NEBRA** (Networking for Ethics on Biomedical Research in Africa)

- NEBRA is a Specific Support Action, funded by the European Commission under FP6 (budget: 427.416 €).

- **Four African institutions** together with **two European organisations and the World Health Organization** have come together to foster networking medical research ethics committees in Africa.
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**NEBRA** (Networking for Ethics on Biomedical Research in Africa)

1) ACTIONS & INSTRUMENTS

- As a first step, trained African students under the guidance of both African and European supervisors will identify existing ethics review capacity and needs in 15 African countries.

- To achieve this, NEBRA’s Steering Committee will be assisted during the key steps by the outstanding expertise present among an **Advisory Group**, which includes representative of the existing **African Networks**.
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**NEBRA (Networking for Ethics on Biomedical Research in Africa)**

- At the end of the project, a group of observers from international public and private institutions interested in ethical aspects of biomedical research in developing countries will help NEBRA in building a sustainable network of ethics committees in Africa which would fit with EDCTP strategy or other related European programmes.
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2) OBJECTIVES

- to obtain an **inventory of resources and specifications of needs** of the existing structures dedicated to ethics in biomedical research in the project implementation area

- to design a process for **gathering the relevant information on the existing structures** dedicated to ethics in biomedical research in the project implementation area as well as an indication of the current gaps and needs

- to provide a **validated and synthesised analysis** of this information to the project end-users
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3) IMPACT

- Likely to have significant impact in the African region because of involvement of broad range of countries and stakeholders
- Likely to have significant impact in the region because of the networking and the identification of locally relevant best practice
- High importance for implementing EDCTP and for facilitating cooperation between the Commission and WHO on this crucial issue of building ethics review capacity in this part of Africa.
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GFBR-Secretariat
(Global Forum on Bioethics in Research)

- A lack of focus on ethical considerations in planning and conducting research has a risk of losing trust between the research establishment and the public, creating the danger that health research programme will be hindered.

  ex. the suspicion of populations in developing countries that they are being used for experimentation that cannot be done in the North

  ex. Tensions that exist between the interest of industry, regulators, the public, researchers and political decision-makers
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**GFBR-Secretariat**
(Global Forum on Bioethics in Research)

- A partnership between the Global Forum on Bioethics in Research and the European Union’s FP6 on science and technology was started to address these issues through constructive dialogue.

- The partnership, supported by a **grant from the EU Science and Society programme**, funds a special secretariat hosted in Geneva at the Council on Health Research for Development (COHRED).
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GFBR-Secretariat

- The secretariat coordinates a number of activities, aimed at increasing learning and raising awareness on research ethics issues worldwide.

- The secretariat is also based on a fellowship programme that aims at building solid professional networks for ethical interaction and the opportunity for developing country specialists, to engage with European Institutions in research ethics.

- This international fellowship programme starts this month with a fellow from China who will have the opportunity to be exposed to research ethics review in EU countries.
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GFBR-Secretariat

- In a nutshell, GFBR-Secretariat contributions:
  - Enhancing networking in international research ethics
  - Capacity-building in health research ethics by operating a fellowship scheme
  - Exchanging perspectives on international research ethics
Dear listeners,

- Thank you for your attention.