



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



Bureau of European Policy Advisers
(BEPA)

***The role of the European Commission
in protecting human participants
in biomedical research***

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EU Policy

The **Berlin Declaration** adopted by the Heads of State and Government of the European Union on the occasion of the 50th anniversary of its founding states:

- "We are striving for **peace and freedom**, for **democracy and the rule of law**, for **mutual respect and shared responsibility**, for **prosperity and security**, for **tolerance and participation**, for **justice and solidarity**."



EU Policy

- The Heads of State and Government of the EU have signed on December 13 the **Lisbon Treaty** in Lisbon. The ratification process is ongoing 2008.
- The **Reform Treaty** inter alia indicates a set of European Values, such as human dignity, freedom, democracy, human right 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**.



EU Policy

The **European Charter of Fundamental Rights** states a set of EU shared values, such as:

Respect for **human dignity**, a **ban on human reproductive cloning**, respect for **people's autonomy**, **non-commercialisation of biological components** derived from the human body, **interdiction of eugenic practices**, **protection of people's privacy**, **freedom of science**, etc.



EU Policy

- The Reform Treaty also reinforces **the role of the EU in international policy arena**; an effort already included in a number of EU policy sectors: from economy and global trade (think of the new version of the Lisbon Agenda and globalisation) to research (the European Research Era and the international dimension in research), from Energy and climate change (think of the role of the EU in the debate on the post-Kyoto Agreement) to Security and immigration. Europe is a global player in a multi-polar world with all the complexity and difficulty this global approach involves.
- The notion of **Europe as a community of values** and **the role of the EU as a main actor in International affairs** explain the **Commission intention to concentrate effort**, in full respect of its Powers and the Institutional role of different International organisations, **in global discussions on research and innovation, science and technology**, a debate where bioethics play a central role..

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The EC policy design



Policy Design

- The relevance of bioethics with regard to the Community policies is particularly marked; some examples of relevant policies include the **Science and Society Action Plan** (COM(2001)714), the **Action plan Life Sciences and Technology** (COM(2007) 175), the **Nanotechnology Action Plan** (COM(2007) 505 final), **Ageing Well Action Plan, COM(2007)33** etc. .



Legislative Proposals

- Issues of bioethics in the legislative sphere cover very many disparate areas of policy; from **clinical trials** (Directive 2001/20/EC) to **patents** (Directive 94/48); from **data protection** (Directive 95/46) to **research** (FP) or production of **medicinal products** (Directive 2001/83/EC and others, e.g. 2003/63/EC); from **animals used for experimental** and other scientific purposes (Directive 86/609/EC) to **animal welfare** (Protocol to the Amsterdam Treaty) etc. The list of Community regulations also includes applications of **biotechnology, information technologies** and several areas of **biomedical sciences**.

The EU legal frame

The Charter of Fundamental Rights of the EU

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the **implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use**

Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the **protection of individuals with regard to the processing of personal data** and on the free movement of such data

• Directive 2001/83/EC on **medicinal products for human use** and Directive 2003/63/EC amending Directive 2001/83/EC

• Directive 2004/23/EC on **tissue banking**

• EMEA Rules etc.



EU Policy: research

- In December 2005 at the end of the UK presidency (**Hampton Court Summit**), security and biometrics were indicated as key actions of the EU. In addition an Independent Expert Group on R&D and has produced this year a rapport on the role of research with regard to the Lisbon agenda.
- The Report indicates the need of affording and reinforcing **European values** as a main milestone to endorse for an effective EU growth policy, within the EU and with third parties. Equality, health social cohesion and common security **are** therefore **indicated as elements conducive to innovation while not sufficient per se to ensure sustainability.**

Legal Basis for Ethical Reviews in FP7

- **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. »



Rules for Participation, Article 10:

« A proposal [...] which contravenes fundamental ethical principles [...] shall not be selected . Such a proposal may be excluded from the evaluation and selection procedures at any time. »

embedding ethics in
clinical trials and
research: how,
when, where?

**The EGE Opinion on ethics review
of FP7 hESC research**





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- n° 11 Ethical aspects of **human tissue banking** (21/07/1998)
- n° 12 Ethical aspects of research involving **the use of human embryo in the context of the 5th framework program** (23/11/1998)
- n° 13 Ethical issues of **healthcare in the information society** (30/07/1999)
- n° 14 Ethical aspects arising from **doping in sport** (14/11/1999)
- n° 15 Ethical aspects of **human stem cell research and use** (14/11/2000)
- n° 16 Ethical aspects of **patenting inventions involving human stem cells** (07/05/2002)
- n° 17 Ethical aspects of **clinical research in developing countries** (04/02/2003)
- n° 18 Ethical aspects of **genetic testing in the workplace** (28/07/2003)
- n° 19 Ethical aspects of **umbilical cord blood banking** (16/03/2004)
- n° 20 Ethical aspects of **ICT implants in the human body** (16/03/2005)
- n° 21 Ethical aspects of **Nanomedicine** (January 2007)
- n° 22 Ethical review of **FP7 hESC** (July 2007)
- n° 23 Ethical aspects of **Animal Cloning for food supply** (January 2008)

Ethical aspects of clinical research in developing countries

The scientific and ethical evaluation of the research protocol should be carried out by ethical committees from all countries involved. Host countries need to have a legal and ethical framework in order to take part in the clinical trial evaluation effectively and independently.

The Group strongly supports EU initiatives to build local ethical committees in the host countries. It should be considered as a priority in terms of capacity building.

It is essential that the members of this committee are independent and include persons representing patients interests. If it is not possible to involve such an independent local representative in the evaluation, then no clinical trial should be implemented in the country.

In the evaluation of a research protocol, special attention should be paid to :

- _ the relevance of the research to be carried out in a developing country.
Specific attention should be paid when the objective of the clinical trial does not comply with health priorities of the host country;
- _ the risk/benefit ratio at the individual level, as well as at the community level
- _ the impact of the project after its completion

Ethical aspects of clinical research in developing countries

The use of placebos should be regulated in developing countries in principle by the same rules as in European countries. Any exception must be justified: an obvious one is when the primary goal of the clinical trial is to try to simplify or to decrease the costs of treatment for countries where the standard treatment is not available for logistic reasons or inaccessible because of the cost. It may thus be justified to derogate from the rule of best proven treatment.

there should be an obligation that the clinical trial benefits the community that contributed to the development of the drug.

This can be e.g. to guarantee a supply of the drug at an affordable price for the community or under the form of capacity building.

Capacity Building

The EC, following the remit on ethics stated in the Treaty, the EGE opinion and FP7 'facilitates' local capacities rather than superimposing European standards.

This implies respect for local socio-cultural identities while promoting relevant documents existing at European and International level -e.g. the European charter of fundamental rights and the CoE bioethics convention.

The EC is therefore working in full cooperation with other relevant bodies such as Unesco, WHO, CoE etc.

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Capacity building of research ethics committees

Capacity Building

**Workshop with representatives of EU 25 RECs,
Brussels December 2005, February 2006**

**Ad hoc subvention of EuREC platform (350.000 € / 2
years) second half 2006.**

**The platform establishes a network of REC across the
EU, facilitate inter-change of best practices,
educational material REC members, establish basis
for future and more systematic copereations (MS
should invest on that on the basis of implementation
of EC 2001/20)**

Capacity Building

Edecp: A series of training and capacity building workshops in several developing countries will be organised. 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)**

NEBRA: Four African institutions together with two European organizations and WHO have come together to **foster networking medical research ethics committees in Africa**. Trained African students under the guidance of both African and European supervisors will identify existing ethics review capacity and needs in **15 African countries**.

Capacity Building

Besha: the study is about **Genomics and Benefit Sharing with Developing Countries** and more in particular will try to overcome the concerns that have been formulated in relation to the Bonn Guidelines of the Convention on Biological Diversity (2002) and the Human Genome Project Ethics Committee's Statement on Benefit Sharing (2000).

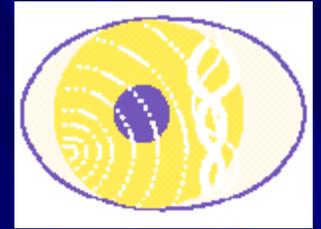
EULABOR network between Europe and Latin-America. It aims to evaluate the systems of ethics regulation of biomedical research involving human subjects and tissues, considering their pertinence and consequences in the context of socio-economic conditions and cultures in Argentina, Brazil, Chile, Mexico,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

Capacity Building

- In the area of ethics, specific activities will be devoted to facilitate capacity building on ethics in developing countries and emerging countries as well as the establishment of international dialogue platforms on research ethics, security and biometrics. The Commission will then reinforce this action and coordination tasks to monitor that EU policies are consistent with the European shared values will be implemented. BEPA will endorse this task.

And now?





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NO



Yes



Capacity Building

- According to EC Competences EC should respect the subsidiarity principle in public policy and research
- Regulatory frame in EU requires the ethics approval of research and clinical protocols
- Different ethics standards exist and are promoted by sponsors of clinical trials
- Ethics colonialism is not the EC method
- Cooperation with Int. Organisation is needed

Capacity Building

Issues that deserve specific efforts:

- Accreditation procedures of REC
- Vocational training
- Databases of approved clinical trials
- sharing of best practices
- standard procedures for data protection
- no financial incentives
- independency from the sponsor of NEC
- informed consent procedures
- post trial policy on drugs used
- IPR and benefit sharing
- support for local infrastructures



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