



## Ethical standards for the 6th FP (2002-2006)

- Participants in research projects must conform to current legislation, regulations and ethical rules **in the countries where the research will be carried out.**
- Where appropriate, participants in research projects must seek the approval of the relevant national or local ethics committees prior to the start of the RTD activities.



## IN FP6: Ethical review

- An ethical review will be implemented systematically by the Commission for proposals dealing with ethically sensitive issues.”
- Multidisciplinary panel of experts
- Ethical review performed after the scientific evaluation
- Possibility of excluding research projects that contravene fundamental ethical principles
- Monitoring during the life of the project



**GUIDE FOR PROPOSERS**  
**Annex B and further explanation on the web**

**A. The applicants are requested to fill in the following table**

**Does your proposed research involve :**

- **Human beings**
  - Persons not able to consent**
  - Children**
  - Adult healthy volunteers**
- **Human biological samples**
  - Human embryonic stem cells in culture**
  - Human foetal tissue/human foetuses**
- **Personal data (whether identified by name or not)**
- **Genetic information**
- **Animals (any species)**
  - Transgenic animals**
  - Non- human primates**
  - Dogs, pigs, cats,**



## **2. In this spirit: “science and society action plan” to improve the mutual understanding**

### **actions proposed in ethics**

- 1. Information and documentation system**
- 2. Public debate**
- 3. Awareness and education of researchers**
- 4. Networking across national and local ethical committees**
- 5. Intercultural dialogue and capacity building for developing countries**
- 6. Improvement on animal protection**



## **Public debate**

### **State of the art:**

- **High level group to prepare new EUROBAROMETER**
- **High level group to draft between industry, NGO and academia a report on genetic testing**
- **What national activities are existing that could be linked together**



## **Awareness and education of researchers state of the art:**

**3 studies launched**

**Results by September 2003**

- 1. Identifying courses in ethics in Europe**
- 2. Select excellent teaching material**
- 3. Collect existing codes of conduct**



**Networking across national  
and local ethical committees  
state of the art:**

**Meeting of the presidents of the national ethics  
councils**

1. Preparatory meeting in Brussels
2. 1<sup>st</sup> meeting in Athens

**Local ethics committees**

1. Study to establish a directory of all local research committees in the 33 countries collaborating in the FP – report about their needs and difficulties
2. Plan to organise next year a first conference (march 2004)



## **The problem when funding research in Europe:**

- **No mandate of the EU in the field of “ethics”**
- **Very different regulation in the different MS**
- **If the EU is regulating a subject related to ethics this is done in the framework of market aspects: e.g. good clinical practice or forthcoming the directive on human tissues**
- **Only 4 out of 15 Member States have ratified the convention on biomedicine and human rights, and these are not the big spenders in research**
- **Ethics in science and research is difficult to handle when funding international and in particular joint European Research**



## **Our tasks**

- 1. Embedding of ethics in the projects of the Framework programme**  
- - -> policy support
- 2. Activities to improve mutual understanding (6 actions - action plan)**
- 3. Helping the co-ordination of national initiatives**



## references

- **The Charter of Fundamental Rights of the EU**
- **EC directives**
- **Convention of the Council of Europe on Human Rights and Biomedicine (1997) and the additional protocol on the Prohibition of Cloning Human Beings (1998)**
- **UN Convention on the Rights of the Child**
- **Universal Declaration on the human genome and human rights adopted by UNESCO**
- **Helsinki Declaration (latest version)**



# 1. Embedding of ethics in the projects of FP6

- **Article 3 of the 6 FP**
- "All the research activities carried out under the Framework Programme 2002-2006 must be carried out in compliance with **fundamental ethical principles.**"