

## **ETHICS FOR RESEARCHERS**

**Facilitating Research Excellence in FP7**

### **Interested in European Research Ethics?**

A full description of the "Governance and Ethics" Unit activities can be found in the "Governance and Ethics" section of the "Science, Economy and Society" Directorate's portal:

<http://europa.eu.int/comm/research/science-society>

### **EUROPEAN COMMISSION**

Directorate-General for Research  
Directorate L – Science, Economy and Society  
Unit 3 – Governance and Ethics  
B – 1049 Brussels

**Cover:** "L'Homme invisible" – "Parce que l'Homme ne sera jamais complètement transparent, les questions éthiques demeureront". Cf. medethic.com

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**Author of the publication:** Eléonore Pauwels



A Drawing by regretted Watta in the framework of the "Groupe Franco-Africain d'Oncologie Pédiatrique – Guérir les Cancers des Enfants en Afrique.

"Every art and every enquiry, and similarly every action and pursuit, is thought to aim at some good; and for this reason the good has rightly been declared to be that at which all things aim."

Aristotle, Nicomachean Ethics, Book I, Chapter I. Translation, J. Bywater, Oxford 1894.

## Forewords...



### **A message to the Research Community by the European Commissioner for Research, Mr Janez Potočnik**

It is an exciting time to be involved in research and as I write many in the research community are busily preparing proposals for 7FP funding. I wish you all the best of luck! While you occupy yourselves finding research partners, reflecting on budgets and mulling over the best experimental approaches I want to make a special plea relating to research ethics.

In my capacity as Research Commissioner, the European Parliament has entrusted me with ensuring ethics is given the highest priority in EU funded research. I take this responsibility seriously. It is my duty to alert researchers at this point, of my determination to ensure ethics is an integral part of research, from concept to publication.

As research scientists you have an obligation to inform yourselves and those whom you seek to participate in your research of the rights that exist to enhance all aspects of human dignity. Issues such as, protection of identity, privacy, obtaining informed consent and communicating benefit and risk are amongst the many ethical issues researchers must address. The involvement of developing countries is a wonderful opportunity to generate solutions; to prevent and cure diseases, to increase our understanding and respect for cultural differences. Such opportunities bring obligations. Through sharing benefits and knowledge a better capacity for ethical compliance is built.

Where research necessitates the use of animals, the objective must always be to seek alternative methods. Where such alternatives are not yet available, reduction and refinement of animal use must be sought.

I count on you as researchers to commit the same energy and enthusiasm that you display for your scientific endeavours to ethics and scientific integrity. Ethics permeates every area of research. It is only by getting the ethics right, that research excellence can be achieved.

Janez Potočnik  
European Commissioner for Science and Research



## Recovering Lost Confidence

Where there is a climate of trust, the results of science are more likely to be accepted, exploited or applied for the benefit of humankind. Building such an environment is a central objective of the European Commission Research and particularly the Directorate L – Science, Economy and Society. Disillusionment with science is due to a loss of public trust. To regain and retain public trust, it is crucial to question the relation between science and society in order to better anticipate the European citizens' hopes and fears. The European Union (EU) must address the issue of how to create social conditions favourable to the development of scientific research: why, how and under which conditions can science possibly contribute to progress?

With this in mind, a budget of EUR 330 million is allocated to the specific programme "Science in Society" in FP7. This programme involves mobilising the 27 EU countries around two objectives: on the one hand, to encourage and support the teaching of science by raising the awareness of young people and women; on the other hand, to promote better research governance based on informed dialogue with civil society and in conformity with EU fundamental values. The major challenge is to create a climate favourable to the elaboration, sharing and dissemination of knowledge within society by giving priority to education and dialogue on ethics, and this within European and international context.

Jean-Michel Baer  
Director of European Commission's Directorate "Science, Economy and Society"



## **Sharing Values and Protecting Human Fundamental Rights**

The *Governance and Ethics* Unit is responsible for defining and supporting analysis and research, and for developing and fostering strategies, processes and best practices contributing to a more inclusive and open approach to governance and ethics of RTD and innovation in Europe based on a better understanding of their role and perception in society. The Unit is committed to ensure that fundamental ethical principles are respected in the implementation of the Framework Programme as a whole and in the research activities arising from it.

The *Governance and Ethics* Unit also intends to promote international dialogue and to build capacity in research ethics. In this sense, the Unit supports regional networks of experts to develop best practices in the field of ethics and science, and to ensure that European research in developing countries complies with fundamental ethical principles. The idea is not to impose European standards, but encouraging peer societies to adopt ethical norms in respect to their cultures and traditions. The objectives are both to develop specific cross-cutting expertise on science and ethics and to facilitate interactions between the EU, emerging economies and developing countries as well as between these targeted countries.

Peteris Zilgalvis  
Head of Unit "Governance and Ethics"



## **CHAPTER I: ETHICS REVIEWS IN CONTEXT**

"Filaments", A Motoneurone, photo made by Christopher Henderson, "Quand la science rejoint l'art" (1999) exhibition directed by Michel Depardieu, © Inserm.

Ethics Reviews are an integral component of the assessment procedure supported by the European Commission. They are intended to ensure that all the research activities carried out under the Framework Programme are conducted in compliance with fundamental ethical principles.

### **The Emperor's New Clothes**

The ethics review process resembles the little child in the fairytale 'The Emperor's New Clothes' by Hans Christian Andersen. It's about getting to the heart of the matter, avoiding the human susceptibility to be easily deceived and challenging predispositions to social conformity. Ethics is about telling the truth and it is central to scientific integrity.

FP7 is a significant source of public funding dedicated to supporting a sound research community for a better European future. Through ethics review the public's concerns relating to science are represented and addressed. The scientific community merits such funding and its appreciation is measured by its approach to ethical issues. For FP7 the Commission will focus on integrating ethics into research. This article is not intended to be an academic text book on ethics, it is a pragmatic guide to help researchers to grasp the basics and apply them with confidence. Remember, in FP7, the ethics review will be carried out on the proposal submitted, no additional information will be requested. It is essential to get it right first time.

### **Context, Consistency and Ethical Sensitivity**

Ethics is often misunderstood in the realm of research. It is closely linked with law, rules and regulations but it is not adversarial: 'Ethics v Research'. Ethics reviews at the Commission aim to be collaborative and constructive. By considering ethical issues from the concept stage of a proposal the quality of research is enhanced. What follows is a description of ethical review from the Commission Services's perspective and hopefully an opportunity to discover that ethics is relevant to research.

#### **(i) Context:**

Ethics is context dependent, consequently definitive mathematical outcomes are rare. The proposal will need to clarify the necessity to use personal data, animals, human tissue and involvement of human beings. Do not believe that the fine reputation of one's institution, or one's publications and track record is sufficient to exempt a proposal from describing these elements.

#### **(ii) Consistency:**

Take time to consider the benefit / burden balance of each work package. Consider the impact of the research, not only in terms of scientific advancement (publications, patents etc) but also in terms of human dignity as well as social and cultural impact.

**(iii) Ethical sensitivity** – the unwritten skill that ethics panels search for! It is a measure of honesty and clarity apparent in the proposal.

## ETHICAL REVIEWS – LEGAL BASIS

Taking into account ethical aspects of research practices has a particular significance in the EU Framework Programme as the EU is founded on a common ground of shared values enounced in the European Charter of Fundamental Rights. These values include the need to ensure freedom of research and the need to work in the interest of the physical and moral integrity of individuals. One of the tasks of the *Governance and Ethics* Unit is to analyse, through ethics reviews, whether these values are respected in the research activities funded by the European Commission.

### The European Charter of Fundamental Rights

#### **Art. 3: Right to the integrity of the person**

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:

- the free and informed consent of the person concerned, according to the procedures laid down by law,
- the prohibition of eugenic practices, in particular those aiming at the selection of persons,
- the prohibition on making the human body and its parts as such a source of financial gain,
- the prohibition of the reproductive cloning of human beings

#### **Art. 8: Protection of personal data**

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

#### **Art. 13: Freedom of the arts and sciences**

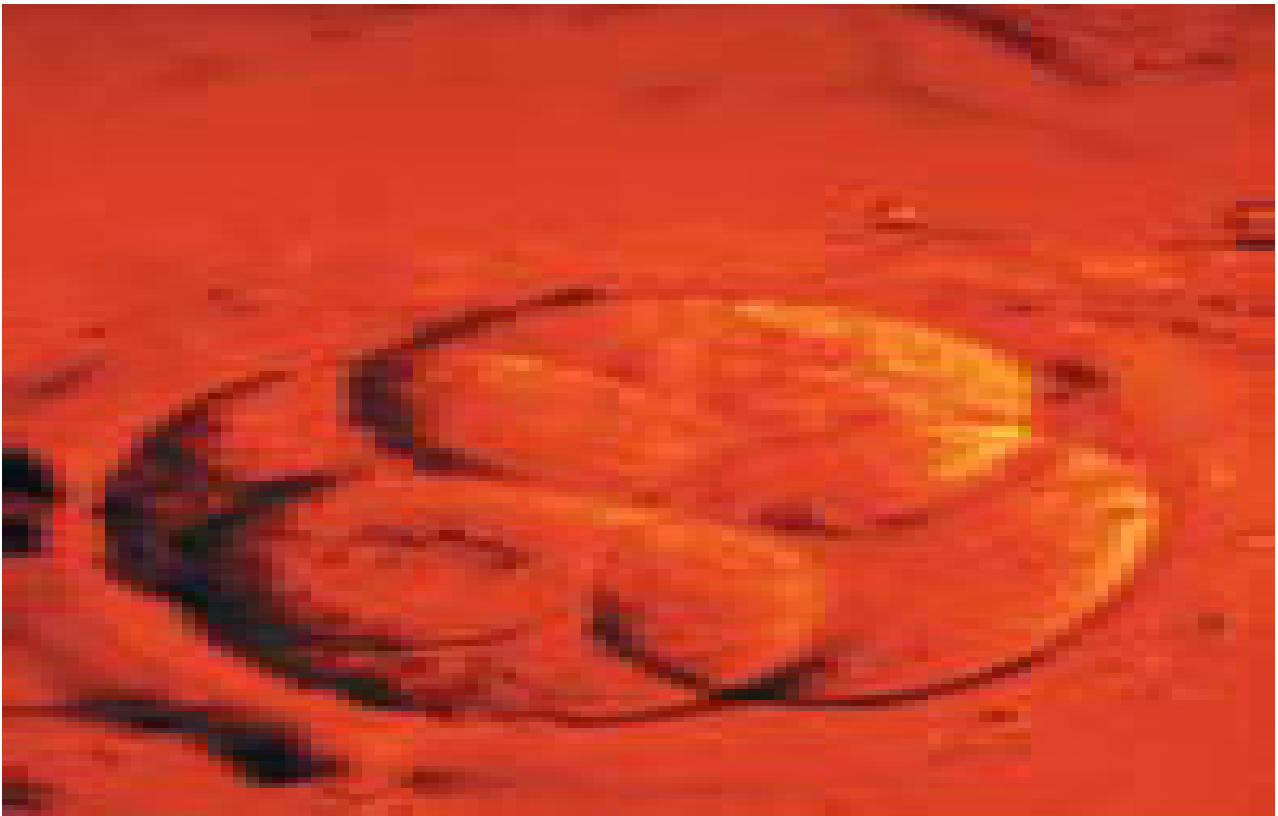
*The arts and scientific research shall be free of constraint. Academic freedom shall be respected.*

**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. »*

**Areas excluded from funding under FP 7, Art. 6 (2§):**

- A)** Research activity aiming at **human cloning for reproductive purposes**
- B)** Research activity intended to **modify the genetic heritage of human beings** which could make such changes heritable (Research related to cancer treatment of the gonads can be financed)
- C)** Research activities intended to **create human embryos solely for the purpose of research or for the purpose of stem cell procurement**, including by means of somatic cell nuclear transfer



"Desert Rose", A two-day-old human embryo obtained by IVF, photo made by Jacques Testart, "Quand la science rejoint l'art" (1999) exhibition directed by Michel Depardieu, © Inserm.

A photograph of a cell nucleus with several chromosomes. The chromosomes are stained with fluorescent dyes, appearing in various colors such as yellow, green, blue, and red. The background is dark, making the brightly colored chromosomes stand out. The image is presented in a slightly blurred, artistic style.

## CHAPTER II: ETHICS REVIEWS IN NUMBERS

"Stalagmites", Chromosomes in a nucleus labelled with fluorescent dye, photo made by Philippe Metezeau, "Quand la science rejoint l'art" (1999) exhibition directed by Michel Depardieu, © Inserm.

## OPTIMAL COMPOSITION OF ETHICS REVIEW PANELS

Ethics Review Panels of the European Commission are performed by a panel of experts from different disciplines such as law, sociology, philosophy and ethics, psychology, information technology, medicine, molecular biology, veterinary science with gender and geographical balance. Representatives of civil society may also be invited such as representatives of patients' organisations.

The experts in the Ethics review panel have the same status as experts performing the scientific evaluation and are bound by the European Commission obligations concerning conflict of interest and confidentiality.

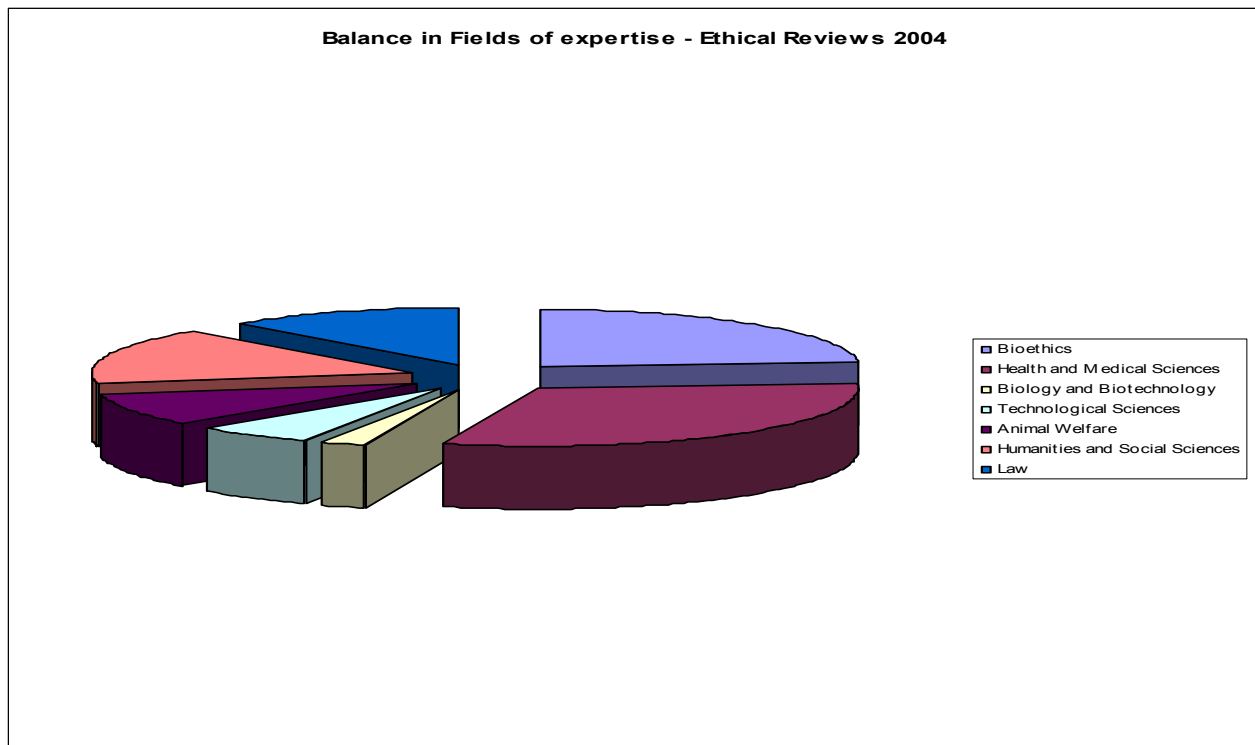
### GENDER BALANCE

Ethics Review Members are selected according to their expertise and several criteria, one of which the most important and the most challenging is gender balance. **The objective in selecting experts for ethics reviews is to have, at least, 45 % of female experts.** This is a condition sine qua non to ensure that ethics review panels are representative of the society as a whole.

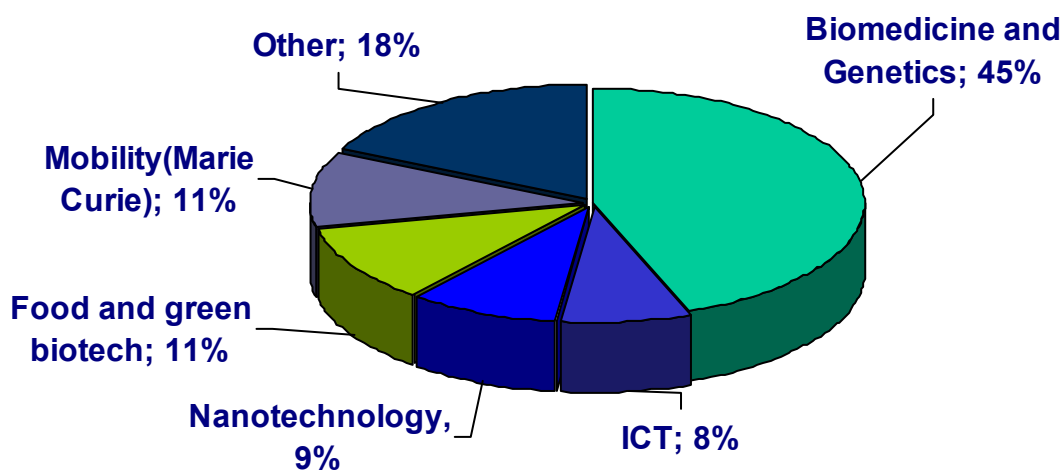


## BALANCE IN THE FIELDS OF EXPERTISE

Ethics Review Panels are multidisciplinary and multisectorial and composed of recognised experts in a wide range of fields. The Graph above shows the proportional representation of the different sectors that participants of the Ethics Reviews 2004 consider as their main field of expertise. **In general, Bioethics and Health & Medical Sciences seemed to be better represented than Humanities and Technological Sciences as Health remained one of the first objectives of the FP6.**



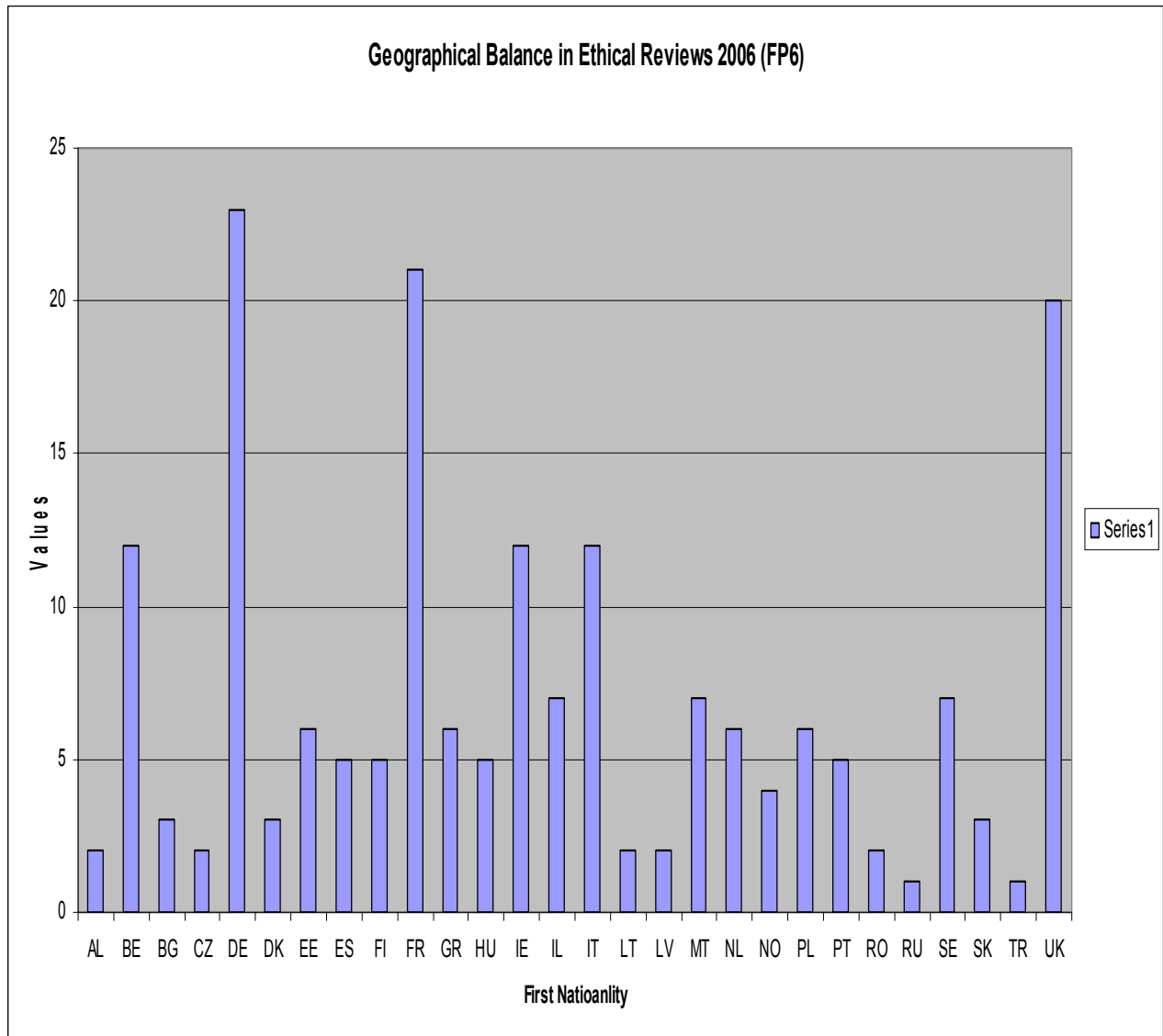
The Graph below illustrates the breakdown of FP6 projects having undergone ethics review, by research area. **As the graph points it up, the biggest client of ethics review are definitely Health and Biomedicine.**



## GEOGRAPHICAL BALANCE

The *Governance and Ethics* Unit makes constant efforts to recruit ethics review participants coming from a wide range of EU countries.

The graph below (2006) shows a positive improvement in recruiting multinational experts: there is still a strong representation of Germany, UK and France, but there is also a consequential increase in the representation of experts coming from new Member States (Estonia, Poland, Malta, Romania). We note also a decisive presence of smaller EU Member States such as Belgium, Ireland and Sweden.





## CHAPTER III: ETHICS REVIEWS IN PRACTICE

"Sands of time", A triple DNA helix, photo realised by Sheng Sun –Jian, "Quand la science rejoint l'art" (1999) exhibition directed by Michel Depardieu, © Inserm.

## HOW TO INTEGRATE ETHICS IN EU FUNDED PROJECTS?

The European Commission provides clear guidance on ethical issues to intending applicants. All applications received by the Commission for research support must describe the ethical, safety and socio-economic issues raised by the project, show how they have been adequately taken into account and how they will be addressed so as to conform to national, European and international regulations.

### SCIENTIFIC EVALUATION OF RESEARCH PROJECT

All proposals submitted to the Commission for funding following a call for proposals, are evaluated on their scientific merit. Independent experts review proposals individually and a panel advises whether they should be retained for funding based primarily on scientific excellence.

During this evaluation, the panel of scientists also makes a first check of the ethical issues raised by a project and identify those projects requiring special attention. In particular this will apply when projects raise sensitive ethical issues or when applicants failed to address ethical issues in an appropriate way. Following the evaluation, those proposals retained by the Commission with a view to funds, but identified by the experts as requiring special attention, will be submitted to an ethics review panel.

Ethics review is automatic for proposals which include a research intervention on human beings, and/or the use of human embryonic stem cells (hESC).



## ETHICS REVIEW PROCEDURE

As a first step, the experts selected as members of the ethics review panel individually read the research proposals. A consensus meeting of all individual ethics readers is then convened in Brussels. The ethics review panel discusses the following elements:

- The awareness of the applicants on the ethical aspects and the social impact of the research they propose
- Whether the researchers respect the ethical standards of the FP7
- Whether the relevant European directives are applied
- Whether the applicants are seeking the approval of relevant local ethics committees
- Whether the relevant international conventions and declarations are applied
- The balance between the research objectives and the means to be used

### ■ COMMON PROBLEMS RELATED TO ETHICS IN RESEARCH:

- Consistency and Research's context
- Insurance
- Incidental Findings
- Incentives (Financial inducements, etc.)
- Issues related to Children: Minimum Risks/ Burden? Real and Direct Benefit?
- Research on Animals: Number; Humane End Points; Checked alternatives?
- Developing Countries: Benefit sharing
- Conflict of Interest: Treating Doctor; Research Interest

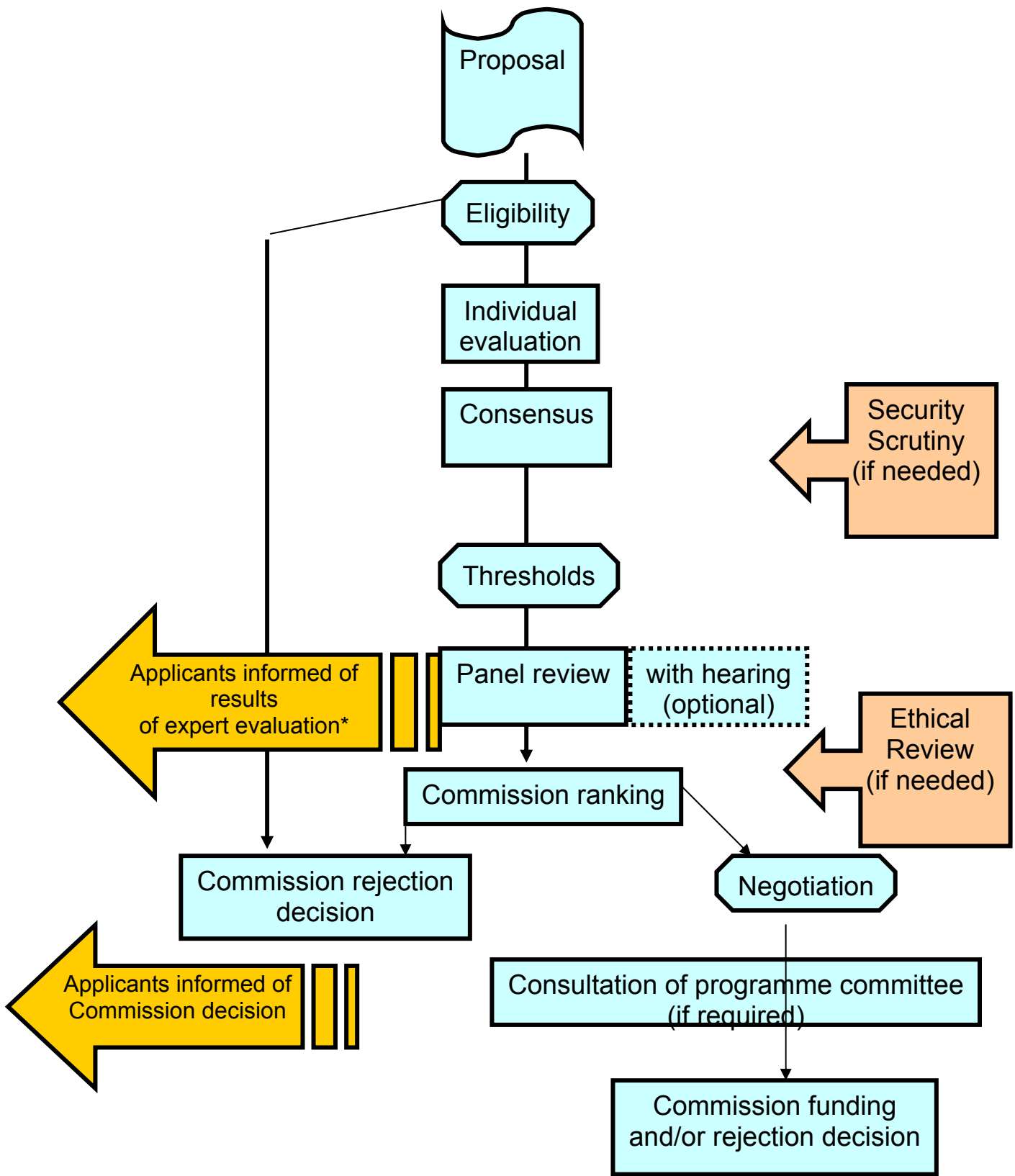
### Major Changes from FP6 to FP7

- The Ethics Review will be carried out on the proposal submitted
- No additional information will be requested from the consortium
- The consortium is asked to submit drafts of Information Sheets and Consent Forms
  - The Consortium does not need to submit copies of legislation

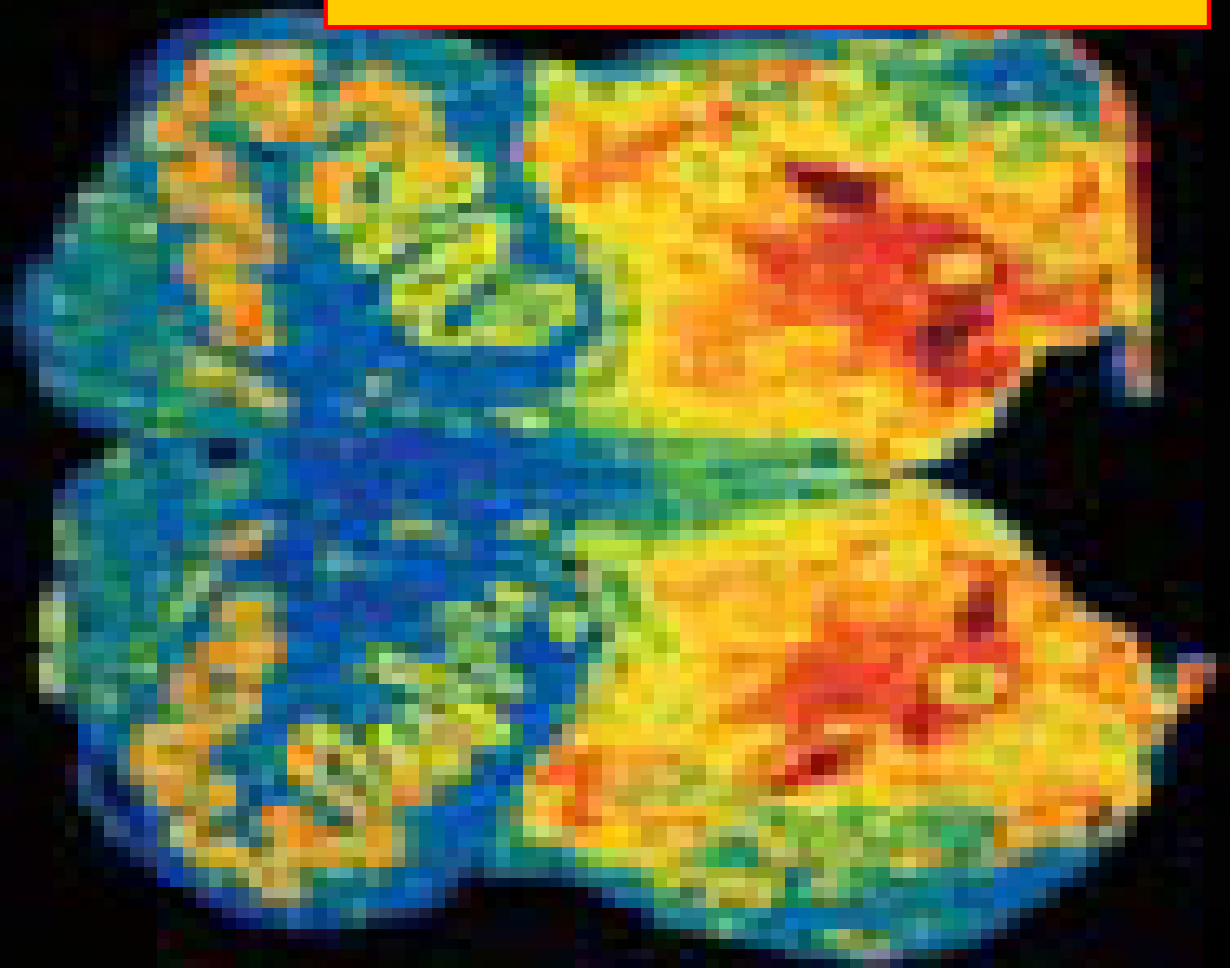
**Take Home Message:  
GET IT RIGHT FIRST TIME!**

Identify and contact the ethics expert in your organisation now!

**FLOW DIAGRAM OF THE EVALUATION PROCEDURE**



## CHAPTER IV: ETHICS REVIEWS METHODOLOGY



"Inkspots", Detection of receptors for the neuropeptide somatostatin, photo made by Valérie Turquier-Carpentier, "Quand la science rejoint l'art" (1999) exhibition directed by Michel Depardieu, © Inserm.

## ETHICS – IT'S A STATE OF MIND

### FOOD FOR THOUGHT

#### *Human Dignity*

The measure of ethical sensitivity in a proposal is directly related to the degree of honesty and truthfulness declared. In the majority of cases the consortium can easily fulfil its ethical obligations by asking themselves: 'how would I like my spouse / child / parent's dignity to be handled in a research setting?' It is essential to consider the social impact the research results. Will the outcome have a dual use that could pose a threat to personal security, privacy and dignity.

#### *Animal Welfare*

The use of animals in research is still necessary. The approach to animal research must be rooted in the application of the 3 Rs (Replace, Reduce and Refine). If the procedure being undertaken on the animal would hurt the researcher it can be assumed that it would also cause distress to the animal.

#### *Developing Countries*

FP7 provides enormous opportunities to include developing countries. The aspiration is that EU regulations are equally applied and upheld in such countries. If it is the case that such standards are not the norm at this time, the aim should be that vast improvements are tangible at the end of FP7. An important objective of the Governance and Ethics unit in the Commission is to facilitate capacity building in such countries.



# TYOLOGY OF ETHICAL ISSUES

## INFORMED CONSENT

### *Defining the problem*

The notion of voluntary participation in research involving human subjects was enunciated for the first time in the Nuremberg Code. Subsequently, several international declarations (Declaration(s) of Helsinki<sup>1</sup>, Convention of the Council of Europe on Human Rights and Biomedicine<sup>2</sup>, UNESCO's Declaration<sup>3</sup>, W.H.O./C.I.O.M.S.<sup>4</sup>, etc.) sanctioned this notion as pivotal in research ethics.

All international declarations stipulate that, prior to consent, each participant in a research project should be clearly informed of its goals, its possible adverse events, and the possibility to refuse to enter or to retract at any time with no consequences. Moreover, no inducement should justify the participation in a research.

### *The way of dealing with Informed Consent*

**Who should consent** is the first question to be asked for. As a consensus, only persons able to freely understand and question, should consent. It does exclude vulnerable persons (prisoners, mentally-deficient persons, severely-injured patients, very young children, etc.). However, to avoid any loss of opportunities for these persons, legal framework should guarantee their participation (notion of surrogate legal/ therapeutic representative).

**How to inform** is the critical part of the process. Numerous anthropological studies have pointed out that participants are rarely able to recall what they have agreed upon by signing an informed consent. The following strategies may be of great help:

- Participation of a linguist for preparing the informed consent
- Presentation of the research project using information technologies (video, power-point, theatre play, etc.)
- Interviews conducted among the participants to ensure that they understand the issues at stake in the research project

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<sup>1</sup> Declaration of Helsinki (Edinburgh, 2000), World Medicine Association ([www.wma.net](http://www.wma.net))

<sup>2</sup> Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo 1997, [www.coe.int](http://www.coe.int))

<sup>3</sup> Universal Declaration on Bioethics and Human Rights adopted by UNESCO's General Conference on 19 October 2005, [www.unesco.org](http://www.unesco.org)

<sup>4</sup> CIOMS/WHO International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993, reviewed in 2001, [www.cioms.ch](http://www.cioms.ch))

**How to get approval** is the third major issue regarding informed consent. It relates to the person autonomy and vulnerability. It depends on the cultures and the traditions of the population concerned: in some communities the notion of individuality is lacking; written agreements do not exist; women's autonomy is unacceptable. Again, some strategies should be used:

- Presence of a community representative trained by the scientific team
- Witnessing the oral approval by the trained community representative
- Presence of a lawyer in case of incompetent patients

Research involving human beings raises two general questions that should be answered in the Informed Consent:

- ➔ **How human subjects can help to contribute to science and/or public health?** It is crucial to explain the impact of the research for all the society and for the individuals involved: to describe the potential and direct benefits of the research as well as the side effects.
- ➔ **How researchers will work to protect subjects and their data?** Often Researchers do not explain what happens to the data, samples or animals at the end of the research period. If the data/ samples are retained for further research they need to ensure that the informed consent shows this.

#### **Case Story: Preventing coeliac diseases – Research involving children**

This case story focused on the influence of the dietary history in the prevention of coeliac diseases. One of the ethical issue raised by this study is the involvement of infants (1000) and children of school age (16 000) not able to give consent.

Article 17 of the Council of Europe Convention on Human Rights and Biomedicine seeks the protection of persons not able to consent (e.g. 4-6 month old babies). Research involving such persons is only allowed if:

*I)The results of the research have the potential to produce real and direct benefit to his/her health*

*(II)The research entails only minimal risk and minimal burden for the individual concerned*

Problem raised by ethics review panellists: Children can only be enrolled in research projects if their participation has the potential to produce real and direct benefits for them or if the intervention imposes minimal burden/risk. An estimated 160 children will fall into neither category and the intervention will impose more than a minimal burden/risk (bowell biopsy) for no direct benefit. In this current design, this population study therefore contravenes the Council of Europe Convention on Human Rights and Biomedicine.

## IN SUMMARY

1) **When do researchers need to obtain informed consent?** Informed consent should be required in the following cases:

- when the research involves children or persons not able to give consent
- when the research involves human beings
- when the research uses Human Genetic Material or biological samples
- when the research involves Human data collection

2) **What needs to be mentioned in the informed consent?**

Certain information should be provided to research subjects before they participate in a study, including:

- A statement that the study involves research subjects, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- Insurance guarantees provided to participants
- For research involving more than minimal risk, an explanation as to whether there are any treatments or compensation if injury occurs and, if so, what they consist of, or where further information may be obtained
- A disclosure of appropriate procedures in case of incidental findings
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- An explanation of whom to contact at any time for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty

### *Defining the Problem*

The core of the ethical dilemma lays on the conflicting nature of some bioethical values. On the one hand, research involving the use of human embryos such as human embryonic stem cell (hESC) research could develop life-saving therapies; on the other hand, such research could involve the use and destruction of human embryos. The Council of Europe argues that ethical aspects should be given priority over aspects of utilitarian and financial nature<sup>5</sup>. Even so, they should be assessed in the light of the potential prospects of future therapies alleviating severe human suffering.

A first issue is the use of embryos for stem cell research. According to a study conducted by the European Science Foundation (2001)<sup>6</sup>, great differences still persist between Member States concerning the state of legislation and control of research of human stem cells. In addition, concerns are raised by the risk of commercialising the human body and its elements. The principle of non-commercialisation (*or non-commodification*) is also linked to the donation of stem cells, as it must not give profit to donors, who should however give their consent. A particular issue arises from the use of the spare embryos created for IVF infertility treatment. Should *supernumerary* embryos be used or should scientists be allowed to create embryos for the sole purpose of research<sup>7</sup>?

### ■ One of the areas excluded from funding under FP 7, Art. 6 (2§):

Research activities intended to **create human embryos solely for the purpose of research or for the purpose of stem cell procurement**, including by means of somatic cell nuclear transfer

***This decision is 100% in line with the Opinion N° 15 of the European Group of Ethics (“Ethical Aspects of Human Stem Cell Research and Use”).<sup>8</sup>***

<sup>5</sup> Council of Europe, Parliamentary Assembly, “Human stem cell research report”, 11 Sept 2003,

<sup>6</sup> European Science Foundation, “Human stem cell research, scientific & ethical dilemmas”, Briefing, June 2001 <http://www.esf.org/articles/3/ESPB14.pdf#search=Human%20stem%20research,%20scientific%20and%20ethical%20dilemmas>

<sup>7</sup> *see*, Council of Europe Oviedo Convention 1997, art.18

<sup>8</sup> EGE, Opinion n°15 “on ethical aspects of human stem cell research and use”, 14.11.2000.

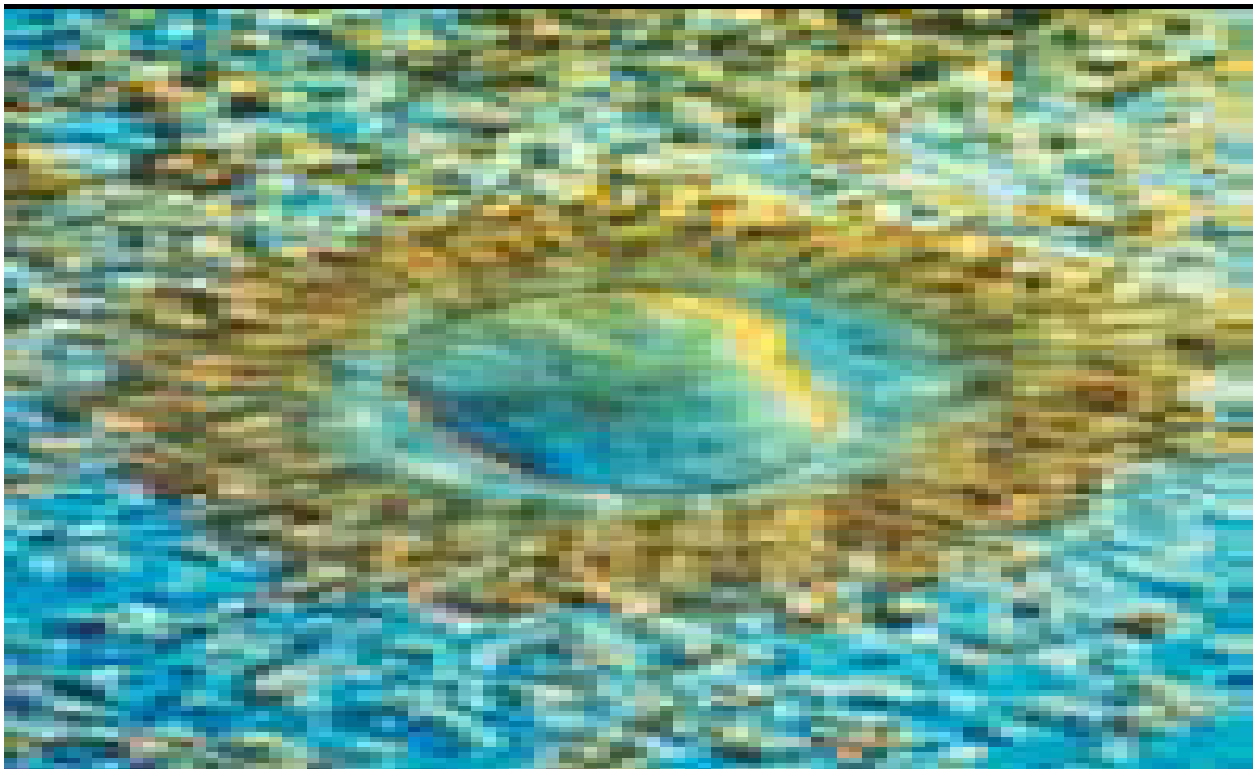
### ***The way of dealing with research involving the use of hESC***

Once the scientific evaluators confirm the necessity of using hESC in the research proposal, the ethics review panel assesses:

- that the proposal does not include research activities which destroy embryos including for the procurement of stem cells;
- whether the consortium has taken into account the legislation, regulations, ethical rules and/or codes of conduct in place in the country(ies) where the research using hESC is to take place, including the procedures for obtaining informed consent;
- the source of the hESC;
- the measures taken to protect personal data, including genetic data, and privacy;
- the nature of financial inducements, if any.

A positive opinion from a Regulatory Committee constituted by Member States' representatives is required.

**Participants in research projects must seek the approval of the relevant national or local ethics committees prior to the start of the research activities.**



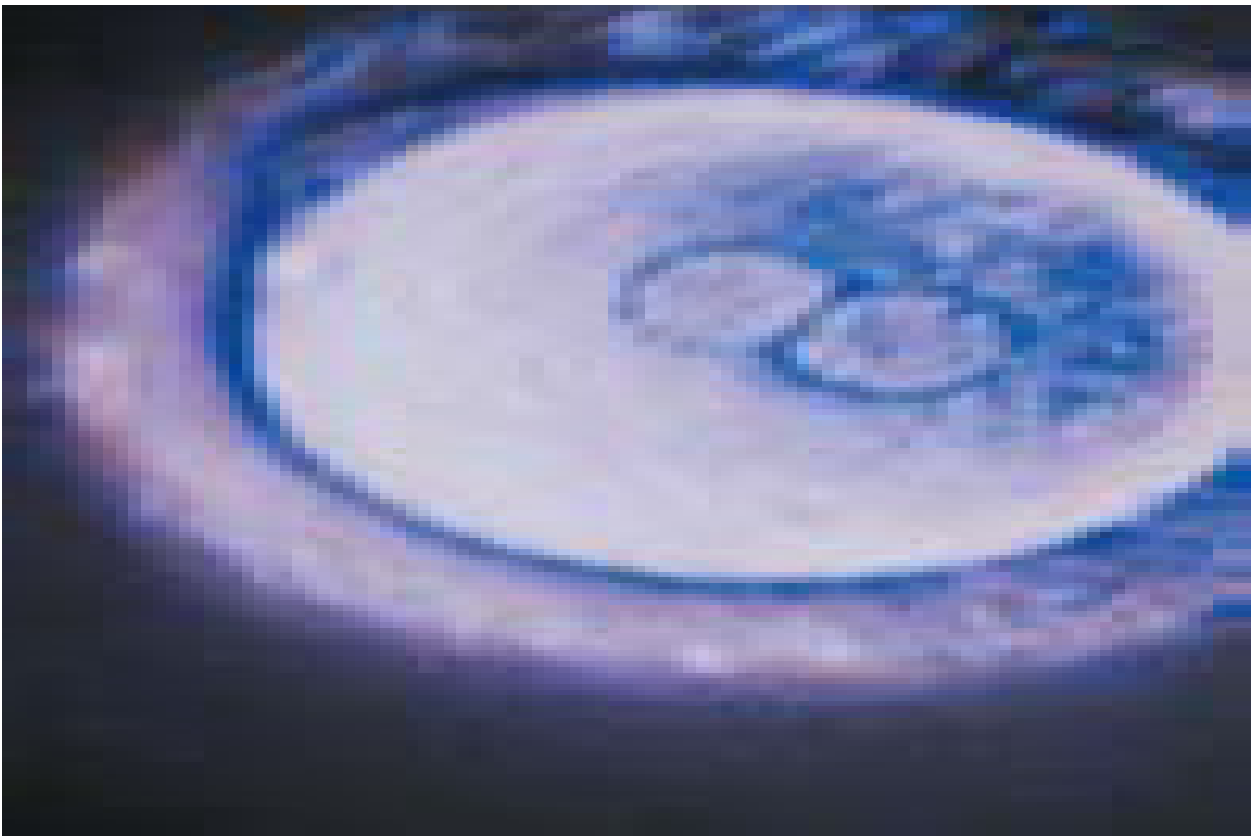
"Journey to the Center of the Earth", Mature human oocyte, photo made by Jacques Testard, "Quand la science rejoint l'art" (1999) exhibition directed by Michel Depardieu, © Inserm.

### ***Case Story: Lab courses in the field of regenerative medicine***

This case story concerns a research project organising 5 one-week long interdisciplinary conferences for scientists (each conference consisting of lectures and lab courses) in the field of regenerative medicine with the focus on neuronal stem cell research and new technologies. The training courses will involve the use of hESC generated by a Swedish stem cell research company. As the research partnership involves Norway, it is important to precise that, up to now, hESC research is prohibited in Norway. Thus the hESC can only be used if the Norwegian Government will change the legislation and the research will be in accordance with the national law.

#### Recommendations given by the ethics review panellists:

- Since hESC research is a very controversial issue, the conferences should give scientists an overview of the ethical debate on this issue. It is important to discuss also the ethical arguments brought for and against hESC research and not only to concentrate on legislation.
- The use of hESC by the Norwegian Partner should be in accordance with the Norwegian legislation or excluded for EU-funding.



"Promise of Life", A newly fertilised human oocyte, photo made by Jean Parinaud, "Quand la science rejoint l'art" (1999) exhibition directed by Michel Depardieu, © Inserm.

### *Defining the problematic*

Data privacy refers to the evolving relationship between technology and the legal right to, and public expectation of privacy in the collection and sharing of data. Privacy problems exist wherever uniquely identifiable data relating to a person or persons are collected and stored, in digital form or otherwise. Improper or non-existent disclosure control can be the root cause for privacy issues. The most common sources of data that are affected by data privacy issues are:

- Health information
- Criminal justice
- Financial information
- Genetic information
- Location information
- Cultural Information

The challenge in data privacy is to share data while protecting the personal identity from the information. Consider the example of health data which are collected from hospitals in a district; it is standard practice to share this only in an aggregate form. The idea of sharing the data in the aggregate is to ensure that only non-identifiable data are shared.

**The European DIRECTIVE on the protection of personal data** contains a number of key principles which must be complied with. Anyone processing personal data must comply with the eight enforceable principles of good practice. They say that data must be:

- Fairly and lawfully processed.
- Processed for limited purposes.
- Adequate, relevant and not excessive.
- Accurate.
- Not kept longer than necessary.
- Processed in accordance with the data subject's rights.
- Secure.
- Not transferred to countries without adequate protection.

### ***The way of dealing with Data Protection and Privacy***

Researchers should describe the procedure for obtaining informed consent of persons to whom the information relates and describe the arrangements for protecting the confidentiality of personal data of the individuals concerned.

If the data is retained for further research they need to ensure that the informed consent form explains and justifies it. Applicants should describe the measures taken to encode or anonymise banked biomaterial (including traceability measures). Even where only anonymised data are used, adequate security for storage and handling of such data must be shown.

### **DISTINCTION BETWEEN CODED AND ANONYMISED**

**CODED → To codify someone's data on the basis that his personal details can still be identified by specific requests and safeguards**

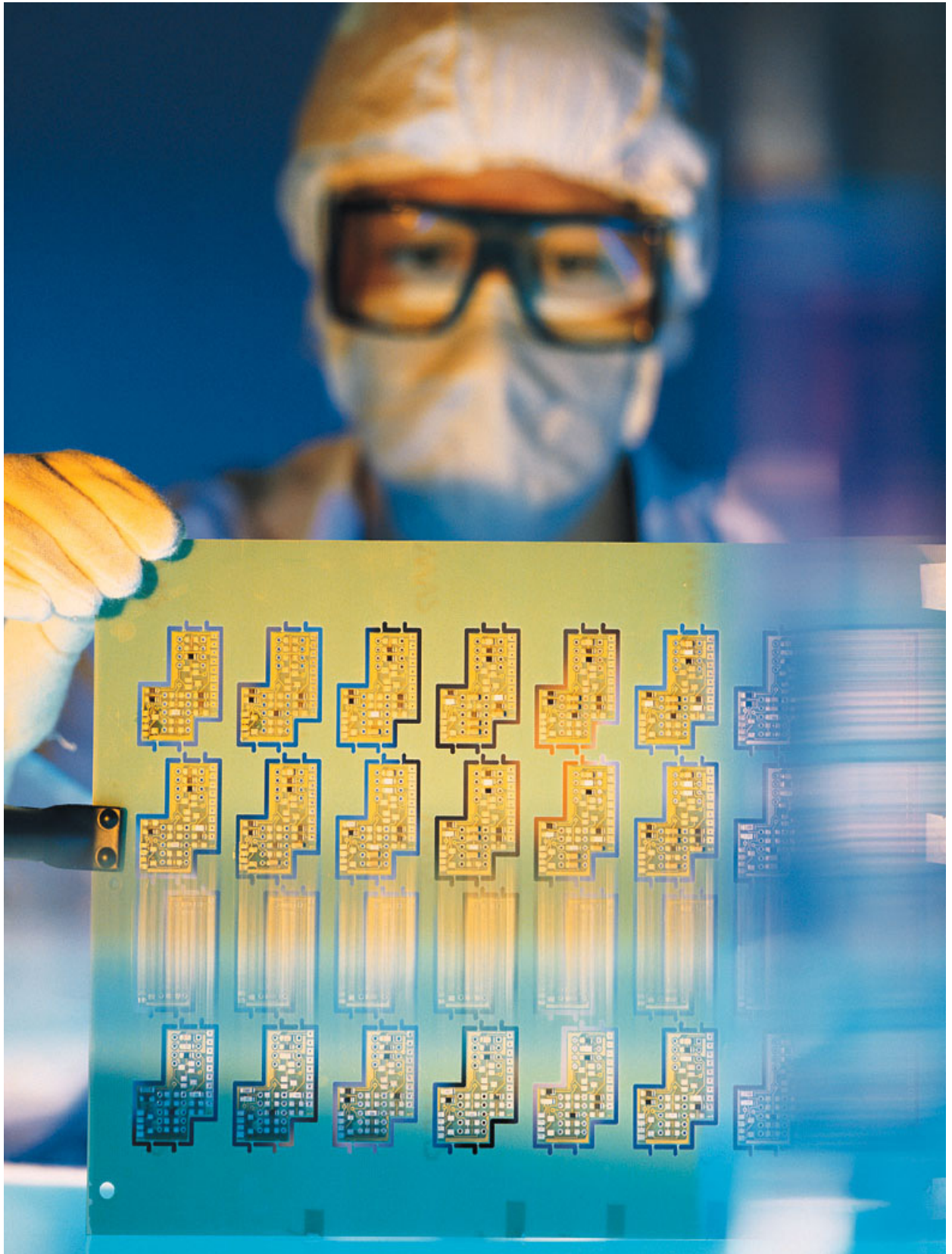
**ANONYMISED → Impossible to link data with an identifiable person**

#### ***Case Story: Radio detection, Data protection and Privacy***

This case story focuses on a research project involving ultra wideband radio application for localisation of hidden people and detection of unauthorised objects. The researches claim that they are confident to confirm that the research results (technology developed) will not provide information which could enable a person to be identified in reference to physical, physiological, mental, economic, cultural or social identity. This statement has clear consequences for some ethical issues like health and safety, data protection and privacy.

#### **Recommendations given by the ethics review panellists:**

- An independent ethics expert must be recruited to advise the project management board on the involvement of human volunteers in any part of the project. The independent expert must ensure that appropriate informed consent is obtained from participants.
- The panel recommends that all personal data collected from the volunteers should be irreversibly anonymised and destroyed at the end of the project.



## DUAL USE

### ***Defining the problem***

Dual-use is a term often used in politics and diplomacy to refer to technology which can be used for both peaceful and military aims, usually in regard to the proliferation of nuclear weapons.

Dual-use can also refer to any technology which can satisfy more than one goal at any given time. Thus, expensive technologies which would otherwise only serve military purposes can also be utilized to benefit civilian and commercial interests (Example: The Internet).

### ***The way of dealing with potential dual use***

Regarding implications for the use of and misuse of the research and products, the following measures and strategies should be applied:

- The setting up of an advisory board to support the research consortium in examining the societal, political and legal aspects of the study applications
- The exploitation strategy of the study results should be reviewed by the advisory board
- The dissemination and communication strategy of the study results to a wider audience should be controlled by the advisory board (organisation of wider stakeholder discussions)

### ***Case Story: Inspecting Systems for Homeland Security***

This case story is centred on a research project to develop an innovative range of passive inspecting systems based on Terahertz (THz) wave detection, to detect harmful materials for homeland security. Main applications will be related to airports security systems, surveillance of crowded areas such as metro and railway stations; detection of chemical and biological harmful substances and hazards in post and goods. It is believed that the implementation of the project and its results should not be in conflict with any national or international ethical regulations. However, it must be mentioned that the project will deal with dangerous (and sensitive to regulations) material such as explosive, fire weapons and drugs.

#### Measures applied following the advices of the ethics review panellists:

- Regarding the use of dangerous materials: such materials will be managed only by a small core group of partners, which have all the experience, facilities and security plans to deal with them
- Regarding the access of study results to unwanted users (criminals, terrorists): a future exploitation plan is clearly defined and approved by the advisory board

## RESEARCH USING ANIMALS

### *Defining the problematic*

Animal testing, or animal research, refers to the use of animals in experiments. It is estimated that 50 to 100 million animals worldwide — from fruit flies and mice to non-human primates — are used annually and either killed during the experiments or subsequently euthanized. The research is carried out inside universities, medical schools, pharmaceutical companies, farms, defense-research establishments, and commercial facilities that provide animal-testing services to industry. Most laboratory animals are bred for research purposes, while a smaller number are caught in the wild or supplied by pounds.

### *The way of dealing with research on animals*

Researchers should provide details of the species (and strains where appropriate) of animals to be used and explain why they have been chosen. They should explain why the anticipated benefits justify the use of animals and why methods avoiding the use of living animals cannot be used. They should also give details and justify the numbers of animals proposed with reference to statistical advice if applicable.

They have to indicate what steps have been taken to comply with the principles of the 3 Rs: reduction, refinement and replacement. In particular, they should describe these procedures adopted to ensure that the amount of suffering to the animals is minimised and that their welfare is protected as far as possible (e.g. improvements in technique, application of human end-points, environmental enrichment).

The "three Rs" are guiding principles for the use of animals in research in many countries:

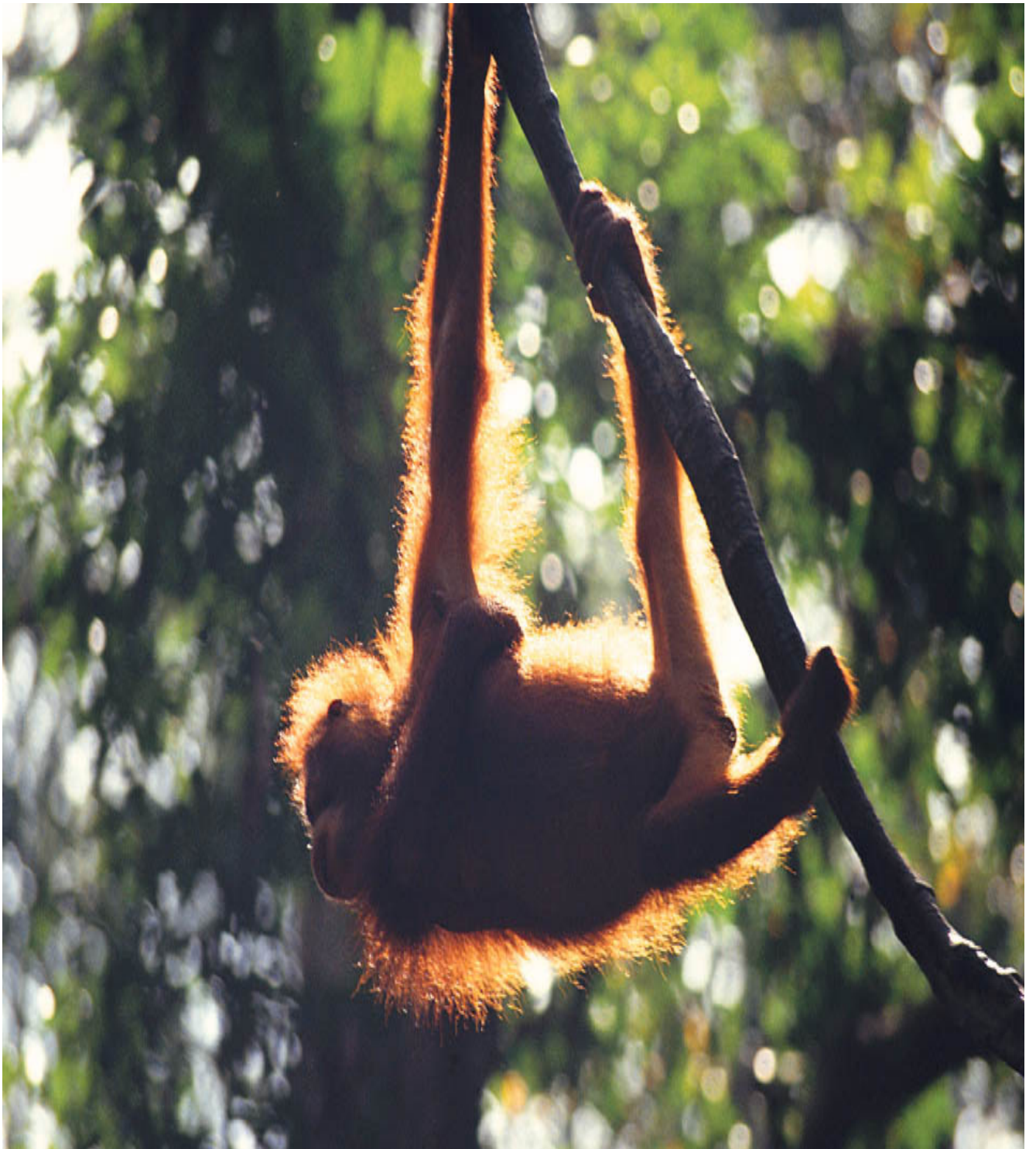
- **Reduction** refers to methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.
- **Replacement** refers to the preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aim.
- **Refinement** refers to methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals still used.

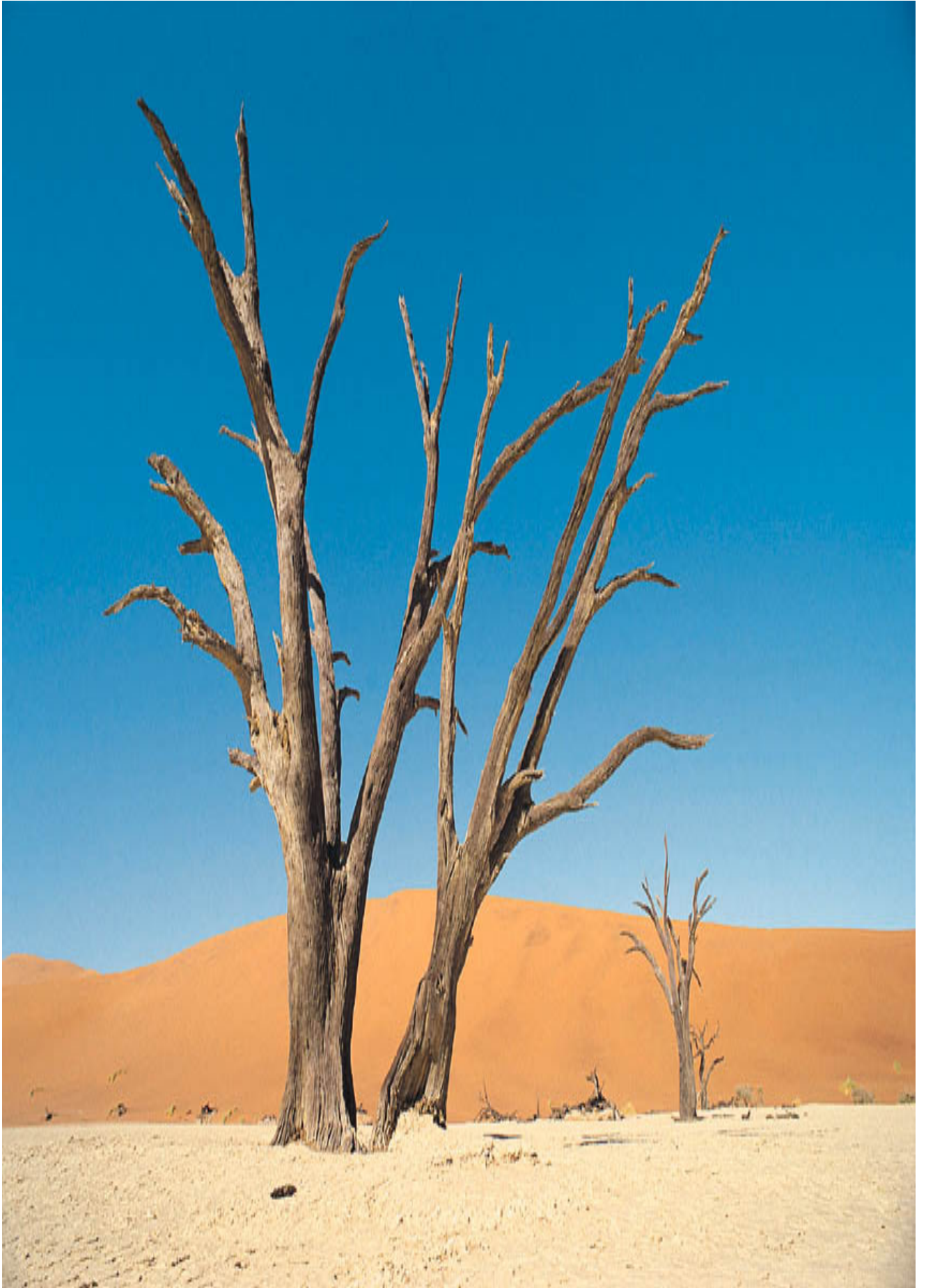
### **Alternatives to the use of Animals? Check the following websites**

<http://ecvam.jrc.it/index.htm>

<http://www.nc3rs.org.uk/category.asp?catID=3>

[http://www.vet.uu.nl/nca/links/databases\\_of\\_3r\\_models](http://www.vet.uu.nl/nca/links/databases_of_3r_models)





## RESEARCH INVOLVING DEVELOPING COUNTRIES

### *Defining the problematic*

When the source of, and justification for, universal ethical standards remain the subject of complex debates, it is generally accepted that there is a need for universal ethical standards for research on humans, and considerable effort has been made towards achieving this goal. Achieving universality in ethical standards requires reflection such as: (1) what constitutes the best interest of subjects – with insightful recognition that individual and cultural preferences, and what can be achieved in any particular context, may differ significantly; (2) what distinguishes the truly universal from imperialistic notions; and (3) the relevance of contextual issues that can be taken into consideration on moral grounds without resorting to ethical relativism.

### *Food for thought*

→ Does the research project provide **benefit to the local community** (in terms of access to healthcare, education, allocation of property rights, capacity to assess and use modern technologies, while respecting the population's own choices and needs, etc.)?

→ Does the research project **use local resources** (genetic resources, animal, and plants)?



### ***The way of dealing with research involving developing countries***

The categories of issues requiring special attention include:

- A disproportionately heavy burden of diseases (particularly infectious diseases); the breadth and depth of poverty; and high levels of illiteracy
- Wide disparities in health systems and in access to health care; and imbalance between the often-ample resources available for research and the meagre resources available for even basic health care
- Inadequate scientific and ethics infrastructures for the compulsory local reviewing process
- The extent of disempowerment of the poor in their personal and communal lives
- Knowledge of the ways in which people of other cultures traditionally view themselves as individuals embedded in communities with respect to the changing boundaries between perceptions of the self that differ from the classical western notion
- The need to understand what it means to be ill in contexts very different from those known to researchers and what can be expected from those one consult for help under those circumstances

#### ***Case story: Collecting human biological samples in developing countries***

This case story is based on a research project dealing with capture and enrichment of emerging pathogens for multiple and ultra-sensitive diagnostic. This study funded by Northern organisations involves patients from developing countries; the human biological samples to be used are whole blood, plasma, serum, saliva, urines containing different types of viruses.

Test results will not be communicated to the patients since the tests are not clinically validated and not yet approved for diagnostic use. The researchers state that the samples will be anonymised and personal data will be protected in compliance with EU ethical and safety standards, irrespective of where the samples are collected.

#### **Recommendations from the ethics review panellists:**

- Before biological samples are collected, a copy of the informed consent literature to be used and appropriate approval by local committees should be submitted to the Ethics Review Panel.
- Ethics Review panellists advice the researchers to consider a kind of benefit sharing with the population involved in case of medical or financial gain, e.g. property right development.

# CONCLUSION

As researchers, you have the opportunity to be part of the FP7, a research programme that aims to promote excellence and innovation, which needs to respect the freedom of research while ensuring the highest standards for the respect of fundamental ethical principles. It also covers many countries with a big diversity of approaches in science and the way it relates to cultural, religious, historical and societal differences.

The FP7 is building up an ethical framework which has solid foundations: scientific and political responsibility, respect of diversity of opinions, search for balance of interests and respect of the subsidiarity principle.

In addition, it is of prime interest for the EU to share with the rest of the world its model of responsible science funding covering many countries with many different values and opinions.

The launch of FP7 has given rise to a flurry of activity within the research community: collaborators are sought, new financial rules are being scrutinised, deadlines underlined on lab calendars and so on. The moral of this publication is not to forget research ethics.