ETHICS FOR RESEARCHERS
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

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Facilitating Research Excellence in FP7

By

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* Prepared as part of a traineeship in the Governance and Ethics Unit

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In memory of Watta who made this painting 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.
A MESSAGE TO THE RESEARCH COMMUNITY

from 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 funding within the Seventh Framework Programme. I wish you all the best of luck.

While you occupy yourselves with finding research partners, reflecting on budgets and mulling over the best experimental approaches, I want to draw your attention to research ethics. Research opportunities indeed bring obligations with them.

Issues such as protection of identity, privacy, obtaining informed consent and communicating benefits and risks are amongst the many ethical issues researchers must always have in minds. I know that there is no book of magic answers for everyone when it comes to ethics in research. However what I know is that through sharing benefits and knowledge, a better capacity for ethical compliance is built.

Ethics must be given the highest priority in EU funded research. It is an integral part of research, from conception to publication. Ethics permeates every area of research and it is only by getting the ethics right that research excellence can be achieved.

Janez Potočnik
European Commissioner for Science and Research
CHAPTER I
ETHICS REVIEWS
IN CONTEXT

“Filaments”, A Motoneurone.
Photograph by Christopher Henderson,
“Quand la science rejoint l’art” (1999)
exhibition directed by Michel Depardieu, © Inserm.
The Emperor’s New Clothes
The Ethics Review process resembles the small child in Hans Christian Andersen’s fairytale ‘The Emperor’s New Clothes’. It is 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.

The Seventh Framework Programme (FP7) is a significant source of public funding dedicated to supporting a sound research community for a better future for Europe. 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 publication is not intended to be an academic ‘textbook’ on ethics, but rather a pragmatic guide to help researchers grasp the basics and apply them with confidence. In FP7, an important change is that the Ethics Review will be carried out on the proposal submitted, with no additional information requested. It is therefore essential for proposers to submit sufficient information in their proposals.

THE OBJECTIVES

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

Context, Consistency and Ethical Sensitivity
Ethics is often misunderstood by researchers as hindering scientific progress. While it is true that ethics is closely linked with law, rules and regulations, it does not go against research. Ethics Reviews at the Commission aim to be collaborative and constructive. By considering ethical issues from the conceptual stage of a proposal, the quality of research is enhanced. What follows is a description of the ethical review process from the Commission Services’ perspective and, hopefully, an opportunity to discover how relevant ethics is to research.

Context
Ethics is context-dependent, and consequently definitive mathematical outcomes are rare. The proposal will need to clarify the necessity to use personal data, human tissue and the involvement of human beings, animals. The reputation of a research institution or a publication track record is not sufficient to exempt a proposal from describing these elements.

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

Ethical Sensitivity
This is the unwritten skill that ethics panels search for. It is a measure of honesty and clarity apparent in the proposal.
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)

Art. 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.
Photograph by Jacques Testart,
“Quand la science rejoint l’art” (1999) exhibition directed by Michel Depardieu, © Inserm.
“Stalagmites” Chromosomes
in a nucleus labelled with fluorescent dye.
Photograph 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 at 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, and veterinary science. Representatives of civil society may also be invited, such as representatives of patient 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 panel members are selected according to their expertise and several criteria, including gender balance. In this respect the objective in selecting experts for ethics reviews is for panels to include 45% of female experts. This is a crucial condition to ensure that ethics review panels are representative of society as a whole.
**BALANCE IN THE FIELDS OF EXPERTISE**

Ethics Review panels are multidisciplinary and multisectorial, composed of recognised experts in a wide range of fields. The pie chart below shows the proportional representation of the different sectors that participants in the Ethics Reviews in 2004 consider as their main field of expertise. In general, bioethics and health & medical sciences are better represented than humanities and technological sciences, as health was one of the primary focuses of FP6.

The second pie chart illustrates the breakdown of FP6 projects having undergone Ethics Review, by research area. 45% of projects submitted to Ethics Review in FP6 were from the field of biomedicine and genetics.

**Balance in fields of expertise**

**Ethics Review 2004 (FP6)**

- 26.89% Bioethics
- 35.29% Health and Medical Sciences
- 6.72% Technological Sciences
- 13.45% Law
- 10.08% Animal Welfare
- 18.49% Humanities and Social Sciences
- 2.52% Biology and Biotechnology

**Breakdown of FP6 projects**

**Ethics Review 2004**

- 45.00% Biomedicine and Genetics
- 8.00% ICT
- 9.00% Nanotechnology
- 11.00% Food and green biotech
- 11.00% Mobility (Marie Curie)
- 18.00% Other
**GEOGRAPHICAL BALANCE**

The Commission makes constant efforts to recruit Ethics Review participants coming from a wide range of EU countries.

The graph below (2006) shows participation in Ethics Review by nationality. There is a strong representation from large countries such as Germany, the UK and France. At the same time, participation from new Member States (Estonia, Poland, Malta, Romania) has increased substantially over the past years. There is a constant 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.
Photograph by Sheng Sun-Jian,
“Quand la science rejoint l’art” (1999)
exhibition directed by Michel Depardieu, © Inserm.
ADDRESSING ETHICS IN EU FUNDED PROJECTS

The European Commission provides guidance on addressing ethical issues for prospective applicants (http://cordis.europa.eu/fp7/ethics_en.html). All proposals received by the Commission must describe the ethical, safety and socio-economic issues raised by the research proposed and how they will be addressed so as to conform to national, European and international regulations.

SCIENTIFIC EVALUATION OF RESEARCH PROJECTS

Following a call for proposals all applications submitted to the Commission are evaluated on their scientific merit. During this evaluation, the panel of scientists also makes a preliminary check of the ethical issues raised by a project and identifies any projects requiring special attention. This applies when projects raise sensitive ethical issues or when applicants fail to address ethical issues appropriately. Following the evaluation, those proposals retained by the Commission with a view to funding, but identified by the experts as raising ethical issues, will be submitted to an Ethics Review panel.
As a first step, the experts selected as members of the Ethics Review panel individually read the research proposals. A consensus meeting then follows during which the Ethics Review panel discusses the following elements:

- Applicant’s awareness of the ethical aspects and the social impact of the research they propose
- Whether the researchers respect the ethical rules and standards of FP7
- Whether relevant European Directives are applied
- Whether the applicants are seeking the approval of relevant local ethics committees
- Whether 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:

- Lack of consistency
- Failure to describe insurance cover
- No information on handling incidental findings
- No information on any incentives used (financial inducements, etc.)
- Issues related to children: failure to describe if child obtains a real and direct benefit. If child is not directly benefitted, a minimum risk and minimum burden must be illustrated
- Research on animals: failure to describe (i) numbers used; (ii) humane end points; (iii) if non animal alternatives were sought
- Developing Countries: failure to describe why it is necessary to include the developing countries and whether any benefits will reach these countries
- Conflict of Interest: independence is central to obtaining informed consent. A treating doctor should not be involved in counselling a patient on the benefits of his / her research

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!
CHAPTER IV
ETHICS REVIEWS
METHODOLOGY

“Inkspots”. Detection of receptors for the neuropeptide somatostatin.
Photograph by Valérie Turquier-Carpentier, “Quand la science rejoint l’art” (1999) exhibition directed by Michel Depardieu, © Inserm.
ETHICS – 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 individual researchers can easily fulfil ethical obligations by asking themselves: “How would I like my spouse’s / child’s / parent’s dignity to be handled in a research setting?” It is essential to consider the social impact of the research results. “Will the outcome have a dual use that could pose a threat to personal security, privacy and dignity?”

TYPOLOGY OF ETHICAL ISSUES

INFORMED CONSENT

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 participation in a research project.

Defining the issue

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

1 Declaration of Helsinki (Edinburgh, 2000), World Medical Association (www.wma.net)
Dealing with informed consent

Who should consent? This is the first question to be posed. Only persons able to freely understand and question should give consent. This excludes vulnerable persons (prisoners, mentally-deficient persons, severely-injured patients, very young children, etc.). However, to avoid any loss of opportunities for these persons, legal frameworks 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 when signing an informed consent form. The following strategies may help:

- Participation of a linguist for preparing the informed consent
- Presentation of the research project using information technologies (video, power-point presentation, play, etc.)
- Interviews conducted with the participants to ensure that they understand the issues at stake in the research project
How to get approval is the third major issue in connection with informed consent. It relates to the person’s autonomy and vulnerability. It depends on the culture and the traditions of the population concerned. In some communities, the notion of individuality is lacking; written agreements do not exist, or women cannot act in autonomy. Again, some strategies can be used:

- Presence of a local 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 form:

--- How can human subjects help to contribute to science and/or public health? It is crucial to explain the impact of the planned research for society and for the individuals involved: to describe the potential and direct benefits of the research as well as the side effects.

--- How will researchers work to protect subjects and their data? Often Researchers do not explain what happens to data, samples and 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 form shows this.

CASE STUDY

PREVENTING COELIAC DISEASES — RESEARCH INVOLVING CHILDREN (FP6 PROPOSAL 2005)

This case study focuses on the influence of the dietary history in the prevention of coeliac diseases. One of the ethical issues raised by this study is the involvement of infants (1,000) and children of school age (16,000) unable to give consent.

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

1. The results of the research have the potential to produce real and direct benefit to his/her health.
2. The research entails only minimal risk and minimal burden for the individual concerned.

Problem raised by ethics review panelists: 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 for no direct benefit. In this current design, this population study therefore contravenes the Council of Europe Convention on Human Rights and Biomedicine.
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 form?

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, that 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 issue

The core of the ethical dilemma lies with the conflicting nature of certain 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 involves the use and destruction of human embryos. The Council of Europe argues that ethical aspects should be given priority over aspects of a utilitarian and financial nature. Even so, they should be assessed in the light of the potential prospects of future therapies alleviating severe human suffering.

A key issue is the use of embryos for stem cell research. According to a study conducted by the European Science Foundation (2001), 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 nevertheless give their consent. A particular issue arises from the use of the spare embryos created for In Vitro Fertilisation (IVF) infertility treatment. Should supernumerary embryos be used or should scientists be allowed to create embryos for the sole purpose of research?
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 in line with Opinion N° 15 of the European Group on Ethics (“Ethical Aspects of Human Stem Cell Research and Use”).

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:

- ascertains itself that the proposal does not include research activities which destroy embryos including for the procurement of stem cells;
- considers 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;
- considers the source of the hESC;
- considers the measures taken to protect personal data, including genetic data, and privacy;
- considers the nature of financial inducements, if any.

In addition 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 on hESC.

8 EGE, Opinion n°15 “on ethical aspects of human stem cell research and use”, 14/11/2000
http://ec.europa.eu/european_group_ethics/docs/avis15_en.pdf
CASE STUDY

LAB COURSES IN THE FIELD OF REGENERATIVE MEDICINE

This case study concerns a research project organising five one-week interdisciplinary conferences for scientists (each conference consisting of lectures and lab courses) in the field of regenerative medicine with a focus on neuronal stem cell research and new technologies. The training courses involve the use of hESC generated by a Swedish stem cell research company. As the research partnership involves Norway, it is important to point out that at the time of proposal submission, hESC research is prohibited in Norway. Thus, hESC can only be used if the Norwegian Government changes legislation so that the research will be in accordance with 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 also important to discuss the ethical arguments 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 be excluded from EU-funding.

“Promise of Life”, a newly fertilised human oocyte.
Photograph by Jean Parinaud,
“Quand la science rejoint l’art” (1999)
exhibition directed by Michel Depardieu, © Inserm.
CHAPTER IV: ETHICS REVIEWS METHODOLOGY

D A T A  P R O T E C T I O N  A N D  P R I V A C Y

Defining the issue

Data protection refers to the evolving relationship between technological opportunities and the legal right to, and public expectation of, privacy in the collection and sharing of data. Privacy issues 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 whilst protecting personal identity in 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 this way is to ensure that only non-identifiable data are shared.

The European Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such 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. 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
How to deal with data protection and privacy

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

If the data are 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 demonstrated.

**DISTINCTION BETWEEN CODED AND ANONYMISED**

**CODED**

→ To codify someone’s data
so that his/her personal details
can still be identified by specific requests and safeguards

**ANONYMISED**

→ Impossible to link data with an identifiable person

**CASE STUDY**

**RADIO DETECTION, DATA PROTECTION AND PRIVACY**

This case study focuses on a research project involving an ultra wideband radio application for the localisation of hidden people and detection of unauthorised objects. The researchers claim that their research results and the technology developed from the project will not provide information which could enable a person to be identified with respect to physical, physiological, mental, economic, cultural or social identity. This statement has clear consequences for some ethical issues such as 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 be irreversibly anonymised and destroyed at the end of the project.
DUAL USE

Defining the issue

DUAL USE IS A TERM OFTEN USED IN POLITICS AND DIPLOMACY TO REFER TO TECHNOLOGY WHICH CAN BE USED FOR BOTH PEACEFUL AND MILITARYAIMS, USUALLY WITH REGARD TO THE PROLIFERATION OF NUCLEAR WEAPONS.

Generally, dual use can also refer to any technology which can satisfy more than one goal at any given time.

How to deal with potential dual use

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

● the setting up of an advisory board to support research consortia in examining the societal, political and legal aspects of potential applications

● the exploitation strategy of the study results should be reviewed by an advisory board

● the dissemination and communication strategy of research results to a wider audience should be controlled by an advisory board (organisation of wider stakeholder discussions)

CASE STUDY

INSPECTING SYSTEMS FOR “HOMELAND SECURITY”

This case study 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. Principle applications will be related to airports security systems, surveillance of crowded areas such as underground 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 conflict with any national or international ethical regulations. However, it must be mentioned that the project will deal with dangerous material such as explosives, firearms and drugs.

Measures applied following the advice of the Ethics Review panellists:

● Regarding the use of dangerous materials: such materials will be managed only by a small core group of partners, who have the necessary experience, facilities and security plans to deal with them.

● Regarding the access of study results to unwanted users (e.g. criminals, terrorists): a future exploitation plan is clearly defined and approved by an advisory board.


\section*{Research on Animals}

\subsection*{Defining the issue}

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 euthanised. The research is carried out inside universities, medical schools, pharmaceutical companies, farms, defence-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 animal shelters.

\subsection*{How to deal 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 the 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 humane end-points, environmental enrichment).

\subsection*{Alternatives to the use of Animals?}

Please see the following websites:

- http://ecvam.jrc.it/index.htm
- http://www.vet.uu.nl/nca/links/databases_of_3r_models

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

- **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 minimise potential pain, suffering or distress, and enhance animal welfare for the animals still used.
Defining the issue

Whilst the source of, and justification for, universal ethical standards remains the subject of complex debate, it is generally accepted that there is a need for universal ethical standards for research on humans, with considerable effort having been made towards achieving this goal. Achieving universality in ethical standards requires reflection such as: (1) what constitutes the best interest of subjects? - within specific cultures and contexts; and (2) what distinguishes universalism from imperialism?

How to deal 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

Criteria to consider

- Does the research project provide benefits to the local community (in terms of access to healthcare, education, allocation of property rights, capacity to access and use modern technologies, whilst respecting the population’s own choices and needs, etc.)?
- Does the research project use local resources (genetic resources, animal, and plants)?

- 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 within their communities
- 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 consults for help under such circumstances

Collecting human biological samples in developing countries

This case study is based on a research project dealing with capture and enrichment of emerging pathogens for multiple and ultra-sensitive diagnostics. Funded by Western organisations, this study involves patients from developing countries. The human biological samples to be used are whole blood, saliva, and urine 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 that 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 advise the researchers to consider a kind of benefit sharing with the population involved in, the case of medical or financial gain, e.g. intellectual property right development.
CONCLUSION

Researchers have the opportunity to be part of FP7, a research programme that promotes excellence and innovation, and which respects freedom of research whilst ensuring the highest standards for the respect of fundamental ethical principles. It covers many countries with a large diversity of approaches to how science relates to culture, religion, history and society.

It is of prime importance for the EU to develop a model of responsible science funding. FP7 builds an ethical framework which has solid foundations: scientific and political responsibility, respect for the diversity of opinions, a search for balance of interests, and respect for the principle of subsidiarity.

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 from this publication is: do not forget research ethics.