Ethical Considerations in EC Research Proposals

Mary Sharp
Acknowledgement

- I would like to acknowledge Francois Hirsch of the European Commission for allowing me permission to include some of his slides in this presentation.
- Francois has just completed a three year term as seconded national expert in the ethics sector of the EC.
European Commission Ethical Reviews - Introduction

Why set up Ethical Reviews? Two Major Objectives

- Assuring citizens and decision-makers that EU-funded research complies with the highest ethical standards
- Facilitating Research Excellence in FP 7
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 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. »

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Areas excluded from funding under FP7, Art. 3 (2§):

A) Research activity aiming at **human cloning for reproductive purposes**

B) Research activity intended to **modify the genetic heritage of human beings**

C) Research activities intended to **create human embryos solely for the purpose of research or stem cell procurement**
Ethics Screening

- Screening divides proposals into three different categories:
  - No Ethical Review required
  - Only approval of relevant national or local Ethics committees required
  - Ethical Review

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Breakdown of projects having undergone ethics reviews, by research area

From July 2007 to December 2008, 535 proposals were reviewed by the EC; ~20% were directly submitted to the national authorities
Legislation, regulations and conventions

European references on ethics and science

This section lists European legislative, regulating and advising documents related to ethics and science.

- Directive 95/46 on the protection of personal data
- Directive 2001/20/EC on good clinical practice
- Directive 2001/83/EC on medicinal products for human use
- COMMISSION REGULATION (EC) No 1084/2003 on the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State
- COMMISSION REGULATION (EC) No 1085/2003 the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93
- Directive 98/44/EC on the legal protection of biotechnological inventions
- Directive 86/609/ECC on the protection of animals used for experimental and other scientific purposes
- Protocol on Protection and welfare of animals (Protocol to the Amsterdam Treaty)
- Directive 90/219/EEC on the contained use of genetically
Ethical Reviews in Practice: The Project Evaluation Process

■ Scientific Evaluation

→ All proposals submitted to the Commission for funding following a call for proposals are evaluated on their scientific merit.

→ Scientific evaluators identify the proposals raising ethical issues and needing ethical reviews.

■ Ethical Review (mandatory)

All proposals for funding involving a research intervention on humans, the use of hESC and/or foetal tissues, and non-human primates will be automatically submitted to an ethical review panel.

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EC Ethics Reviews Panels

- EC Ethics Reviews 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.
What is expected

- It is expected that applicants will first of all identify in the Ethical Issues Table all items that apply to the research proposal.
- Apart from identifying the issues in the Ethical Issues Table it is expected that the applicants will expand on each.
  - Give details of inclusion and exclusion criteria
  - Number of humans/animals to be used
  - Relevant legislation that applies to the research
  - Examples of information sheets and informed consent forms
  - How data will be protected etc.

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Ethical Issues Table (1)

- Items requiring automatic Ethical Review – Research on Human Embryo/ Foetus:
  - Does the proposed research involve human Embryos?
  - Does the proposed research involve human Foetal Tissues/ Cells?
  - Does the proposed research involve human Embryonic Stem Cells (hESCs)?
  - Does the proposed research on human Embryonic Stem Cells involve cells in culture?
  - Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos?
### Ethical Issues Table (2)

- **Items requiring automatic Ethical Review (Cont’d) – Research on Humans**
  - Does the proposed research involve children?
  - Does the proposed research involve patients?
  - Does the proposed research involve persons not able to give consent?
  - Does the proposed research involve adult healthy volunteers?

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Ethical Issues Table (3)

- Items requiring automatic Ethical Review (Cont’d) – Research on Animals
  - Are those animals non-human primates?

Research Involving Developing Countries

- Does the proposed research involve the use of local resources (genetic, animal, plant, etc)?
- Is the proposed research of benefit to local communities (e.g. Capacity building, access to healthcare, education, etc)?

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**Ethical Issues Table (4)**

- Other items listed on table not requiring automatical Ethical Review – research on humans
  - Does the proposed research involve Human genetic material?
  - Does the proposed research involve Human biological samples?
  - Does the proposed research involve Human data collection?

- Privacy
  - Does the proposed research involve processing of genetic information or **personal data** (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?
  - Does the proposed research involve tracking the location or observation of people?

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# Ethical Issues Table (5)

- **Research on Animals**
  - Does the proposed research involve research on animals?
  - Are those animals transgenic small laboratory animals?
  - Are those animals transgenic farm animals?
  - Are those animals cloned farm animals?

- **Dual Use**
  - Research having direct military use
  - Research having the potential for terrorist abuse

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In particular, the Ethical 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 FP7 ethical standards
- Whether the relevant European Directives, international Conventions and Declarations are applied
- Whether the consortium is seeking the approval of relevant local ethics committees.
Ethics Review Methodology

- **COMMON PROBLEMS:**

  → Issues related to Clinical Trials (children, informed consent, insurance...)

  → Data protection

  → Developing Countries

  → Research on Animals

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Clinical Trial

- **main first concerns:**
  - benefit
  - outcome (data, samples)

- **the Informed Consent:**

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INFORMED CONSENT (1)

- Two key issues
  - Who benefits
  - What happens to data, samples and animals at end?

- Who should consent?
  - Persons able to freely understand and question
  - Vulnerable persons generally excluded BUT to avoid
    loss of opportunity possibilities exist

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INFORMED CONSENT (2)

■ How to Inform?
   → Culture, Literacy, use of linguist in preparation of consent forms

■ How to get the approval?
   → Literacy, Responsible adult, written agreements not always provided (Developing Countries)
   → Notion of Individuality is lacking in some cultures
   → Gender issues

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Content of Information Sheet - General

• Explanation of the purpose of the research
• Expected duration
• Description of the procedures
• Voluntary
• Risks, discomfort or disadvantages
• Benefits to the subject or others
• Alternative procedures for treatment/diagnosis
• Data protection and confidentiality and privacy policies
• Incidental findings and their handling
• Genetic tests
• Treatments or compensation if injury occurs
• Where to get more information
• What happens to data, samples and results at the end of the research

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Specific Information

- **Children**
  - Informed consent of parents/legal guardians in addition to children’s consent if child able to give consent.
  - In accordance with the age of the child – e.g. Under 5 pictorial
  - Up to 16 simple terms that can be easily understood
  - 16 to 18 written consent required
  - How the study will affect the child at home, school or other activities

- **Imaging**
  - Type of exposure
  - Contrast fluid
  - Medical information

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Clinical trial on children

For which purpose?
- Research involving children mainly concerned **biomedical research**.
- A significant part of research on children applied to **behavioural studies**.

Criteria to be taken into account?
- **Number** of children involved
- **Direct benefit** from the study
- **Burden** of the study
- **Informed consent** from parent/tutors
- **Assent** of children (when possible)
Data Protection

■ Personal Data:
  Health Information, Genetic Information, Location Information...

■ Challenges:
  → Process data while protecting identity
  (Processing = Obtaining, Holding, Disclosing)
Research in DCs

- should justify the involvement of Developing Countries

- should consider:
  - Culture and Literacy (how to inform and to consent?)
  - Best Interest
  - Benefit sharing
  - Use of local resources (human, plants, animals...)

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Animal Research

- **Convincing** Application of the **3Rs**
  - Reduction (number), Replacement, Refinement (humane end points, pain suffering)

- To Check for alternatives (cf. the following websites):
  - [http://www.nc3rs.org.uk/category.asp?catID=3](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)
“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.
When proposals involve the use of hESC, the Ethics Review Panel assesses:

- Whether the consortium has taken into account the legislations, regulations, ethical rules and/or codes of conduct in place in the country(ies) where the research is to take place,
- The source of the banked or isolated hESC in culture
- The measures taken to protect personal data, including genetic data and privacy
- The nature of financial inducements, if any
hESC in FP7 (Ctd)

- **In addition, when research proposals involve the use of hESC, the Ethics Review Panel requires:**
  - A positive opinion from a Regulatory Committee constituted by Member States’ representatives is required
  - The approval of the relevant national or local ethics committees prior to the start of the research activities

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Ethical Review Report (1)

- Were the \textit{ethical} aspects of the objectives of the proposed research well examined?
- Were the \textit{ethical} aspects of the methodology of the proposed research well described?
- Were the potential \textit{ethical} impacts of the proposed research well considered?
Ethical Review Report (2)

- Have all the relevant legal and ethical requirements been taken into account by the applicant(s)?
- Does the proposal contain a time-frame for meeting the relevant legal and ethical requirements?
- Overall Impression
Ethical Review Report (3)

- Recommendations
- Requirements
- Ethical Follow-up
  - Would you recommend the resubmission of the proposal to an ethical review panel before the beginning of the project?
  - Would you recommend this project for an Ethical Audit?

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Areas often not addressed

- Insurance
- Incidental findings
- Incentives
- Issues relating to children with respect to benefits
- Number of participants either humans or animals with a scientific justification for them
- Developing Countries

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Examples not to be followed...
Ethical Issues Raised by this Proposal.

X Adults □ Children X Vulnerable Adults
□ Human Intervention ¹ □ Human Tissues
□ Foetal Tissues □ hESC
□ Developing Countries
X Privacy □ Dual Use X Data Protection
□ Animals □ Non Human Primates □ Transgenic Animals

Agreed consensus commentary

This proposal concerns a socio-ethnographic study to describe and analyse how individuals and groups experiment with and adapt to novel forms of citizenship (called ‘profile citizenship’) and how they participate in society and exercise their democratic rights in complex, hybrid situations. The applicants indicate that these phenomena and processes will be studied using cases of socially isolated, often marginalized and vulnerable groups of people (the deaf community, analphabetic and illiterate people, illegal immigrants seeking asylum in churches, suburban unemployed youth). These groups will be studied using interview and observation methodology.

The applicants have indicated that this study will raise no sensitive ethical issues that need to be specifically addressed. However the review panel is of the opinion that this type of study and in particular the fact that the subject of the proposed case studies is vulnerable groups/individuals, does raise a number of ethical issues that must be adequately addressed before such a study is to be conducted. In the present proposal the applicants fail to identify these issues and deal with them in a satisfactory way. In fact, in its present form the proposal is not open to proper ethical review.

Overall Impression: X Insufficient**

¹ The proposal identifies and addresses the relevant ethical issues. Specific requirements, if any, are addressed in the 'Requirements' section.
** While the proposal broadly addresses the ethical issues, there are significant weaknesses which should be amended. These are addressed in the 'Requirements' section.

¹ such as clinical trials and research involving invasive techniques on persons (e.g. taking of tissue samples, examinations of the brain…)

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Ethics Review 7FP
Ethical Review Report

(3 pages maximum)

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☐ Adults  ☑ Children  ☑ Vulnerable Adults
☐ Human Intervention  ☐ Human Tissues
☐ Focetal Tissues  ☐ hESC
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☐ Privacy  ☐ Dual Use  ☑ Data Protection
☐ Animals  ☐ Non Human Primates  ☐ Transgenic Animals

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(3 pages maximum)

<table>
<thead>
<tr>
<th>PROPOSAL PROGRAMME</th>
<th>PROPOSAL ID &amp; ACRONYM</th>
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**Recommendations**
It is strongly recommended that an ethical expert be included in the consortium to manage the sensitive ethical issues.

**Requirements**
The applicants must submit a new, additional paragraph on ethical issues in this study proposal, dealing with at least the following issues:
- Recruitment of groups and/or individuals in the case studies
- Ensuring informed consent of these groups/individuals (copies of information sheets and consent forms to be provided to the Commission)
- Proper handling of sensitive personal data
- Approval by relevant ethics committees (copies to be provided to the Commission)
- Dissemination of personal/sensitive data in final report

Following the submission of this additional paragraph, the proposal must be subjected again to ethical review.

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**Ethical Audit** (to ensure compliance with ethical principles and with contractual requirements detailed above, the Commission Services will undertake an ethical audit of selected project)

Would you recommend this project for an Ethical Audit?

X Yes  □ No

3 Dependent on the content and clarity of the requested additional ethical paragraph, and the outcome of the new ethical review, an Ethical Audit by the Commission can be considered.
Ethics Review 7FP
Ethical Review Report
(3 pages maximum)

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Following the submission of this additional paragraph, the proposal must be subjected again to ethical review.

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**Ethical Audit** (to ensure compliance with ethical principles and with contractual requirements detailed above, the Commission Services will undertake an ethical audit of selected project)

**Would you recommend this project for an Ethical Audit?**

X Yes □ No

\(^1\) Dependent on the content and clarity of the requested additional ethical paragraph, and the outcome of the new ethical review, an Ethical Audit by the Commission can be considered.
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Ethical Audit (to ensure compliance with ethical principles and with contractual requirements detailed above, the Commission Services will undertake an ethical audit of selected project)

Would you recommend this project for an Ethical Audit?

X Yes □ No

*Dependent on the content and clarity of the requested additional ethical paragraph, and the outcome of the new ethical review, an Ethical Audit by the Commission can be considered.*
Clinical trial on children


This case aimed to extend an EC-funded survey in several European countries to non-developing countries (Ethiopia, Gambia).

- The first ethical issues raised by this study is the lack of authorization by RECs from these two countries.
- The other issue was the involvement of children of school age unable to give consent. Teachers were supposed to select the children involved.../...
Case study: Survey on the family impact of contraception in African rural villages (ctd)

- Problems raised by ethics review panellists:
  - A clearance was not obtained from local RECs.
  - There is no clear benefit for local population.
  - There is a clear risk of stigmatisation of involved children.

The Commission decided to reject this project upon recommendation of the ethics panel.

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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 panelists:

- 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.

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Example of a proposal dealing with a disease in adults

- Only items ticked in the Ethical Issues Table were Patients and Human Tissue with no explanation given.
- The reviewers found the following should have been included:
  - Healthy Adults – there was an age and sex matched control group
  - Patients - identified
  - Vulnerable Adults – It was considered that the patients can be vulnerable
  - Human Intervention – Blood samples will be taken
  - Human Tissues – 100ml of Blood
  - Data Protection – the data of the patients and controls
  - Privacy – the privacy of the patients and controls

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Other areas of concern – not included

- The participants selection procedure and the inclusion/exclusion criteria were not described at all
- The data protection or privacy strategy is not outlined by the applicant
- The following statement was included in the proposal
  - Six samples from patients and 6 non-patient samples from different donors will be used initially. This number will be increased if the variability does not enable a reliable analysis....
- Conclusion of the panel
  - Based on the information provided by the applicant no assessment of the conformity of the research with European Union ethical standards can be made. Therefore, the proposal must be resubmitted after comprehensive information relating to the ethical issues of the proposed studies is supplied by the applicant.

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Getting Through Ethics Review

Introduction

The information which follows identifies the main ethical dilemmas that arise in research and indicates how each topic might be addressed to ensure compliance. It is also advisable to identify the expert(s) within your organisation or your consortium that can provide further advice.

Ethics check list

Informed Consent [DOC]

- Does the proposal involve children?
- Does the proposal involve patients or persons not able to give consent?
- Does the proposal involve adult healthy volunteers?
- Does the proposal involve Human Genetic Material?
- Does the proposal involve Human biological samples?
- Does the proposal involve Human data collection?

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Privacy [DOC]

- Does the proposal involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?
- Does the proposal involve tracking the location or observation of people?

Research on Animals [DOC]

- Does the proposal involve research on animals?
- Are those animals transgenic small laboratory animals?
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Research Involving Developing Countries [DOC]

- Use of local resources (genetic, animal, plant, etc.)?
- Benefit to local community (capacity building ie access to healthcare, education, etc. )

Dual Use [DOC]

- Research having potential military/terrorist application

Documents

- Ethics for Researchers [PDF]
- The EU gets tough on ethics [PDF]
- Integrating Ethics in EU Research [PDF]
- Concepts on Ethics [PDF]

Should there be further ethical issues in your proposal that are not addressed here please contact: Mary.Fitzgerald
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Thank you

Questions?

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