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# Ethics Review and the FP7 Ethics Framework

Isidoros Karatzas  
Head of the Ethics  
Review Sector  
DG RESEARCH  
European Commission

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# Moral Theories I

## Consequentialism

### “The End Justifies the Means”

- In consequentialism, the consequence of an action justifies the moral acceptability of the means taken to reach that end. The results of actions outweigh any other consideration

Example : the homeless person in the ER.....

# Moral Theories II

## Deontology

- Deontology or Kantianism is an obligation-based theory whose chief author was Immanuel Kant, who lived in the 18th century. This theory emphasises the type of action rather than the consequences of that action. Deontologists believe that moral decisions should be made based on one's duties and the rights of others

Example.....the same poor person.....

# Moral Theories III

## Bioethics (Principles of ...)

Some of the early founders of bioethics put forth four principles which form this framework for moral reasoning.

**Autonomy** – one should respect the right of individuals to make their own decisions

**Nonmaleficence** – one should avoid causing harm

**Beneficence** – one should take positive steps to help others

**Justice** – benefits and risks should be fairly distributed

## The Nuremberg Code (1947)

States research ethical principles for human experimentation

## The Declaration of Helsinki (1964-2008)

Details ethical principles related to the protection of the life, privacy, health and dignity of the human subject

## The Oviedo Convention (1997)

Seeks the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine

## The European charter of Fundamental Rights (2000)

The first formal EU document that tries to combine and declare all the values and fundamental rights (economic and social as well as civil and political) to which EU citizens should be entitled

## The UN Convention on Biological Diversity (1992)

Seeks to ensure the conservation and sustainable use of the diversity of species, habitats and ecosystems on the planet

### The Cartagena Protocol on Biosafety (2000)

Seeks to protect biological diversity from the potential risks posed by living modified organisms, taking into account human health

# Compliance of applicants with ethical rules: A Legal obligation (1)

**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**'*

# Compliance of researchers with ethical standards

A case-to-case review of all research proposals submitted in FP7  
and

have been selected for funding

and

raise ethical issues (EIT: human subjects, animals, data protection,  
improper/dual use.....)

Organisation of the Ethics Review (two stages; Ethics Screening and Ethics  
Review)

- appointment of the members of the Ethics Screening and Review panels
- procedural coordination of the entire evaluation process.

*From 2010 :an ex-post evaluation (ethics follow-up/audit)*

# Compliance of applicants with ethical rules: A Legal obligation (2)

FP7 Grant Agreement -

Special Clauses applicable to the FP7 Model Grant Agreement for the implementation of the Seventh Framework Programmes of the European Communities (EC-EURATOM)

See more on this:

[ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-ga-clauses-v3\\_en.pdf](ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-ga-clauses-v3_en.pdf)

# Special clauses on ethics in research

## Clause 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.**'*

# Special clauses on ethics in research

## Clause 13

*'The beneficiaries shall comply with the ethical framework of FP7, all applicable legislation, any relevant future legislation and FP7 specific programmes on "Cooperation", "Ideas", "People", "Capacities" (2007-2013) and "Euratom" (2007-2011).'*



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# Special clauses on ethics in research

## Clause 14

### Research Activities Involving The Use Of Human Embryos And Human Embryonic Stem Cells

*The beneficiaries shall inform the Commission in writing of any research activities that may involve the use of human embryos or human embryonic stem cells, unless such provisions in Annex I to the grant agreement have specifically been approved. Such research may not take place without the prior written agreement of the Commission.*

# Special clauses on ethics in research

## Clause 15

The *beneficiary(ies)* shall provide the *Commission* with a written confirmation that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval(s) of the competent national or local authority(ies) in the country in which the research is to be carried out before beginning any *Commission* approved research requiring such opinions or approvals. The copy of the official approval from the relevant national or local ethics committees must also be provided to the *Commission*.

# Special clauses on ethics in research

## Clause 16

**Clinical Research** (specific to biomedical research involving human beings)

*The beneficiary(ies) shall provide the Commission with a statement confirming that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval of the competent national authority(ies) in the country concerned before beginning any biomedical research involving human beings.*

# Human Embryonic Stem cells

## Specific procedural modalities for research activities involving human embryonic stem cells\*

Assessment of the project:

- *Advance in scientific knowledge in basic research;*
- *Increase in medical knowledge for the development of diagnostic, preventive or therapeutic methods to be applied to humans;*
- *is the use of hESC is necessary in order to achieve the scientific objectives set forth in the proposal*

\* Rules for submission of proposals, and the related evaluation, selection and award procedures, Version 3, 21 August 2008 COM (2008) 4617, Annex A

# Legal bases for stopping scientific research on ethical grounds

- ***The Commission may reject proposals on ethical grounds following an ethical review*** (Part 4.3 Rules for submission of proposals, and the related evaluation, selection and award procedures)
- ***Any proposal that contravenes fundamental ethical principles shall not be selected*** (Article 15.2 of the EC Rules for Participation, and article 14.2 of the equivalent Euratom Rules for Participation).

## Areas excluded from funding under FP7, Art. 6 (2§)

- i) Research activities aiming at **human cloning for reproductive purposes**
- ii) Research activities intended to **modify the genetic heritage of human beings**
- iii) Research activities intended to **create human embryos solely for the purpose of research or stem cell procurement**

# Ethics Review: what is examined? (1)

The ethical review panel discusses the following elements:

- Whether the researchers respect the FP7 ethical standards;
- Whether the relevant EU legislation is taken into account in the design of the proposed research frame;
- Whether the applicants have sought/ are planning to seek the approval of relevant local/national (ethics) committees;

## Ethics Review: what is examined? (2)

- The awareness of the applicants on the ethical aspects and the social impact of the research they propose;
- Whether the relevant International Conventions, Treaties and Declarations are followed;
- The balance between the research objectives and the means to be used;

# Main steps of the Ethics Review/Follow-up process

- 1) Completion of the scientific evaluation process
- 2) Ethics screening conducted in Brussels by ethics experts

3)

Depending on the type  
of ethical issues

proposal sent  
to Brussels  
for a mandatory  
Ethics Review

or to the national  
competent bodies  
on the basis  
of the subsidiarity principle

# ETHICS SCREENING

- From 2010

All proposals that raise ethical issues and are selected for funding are screened by the programmes . The process is common for the DGs in the research family and the agencies

# Ethics Screening

- Screening covers all ethics issues raised by an application and separates : all proposals that are covered by European and National law go to national bodies
  - CT
  - Data protection
  - Animal welfare
  - Human tissue directive

.....

# Ethics Screening

.....proposals that raise ethical issues in three categories:

- hESCs
- Interventions on humans
- non human primates

Go automatically to ETHICS REVIEW by the DGRTDL3- the Ethics Review Sector

## ER “Gray areas”

There is no legal void (apparently)

If no directly-applied national legislation exists, EU law is used.

If no EU law exists “neighbouring” legislation is used .

For FP7 :All proposals that fall in grey areas are discussed and decided on a case by case basis....

# The Ethics Review stage

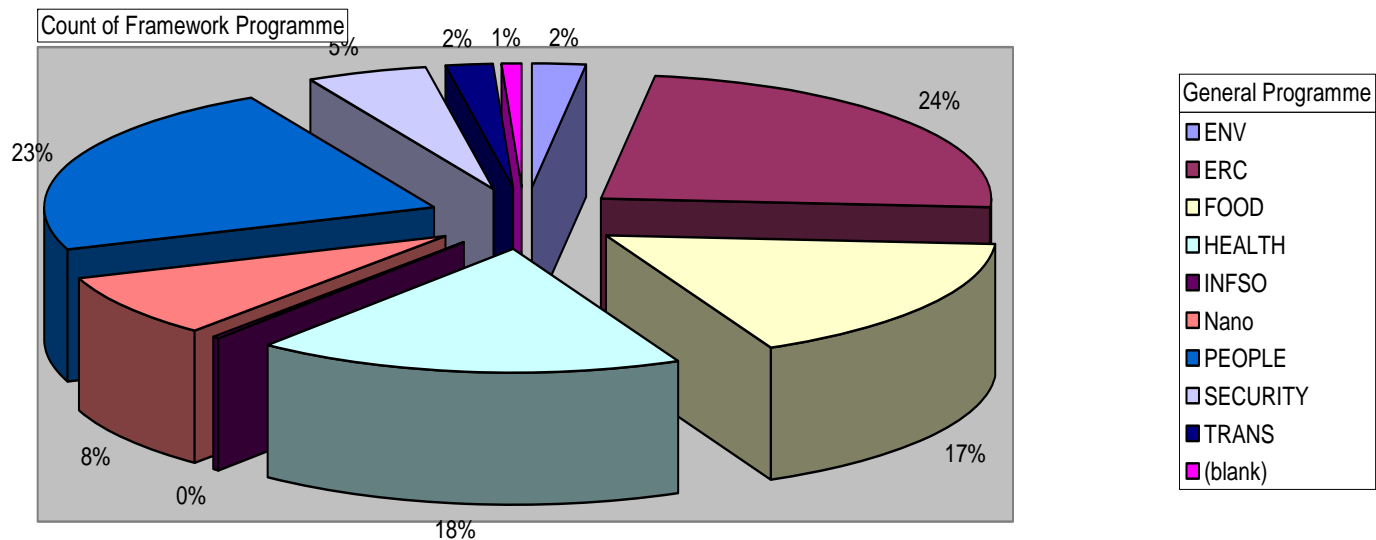
- Individual reading of the proposals
- Meeting as an ethical review panel : discussion for a consensus
- Production of an Ethical Review Report (sent to the participants)
- The Panel's requirements become contractual responsibilities for the Project participants
- The Ethical Review report may indicate the need to organise a follow-up review/audit at a later stage of the project.

# What happens after the formulation of the Ethics Review Report?

- The applicants are informed of the outcome of the ethical review through the Ethical Review report. This is sent without the signatures of the experts.
- The Ethical Review report may indicate the need to organise a follow up review at a later stage of the project.
- In its decision to fund a project the Commission takes into account the results of the ethical review. This may entail changes in annex 1 of the project grant agreement following negotiation, or in extreme cases, termination of negotiations.

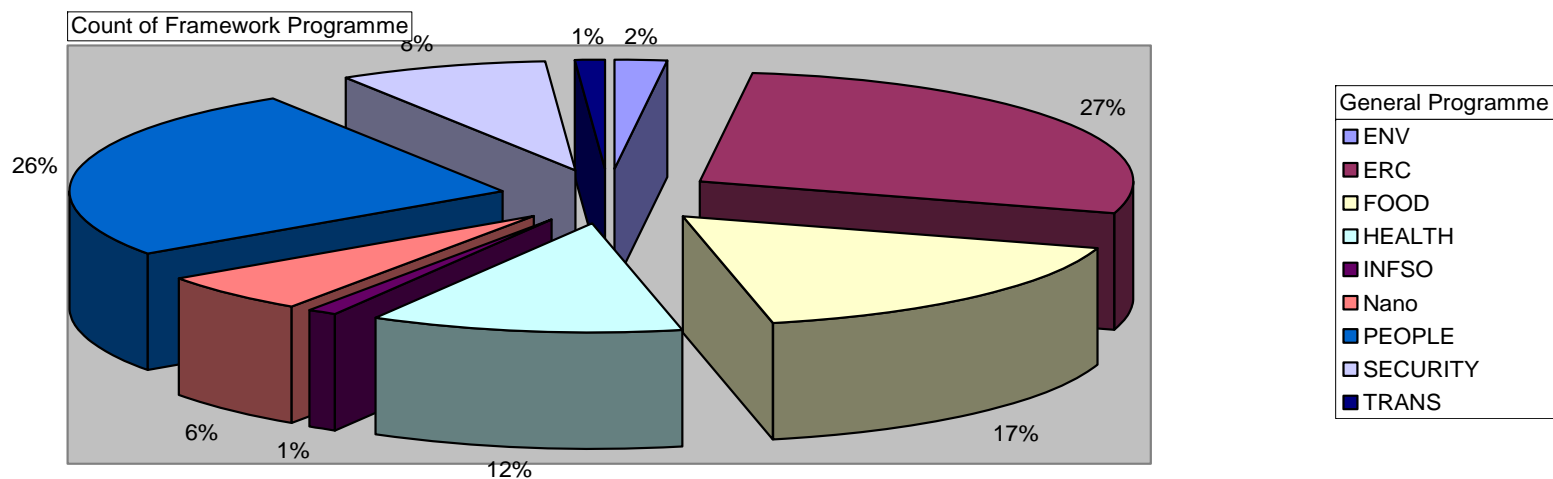
# Number of proposals per programme

Total



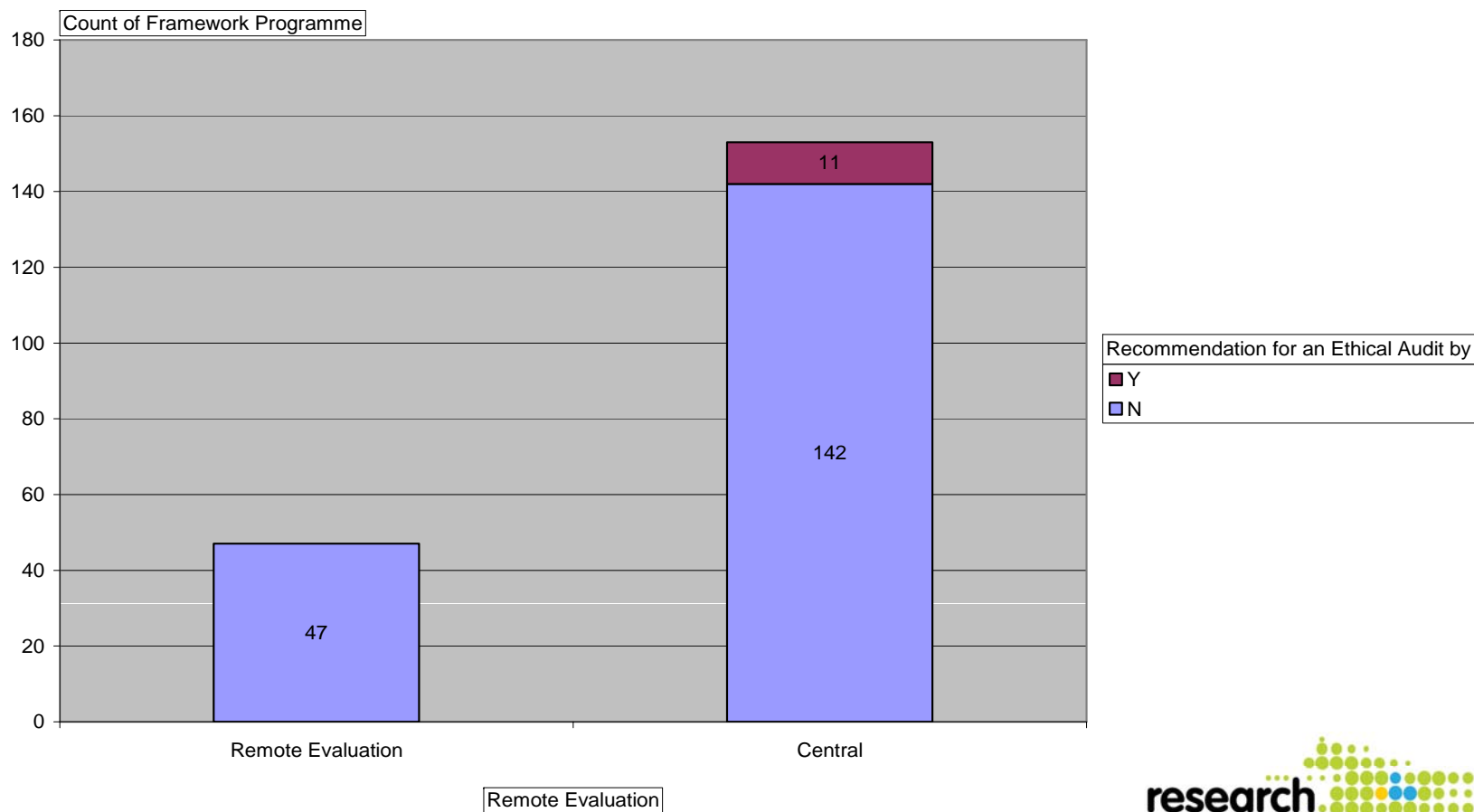
# Sufficient- Insufficient

Insufficient per Programme



Overall Impression

## All the decisions to recommend a project to an Ethical Audit where made during Central evaluations



# Ethics Review: what are we looking for?

Rules for submission of proposals, and the related evaluation, selection and award procedures,  
Annex A: the Ethical Review Procedures

[ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-evrules\\_en.pdf](ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-evrules_en.pdf)

(Rules are being revised to reflect the new ER process)

- **ETHICS specific sites**

[http://cordis.europa.eu/fp7/ethics\\_en.html](http://cordis.europa.eu/fp7/ethics_en.html)

<http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=36>

# Common shortcomings (1)

- Lack of consistency
- Minimum or No information on consent/information sheets/ handling incidental findings
- Issues related to children: direct benefit/ minimum risk and minimum burden must be illustrated

## Common shortcomings (2)

- Developing Countries: failure to describe why it is necessary to include the developing countries and whether any benefits will reach these countries and the local populations
- Clinical trials: failure to justify human intervention from an ethical perspective, safeguard data protection, design of informed consent forms
- Research on animals: failure to describe
  - (i) numbers used;
  - (ii) humane end points;
  - (iii) if non-animal alternatives were sought
- Data protection and privacy: codification, storage and anonymization of personal data

# Challenges when reviewing ethics in research projects

- Proposals that involve dual use (not a problem for the applicants, not a problem for you, but an issue for the Commission services to address)
- Social sciences
- Application of EU ethical standards in non-EU countries
- Scientific design/methodology: a scientific and an ethical question?
- Property rights: any ethical dimension?



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# Ethics Audit/Follow-up

The Ethics Review Sector is also organising **Ethics Audits / Follow-ups**

The Screening and Ethical Review report may indicate the need **to organise a follow-up review at a later stage of the life of a project**

# Objectives of the Ethics Audit/follow-up

- Management of ethical issues: are the ethical issues periodically reviewed at the management level, are the correct actions taken to manage the risks?
- Fulfilment of contractual requirements related to Ethics: are the ethical requirements mentioned within the contract successfully implemented (e.g. informed consent forms or sheets, legal authorisations, etc)
- Quality of the deliverables related to Ethics (i.e. Workpackage on Ethics section within the annual report)

# Ethics Review and the FP7 Ethics Framework

**Any questions?**

Contact:

Isidoros Karatzas.

Head of the Ethics Review Sector

Unit for Governance and Ethics

Directorate L: Science, Economy and Society

European Commission, Research Directorate-General

[Isidoros.karatzas@ec.europa.eu](mailto:Isidoros.karatzas@ec.europa.eu)

# I have one Q:

What is the role of the PO's/SO's/FO's?

- Read Annex A of the Rules for submission of proposals
- Brief your scientific experts –emphasise their role in ethics
- If involved in screening for the first time: call us
- Brief your NCPs before the calls- we can help
- Remind the future applicants that good ethics is good for their (timely) funding .....do it early and do it once!
- Always refer to Special clauses (at least 15) in the contracts