EUROPEAN COMMISSION

European Research Area

Ethics Review and the FP7 Ethics Framework :Do the right think.....

Isidoros Karatzas
Head of the Ethics Review Sector
European Commission

research connection join us 09

EUROPEAN COMMISSION
European Research Area

Compliance of researchers with ethical standards

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

with a successful scientific evaluation and sensitive ethical issues

Organisation of the Ethics Review

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

In 2010 we will start an ex-post evaluation (ethical follow-up/audit)

research connection join us 09

EUROPEAN COMMISSION
European Research Area

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**'*

EUROPEAN COMMISSION
European Research Area

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 the FP7 grant agreement in CORDIS 'find a document'

research connection join us 09

EUROPEAN COMMISSION
European Research Area

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****.'*

EUROPEAN COMMISSION
European Research Area

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).'*

research connection join us 09

EUROPEAN COMMISSION
European Research Area

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.

research connection join us 09

EUROPEAN COMMISSION
European Research Area

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*.

EUROPEAN COMMISSION
European Research Area

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.

research connection join us 09

EUROPEAN COMMISSION
European Research Area

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

EUROPEAN COMMISSION
European Research Area

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)

research connection join us 09

EUROPEAN COMMISSION
European Research Area

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**

EUROPEAN COMMISSION
European Research Area

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;**

research connection join us 09

EUROPEAN COMMISSION
European Research Area

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;

research connection join us 09

EUROPEAN COMMISSION
European Research Area

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

research connection join us 09

EUROPEAN COMMISSION
European Research Area

What happens after the formulation of the Ethics Review Report?

- The applicants are informed of the outcome
- 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.

EUROPEAN COMMISSION
European Research Area

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

research connection join us 09

EUROPEAN COMMISSION
European Research Area

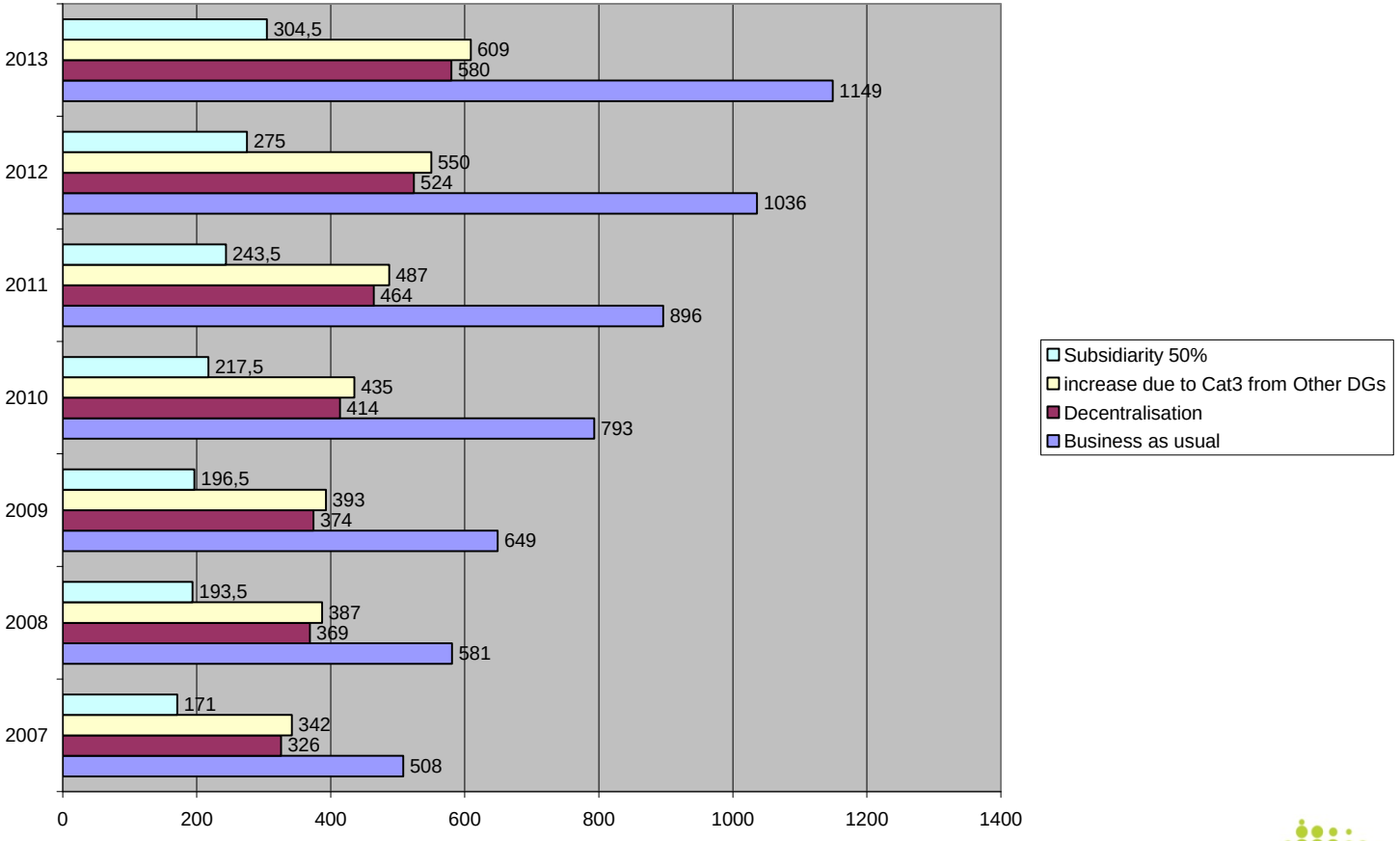
Automatic Ethics Review

- **Research Intervention on human beings (list to be available on Cordis next month)**
- **Use of Human Embryonic Stem Cells or Foetal Tissue – Scientific Evaluators to confirm NECESSITY to use hESC**
- **Use of Non Human Primates**

research connection join us 09

EUROPEAN COMMISSION
European Research Area

Ethics Review Process Projection for 2009-2013



research connection join us 09

EUROPEAN COMMISSION
European Research Area

Common shortcomings (1)

- Lack of consistency between the research work proposed and the ethics annex of the application
- No information on handling incidental findings
- Issues related to children: failure to describe if child obtains a real and direct benefit. If child is not directly benefited, 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

research connection join us 09

EUROPEAN COMMISSION
European Research Area

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**

- **Data protection and privacy: codification, storage and anonymizaton of personal data**

research connection join us 09

Common shortcomings (3)

Issues that we face when dealing with the researchers (as FP7 applicants)

- Lack of awareness
- Lack of training
- Connecting ethics to the methodology and impact of research
- Connecting ethics to the public image of research and researchers
- Deal with the ethics early in the design of the proposal

EUROPEAN COMMISSION
European Research Area

Ethics Audit/Follow-up

Ethics Audits / Follow-ups are not “policing” actions

research connection join us 09

EUROPEAN COMMISSION
European Research Area

Challenges when reviewing ethics in research projects

- Proposals that involve dual use
- Improper use of research results
- Application of EU ethical standards in non-EU countries
- Scientific design: a scientific and an ethical question? (a bad scientific methodology has an ethical impact)

- Intellectual property rights: any ethical dimension?

EUROPEAN COMMISSION
European Research Area

The role of the ethics committees

- From Advisory to Regulatory
- The membership (what does it mean to be an ethics expert?)
- Dealing with non medical research areas (social sciences, education studies…..) and
- Deciding on the appropriate deliberation process

research connection join us 09

EUROPEAN COMMISSION
European Research Area

ETHICS HELP DESK

For all FP running projects….

Information under Cordis : Get Support

http://cordis.europa.eu/fp7/get-support_en.html

research connection join us 09

EUROPEAN COMMISSION
European Research Area

Ethics Review and the FP7 Ethics Framework

THANK YOU

Ethics help desk for all FP7 projects: (under Cordis : Get Support)

research connection join us 09