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Ethics Review and the FP7 Ethics Framework

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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)

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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**'*

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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

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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****.'*

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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.

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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*.

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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.

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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

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National vs EU evaluation

- Clause 15 and 16: Research proposals that raise research ethical issues that fall under the scope of EU Law (such as **clinical trials**, **data protection**, **animal welfare**, and **human tissue collection** and **use**) are approved, in principle, on the condition that copies of the required **national approvals** and/or positive opinions of the relevant **competent authorities** are submitted to the **Commission prior** to the commencement of the relevant part of the research.
- All other types of research (such as those relating to **new and emerging technologies**, **social sciences**, research involving **children**, and research in **developing countries**) that merit special attention on ethical grounds are handled centrally at the EC level

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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.

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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**

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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;

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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;

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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

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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.

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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.

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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

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Ethics Review: what are we looking for?

- Awareness of applicants on the ethical/social impact of research
- Application of relevant EU Directives/Regulations international conventions/declarations and codes of conduct
  (ie: Data Protection Directive, Clinical trials directive, Animal welfare directive)
- Respect of FP7 ethical standards
- Approval of relevant local/national (ethics) committees

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Automatic Ethics Review

- Research Intervention on human beings
- Use of Human Embryonic Stem Cells or Foetal Tissue – Scientific Evaluators to confirm NECESSITY to use hESC
- Use of Non Human Primates

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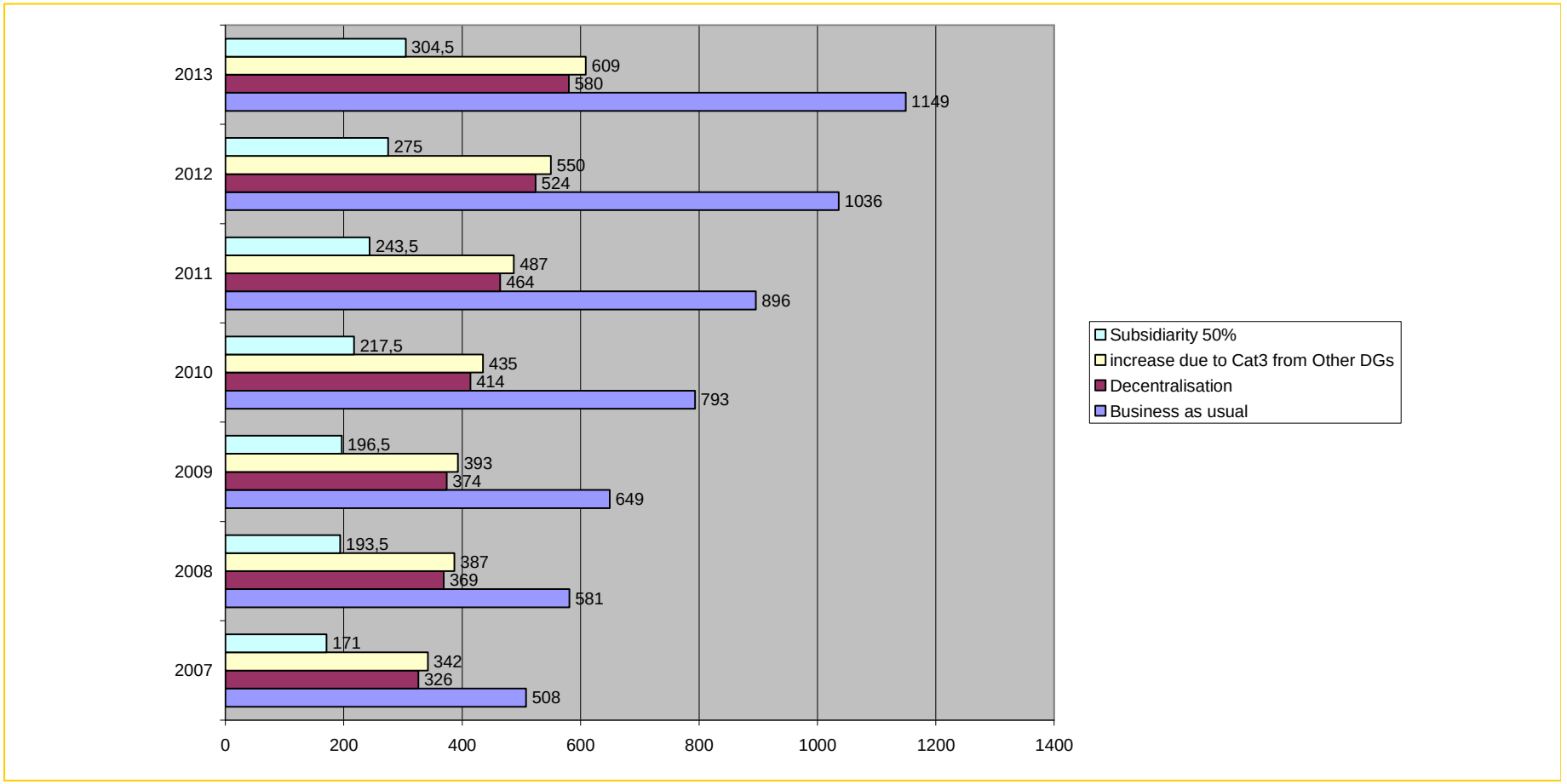
Ethics Review Process Projection for 2009-2013



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Common shortcomings (1)

- Lack of consistency
- 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

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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 anonymizaton of personal data

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Ethics Audit/Follow-up

The Unit is also organising **Ethics Audits / Follow-ups**

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

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

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Objectives of the Ethics Audit/follow-up

- Identification of the ethical issues raised by the project

- 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)

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Challenges when reviewing ethics in research projects

- Proposals that involve dual use
- Application of EU ethical standards in non-EU countries
- Scientific design: a scientific or an ethical question?
- Intellectual property rights: any ethical dimension?

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Any questions?

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