



Integrating Ethics in EU Research

European Commission
Research DG

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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 – (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 carried out 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. »



Legal Basis for Ethical Reviews in FP 7 – (2)



■ 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



Ethical Reviews in Practice: The Project Evaluation Process



■ Scientific Evaluation

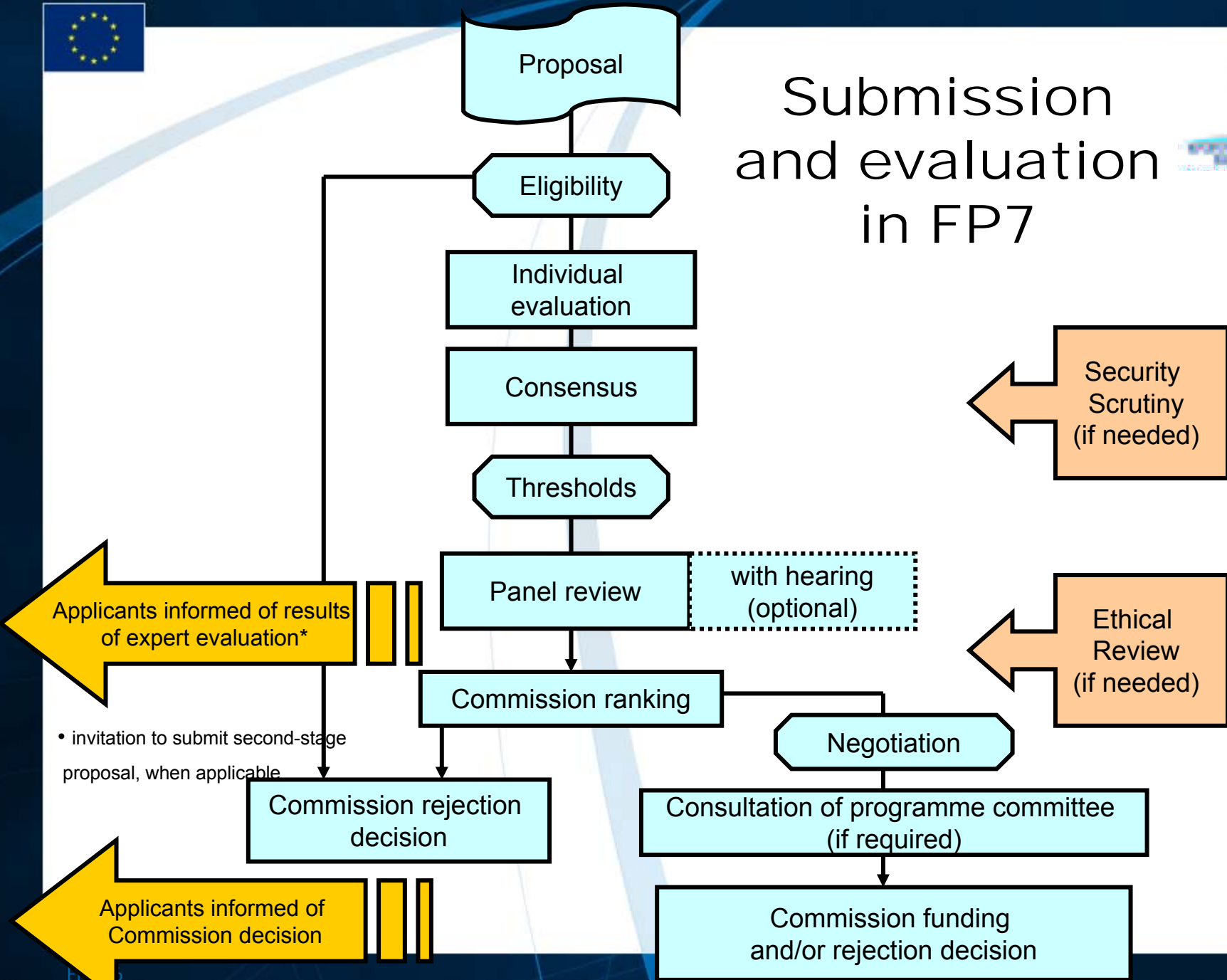
- All proposals submitted to the Commission for funding following a call for proposals are **evaluated on their scientific merit**.
- **Scientific evaluators identify** the proposals raising ethical issues and needing ethical reviews.

■ Ethical Review (if required)

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



Submission and evaluation in FP7





Ethical Reviews' Methodology

- **Two General Questions asked in ethical reviews**
 - **The necessity** to use i.e. personal data, animals, human tissue in order to achieve the scientific objectives set forth in the proposal; **is there an alternative?**
 - **The benefit/burden balance of the research project; what will be the impact of this research** not only regarding scientific advance but also in terms of Human dignity as well as social and cultural impact?



Ethical Review Methodology – (2)



- 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** are applied
 - Whether the consortium is seeking the **approval of relevant local ethics committees**
 - Whether the relevant **international Conventions and Declarations** are applied
 - The **balance between the research objectives and the means** the applicants intend to use



Ethical Review Methodology – (3)

■ MAJOR CHANGES FROM FP6 TO FP7:

- The Ethic 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 Sheet and Consent Form
- The Consortium does not need to submit copies of legislation

TAKE HOME MESSAGE:

GET IT RIGHT FIRST TIME!



Ethical Review Methodology – (4)

■ COMMON PROBLEMS:

- Consistency and context
- Insurance
- Incidental Findings
- Incentives (Financial inducements, etc.)



Ethical Review Methodology – (5)

■ COMMON PROBLEMS:

- Issues related to Children: Minimum Risks? Minimum Burden? Real and Direct Benefit?
- Research on Animals: Number; Humane End Points; Checked alternatives?
- Developing Countries: Benefit sharing
- Conflict of Interest: Treating Doctor; Research Interest



Typology of Specific Ethical Issues (1)

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



Typology of Specific Ethical Issues (2)

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 (DC)

→ **Notion of Individuality** is lacking in some cultures

→ **Gender issues**



Typology of Specific Ethical Issues (3)

DATA PROTECTION (1)

■ Personal Data:

Health Information, Criminal Justice, Financial Information, Genetic Information, Location Information

■ Challenge:

→ Process data while protecting identity

→ Processing = Obtaining, Holding, Disclosing



Typology of Specific Ethical Issues (3)

DATA PROTECTION (2)

■ 8 ENFORCEABLE PRINCIPLES:

- **Fairly** and **lawfully** processed
- Processed for **limited purposes**
- **Adequate, relevant** and **not excessive**
- **Accurate**
- Not kept longer than is necessary
- Processed in accordance with **data subject's rights**
- **Secure**
- Not transferred to countries **without adequate data protection**



Typology of Specific Ethical Issues (4)

ANIMAL RESEARCH (1)

- **Convincing Application of the 3Rs**
 - **Reduction, Replacement, Refinement**

- **To describe and justify:**
 - **Species and Numbers**
 - **Humane End Points and Pain Suffering**

- **To Check for alternatives** (cf. the following websites):
 - <http://www.nc3rs.org.uk/category.asp?catID=3>
 - http://www.vet.uu.nl/nca/links/databases_of_3r_models



Typology of Specific Ethical Issues (4)

DEVELOPING COUNTRIES (1)

- To justify **the involvement of Developing Countries**

- To consider:
 - Culture and Literacy
 - Best Interest of the subject
 - Informed Consent
 - Benefit sharing
 - Use of local resources
 - Avoiding Double Standards



Typology of Specific Ethical Issues (5)



RESEARCH ON HUMAN EMBRYONIC STEM CELLS

- **Specific Procedural Modalities:**
→ They are exactly the same as in FP6

- **Scientific Evaluation:**

Independent experts assess the **NECESSITY** of using hESC for achieving the objectives set forth in the proposal.

All proposals for funding involving the use of hESC and/or foetal issues will be automatically submitted to an ethical review panel.



Typology of Specific Ethical Issues (6)



Once the scientific evaluators confirm the necessity of using hESC in the research proposal, the ethical review panel assesses:

- That the proposal does not include research activities which destroys embryos including for the procurement of stem cells;
- 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*
- The source of the hESC;
- The measures taken to protect personal data, including genetic data, and privacy;
- The nature of financial inducements, if any

* **Cf. Directive 2004/23/EC**



Typology of Specific Ethical Issues (7)

RESEARCH ON HUMAN EMBRYONIC STEM CELLS

- In addition, when research proposals involve the use of hESC, the following procedures are required:
 - A **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 (**General Clause in the contract!**)



Typology of Specific Ethical Issues (8)



RESEARCH ON HUMAN EMBRYONIC STEM CELLS

In conclusion, each research proposal involving the use of hESC, which is supported within FP7, is assessed by at least **two independent ethical reviews**: one **in the country itself where** the research will be carried out) and one **at the EU level.*** **No System in the world offers a higher guarantee regarding the respect of fundamental ethical principles.**

*** If the research raising ethical issues is performed in more than one country (i.e. n countries), it implies that more than two ethical reviews will be performed (i.e. in fact n+1 ethical reviews)**