



# Integrating Ethics in EU Research

European Commission  
Research DG

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**Unit L 3, Governance and Ethics**



# 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

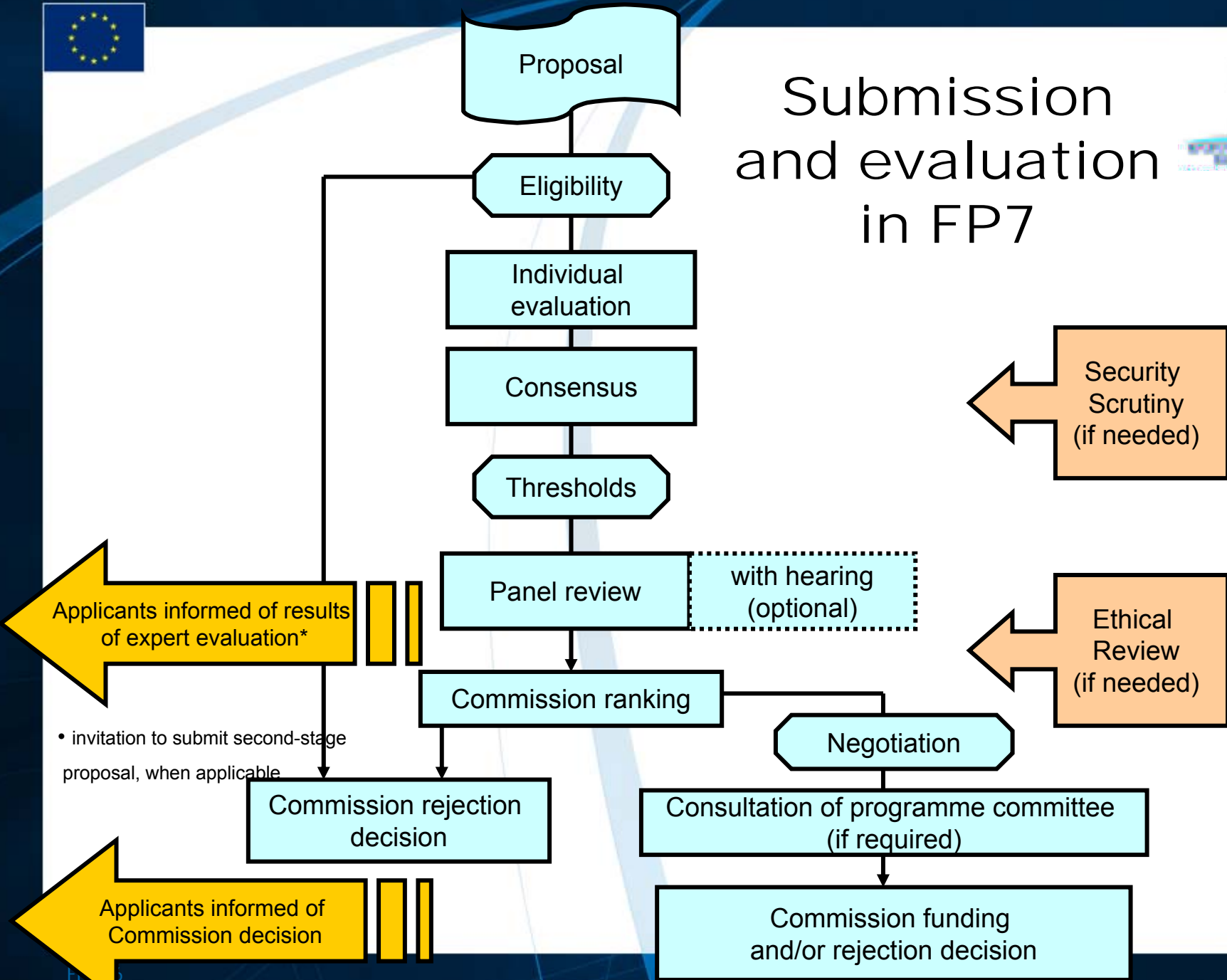
- All proposals submitted to the Commission for funding following a call for proposals are **evaluated on their scientific merit**.
- **Scientific evaluators identify** the proposals raising ethical issues and needing ethical reviews.

## ■ 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](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)**