

# The European Research Council

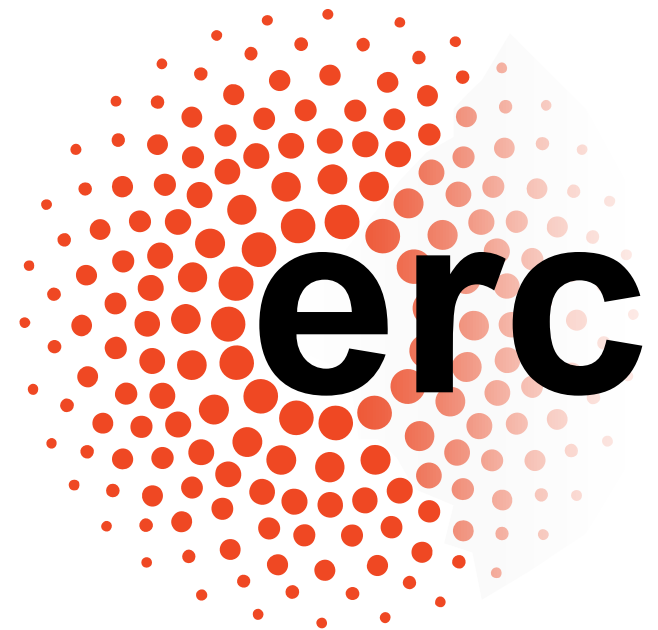
## The Ethics Review

### Ethics review procedures and main issues

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# Why an Ethics Review

- Research compliant with ethical principles
- Response to citizens' demand.
- Challenge of media

## Legal base:

Seventh Framework Programme (Decision N 1982/2006/EC), Article 6 (1 )

**ERC** - *no grant is given if may contravene ethical legislation or regulations (EU and/or national legislation and regulation)*

## Areas Excluded From Funding

- Human cloning for reproductive purposes.
- Modify the genetic heritage of human beings.  
*(except research relating to cancer treatment of the gonads)*
- Create human embryos solely for the purpose of research or stem cell procurement.

# What is an ethical issue?

- **Human Embryonic Stem Cells or Foetal Tissue**

- *Scientific Evaluators to confirm NECESSITY to use hESC.*

- **Non Human Primates**

- **Intervention on human beings**

- *Where the **human body** is physically involved in the research (taking a blood sample, doing an ECG, MRI, XRAY)*
- *Involvement of **Children** in research is sensitive, so proposals with children receive specific attention.*

- **Privacy and personal data**

- *Coded data  $\neq$  anonymised data*
- ***Informed Consent** issues (healthy/adult volunteers, genetic/biological samples, human data)*

- **Research on animals**

- *3Rs, animal welfare*

- **Research in Developing countries**

- *Use of local resources*
- *Benefit to local community*

- **Dual Use**

- *Potential military/terrorist application*



# What Applicants should take into account

- The **Guide for Applicants** (GfA) clearly states that ethical issues have to be addressed in the proposal.
- A **website** containing clear and pragmatic information was launched in March 2007  
[http://cordis.europa.eu/fp7/ethics\\_en.html](http://cordis.europa.eu/fp7/ethics_en.html)
- Applicants must identify and address **ALL ethical issues** in their proposal

# What is expected from the applicant?

- **Describes** the potential **ethical aspects** of the proposed research regarding its objectives; the methodology and the possible implications of the results;
- **Explains** how the ethical requirements set out in the work programme will be fulfilled;

*In accordance with article 3 of the Ideas Specific Programme and including those fundamental ethical principles reflected in the Charter of Fundamental Rights of the European Union.*

- Indicates how the proposal meets the **national legal** and **ethical requirements** of the EU and/or the country where the research is performed;
- Applicants are encouraged to **indicate** which particular authorisations may be needed.

# Some Common Problems related to Ethics in Research

- **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*

## **Special note: Issues related to children**

- *failure to describe if children obtain a real and direct benefit,*
- *if children are not directly benefited, a minimum risk and minimum burden must be illustrated*

# Flagging proposals for ethical issues

- After being evaluated on their scientific merit **all proposals** retained for possible funding are reviewed for ethical clearance.
- **Principal Investigator** should submit an ethics table and annex together with the application, before the call deadline.
- **Ethics Scientific Officers** identify the proposals raising potential ethical issues and needing an “ethics review”.

*Applicants can access a website on ethics for automatic referrals and to provide appropriate information to prepare the ethics annex*

# How it is done: Ethics Procedure

- **Pre-screening** – by *Scientific officers in Ethics Team B1 Unit*
- **Ethical Screening** – by *External experts in ERCEA*
- **Ethical Review**
  - by *External experts in RTD (hESC; Primates; Human intervention)*
  - by *External experts in ERCEA*
- **Ethics Clearance** – by *Scientific officers in Ethics Team B1 Unit*

**Communication to PIs and Granting Unit** - by *Scientific officers in Ethics Team B1 Unit*

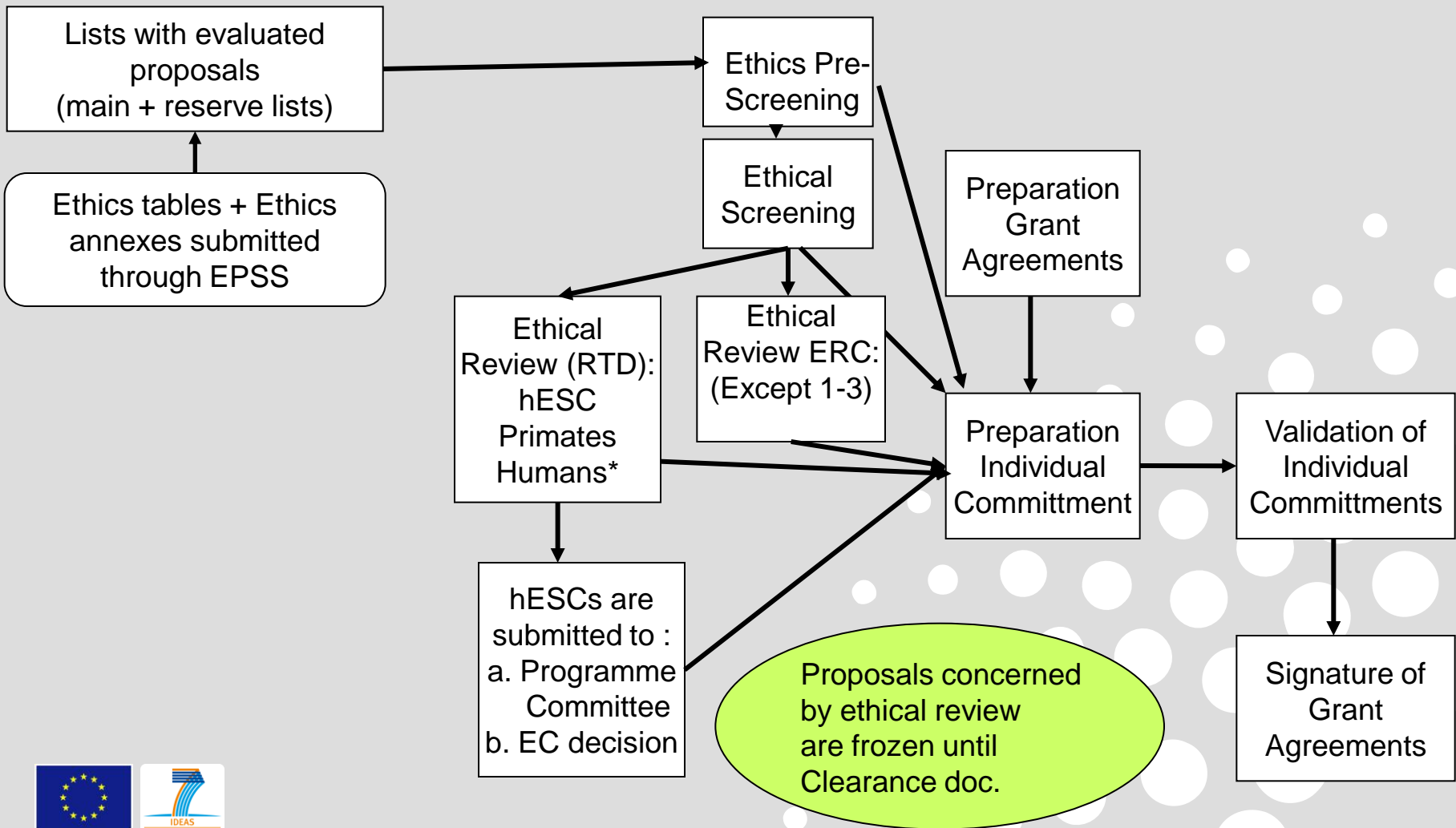
**Authorizations of hESCs proposals** – by *Programme Committee at the IDEAS programme*



# Time-line for the Ethics Clearance

- **Pre-screening** – *carried out right at the end of the scientific evaluation*
- **Ethics Screening** – *carried out within weeks after the end of the scientific evaluation (2-4 weeks)*
- **Ethics Review** – *carried out within 5-6 months after the scientific evaluation*
- **hESC projects** – *need approval by Programme Committee and EC selection decision – further significant longer procedure*
- **Ethics Clearance** – *can be issued only when the documentation is satisfactorily completed*

# The Ethical Clearance process



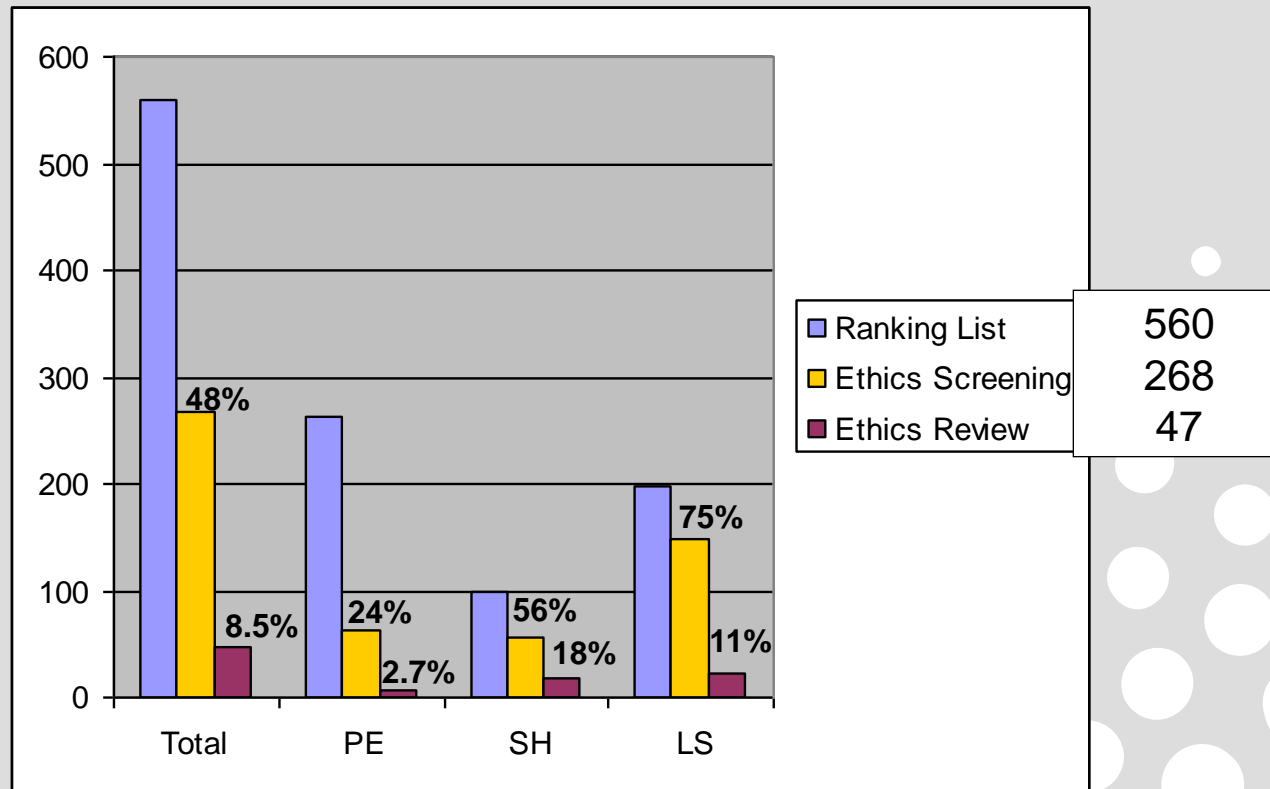
# Ethical Review Experts

- **Ethical Review Experts**
  - *High level of relevant scientific expertise*
  - *Profound knowledge/experience of ethics in the relevant area of research*
  - *Knowledge about ethics regulations at European Union and national level*
- **Experts for remote Ethical Review**
  - *Acting as specialists on the ethics issues of the proposal reviewed*
- **Experts for Ethical Review Panel**
  - *In role of senior generalists*

# Areas of ethical expertise

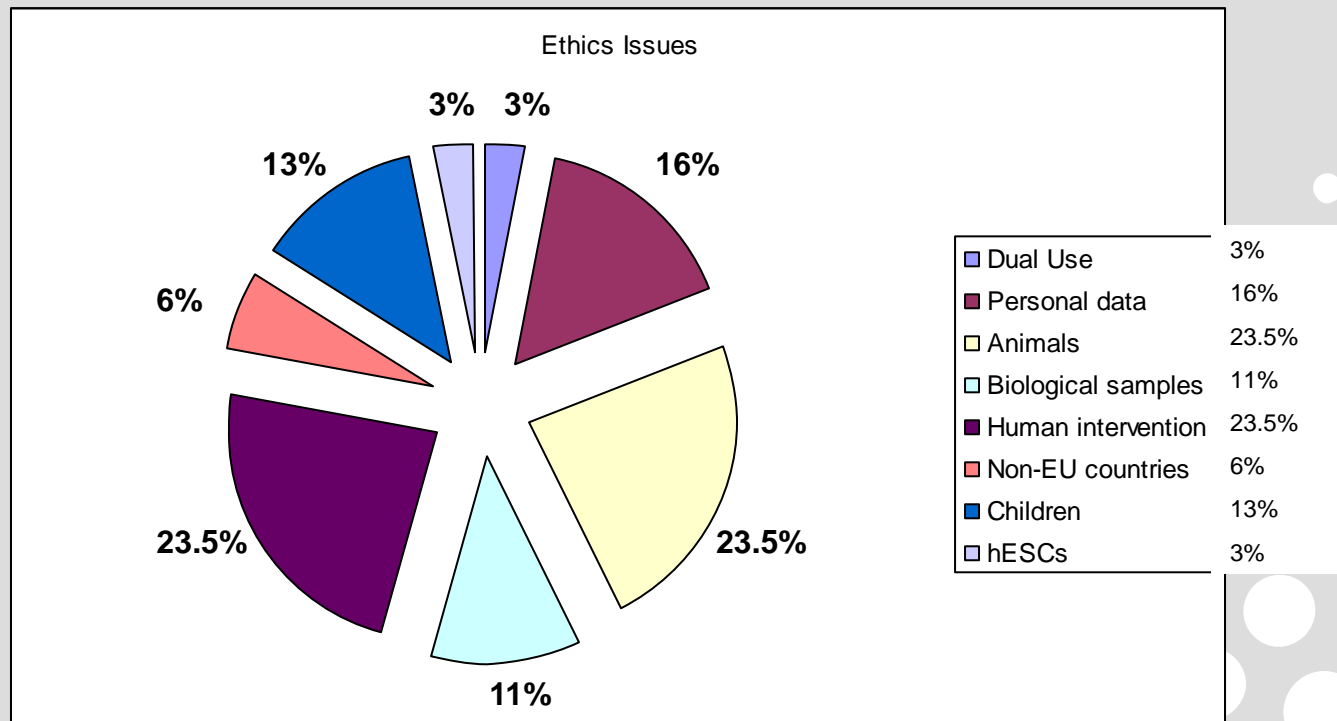
- **Clinical trials**
  - » *Directive 2001/20/EC and Directive 2001/83/EC*
- **Human genetic material and biological samples**
  - » *Directive 2004/23/EC*
- **Animal experimentation**
  - » *Directive 86/609/EEC; Directive 2003/65/EC, COM (2008) 543*
- **Data protection**
  - » *Directive 95/46/EC*
- **Developing countries and politically sensitive issues**
  - » *Declaration/Charter (EU Fundamental Rights; UN Rights of Child, UNESCO Universal Declaration)*
- **Dual use**
  - » *In the context of security/dissemination*

# StG10 Ethics Review by domain



Total StG10 Grants awarded: 345 (as of end October 2010)

# StG10 Ethics Review by issues



# The end

Thank you for your attention