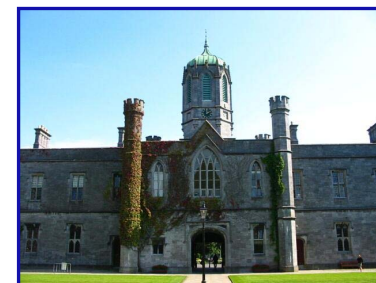


# ETHICS REVIEW AND THE FP7 ETHICS FRAMEWORK

## Introduction



**James A Houghton**  
**Director of Quality**  
**and**



**Head of School of Natural Science**  
**National University of Ireland, Galway**  
**Ireland**





European  
Research Area

EUROPEAN  
COMMISSION



# FORUM ON ETHICS

**Prerequisite in the governance of European research is a commitment to ethical responsibility.**

**European Commission is committed to ensuring that all research that it supports must fully comply with the highest standards of ethical probity.**

**All research activities carried out under FP7 must be in accordance with fundamental ethical principles.**

**Ethical Review is an integral component of the assessment procedure for research funded by the Commission.**



## FORUM ON ETHICS

Commission provides clear guidance on ethical issues to intending proposers.

Applications for research support must describe ethical, safety and socio-economic issues.

Demonstrate that they have been adequately taken into account and will be addressed so as to conform with national and European regulations and legislation.

Participants must respect international conventions and declarations.

If the proposal does not deal adequately with the ethical issues, or if the project involves sensitive ethical issues, then an **Ethical Review Panel** will be asked to determine its compliance with the rules of FP7.



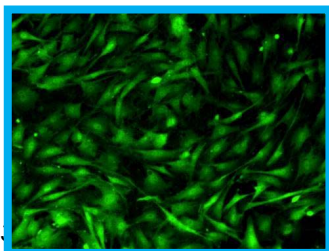
## FORUM ON ETHICS



**At present, certain areas of research are excluded from funding under FP7:**

- Research activity aimed at human cloning for reproductive purposes.
- Research activity intended to modify genetic heritage of human beings that could make such changes heritable.
- 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.

This means that only research activities involving hESC in culture can receive Community funds



## Ethical issues to be addressed in research involving:

### 1. Research on Human Beings:

Vulnerable adults or persons not able to give consent

Children

Adult healthy volunteers

Human intervention (such as clinical trials and research involving invasive techniques)

Human tissues, embryos/foetal tissue, hESCs

### 2. Privacy and data collection:

Including human genetic information, sensitive data about health, sexual lifestyle, ethnicity, political, religious or philosophical opinions

### 3. Use of Animals:

Non-human primates

Genetically modified laboratory animals

Genetically modified farm animals

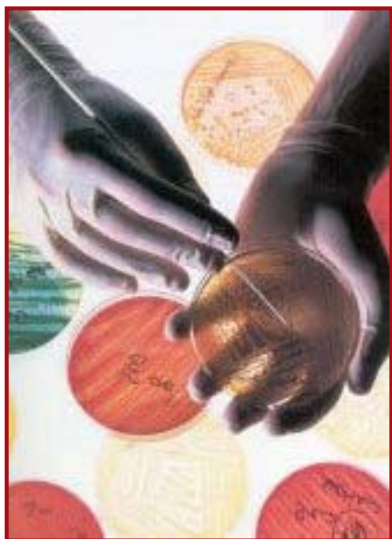
### 4. Research involving Developing Countries:

Sharing benefits

Contribution to capacity building

### 5. Dual use:

Possible military or terrorist applications of research outcome





European  
Research Area

EUROPEAN  
COMMISSION

# ETHICAL REVIEW PANELS



- As part of the monitoring process, Ethics Unit establishes **Ethical Review Panels** to ensure that projects funded under FP7 will be fully compliant with ethical standards.
- Commission has clearly defined the role and duties of Ethical Review Panels and issued comprehensive guidelines.
- Protect welfare of the patient (or animal) and rights of participants in research.
- Duty of Ethical Review Panels to function impartially and confidentially.
- Provide reasoned and well-documented decisions to assist Commission in the project evaluation process.



## COMPOSITION OF ETHICAL REVIEW PANELS

- Review may be carried out remotely, on SINAPSE, or centrally for very sensitive topics (hESCs, clinical trials with children, Dual Use, etc).
- Panels are multidisciplinary and multisectorial. Composed of recognised experts in many different fields.
- Range from experimental science, molecular biology, clinical medicine, veterinary medicine to philosophy, theology or law.
- Balance of scientific and non-scientific members.
- Gender and geographical balance and may include representatives of civil society.
- Panels usually consist of 6 or more experts + Chair. Each project is read in depth by at least 3 readers and discussed at length by Panel.



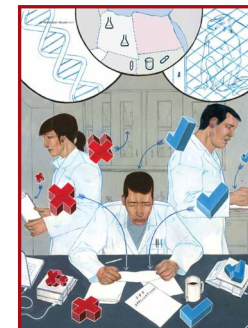
## WHAT ETHICAL REVIEW PANELS DISCUSS

- Does the research comply with FP7 standards?
- Are ethical issues within the **entire** proposal explicit and have the researchers fully engaged with the concerns?
- Are the researchers fully aware of relevant national and EU regulations and have they sought appropriate approvals etc?
- Are they aware of their responsibilities when working with humans and have implemented appropriate informed consent, data storage and protection measures?
- Are they sensitive to the issues of working with animals and have implemented the Principle of the 3Rs?
- Are they sensitive to issues that may arise when carrying out research in Developing Countries
- Etc!



## Common Problems Encountered by Ethics Panels

- Failure to identify or adequately engage with ethical issues.
- Inadequate informed consent procedures.
- Failure to implement appropriate insurance cover.
- Inadequate information on handling of incidental findings.
- Conflict of interest: treating doctor should not advise on informed consent etc if participating in project.
- Inadequate sensitivity to issues related to children: assent, benefit, distress etc.
- Inadequate sensitivity to research on animals: implementation of Principle of 3Rs, care, humane endpoints etc.
- Developing Countries: there should not be exploitation but, rather, benefit or capacity building should accrue.
- Dual Use: potential exploitation of results by military or terrorists may be unrecognized.



## LESSONS LEARNED

### 1. SCREENING

- Pioneered in 2007 as a pilot scheme in Health Programme.
- Projects can be screened for ethical issues that can be handled at national level or need to be referred to Ethical Review.
- Must be consistent, transparent and accountable.

### 2. SUBSIDIARITY

- Ethical issues that can be effectively handled at local/national level need not be handled at Commission level.

### 3. AUDIT

- Implementation of formal, standardised procedures is being piloted.

### 4. FUTURE CHALLENGES!

