Ethics of Clinical Trials in Children

European Commission
Research DG
F Hirsch, P Zilgalvis, M Fitzgerald, E Pauwels
Unit L 3, Governance and Ethics

I. EC Ethical Reviews in Context

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 FPs

EC Ethics Reviews – Historical Overview

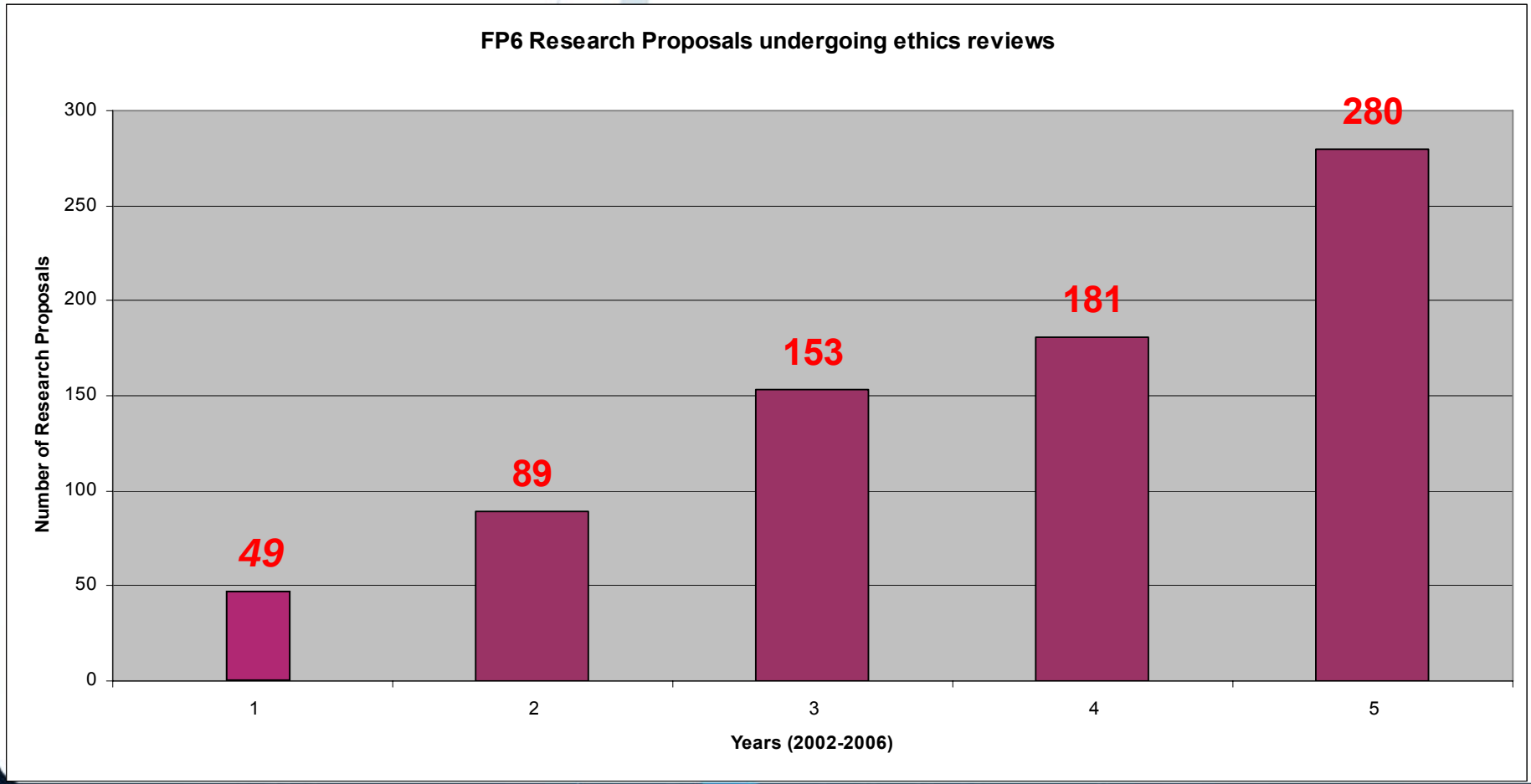
- Since the 1980s, the Framework Programmes have increasingly emphasized the **importance of ethics** as **essential principles** and **best practices framing research activities**.

- This emphasis on ethics is particularly in line with the current European Commission objectives **to promote** a **responsible governance of research** and **to bring science closer to society**.

EC Ethics Reviews–Historical Overview

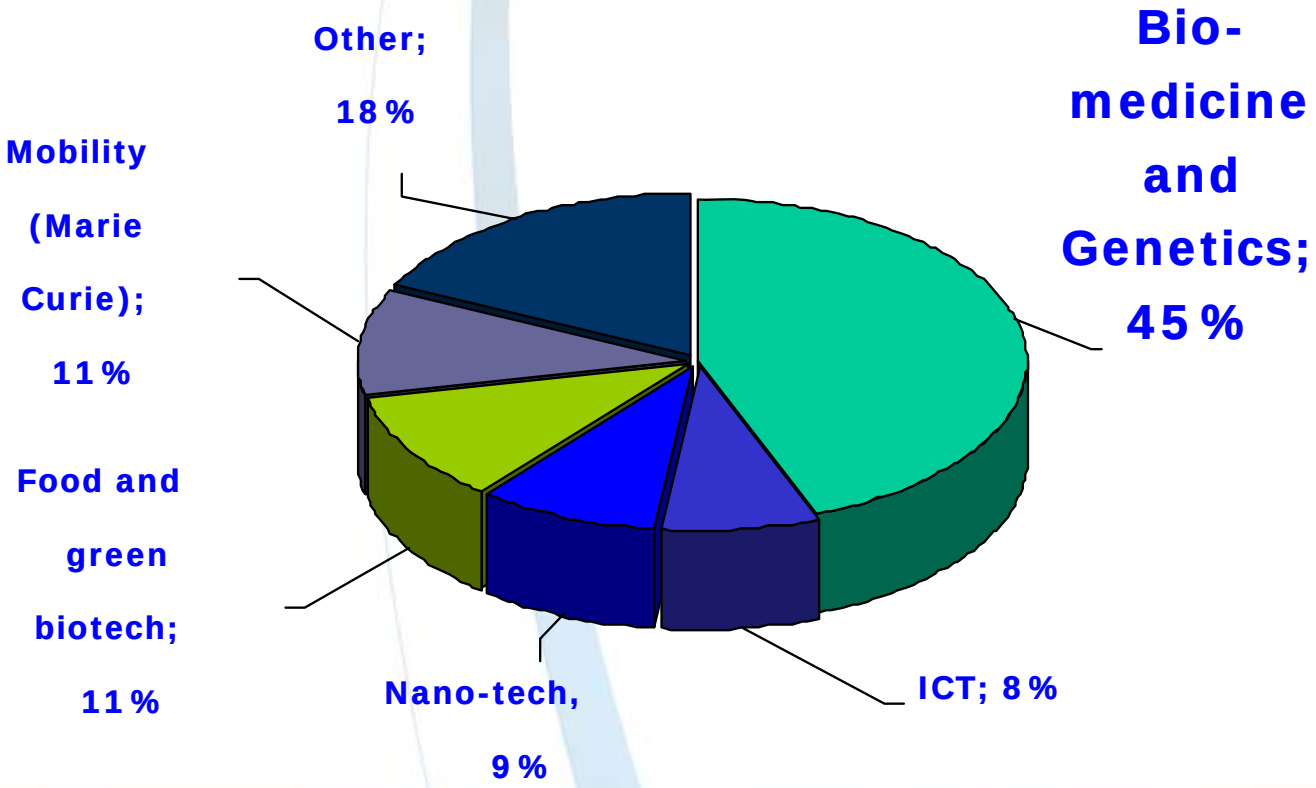
Sixth Framework Programme (FP6)

- FP6 shows a substantive increase of research proposals undergoing ethics reviews.



Breakdown of projects having undergone ethics reviews, by research area

11% of all funded FP6 projects

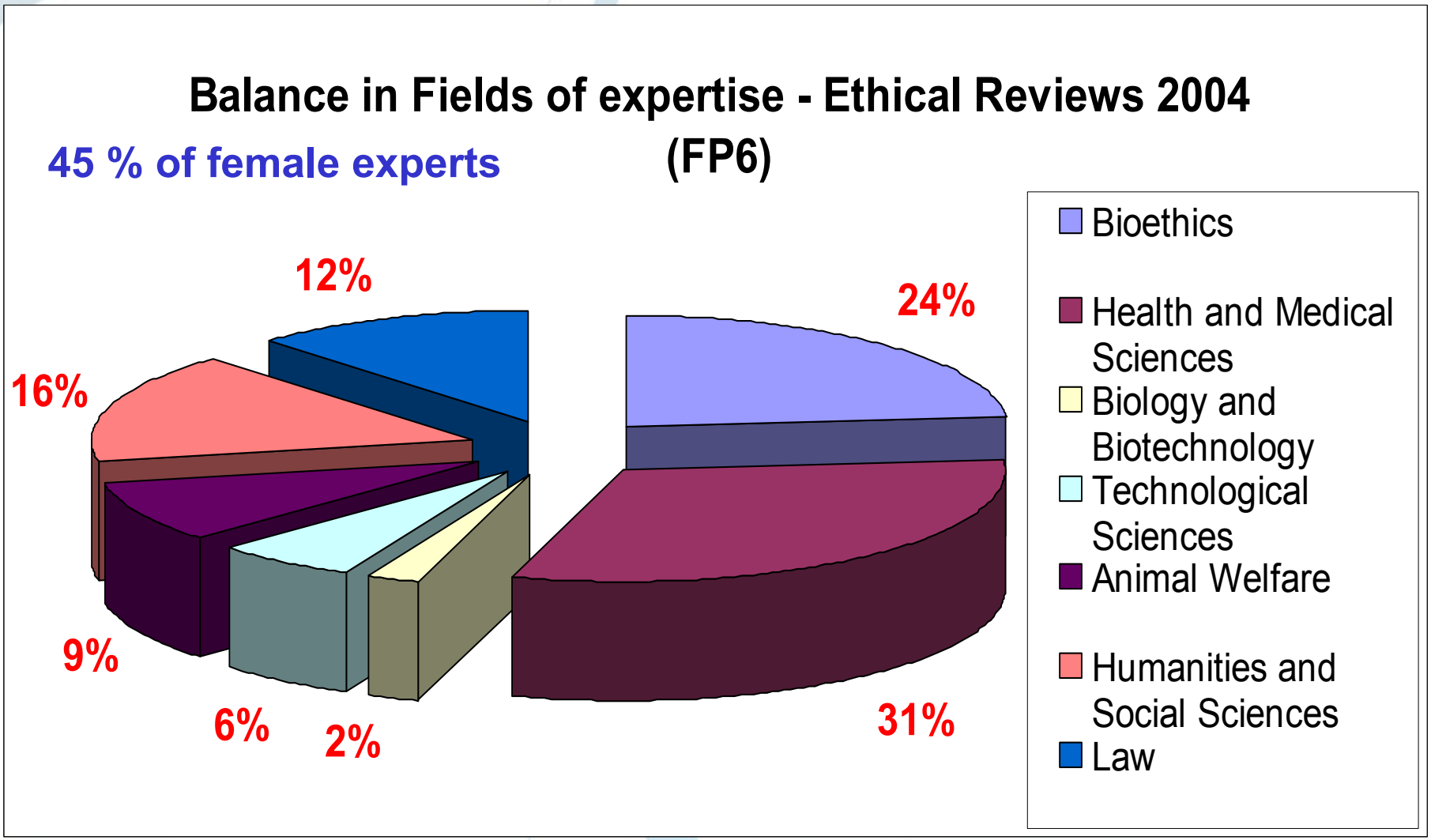


II. EC Ethics Reviews in practice

EC Ethics Reviews Panels – Optimal Composition (1)

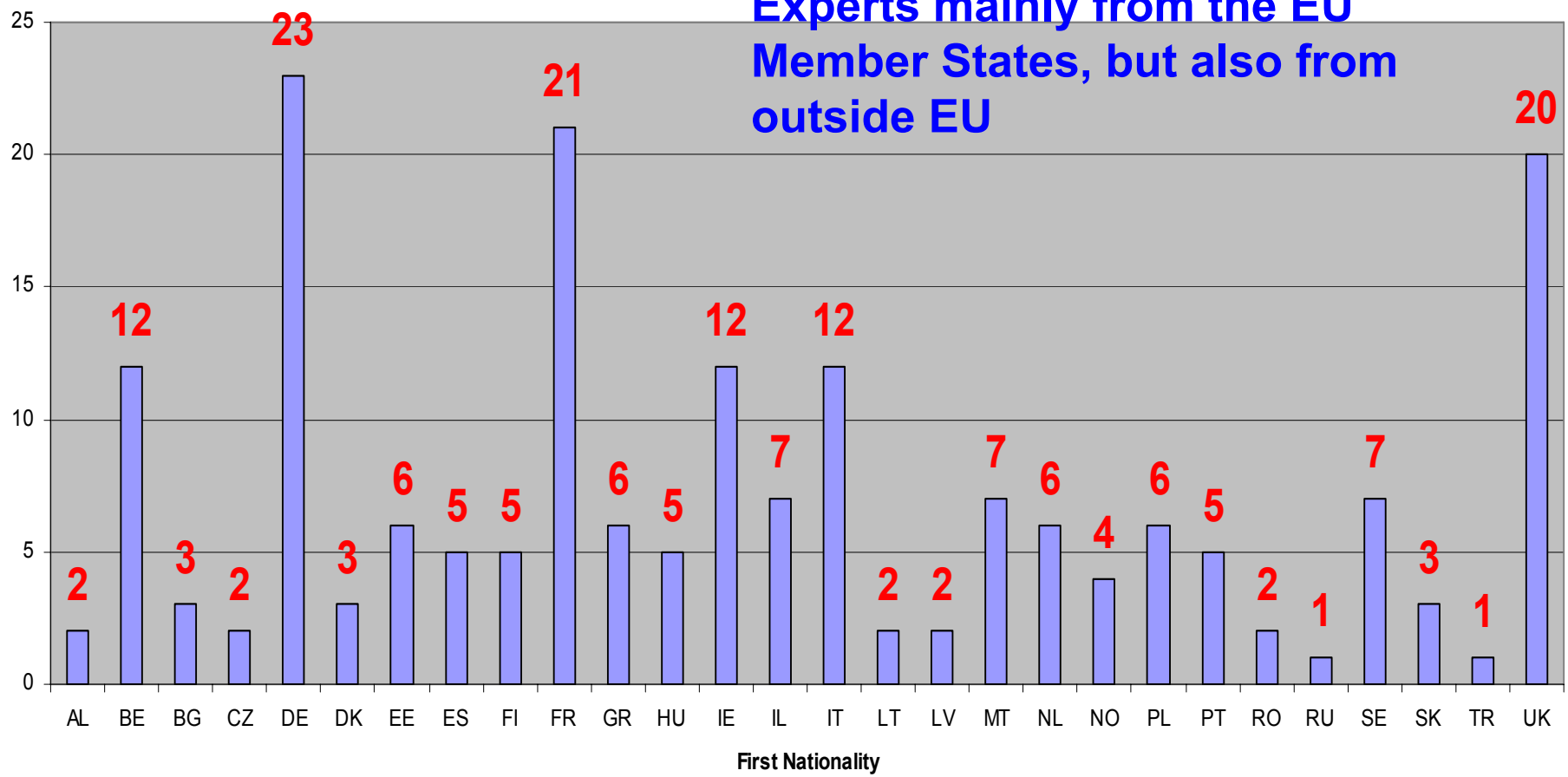
- EC Ethics Reviews are performed by a **panel of experts from different disciplines** such as law, sociology, philosophy and ethics, psychology, information technology, medicine, molecular biology, and veterinary science.
- Representatives of **civil society may also be invited**, such as representatives of patient organisations.
- The experts in the Ethics Review panel have the same status as experts performing the scientific evaluation and are **bound by the European Commission obligations concerning conflict of interest and confidentiality**.

Optimal Composition (2)



Optimal Composition (3)

Geographical Balance in Ethics Reviews in 2006



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. »*


Research - Science and Society - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://ec.europa.eu/research/science-society/page_en.cfm?id=3181
RESEARCH
EUROPA > European Commission > Research > Science and Society
SCIENCE AND SOCIETY
CORE ACTIVITIES
Contests and prizes
Ethics
Policy and strategy
Science education
Scientific advice and governance
Women and science
Science and Society Action Portfolio
EMBEDDING SCIENCE AND SOCIETY INTO EU RESEARCH
Communicating research
Ethics in EU projects
Mainstreaming gender in European projects
EU Calls for proposals:
Ethics > Legislation, regulations and conventions | Updated 11/11/2005
Legislation, regulations and conventions
European references on ethics and science
This section lists European legislative, regulating and advising documents related to ethics and science.
Directive 95/46 on the protection of personal data
Directive 2001/20/EC on good clinical practice
Directive 2001/83/EC on medicinal products for human use
COMMISSION DIRECTIVE 2003/63/EC amending Directive 2001/83/EC
COMMISSION REGULATION (EC) No 1084/2003 on the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State
COMMISSION REGULATION (EC) No 1085/2003 the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93
Directive 98/44/EC on the legal protection of biotechnological inventions
Directive 86/609/EEC on the protection of animals used fore experimental and other scientific purposes
Protocol on Protection and welfare of animals (Protocol to the Amsterdam Treaty)
Directive 90/219/EEC on the contained use of genetically
SEARCH on this site
GO
What's new
Who's who
Library
Press
Youth corner
Science for you!
Science and the media
Gallery of initiatives in Europe
See also
Crucial information for proposal applicants
International references on ethics and science
Policy documents on Ethics in Research
Democratic fundamentals
Ethics
Ethical review of research proposals
The Charter of Fundamental Rights of the

Ethical Reviews in Practice: The Project Evaluation Process

- **Scientific Evaluation**

  → **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 fœtal issues, and non-human primates will be automatically submitted to an ethical review panel.

Ethical Review Methodology

- **COMMON PROBLEMS**:

→ **Issues related to Children**: Minimum Risks, Fear, Pain and Distress? Real and Direct Benefit?

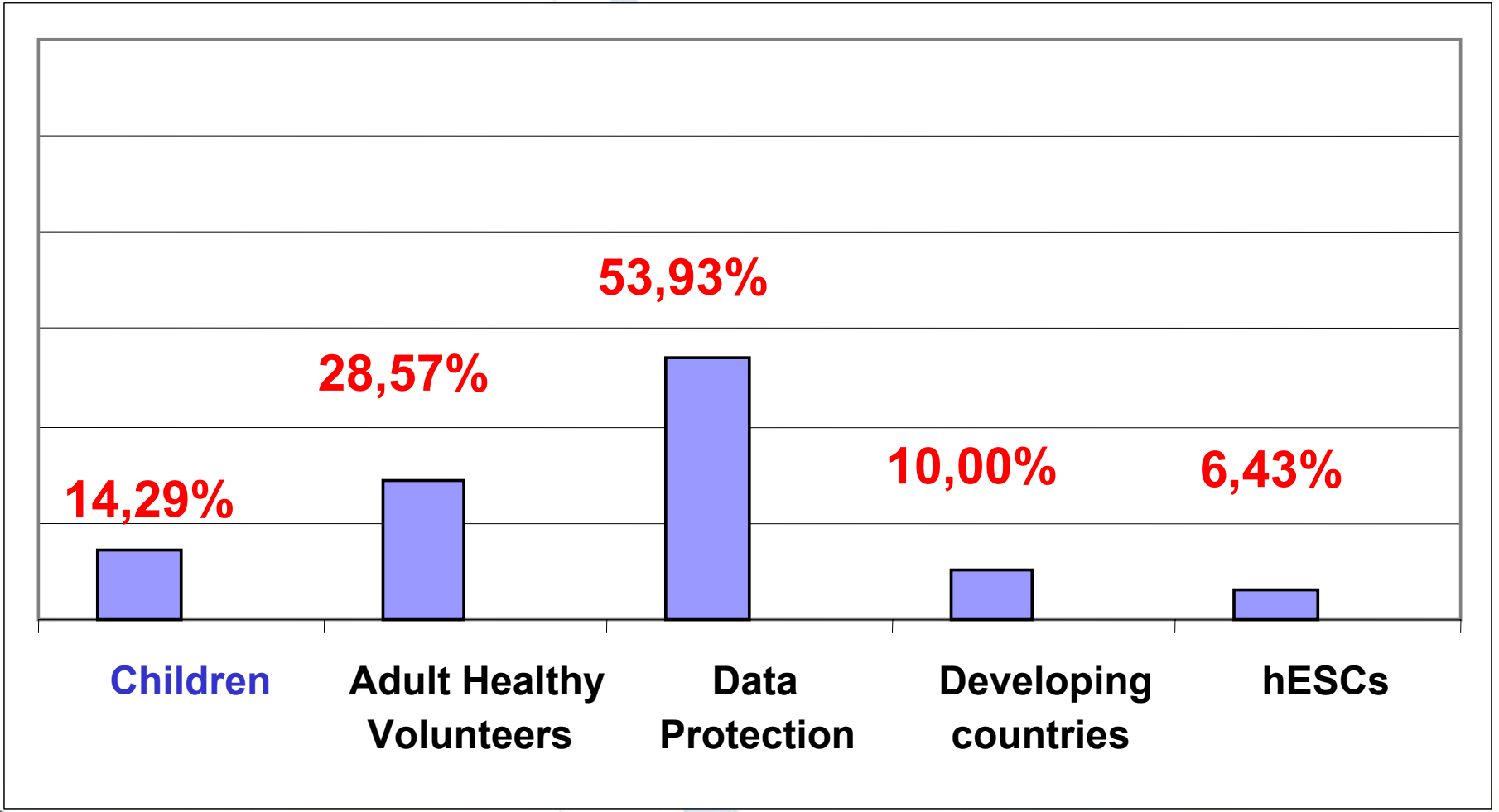
→ Research on Animals: Number; Humane End Points; Checked alternatives?

→ Developing Countries: Benefit sharing

→ Conflict of Interest: Treating Doctor; Research Interest

III. Typology of ethical issues

Sensitive ethical issues in FP6 proposals having undergone ethics reviews (2006)



Research involving children (1)

For which purpose?

- Research involving children mainly concerned **biomedical research**.
- A significant part of research on children applied to **behavioural studies**.

Criteria to be taken into account?

- **Number** of children involved
- **Direct benefit** from the study
- **Burden** of the study
- **Informed consent** from parent/tutors
- **Assent** of children (when possible)

Research involving children (2)

Case study 1: Preventing coeliac diseases – Research involving children (FP6 Proposal 2005)

This case study focuses on the influence of the dietary history in the prevention of coeliac disease.

- One of the ethical issues raised by this study is **the involvement of infants (1 000)** and **children of school age (16 000)** unable to give consent.
- The other issue was the **biopsy** performed on children with family history of coeliac disease.

Case study 1: Preventing coeliac diseases (ctd)

- Article 17 of the **Council of Europe Convention on Human Rights and Biomedicine** seeks the protection of persons not able to give consent (e.g. 4-6 month old babies).

  Research involving such persons is only allowed if:

  I) *The results of the research have the potential to produce **real and direct benefit** to his/her health.*

  (II) *The research entails only **minimal risk and minimal burden** for the individual concerned.*

Case study 1: Preventing coeliac diseases (ctd)

- Problems raised by ethics review panellists:

  → Children can only be enrolled in research projects if their participation has the potential to produce **real and direct benefits for them**, or if the intervention imposes **minimal burden/risk**.

  → An estimated 160 children will fall into neither category and **the intervention will impose more than a minimal burden/risk for no direct benefit**. In this current design, **this population study therefore contravenes the Council of Europe Convention on Human Rights and Biomedicine**.

→ As a consequence, the PI did modify the study design in order to get EU funding.

Research involving children (2)

Case study 2: Survey on the family impact of contraception in African rural villages – Research involving children (FP6 Proposal 2005)

This case aimed to extend an EC-funded survey in several European countries to non developing countries (Ethiopia, Gambia).

- The first ethical issues raised by this study is **the lack of authorization by RECs** from these two countries.
- The other issue was **the involvement of children of school age** unable to give consent. Teachers were supposed to select the children involved.

Case study 2: Survey on the family impact of contraception in African rural villages (ctd)

- Problems raised by ethics review panellists:

  → A clearance should be get from local RECs.

  → There is no clear benefit for local population.

  → There is a clear risk of stigmatisation of involved children.

➡ The Commission decided to reject this project

Our address:

European Commission

DG RTD

Unit L3, Governance and Ethics

http://cordis.europa.eu/fp7/ethics_en.html