Information Society Technologies

European Commission

Information Society Technologies In the 6th Framework Programme

Ethical issues

Evaluation IST Call 1

24 April 2003

Ethical issues “General Rules”

FP Article 3 says :

"All the research activities carried out under the Framework Programme 2002-2006 must be carried out in compliance with fundamental ethical principles.”

Rules for participation say:

“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.”

Fields of research excluded on grounds of ethical sensitivity

- Research activity aiming at **human cloning for reproductive purposes;**
- Research activity **intended to modify the genetic heritage of human beings** which 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.
- **In addition during 2003 the Commission will not fund:**
  - **research involving the use of human embryos or embryonic stem cells except for banked or isolated human embryonic stem cells in culture**

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Guidance for evaluators

Individual Evaluation:

"If during their reading of a proposal evaluators have noted that there are ethical issues touched on by the proposal, **they must flag this by using the tick box provided on the Form IAR**. The issue will then be further discussed at the consensus step and, if necessary, Form EIR will be completed"

The role of IST evaluators

- **Look out for Infoethics issues in IST proposals**
- **If you believe these issues have not been properly addressed by the proposers you should highlight an ethical concern**

- Has proper informed consent been obtained from all real people taking part in a study?
- Is data Protection adequately addressed
  - has the data subjects consent been sought ?
  - are the uses of the data fully described and are the data subjects aware of all possible uses?
  - Have the relevant national Data Protection Authorities been informed about use of identifiable data
- are security issues for storing and handling of personal data adequately addressed - including for anonymised data?

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Relevant EU Law & Regulations

- **Community law**
- **The Charter of Fundamental Rights of the EU**
- **The Key EU Directives (paper copies available if required)**

- Directive 95/46/EC - **protection of personal data**
- Directive 2001/20/EC - **clinical trials**
- Council Directive 83/570/EEC - **proprietary medicinal products**
- Directive 98/44/EC - **legal protection of biotechnological inventions**
- Directive 90/219/EEC - the contained use of **genetically modified micro-organisms**
- Directive 2001/18/EC - deliberate **release into the environment of GMO**

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Implications for Individual Assessment

IAR FORM

Cover page asks evaluator to indicate whether further ethical attention is required

- ***"Does this proposal have ethical issues that need further attention? Yes ¤ No ¤ "***

Last page indicates that ethical issues have been adequately taken into account:

"Have the applicants identified the potential ethical and/or safety aspects of the proposed research regarding its objectives, the methodology and the possible implications of the results? Yes ¤ No ¤

If "no", which ethical and/ or safety issues have not been identified?"

Implications for Consensus Assessment

- **Both the Consensus report (CR) and the Evaluation Summary Report (ESR) will indicate whether further ethical attention is required**

> ***"Does this proposal have ethical issues that need further attention?*** *If yes, fill in Form EIR* ***Yes ▫ No ▫"***

- **On Form EIR, evaluators are asked to:**

> ***"List the ethical issues and comment"***

Ethical review at EU level

to be <u>implemented systematically</u> by the Commission for proposals dealing with ethically sensitive issues**,**

- in particular proposals involving the use of human embryonic stem cells in culture.
- If needed, this will take place in parallel with the "technical" evaluation carried out by the Priority

- In specific cases, **<u>further ethical reviews</u>** may take place **<u>during the implementation</u>** of a project
- **Your role ends with highlighting the Ethical Issue - the Ethical review is carried out by specialists**
- **Your job is to be vigilant in spotting infoethics issues that proposers may have missed**