



*EUROPEAN COMMISSION*

*Directorate L - Science, Economy &  
Society*

*Unit L3 - Governance & Ethics*



**upspring**

PEOPLE & VALUE SKILLS

# Today's question

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## Background

A major change in FP7, compared to FP6, is that the ethics review will be carried out on the proposal that is originally submitted with no additional information requested on ethical questions after scientific evaluation.

## Question:

How do you introduce, at the outset, the ethical perspective into the working structure of a research consortium?

# Assumptions about people and organisations

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- People
  - Most people can act freely and responsibly
  - The human condition is one of continual trade-offs between personal and collective considerations as well as short-term and long-term interests
- Organisational theory (Peter Senge)
  - Through systems thinking, shared visions and personal commitment, organisations can rise to meet new challenges.
  - Organisations have a tendency to think and act short-sightedly, incohesively and politically.

# What is ethics?

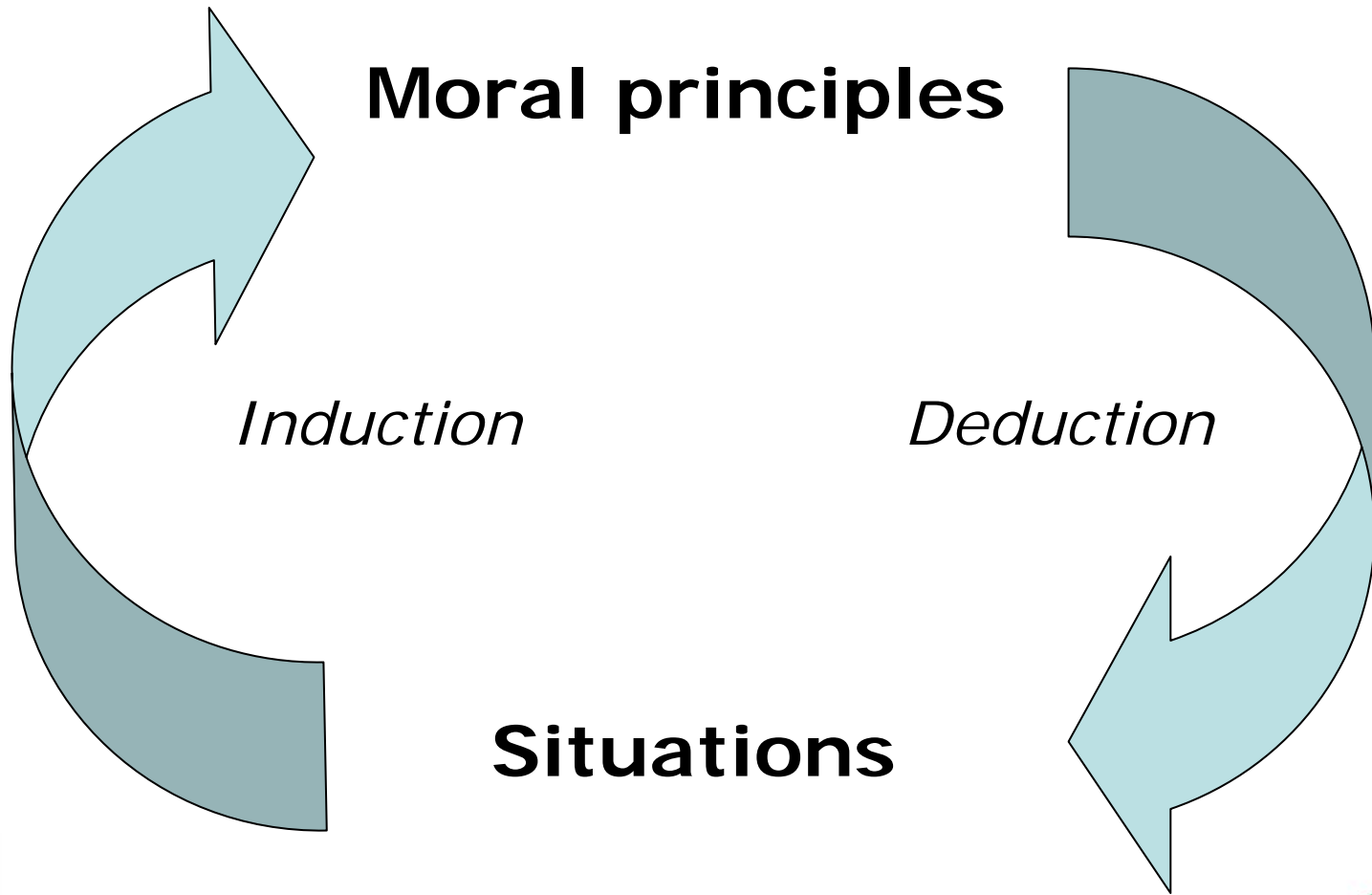
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- An academic discipline. Ethics is the critical study of the norms that guide our actions.
- Practical skills. Ethics is the practical art of knowing how to apply moral principles in concrete situations
- Value systems. Ethics deals with the core values that guide a person or an organisation on the way to its shared vision

*Ethics is the result of our pursuit to systematically reflect on, analyse, and question the norms and values that guide human action.*

Göran Hermerén, President of the European Group on Ethics (EGE)

# How do you know what is right and wrong?



# Principles of European research ethics

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- The principle of respect for human dignity
- The principle of utility
- The principle of precaution
- The principle of justice

A moral principle is a general guide of action that provides a standard of relevance or "reasonableness"

A moral principle is applied *prima facie*, i. e. it must be observed unless it comes in conflict with any other, equally pertinent, consideration.

# Human dignity I

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*"Act in such a way that you treat humanity, whether in your own person or in the person of any other, always at the same time as an end and never simply as a means" I. Kant*

- Primacy of the individual over the sole interest of society or science
- Requirement of consent
- Privacy of health information
- Protection of the human embryo
- Prohibition of financial gain from use of any human body parts

# Human dignity II

*"Parties shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine." Oviedo Convention, art. 1*

- Strict requirements for consent procedures. Relevant consent forms and information sheets must be provided in FP7 according to the standards laid down by *Additional Protocol on Biomedical Research* Art. 13
- Proper justification for the involvement of vulnerable persons and persons not able to consent must be provided.
- Consortium must show knowledge and adequate application of the eight enforceable principles of data protection. (*EC Directive on the protection of personal data*)
- Consortium must detail how it will respect research participant's right to know or not know information about their health, including handling of incidental findings.
- Special justifications for research with human embryos must be provided along with documentary evidence of formal requirements.



# Utility I

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*"An action then may be said to be conformable to the principle of utility...when the tendency it has to augment the happiness of the community is greater than any it has to diminish it." J. Bentham*

.....translated in modern language into "benefit"

Research on human beings can only be carried out if there no alternative of comparable effectiveness.

The rights of the individuals provided in the Convention can be restricted for reasons of

- Public safety
- Protection of human health
- Prevention of crime
- Protection of the rights and freedoms of others (Oviedo art. 26, see also exceptions listed in paragraph 2)

This principle includes animal welfare issues

# Utility II

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*"Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the result of that research" Helsinki Declaration, art. 19*

- The burden of proof lies with the consortium to show that the participation of human beings and/or animals is necessary for research being undertaken in each workpackage.
- A detail description of all interventions dealing with humans and animals must be provided. A summary in lay language is appreciated.
- Proposals must show adequate knowledge of and sensibility to animal welfare principles and provisions, including the 3R principles (reduce, refine and replace) and humane endpoints.
- The use of non-human primates is especially sensitive and requires further ethical justification and more detailed information about treatment of the animals.

# Precaution I

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*"Act so that the effects of your action are compatible with the permanence of genuine human life."* H. Jonas

- Every research project should be preceded by a careful assessment of predicable risks and burdens in comparison with foreseeable benefits to the subject or to others.
- Risk assessment consists of hazard identification, hazard characterisation, appraisal of exposure and risk characterisation.
- Proportionality must be established between the risks which research participants face and the potential benefits of the research to those persons.

# Precaution II

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*Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed.” Helsinki Declaration art. 17*

- Identify risks that research entails
- Indicate safety measures that are in place or are planned to protect the health and well-being of research participants
- For novel technologies, an ELSI study (i.e. study of ethical, legal and social issues) may be required for larger proposals (IPs) to evaluate endpoint impact of product or procedure.
- Address possible dual-uses of novel procedures or technologies
- Proof that this research will involve “minimum risk and minimal burden” (*Oviedo, art. 17*) for persons not able to consent must be detailed.

# Justice I

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*"Justice is giving to each that which is his due."*  
Aristotle

- Equitable access to health of appropriate quality
- Compensation for injury from any intervention
- Non-discrimination on the basis of genetic heritage
- Equitable selection of human research subjects
- Equitable distribution of risks and benefits of research

# Justice II

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*"Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognised." Helsinki Declaration, art. 8.*

- Detail recruitment procedure of research participants, including inclusion/exclusion criteria
- Detail and justify inducements to research participants
- Detail benefit sharing initiatives, especially when research is conducted in developing countries
- Address possible IPR issues?

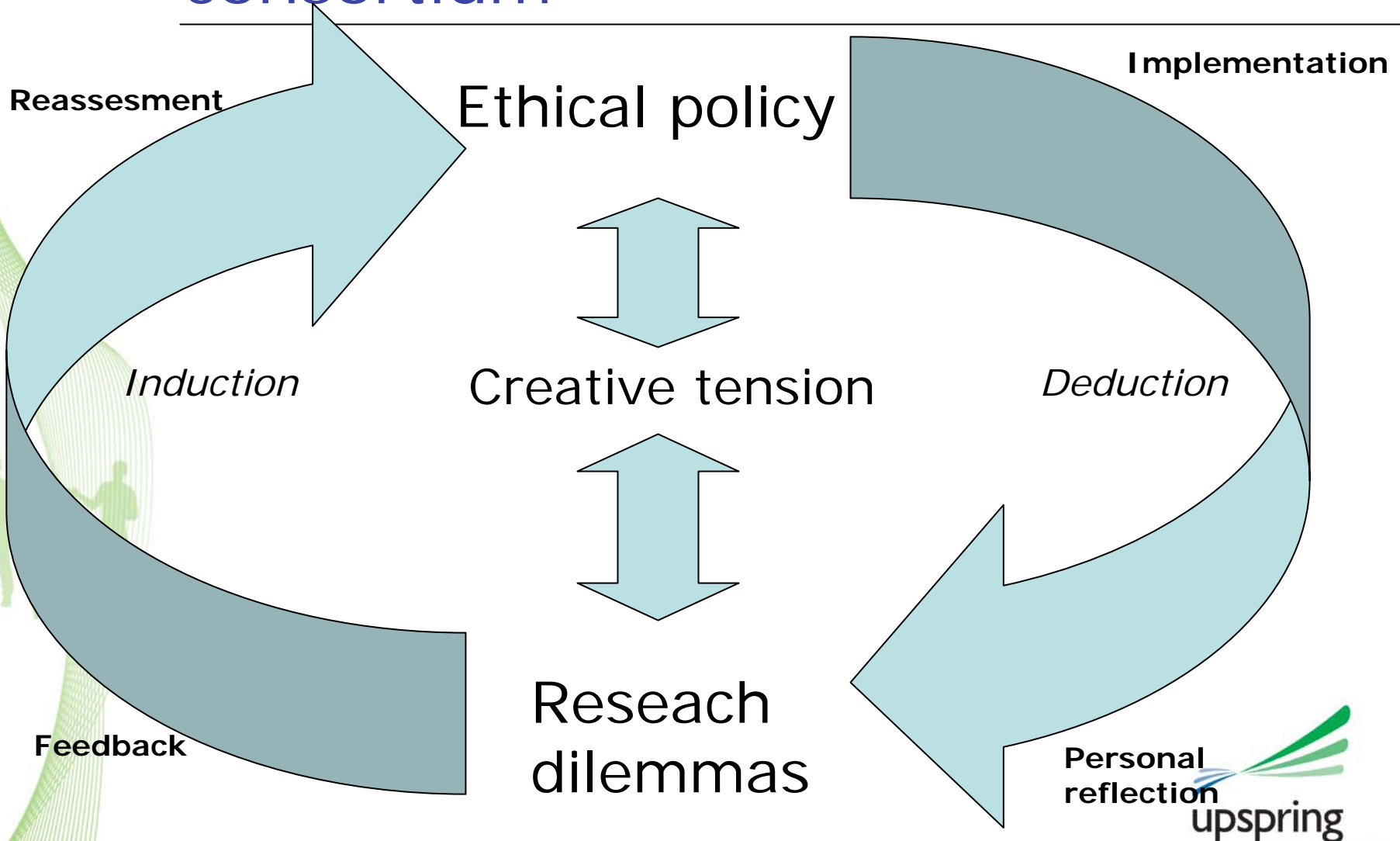
# How do you strengthen the ethical perspective?

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## Conditions:

- The initiative must include all partners and all individual researchers participating in research
- Ethical questions that arise must be addressed with transparency
- The initiative must reflect the genuine desire to foster best ethical practices (no window dressing)
- Recourse to independent expert advice in ethics may be necessary
- Need for periodical review within the management structure of how ethical issues are dealt with

# Ethics in the learning research consortium





# Sketch of a development program in ethics

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## Before submission of proposal

- Identification by all partners of actual and potential ethical issues in the research program
- Preliminary reflection on how these will be addressed in the proposal
- Formulation of a policy outlining how ethical issues will be dealt with overall and within each individual workpackages

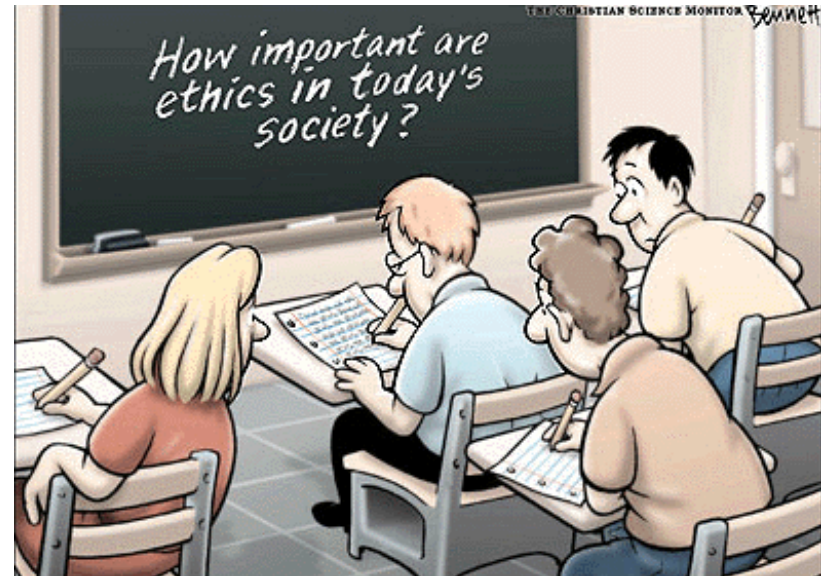
## During funding period

- Implementation of the ethical policy
- Continual feedback from parties about ethical issues
- Periodic review of ethical strategy in view of feedback
- Formulation of updated ethical policy as need be

# Thank you!

*"Tell me and I forget,  
show me and I  
remember, involve me  
and I understand."*

Benjamin Franklin



[Axel.Carlberg@upspring.se](mailto:Axel.Carlberg@upspring.se)

+46 705 - 614 616