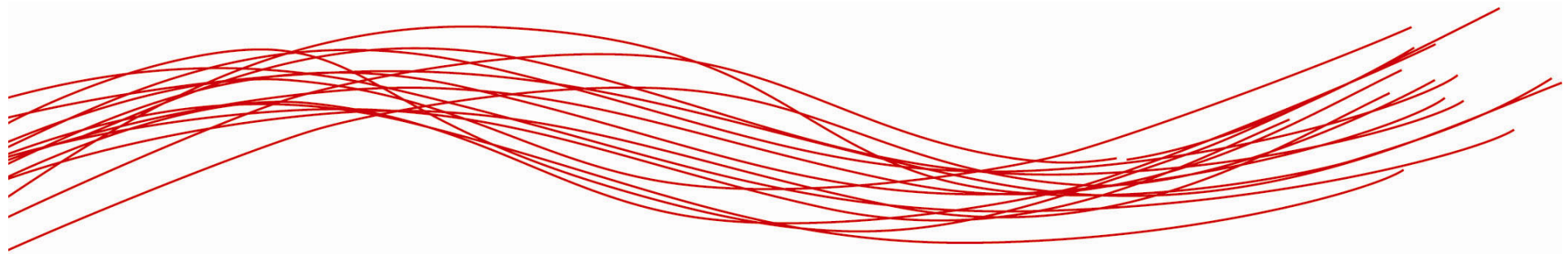


Health NCP Ethics Training



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Ethics, Gender Issues

07/03/2011

Not legally binding



Presentation overview

- 1. General information on Ethics and FP**
- 2. Legal Basis**
- 3. Special Clauses**
- 4. Ethics Review why**
- 5. What is bioethics?**
- 6. Ethics review in practice**
- 7. Tricks and tips**



Why an Ethical Scrutiny ?

- **Ethics Review is Required to repond to demand for scrutiny of research by Society.**
- **Screening is THE FIRST PART OF THE ETHICS REVIEW**
- **Responding to the challenge of media on scientific community**
- **Ensuring that the EU doesn't fund research disapproved by EU Citizens**



Legal Basis for Ethical Reviews in FP7

- 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. »

Areas excluded from funding under FP 7, Art. 6 (2§):

07/03/2011



Legal Basis for Ethical Reviews in FP7 –

- Areas excluded from funding under FP 7, Art. 6 (2§):
 - **Research activity aiming at human cloning for reproductive purposes**
 - **B) Research activity intended to modify the genetic heritage of human beings which could make such changes heritable (Research related to cancer treatment of the gonads can be financed)**
 - **C) 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**

Compliance of applicants with ethical rules: A Legal obligation

Seventh Framework Programme (**Decision N° 1982/2006/EC**), **Article 6 (1§)**:

'All the research activities carried out under the Seventh Framework Programme shall be in compliance with fundamental ethical principles'

Compliance of applicants with ethical rules: A Legal obligation

FP7 Grant Agreement -

Special Clauses applicable to the FP7 Model Grant Agreement for the implementation of the Seventh Framework Programmes of the European Communities (EC-EURATOM)

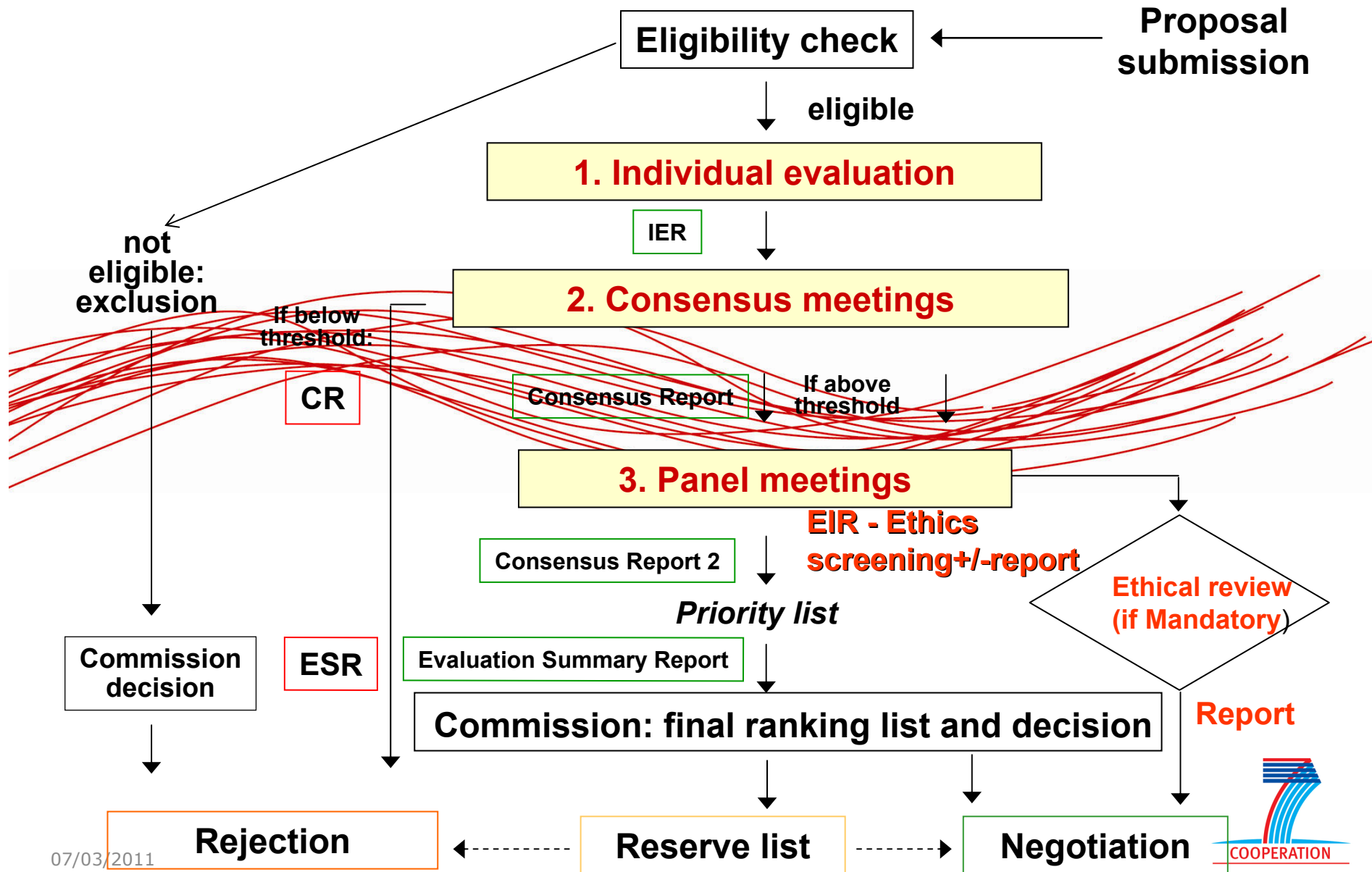
See more on this:

ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-ga-clauses-v3_en.pdf

Special Clauses in Contract (5)*



Evaluation process



07/03/2011



Legal bases for stopping scientific research on ethical grounds

- *The Commission may reject proposals on ethical grounds following an ethical review (Part 4.3 Rules for submission of proposals, **and the related evaluation, selection and award procedures**)*
- *Any proposal that contravenes fundamental ethical principles shall not be selected (Article 15.2 of the EC Rules for Participation, and article 14.2 of the equivalent Euratom Rules for Participation).*



Main steps of the Ethics Review/Follow-up process

- 1) Completion of the scientific evaluation process
- 2) Ethics screening conducted by ethics experts

Depending on the type
of ethical issues

proposal sent
to a **mandatory**
Ethics Review

or licence requests to
competent local bodies
(on the basis
of the subsidiarity principle)



Ethics: Process for FP7

Ethical Review Process

1. Applicants identify key ethical issues explain how they address them then list them.
2. Scientific Evaluation +EIR
3. Ethics Review (at EC level) -2 STEPS 1: Ethics Screening-: 2: Ethics Review at EC level
4. Ethics (Screening or Review) Report
5. Requirements incorporated in Grant Agreement
6. Possibility of Ethics Audit



The Ethics Review in 2 stages

- **Individual reading of the proposals (same for stage 1+ 2)**
- **Meeting as an ethical review panel : discussion for a consensus – Mandatory central or local management)**
- **Production of an Ethical Review report (or screening report - information sent to the participants) during Negotiation**
- **The Panel's requirements become contractual responsibilities for the Project participants**
- **The Ethical Review report may indicate the need to organise a follow-up review/audit at a later stage of the project.**

Ethics Review: what are we looking for?

- **Awareness of applicants on the ethical/social impact of research**
- **Application of relevant EU Directives/Regulations international conventions/declarations and codes of conduct**
(ie: Data Protection Directive, Clinical trials directive, Animal welfare directive)
- **Respect of FP7 ethical standards + Subsidiarity**
- **Approval of relevant local/national (ethics) committees**



What happens after the drafting Ethics Review Report?

- **The applicants are informed of the outcome of the ethical review through the Ethical Review report. This is sent without the signatures of the experts.**
- **The Ethical Review report may indicate the need to organise a follow up review at a later stage of the project.**
- **In its decision to fund a project the Commission takes into account the results of the ethical review. This may entail changes in annex 1 of the project grant agreement following negotiation, or in extreme cases, termination of negotiations.**



Ethics Audit/Follow-up

The Ethics Unit is organising Ethics Audits / Follow-ups

The Ethical Review report may indicate the need to organise a follow-up review at a later stage of the project

(Rules for submission of proposals, and the related evaluation, selection and award procedures, Annex A: the Ethical Review Procedures)



Objectives of the Ethics Audit/follow-up

- **Identification of the ethical issues raised by the project**
- **Management of ethical issues: are the ethical issues periodically reviewed at the management level, are the correct actions taken to manage the risks?**
- **Fulfilment of contractual requirements related to Ethics: are the ethical requirements mentioned within the contract successfully implemented (e.g. informed consent forms or sheets, legal authorisations, etc)**
- **Quality of the deliverables related to Ethics (i.e. Workpackage on Ethics section within the annual report)**

Bioethics in General

- **Ethics of behaviour towards same species**
 - ◆ Consent- clinical trials
 - ◆ Data privacy- data protection
 - ◆ Protection of data in databases and Institutions
 - ◆ Deontology (behaviour in the wrk environment)
- **Ethics of behaviour towards other species**
 - ◆ Research with animals
- **Ethics of behaviour towards the planet**
 - ◆ Environment, conservation, biodiversity, pollution
- **Ethics of behaviour towards other planets**
- **And so on**



Informed Consent

- **Does the proposal involve children?**
- **Does the proposal involve patients or persons not able to give consent?**
- **Does the proposal involve adult healthy volunteers?**
- **Does the proposal involve Human Genetic Material?**
- **Does the proposal involve Human biological samples?**
- **Does the proposal involve Human data collection?**

Research on Human embryos/foetus

- **Does the proposal involve Human Embryos?**
- **Does the proposal involve Human Foetal Tissue/Cells?**
- **Does the proposal involve Human Embryonic Stem Cells?**

Privacy

- **Does the proposal involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?**
- **Does the proposal involve tracking the location or observation of people?**

Research on Animals

- **Does the proposal involve research on animals?**
- **Are those animals transgenic small laboratory animals?**
- **Are those animals transgenic farm animals?**
- **Are those animals cloning farm animals?**
- **Are those animals non-human primates?**

Research Developing countries

- **Use of local resources (genetic, animal, plant, etc.)?**
- **Benefit to local community (capacity building ie access to healthcare, education, etc.)**

Dual Use

- **Research having potential military/terrorist application**

* **Found in the Science and Society w.page**



People : Informed Consent*

When is it needed?

Review at EU level

- *When Children involved*
- *Developing Countries*

Screening+National regulators

- *Healthy volunteers*
- *Human genetic material*
- *Human biological samples*
- *Human data collection*

*What must be in Consent form ?
State + explain*

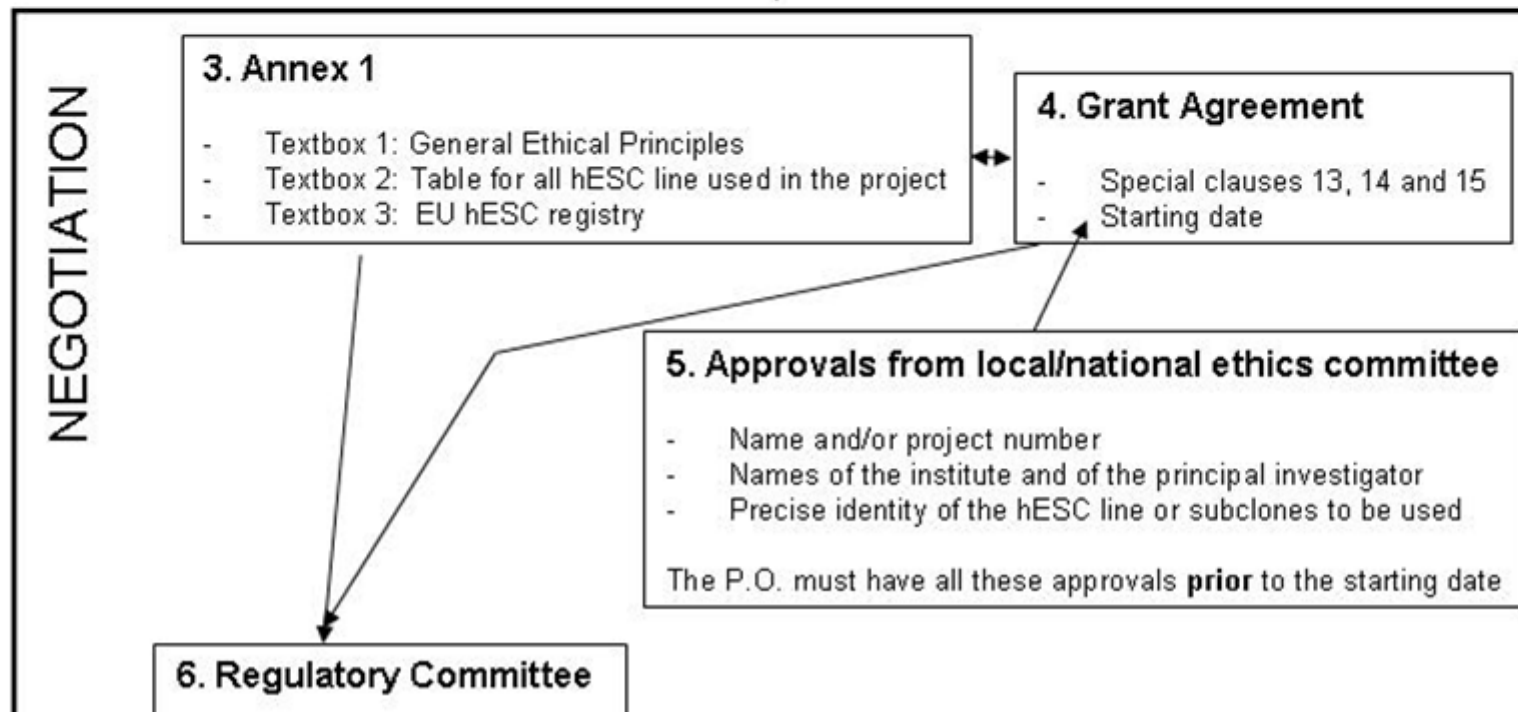
- *That it is research*
- *Purpose+duration+description*
- *foreseen risks*
- *benefits*
- *Alternative*
- *confidentiality*
- *Treatment/compensation +information*
- *contact for rights/claims*
- *contact for injury to the subject*
- *Voluntary participation*
- *No penalty or loss on stopping*



Human Embryonic Stem Cells: Ethics Review at EU level

When involving the use of hESC in their research project, researchers should take into account and specify:

- **It does not destroy embryos (including to procure stem cells;**
- **Has the consortium taken into account *the legislation, regulations, ethical rules and/or codes of conduct in place in the country(ies) where the research using hESC is to take place,* including the procedures for obtaining informed consent**
- **The source of the hESC;**
- **The protection of personal data (genetic data and privacy)**
- **The nature of financial inducements, if any**
- **Positive opinion from a Regulatory Committee constituted by Member States' representatives.**
- **Approval of the relevant national or local ethics committees *prior to the start of the research activities.***





Privacy and Data Protection *

Refers to relation between tech and the right to privacy

- **identifiable data collected and stored,**
- **Improper or non-existent disclosure control**

Data affected by privacy issues

- **Health information.**
- **Criminal justice.**
- **Financial information.**
- **Genetic information.**
- **Location information.**
- **Data privacy / share data while protecting identifiable information.**

How to Deal with Data Protection and Privacy?

- **describe the procedures for informed consent + confidentiality**
- **inform consent for duration +**
- **code or anonymised banked biomaterial, security for storage and handling**
- **Fairly and lawfully processed**
- **limited purposes**
- **Adequate, relevant sufficient**
- **Accurate**
- **Timely storage**
- **Processed in due form subject's rights**
- **Secure**
- **Not transferred abroad unprotected**



Research on Animals***

In Summary,

- **NHP use = MANDATORY EU level Ethics Review**
- **Convincing Application of the 3Rs**
 - Reduction, Replacement, Refinement
- **■ To describe and justify:**
 - Species **and** Numbers
 - Humane End Points **and** Pain Suffering
- **■ To Check for alternatives (cf. the following websites):**
 - <http://www.nc3rs.org.uk/category.asp?catID=3>
 - http://www.vet.uu.nl/nca/links/databases_of_3r_models
 - Plus Application of new EU Directive

Research in Developing Countries* – DOUBLE Standards

- → Does the research project provide **benefit to the local community** (in terms of access to healthcare, education, allocation of property rights, capacity to assess and use modern technologies while respecting the population 's own choices and needs, etc.)?
- → Does the research project **use local resources** (genetic resources, animal, and plants)? **Result in their benefit or?**
- **Ethics Equal or Similar EU Member States Standards**

Ethics contributes to Quality objectives

- **Quality:**
proposals selected for funding demonstrate high scientific, technical and managerial quality. The ethics must be on equal level.
- **Equality of treatment:**
all the projects need to have a uniformly excellent ethics from beginning to end of the research.
- **Input for contract negotiation**
The requirements of the Ethics Reports MUST be incorporated into the technical annex
- The indications given are vital for successful and rapid negotiation.
- Help to successful projects during negotiation.
- Maintain an updated « ethics » file for the project duration (+5 years)



Thank You



Special clauses on ethics in research

Clause 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.'

Clause 13

'The beneficiaries shall comply with the ethical framework of FP7, all applicable legislation, any relevant future legislation and FP7 specific programmes on "Cooperation", "Ideas", "People", "Capacities" (2007-2013) and "Euratom" (2007-2011).'





Special clauses on ethics in research

Clause 14

Research Activities Involving The Use Of Human Embryos And Human Embryonic Stem Cells

The beneficiaries shall inform the Commission in writing of any research activities that may involve the use of human embryos or human embryonic stem cells, unless such provisions in Annex I to the grant agreement have specifically been approved. Such research may not take place without the prior written agreement of the Commission.

Clause 15

The beneficiary(ies) shall provide the Commission with a written confirmation that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval(s) of the competent national or local authority(ies) in the country in which the research is to be carried out before beginning any Commission approved research requiring such opinions or approvals. The copy of the official approval from the relevant national or local ethics committees must also be provided to the Commission.

Special clauses on ethics in research

Clause 16

Clinical Research (**specific to biomedical research involving human beings**)

The beneficiary(ies) shall provide the Commission with a statement confirming that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval of the competent national authority(ies) in the country concerned before beginning any biomedical research involving human beings.

