(Re) Integrating Ethics into SSH Research:

an EC Perspective

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(...) European integration must mean more than establishing a single market; progress in science and technology must be given a <u>human, social, and ethical dimension, otherwise European citizenship cannot be established"</u>

Under FP7 → Ethics Review is a legal requirement

To ensure that **ALL** research activities carried out under FP7:

- Respect fundamental ethical principles

- Conform with national, European and international regulations

Ethics Review...legal basis

- Decision 1982/2006/EC of the European Parliament and of the Council (Recital 30 and Article 6)

- Council Decisions of 19 December 2006 concerning the EC and Euratom Specific Programmes

- **Rules for submission of proposals.......(Annex A : Ethics Review)**

ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-evrules_en.pdf
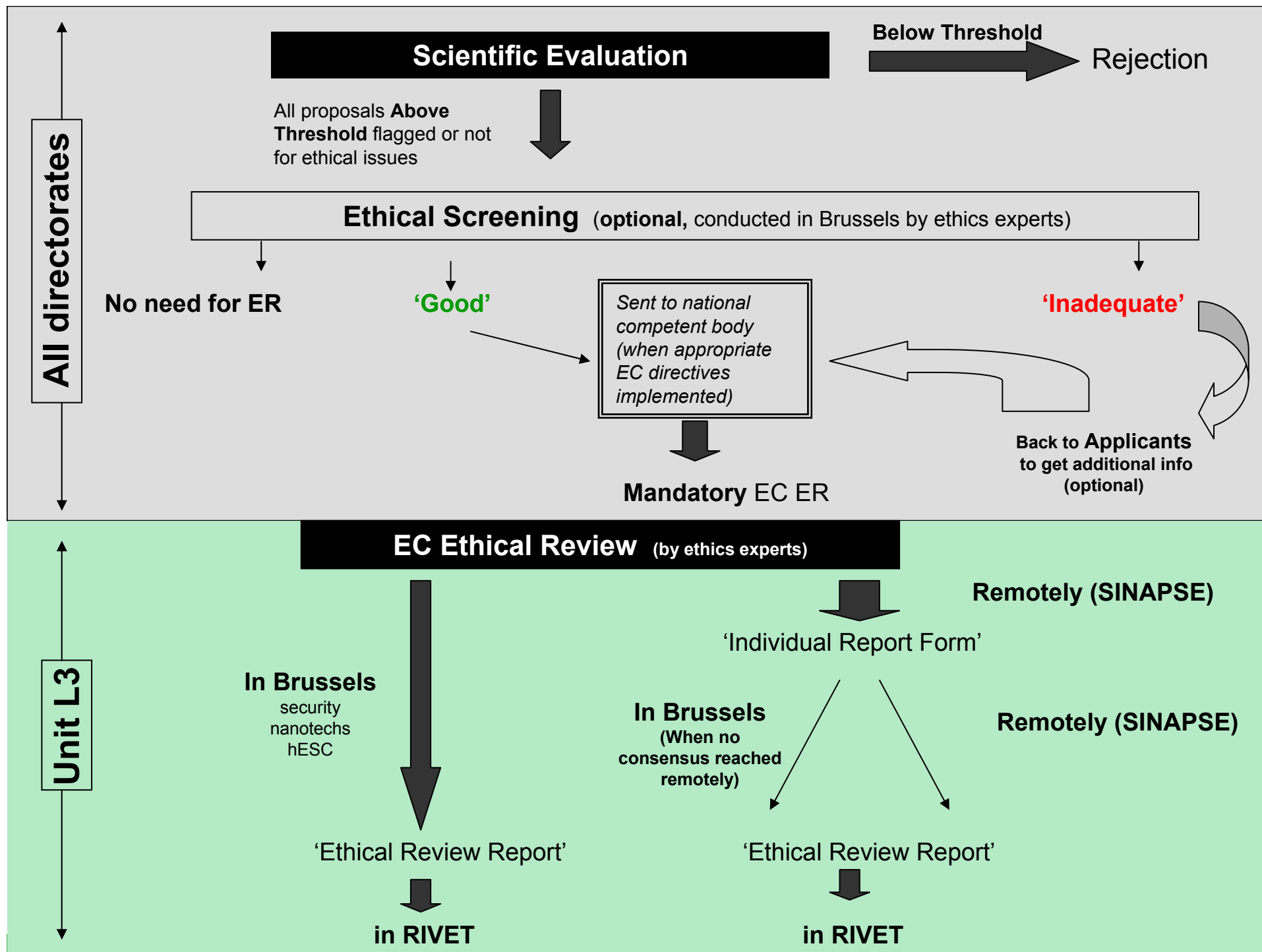
Ethics Review...research areas excluded

➢ *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 relating to cancer treatment of the gonads can be financed), and*

➢ *Research activities intended to create human embryos for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer"*

(FP7, Art.6, pg 2)

Scientific Evaluation

Below Threshold → Rejection

All proposals **Above Threshold** flagged or not for ethical issues

Ethical Screening (**optional,** conducted in Brussels by ethics experts)

All directorates

No need for ER

'Good'

Sent to national competent body (when appropriate EC directives implemented)

'Inadequate'

Back to Applicants to get additional info (optional)

Mandatory EC ER

EC Ethical Review (by ethics experts)

Remotely (SINAPSE)

'Individual Report Form'

Unit L3

In Brussels
security
nanotechs
hESC

In Brussels
(When no consensus reached remotely)

Remotely (SINAPSE)

'Ethical Review Report'

'Ethical Review Report'

in RIVET

in RIVET

Ethics Review...composition of panels

- chosen from Commission's FP7 expert database

- expertise in law, medicine, sociology, philosophy, information technology, molecular biology, veterinary science, etc.

- gender and geographical balance taken into account

- may also include representatives of civil society and/or experts from non EU Members states

Ethics Review...looking for

- Awareness of applicants on the ethical/social impact of research

- Application of relevant European Directives/ international conventions/declarations

  (for SSH – DATA PROTECTION directive and Informed consent processes)

- Approval of competent national authorities (such as in data protection) and positive opinions of local ethics committees (Special Clause 15 of the FP7 Grant agreement)

  ftp://ftp.cordis.europa.eu/pub/fp7/docs//fp7-ga-clauses-v4_en.pdf

Issues to deal with:

- Lack of awareness of FP7 Ethics Framework (your help is needed)

- Lack of awareness of EU and national legislation (including "soft law" and guidelines) (your help…)

- Specialized expertise (your help….)

- Role of Ethics Review Panels (your help: no, not yet…)

….. Understanding the issues involved

- Respect for autonomy and informed consent

- Protection of Children and vulnerable (immigrants, prisoners, war area populations)

- Data protection and Privacy

- Approvals of competent authorities

Ethics Review and SSH (3)

- Benefit sharing and IPRs

(are there any ethical issues????)

- Training (Researchers, EC personnel, NCPs- organization of information days)

What we (ER sector) need to do …yesterday:

- Guidance notes to applicants -SSH in early 2010
- Specific methodology for the SSH panels -started

  including "new" SSH Deliberation methods

  ›ID the problem (what are the issues in SSH)

  ›ID principles at stake –including legislation if at all possible (who is "responsible" for the conduct of SSH   research)

  ›Describe courses of action (educate, do not alienate)

- A great volume of the research on deliberation theory, on human dignity, on informed consent and….almost all types of social impacts of research comes from the social sciences……..embedded in the legal and medical faculties and philisophy departments of research institutions

- The ethics review of SSH research is , in my opinion, the most challenging task in ethics review

- there seems to be very low awareness (not my problem syndrome?) on the ethical issues raised…..by the SSH research itself…

- Training

  We are developing training actions that will include the NCPs –in the 2010 WP

- Ethics Review Help Desk (for FP7 running projects)- done

- Courses for Commission personnel-done

- Introduction of Follow-up and Audit-done

Always keeping in mind that Ethics review has an advisory role as well…

…….to improve the process from "inside"

- Panel reports
- Panels Self assessment
- Expert Working groups to produce guidance on specific topics (How to deal with……..)
- Updating the ethics forms (EIT, IRR, ERR….)
- Updating legal documents (such as the rules for submission)
- improving the ethics www sites

...Conclusion

The ethical issues raised by FP7 research need
to be addressed, based on the **European legislation** and **ethos**.

SSH scientists should become aware of their ..."responsibilities"

<u>NCPs play a pivotal role in the awareness efforts!</u>

Any proposal that is found to contravene fundamental ethical
principles **SHALL NOT** be selected.

Thank you for your attention

- ETHICS

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

http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=36

Any Questions?