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Ethics Review and the FP7 Ethics Framework :Do the right thing and do it right……

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Balance

Things only have the value that we give them

Moliere

Including the value of human life (VSL)

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Charter of Fundamental Rights of the European Union

- Following the entry into force of the Lisbon Treaty in 2009 the fundamental rights' charter has the same legal value as the European Union treaties.

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Compliance of applicants with ethical rules: A Legal obligation (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 **in compliance with fundamental ethical principles**'*

OR in other words:

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Ethics in ERA

- European research policy should be deeply rooted in European society. Besides the pursuit of scientific excellence, European research should …… experiment with new ways of involving society at large in the definition, implementation and evaluation of research agendas and of **promoting responsible scientific and technological progress, within a framework of common basic ethical principles and on the basis of agreed practices that can inspire the rest of the world**

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- Barroso statement-2012

"I believe we have to be clear on values, firm on principles , fair on the method and sensible on the communication"

European Values and principles !!!!!

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Compliance of applicants with ethical rules: A Legal obligation (2)

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 the FP7 grant agreement in CORDIS 'find a document'

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"In God we trust, all others bring data"

Dr. W.E.Deming, 1900-1993, Statistician

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- For the last year of FP7 and the future, In brief:

-The changing nature of research

-The "end" of Nature

-And the new researcher

- Societal WTP
- The new FP proposal :innovation and ethics

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Special clauses on ethics in research

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).'*

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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.

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Special clauses on ethics in research

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*.

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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)

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What happens after the Ethics Review?

- The applicants are informed of the outcome, they receive the ERR
- The ERR may indicate the need to organise a Follow up /Audit review at a later stage of the project.
- In its decision to fund a project the Commission takes into account the results of the Ethics Review.

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Ethics Review: what are we looking for?

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

ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-evrules_en.pdf

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Three steps to ER

- Ex-ante (Ethics review by experts)
- On –going (Commission and experts)-(G University case and Indect case)
- Ethics Audit

- There are projects that in the ex-ante phase will be reviewed by 3 RECs and then mostly be forgotten (Harvard case)

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For Horizon 2020

- Trust and simplification
- More on-going , less ex-ante

- MML in Ethics

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Automatic Ethics Review

- **Research Intervention on human beings**
- **Use of Human Embryonic Stem Cells or Foetal Tissue – Scientific Evaluators to confirm NECESSITY to use hESC**
- **Use of Non Human Primates**

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Common shortcomings (1)

- **Lack of consistency between the research work proposed and the ethics annex of the application**
- **No information on handling incidental findings**
- **Issues related to children: failure to describe if child obtains a real and direct benefit. If child is not directly benefited, a minimum risk and minimum burden must be illustrated**

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Common shortcomings (2)

- **Developing Countries: failure to describe why it is necessary to include the developing countries and whether any benefits will reach these countries and the local populations**

- **Clinical trials: failure to justify human intervention from an ethical perspective, safeguard data protection, design of informed consent forms**

- **Data protection and privacy: codification, storage and anonymizaton of personal data**

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Common shortcomings (3)

Issues that we face when dealing with the researchers (as FP7 applicants)

- Lack of awareness
- Lack of training
- See ethics as red tape
- Connecting ethics to the methodology and impact of research
- Do not deal with the ethics as part of the design of the proposal but only as a “necessary burden” in the best cases and as an “unnecessary” one on the average....

WGS related

- Re-consent vs. open consent
- Duty to Re-contact
- Right to withdraw
- Right to be forgotten (new regulation)
- Risk\benefit of public data sharing
- Governance structures\Community involvement

US IRB chairs survey 2010

from 'IRB Ethics and Human Research'

- 376 Public and 30 Commercial IRBs

White ,males,non-hispanic over 50 with medical and SSH background - 80% academic

US IRB survey

- When asked about certain ethical dilemmas IRB chairs selected as deserving more weight avoiding unwelcome contact and avoiding disclosure of unwanted genetic information

US IRB survey

- 46% chose avoiding disclosure of genetic info with uncertain clinical utility over promoting participants autonomy to make their own determinations about the usefulness of the information (39%)

A chairman's statement:

'autonomy is the most important principle. We should give the participants the right to be contacted, to know their results and to participate in future research…..

A chairman's statement:

….a blanket disapproval is not waranted as it not only prevents the advancement of science but also prevents giving subjects the opportunity to participate in science'

A chairman's statement:

…..investigators who did not have the simple common sense to ask permission for future contacts can just go out and replicate\extend their critically important research finding that spurs the need to contact people based on their private research records

A chairman's statement:

…I draw the line at informing people about findings whose significance is not clear even to the researchers: it is bad enough we burden patients with information that turns out to be wrong. We should not load them with information whose significance is unclear even to us….

A chairman's statement:

….when 'autonomy' and 'do no harm' are in tension , I give 'do no harm' the right of way…..

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Ethics Review and the FP7 Ethics Framework

THANK YOU

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