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THE ETHICS REVIEW OF EU FUNDED RESEARCH PROJECTS

Abstract: The requirement for all research activities conducted under the auspices of the Framework Programme for Research of the European Union to be carried out in compliance with fundamental ethical principles was introduced in the Decision establishing the 5th Framework Programme in 1998. The mechanism for assessing the ethical soundness of research funded under the Programme was inaugurated in the frame of the 6th Framework Programme in 2002, and since then it has become a fundamental component of the assessment process for research supported by the European Commission. Article 6.1 of the Seventh Framework Programme (FP 7- 2007-2013) states that all research *'must be carried out in compliance with fundamental ethical principles'*.

All Research applications that are submitted for funding in the Seventh EU Research Framework Programme, and raise ethical issues, must be submitted to an Ethics Review. This procedure addresses research ethics areas such as clinical trials, intervention on humans, use of animals, data protection issues, use of children and cooperation with developing countries among others

The Ethics Review procedure, which has been provided with the responsibility of assessing the ethical dimensions of preselected pieces of research and the compliance of the latter with fundamental ethical principles and legal standards, constitutes the cardinal institutional structure for the strengthening of the social responsiveness and responsible governance of research and science in Europe. Within this frame, this procedure has been efficient in highlighting the ethical aspects of research proposed for funding and in guiding the researchers through the maze of their respective legal responsibilities. However, the operation of this mechanism brings into surface the challenges of an integrated research ethics approach at the EU level, the disparity of legal instruments and plurality of local/national 'readings' of ethical norms as well as the prevalence of the biomedical ethics paradigm among researchers and reviewers when elaborating the ethical dimension of research.

The impact of the Ethics Review is significant and multilevel. First of all, the Ethics Review Report (ERR) contains a standard question that requests the reviewers – and in effect the applicants – to consider the potential and possible implications of the proposed research

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PowerPoint presentation delivered at the Conference.

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in terms of social short- and long-terms effects of the eventual results and findings. So, each ERR evaluates the social dimension of the proposed research and requires the research to reflect upon and elaborate on how the under review research protocol can be of some added value to and benefit the society and the research participants in the immediate future.

Furthermore, all proposals that are planned to take place in developing countries are required – in the frame of the Ethics Review procedure – to illustrate and demonstrate how exactly the applicants will contribute to the strengthening of the capacities of the area where the research is supposed to take place (i. e. through the inclusion of requirement on the need to design and organise training programmes) as well as how exactly they will share the benefits of their research with the local populations (especially in the field of health and environmental sciences research).

Moreover, the Ethics Review pays particular attention to the protection of vulnerable population groups including children, minorities, people with disabilities, etc. through the drafting of requirements that safeguard their well-being and the eventual benefit arising from the research under funding. The emphasis of this procedure on issues such the prior informed consent of the research participants, the protection of his/her personal data, the safety and integrity of all those involved in the research protocol and the notion of proportionality, autonomy and beneficence provide ample evidence for the inherent social dimension of this assessment procedure and its crucial role in enforcing and monitoring the application of socially accepted ethical standards.

The social impact of research funded the 7th Framework Programme is also assessed and monitored through the Ethics Follow-up/Audit procedure organised by the ER Sector in DG RTD). All proposals that pass the Ethics Review and that are finally selected for funding can, in principle, be subject to an Ethics Follow-up/Audit. Proposals that undergo an Ethics Review can be flagged by the independent reviewers as requiring an Ethics Follow-up/Audit (EFA). EFA is conducted by ethics experts, not earlier that the first reporting period of the proposal. This is composed of two steps: a) the Ethics Follow-up which aims at identifying issues that are not properly addressed by the project and is performed usually after the first reporting period of the project and b) the Ethics Audit, reserved for projects that did not satisfy the experts during the follow-up stage and will be performed only for the most ethically underperforming cases. The objective of the EFA procedure is to assist the participating scientists to deal with the ethics issues that are raised by their work and if necessary take corrective measures also in view of the need to safeguard that the project will produce social benefits that extent beyond its contractual timeframe. It is the first time – both at the international and at the national levels – that such a process is put in place.

Last but not least, the Ethics Review Sector exerts a capacity-building function through the organisation of special training programmes and seminars and other outreach activities addressed and tailored to the needs of the Commission staff, researchers/FP funding applicants and ethics reviewers. Beyond the obvious educational aspect of the Ethics Review procedure, the organisation of dissemination activities that aim at the building of a knowledge base in the field of research ethics and at the exchange of best practices also highlights the social aspect of this *ethics by design* approach.

Key words: *European Legislation, Framework Programme for Research, Ethics Review, Ethics Audit, Social Impact, Ethics Expert Panels*


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Aristotle 384 BC-322 BC
"We do not act rightly because we have virtue or excellence, but we rather have those because we have acted rightly"


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…We have to be clear on the values, firm on the principles , fair on the method and sensible the communication….
J. M. Barroso, President of the European Commission


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Ethics in ERA
....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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What do we mean with « ethics » in the EU funded research?
ETHICS REVIEW and RESEARCH on ETHICS

Thus....

"In God we trust, all others bring data"

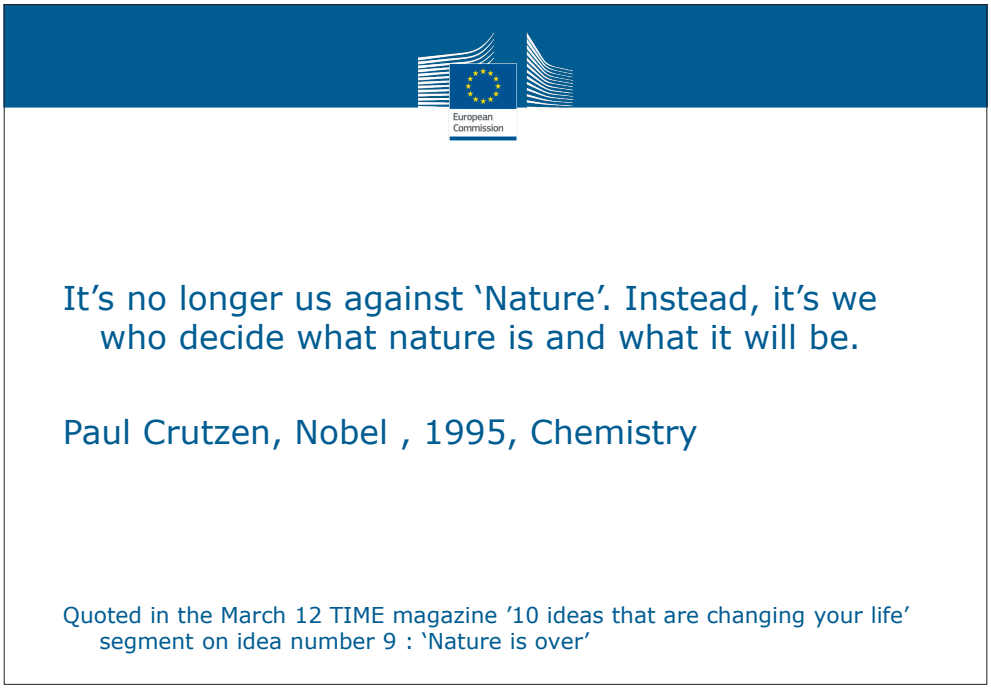
Dr. W.E.Deming, 1900-1993, Statistician

A changing research environment

A new ethics era in the Horizon 2020 Ethics framework?

from Socrates to Darwin to Venter ["God has competition"]

But also increased pressure on scientists to come up with new and "exciting" results so that they will be selected for publishing and beat the competition furthering their carriers and inviting more funding to carry out more research….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It’s no longer us against ‘Nature’. Instead, it’s we who decide what nature is and what it will be.
Paul Crutzen, Nobel , 1995, Chemistry
Quoted in the March 12 TIME magazine ’10 ideas that are changing your life’ segment on idea number 9 : ‘Nature is over’


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Innovation Basics[1]
-Innovations are changing the way a community behaves
- Many actors (people) are affected
- Innovations disrupt the status quo
- Innovations are a shared responsibility
- Successful innovations require continuous modifications
(and also cause continuous modifications -ALCOA ex)
[1]From Institute of corporate ethics, Innovation ethics and business, by K.E. Martin


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Innovations in ethics have many sources:
-ethics related research (philosophy, law, medicine)
-SSH research and embedding (psychology-why good people do bad things, sociology-the impact of privacy legislation of research, etc)
-risk assessment
-business studies
-LBD
ETHICS IS ABOUT PEOPLE not about processes


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Ethics is an enabler and not a red tape
Procedures and rules are only a part of what Ethics is all about
By disassociating ethics from the design of the research and limiting it only to compliance , actually you achieve very little longeterm


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Commission
We are externalizing almost everything (case or CROs)
There is a question of who does the thinking that is required for social impact, ethics, security, human rights, privacy protection, dignity, freedom of researchers


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The Changing Role and Impact of Research Ethics Committees
From advisory to regulatory (including self-regulation)
-The Innsbruck case
-Clinical Trials in India
-Security research (the INDECT project case)
-The Influenza biosecurity research
-hESCs
ALWAYS:
if something goes wrong, the public administration system (including the RECs) will be implicated and blamed


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Embedding Ethics in Research
-For non medical research ; Moving away from the biomedical model (but where to go ?)
-Moving away from the tick box approach in the ethics content
-'Externalization' – Ethics is resolved away from the lab by 'experts' (who are they?)
-Follow-up and Audit
-What to do with issues that are of differing cultural and ethical value? (hESCs, privacy, security, consent)
ETHICS IS NOT A RED TAPE MECHANISM nevertheless we need to have an idea of the WTP values and the Cost of Being Ethical (different types of "costs")


European Commission
If we assume that some values and principles are not negotiable (but processes are), how can procedures and practices help in Horizon 2020?
Enhance Dialogue : responsible research and innovation
New Legislation (e.g. Medical devices law in Germany, new bioethics law in France)
Professional Codes (ESF and Singapore Statement on Research Integrity)
Global ISO type standards
World wide joint programmes in Education and Training
Using REC participation as "promotion" criterion

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****'*

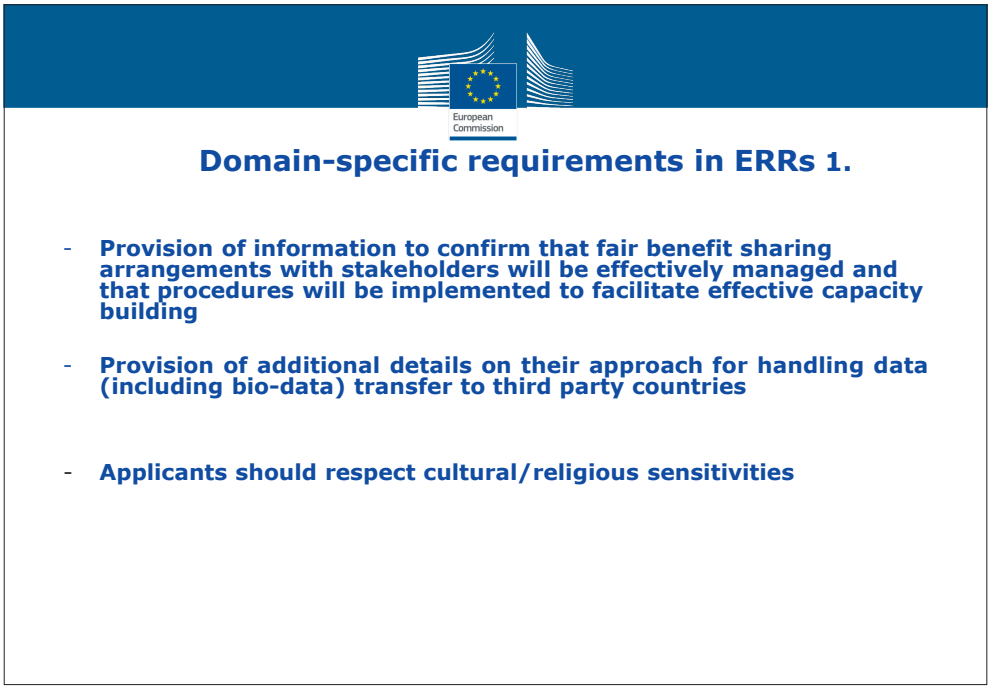
Stopping scientific research on ethical grounds?

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)*


European Commission
Main steps of the Ethics Review process
1) Completion of the scientific evaluation process
2) Ethics screening conducted in Brussels by ethics experts
3)
Depending on the type of ethical issues
proposal sent to Brussels for a mandatory Ethics Review
or to the national competent bodies on the basis of the subsidiarity principle


European Commission
Most common ethical issues in projects involving international cooperation
In 2011 Ethics Review:
- 80/315 projects involving international cooperation
- Use of local resources (genetic, animal, plant, etc.)
- Benefit to local community (capacity building , access to healthcare, education, etc.)


European Commission
General requirements in ERRs
(most frequent requirements)
- Submission of opinions of ethics committees
- Submission of approvals/notifications from national competent legal bodies of the countries where the research takes place before the research work begins(data protection, clinical trials, animal welfare....)
- Provision of details on EU and national legislation in place,
- Adequate insurance, specific for the nature of the work, must be provided to all participants
- Appointment of an Ethics Board/Expert to monitor the ethical concerns in this project
- Rigorous application of ethical standards and guidelines compatible with, and equivalent to those of FP7, regardless of the country of research


European Commission
Domain-specific requirements in ERRs 1.
- Provision of information to confirm that fair benefit sharing arrangements with stakeholders will be effectively managed and that procedures will be implemented to facilitate effective capacity building
- Provision of additional details on their approach for handling data (including bio-data) transfer to third party countries
- Applicants should respect cultural/religious sensitivities


European Commission
Overall assessment of proposals
1. The proposal adequately identifies and addresses the relevant ethical issues. Specific requirements, if any, are provided in the 'Requirements'
2. The proposal addresses the ethical issues only in general terms but there are aspects which require substantial clarification. These are highlighted in the 'Requirements' section
3. The proposal fails to identify and to address the relevant ethical issues. A supplementary Ethics Review is recommended (resubmission)
To be considered...
1. The description of ethical aspects of the research regarding the objectives
2. The description of ethical aspects of the research regarding the methodology
3. The description of ethical aspects of the research regarding the possible implication of the results
4. The indication how the proposal meet the national legal and ethical requirements of the country of the research
5. The indication of timeframe for approval by relevant authority at national level


European Commission
Ethics in research and international cooperation
Guidance when dealing with specific ethical issues in research activities in developing countries
Three overall considerations
The proposed research must:
1. be responsive to the needs of the country where research is carried out (e.g. the study must be of added value for the health and welfare of the intended participants, their community, and/or their country)
2. be scientifically sound (although not within the scope of the ethical review)
3. abide by relevant EU/national legislation as well as by the relevant international guidelines
ftp://ftp.cordis.europa.eu/pub/fp7/docs/developing-countries_en.pdf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Projects involving international cooperation
three examples
1. GEST - Global Ethics in Science and Technology
GEST aims to explore the role of ethics in science and technology (S&T) policy as it is currently developing both in Europe and in the two main global emerging economies of China and India. S&T ethics has been widely debated in Europe leading to a number of policy initiatives that have influenced the development of new technologies in the European Research Area.
ACADEMY OF SCIENCE AND TECHNOLOGY FOR DEVELOPMENT (CHINA)
RESEARCH AND INFORMATION SYSTEM FOR DEVELOPING COUNTRIES (INDIA)


European
Commission
Projects involving international cooperation
2. ETHICAL - Promoting international debate on ethical implications of data collection, use and retention for biometric and medical applications
Objectives
1. To formulate an international dialogue on ethical implications of data collection, use and retention in medical and biometric applications, in three specific themes: potential data misuse, development of a unique identifier and international standardization of ethical requirements
2. To develop a guide on government industry collaboration prerequisites concerning the data collection, use and retention in medical and biometric applications.
3. To develop a code of conduct for FP7 researchers, concerning the data collection, use and retention in medical and biometric applications.
4. To identify the set of ethical requirements for international biometric and medical data sharing.
Universiti Malaysia Sarawak

Projects involving international cooperation

3. RISE - Rising pan-European and international awareness of biometrics and security ethics

The aim is to promote pan-European and International Awareness on Ethical Aspects of Biometrics and Security Technologies.

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RISE's point is the new political landscape created by the Treaty of Lisbon of the European Union. The EU is now on the verge of a multifaceted reform of its decision-making rules for security, which may have deep ethical and political implications. RISE will address this issue.

Hong Kong Polytechnic University, Biometric Research Centre (PRC)
DSCI – Data Security Council of India (INDIA)
NCCU – National ChengChi University (Taiwan)

……That means we have to do a lot more research on why ethical people do unethical things……

And it is clear from *current research that "administrative" reasons are among the main contributors*