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Research ethics and the EC Framework programme: Do the right thing and do it right[*]

Research Ethics

In the European Commission research policy and funding system known as the Framework Programme, Ethics Reviews were introduced almost nine years ago and ever since have been a part of the research evaluation procedures. The current Framework Programme (FP 7)[1] states in Article 6 that „*All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles*". The introduction of the Ethics Reviews reflected a changing environment in research. While the pursue of research and scientific excellence is the main concern of all involved (policy makers, decision makers, managers and the researchers), the research environment itself has been changing rapidly with pressure put on researchers to get involved on management, dissemination, public awareness issues and thus be involved in the broader areas surrounding and defining at times the research scope and objectives.

With the extensive use of new IT tools in collecting, recording, analyzing, storing and transferring different types of data and the change in the way researchers did their research (new science-industry and science-society relations, expensive high performance equipment, costly research materials

[*] The paper is printed as submitted.

[1] http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2006:412:SOM:EN:HTML Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013)

among others) and the resulting new regulatory environment imported to research from, for example, privacy and data protection, security related research and others, all or almost all research areas are participants in the ethics review process. Research ethics have become, in a number of disciplines, part of the immediate research environment. For a researcher it is not sufficient any more to consider the hypothesis and experimental approach to his research interest. It is necessary to consider also the research impact and the dissemination of the results on top of the traditional publishing practices.

In medical research ethics has been part of the research agenda since at least, to take a pivotal date, the publication of the Nuremberg code in 1947 and the social and political pressures that followed the unravelling of the Tuskegee scandal (a scandal that lasted from the late 30 s to 1972) and the Bridgewater State Hospital film saga that started in 1967 and finished in 1991 in the US.

Of course these dates are only indicative. Equally important in the history of ethics are the writings of the Greek and Roman philosophers and the historical and political significance of the Hippocratic Oath. Actually it will be hard to identify a period in human history where ethics does not influence the social and political agendas and through them the research endeavour.

In the 1950 s and 1960 s we have the emergence of the bioethics field. The Encyclopaedia of Bioethics (3 d Edition, S. G. Post editor in chief, 2004) defines bioethics as ***„the systematic study of the moral dimensions—including moral vision, decisions, conduct, and policies—of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting."***

The definition can be applied to almost all disciplines by a substitution of the research area in the definition: „life sciences and health care", with many other research areas.

The Encyclopaedia cited above also mentions that „the word *bioethics* was coined in the early 1970 s by biologists in order to encourage public and professional reflection on two topics of urgency: (1) the responsibility to maintain the generative ecology of the planet, upon which life and human life depends; and (2) the future implications of rapid advances in the life sciences with regard to potential modifications of a malleable human nature".

The definition, as it currently stands, covers also new areas that fall under the bioethics umbrella: the environment and the development of green ethics and the emerging field of synthetic biology. The issues raised by synthetic biology are already debated openly and actively, engaging both researchers and society and statements such as: „For the first time, God has competition" as quoted in articles on synthetic biology („A life of its own" by M. Specter, New Yorker, September 28, 2009) would further spark the discussions for some time to come.

One of the latest additions to the list of research areas and disciplines that have to adjust to the new ethics related realities of thinking, designing and implementing research protocols are the social sciences. In terms of adjustments needed and in relative terms, the social sciences will adopt extremely fast, because the changes needed in the design of research protocols in these areas are minimal. As long as ethics requirements are included in the design of the research and incorporated into the preparatory steps concurrently with the consideration of funding options for the research, the adjustment is relatively straight forward. The discussion concerning the ethics of social sciences research methodology (for example the use of deception in social science research and the parallelisms with the use of placebos in medical research), will undoubtedly continue and might even help in bringing the „two cultures" closer to each other and also close to the budding culture of research ethicists.

In a sense, it is possible that the social sciences require their own „Helsinki Declaration".

Interestingly enough a great volume of the theoretical and applied work supporting the current paradigms of research ethics comes from social sciences research. Social scientists embedded mostly in law and health research departments, are carrying out a substantial part of this work. A look at the host departments of authors publishing in the *Journal of Medical Ethics* for example, might support this assertion. This research could easily find its way to social sciences departments and assist in incorporating ethics processes in the social sciences research to be undertaken.

Throughout the research field and across disciplines, the new environment has lead to an administrative reorganization of the peer review system and the funding approval mechanisms to include the ethics requirements. This evolution has lead to a plethora of administrative solutions that are as varied as the funding sources and structures in each country and lead to an increase in work load (for both the research community and the ethics committee mem-

bers) and in paperwork, requiring sometimes more than one approval for the same research project (one opinion from a local ethics committee and one approval from the appropriate national competent authority; i. e. data protection authority). Clearly there is a need for a drastic re-think of the approval/review/evaluation system. But it must be noted that recent studies in the operation of research ethics committees has shown that their concern is primarily the care and protection of participants (Clinical Discovery, October 2008, „What troubles Research Ethics Committees"). These Committees generally seek assurances that the researchers have considered carefully the risks, inconveniences and discomforts to which participants might be exposed. A hard learnt lesson, if one refers to the first gene therapy trial in 1999 that ended in the death of 18 year old Jesse Geslinger. The scientist heading this trial has spoken recently to Scientific American (September 2009) and argued that clinical scientists „should always ask themselves if the worst case scenario played itself out –not the potential or likely, but the worst-would that be acceptable?"

Adapting to an administrative reality is only part of the current research management equation. Implementing the rules and procedures and through them acquire new knowledge and training is another equally important part. Submitting an application to an ethics committee has to be seen not as a red tape procedure but rather as a learning process in itself that can improve the positive impact and image of research. The ethics review procedure reflects laws that are generally widely accepted across national borders and are based on international conventions and agreements. At times local customs also need to be considered. „Custom is the king of all things" according to Herodotus and a researcher is bound by this decree even today. This is another reason why researchers should be involved in public debates and deliberations in areas that raise ethical concerns. Customs can change but require strong and informed interaction and in research areas also require a well thought strategy for maximizing the positive impacts of research results.

FP 7 Ethics Review

Legal Requirements for Ethics Review

Ethics review of research projects is a legal requirement under FP 7

- In the EC FP 7[2] (Recital 30 and article 6) as well as under the Euratom FP 7[3] (Recital 8 and article 5).
- In each Specific programme, the purpose of the ethics review and the applicable general framework, including reference to international conventions, guidelines are indicated as well as the related modalities (Guide to Applicants).
- In the EC rules for participation[4] (article 15) and, in the equivalent Euratom rules for participation[5] (article 14).

At the European level, all research applications that are selected for funding in the FP 7 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. All applicants have to submit an Ethics Issues Table (see table below) where they declare which of the listed areas are included in the application.

	Research on Human Embryo/ Foetus	YES	NO
*	Does the proposed research involve human Embryos?		
*	Does the proposed research involve human Foetal Tissues/ Cells?		
*	Does the proposed research involve human Embryonic Stem Cells (hESCs)?		
*	Does the proposed research on human Embryonic Stem Cells involve cells in culture?		
*	Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos?		

	Research on Humans	YES	NO
*	Does the proposed research involve children?		
*	Does the proposed research involve patients?		
*	Does the proposed research involve persons not able to give consent?		
*	Does the proposed research involve adult healthy volunteers?		
	Does the proposed research involve Human genetic material?		
	Does the proposed research involve Human biological samples?		
	Does the proposed research involve Human data collection?		

2 OJ L 412 of 30. 12. 2006, p 1.

3 OJ L 400 of 30. 12. 2006, p 60 as last amended by Corrigendum OJ L 54 of 22.02.2007, p 21.

4 OJ L 391 of 30. 12. 2007, p 1.

5 OJ L 400 of 30. 12. 2006, p 1 as last amended by Corrigendum OJ L 54 of 22.02.2007, p 21.

	Privacy	YES	NO
	Does the proposed research involve processing of genetic information or personal data (e. g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?		
	Does the proposed research involve tracking the location or observation of people?		

	Research on Animals	YES	NO
	Does the proposed research involve research on animals?		
	Are those animals transgenic small laboratory animals?		
	Are those animals transgenic farm animals?		
*	Are those animals non-human primates?		
	Are those animals cloned farm animals?		

	Research Involving Developing Countries	YES	NO
	Does the proposed research involve the use of local resources (genetic, animal, plant, etc)?		
	Is the proposed research of benefit to local communities (e. g. capacity building, access to healthcare, education, etc)?		

	Dual Use	YES	NO
	Research having direct military use		
	Research having the potential for terrorist abuse		

Other Ethical Issues	YES	NO
Are there **OTHER** activities that may raise **Ethical Issues**?		
If **YES** please specify:		

The above table can be seen as a stimulus for the applicant to ask why these areas are considered as ethics related (if he/she is not already aware). If any of the above areas are included in the application, then explanatory text should accompany the table (an Ethics Annex). In this annex an applicant should analyse the way the ethical issues are dealt with. For example, by using power analysis the number of human subjects or animals used should be justified. Also, the process of recruitment should be explained (informed consent and information sheets) on the basis of the guidelines offered (Getting through Ethics review: http://cordis.europa.eu/fp7/ethics_en.html#ethics_cl).

The application is firstly evaluated by scientific experts[6] and is selected -or not- for funding. The scientific experts may also offer a brief comment of the ethics issues raised by the application on the basis of the Ethics Issues Table. Usually the scientific experts do not enter into a discussion of the ethics issues. There role is to signal to the Commission services that a proposal merits Ethics Review.

The Ethics Review[7] is carried out in two steps:

1. *Ethics Screening:* Proposals that raise ethical issues that fall under European Law (such as clinical trails, data protection, animal welfare, human tissue collection and use), are screened by independent ethics panels. These proposals are usually given the green light following the submission of national approvals (Clause 15 and 16 of the FP 7 Grant Agreement: ftp: //ftp. cordis. europa. eu/pub/fp 7/docs//fp 7-ga-clauses-v 6_en. pdf, page 10.)

2. *Ethics Review:* Proposals selected for funding and involve:

– intervention on humans,
– research on/with primates and
– research using human embryonic stem cells

are submitted automatically to Ethics Review, conducted also by independent ethics panels. Research involving children and cooperation with developing countries merit special attention and are also submitted to Ethics Review

[6] The process of submission and evaluation of applications is described in the „Rules for submission of proposals, and the related evaluation, selection and award procedures", Version 3, 21 August 2008 COM (2008)4617 (ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-evrules_en.pdf)

[7] See Annex A of the Rules for Submission above

following consultation with the Commission services responsible for the funding of the specific proposals.

Ethics Requirements for applicants

The applications are reviewed on the basis of the following criteria:

– How adequately the applicant describes the potential ethical aspects of the proposed research regarding its objectives; the methodology and the potential implications of its results ;

– If the design of the research project is justified from an ethical viewpoint;

– If the manner by which the ethical requirements set out in the work programme will be fulfilled, is outlined;

– If and how the proposal meets the national legal and ethical requirements of the country where the research is planned to be performed;

– If a timeframe is indicated for applying for opinion and/or approval by any relevant authority at national level.

In Ethics Review Report also includes a section of requirements, where the reviewers note all necessary actions that an applicant needs to take in order that the research is conducted according to the FP 7 ethics framework. The requirements become part of the contractual responsibilities of the applicant towards the European Union.

In addition the panel would offer, if necessary, a number of recommendations to the applicant. These recommendations are basically suggestions that can improve the ethical conduct of the research. They are not obligatory and they do not become part of the contract.

Last but not least, the ethics review panel might indicate the necessity for follow-up actions. These are foreseen for applications that raised a number of ethical concerns and the panel was not convinced of the ability of the applicant to perform the necessary tasks unaided. The follow-up actions could lead to full ethics audits if the applicant has not fulfilled the contractual responsibilities or failed to take into account the ethics follow-up measures recommended.

Ethics Review Support Activities

The above procedures constitute the Ethics Review in its entirety. Through this process the European Union ensures the compliance of the FP participants to the FP 7 ethics framework. This process is incomplete unless it is seen in light of the overall actions in Ethics Review. Actions that are complementary to the Ethics Review process but target a change in attitude and an understanding of the principles that have lead to the design of the process. These actions include:

– *The Ethics Review Help Desk*: a service provided to all FP 7 projects that in the course of their research have encountered ethical questions and challenges that require expert advice. The advice is offered free of charge and only upon request by the FP 7 participant through the help desk web site (http://cordis.europa.eu/fp7/get-support_en.html). It is delivered either directly by the Ethics Review Sector of DG RTD or with the help of independent experts and in a confidential manner.

– Ethics Review training: These actions target the research community, the Commission staff that deals with the evaluation, funding and management of the research projects, the National Contact Points and related national authorities in order to achieve a better diffusion of information and awareness and last but not least, the ethics reviewers themselves in order to adapt their experience from national reviews to the European needs and to familiarize with the type of projects that are funded by FP 7.

– *Ethics Review Lessons learnt exercises*: these are self assessment actions that are carried out by members of the ethics review panels. Their target is to improve the ethics review procedure itself by making recommendations on (primarily) methodological issues such as the review forms used, the IT support systems, the constitution of the ethics review panels, the improvement of the consistency of the requirements put forward to the applicants and the workload of the panels.

Ethics Review Impact Assessment

In 2010 the Ethics review Impact Assessment exercise will be launched in order to examine the impact of this process on the participating scientists. Although all care has been taken in order not to increase the workload that

accompanies the design and implementation of a research project, it is possible that the process can be further streamlined and improved. The impact assessment exercise will involve the main actors:

– The researchers that have been through the process
– The experts that have participated in the ethics review committees of FP 7
– The national authorities (ethics committees and competent authorities) that have provided the opinions and the approvals for the implementation of the research protocols, and
– The national contact points that are tasked with providing the necessary guidance and information to the research community.

Ethics Review cites:

http://cordis.europa.eu/fp7/ethics_en.html
http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=36