

**Ethics and Governance Aspects in the Technology
Projects of the European Union Framework Program:
Implications within EU Research Policy**

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Ethics and Governance Aspects in the Technology Projects
of the European Union Framework Program:
Implications within EU Research Policy

Master's thesis

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Abbreviations

(AmI) - ambient intelligence

CFREU - Charter of the Fundamental Rights of the European Union

DG – Directorate General of the European Commission

EC – European Commission

EGAIS - EU FP7 project “The Ethical GovernAnce of technologies”

EGE – European Group of Ethics in Science and New Technologies

EMU – Evaluation and Monitoring Unit (within DG Information, Society, Media)

ERS - Ethics Review Sector (within UEG)

ETICA – EU FP7 project “Ethical issues of emerging ICT”

EU – European Union

FP7 – 7th Framework Program

ICT – information and communication technologies

NECs – National Ethical Committees

SCOT – Social construction of technologies

UEG - Unit of Ethics and Governance (within DG Research)

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Introduction

General background for the research

The scientific and technological progress of the 21st century offers new opportunities for enhancing various aspects of living and social interaction, especially in relation to innovative applications of information and communication technologies (ICT). At the same time, this raises new questions of ethics which are often hard to identify and deal with. This has been proved by various cases in recent research history, for example, the research on genetically modified organisms (GMO)¹, where the resulting controversies and ethical issues had a broad resonance in society. Such fields of study and application as the ICT (e.g. neuroelectronics), nuclear research, nanotechnology already have and in future will have impact on society at large, as has been pointed out, for example, by the European Group of Ethics in Science and New Technologies (EGE)² in its report *Citizens Rights and New Technologies*: “ICT is increasingly pervasive, transforming people’s lifestyles, identities, and choices on many levels, and contributes to changing education, health, social services and other domains” (p. 7). Consequently, the ethical challenges accompanying this research cannot any more be attributed to research community only, but have to be addressed with the ethical interests of the whole of the society in view.

Not only the growing desire of society to be involved in decision making mechanisms is becoming more visible, but also the policy makers have become increasingly aware that the public has and must have a role in the decision making process regarding the new technologies. As pointed out in the Report by the European Commission

¹ According to Goujon and Dedeurwaerdere, the GMO case showed that the nature of simple risk assessment and the use of the precautionary principle was insufficient to understand the actual impact that the GMOs would have on the European society. The way the GMOs were imposed on the society and the reaction it caused was not predicted by any scientific analysis (Goujon and Dedeurwaerdere, 2009).

² The European Group of Ethics in Science and New Technologies is an independent, pluralist and multidisciplinary body which advises the European Commission on ethical aspects of science and new technologies in connection with the preparation and implementation of Community legislation or policies (http://europa.eu.int/comm/european_group_ethics/index_en.htm).

(EC)³ “a deliberative approach to the policy-making process would complement and connect with deliberative mechanisms outside policy” (p.10). The new technological challenges clearly have implications beyond the field of science and technology alone. They are linked to the political processes where deliberation is needed inside the political circles and beyond, thus calling for new and innovative modes of governance⁴.

As we shall show in our work, in today’s ongoing discussion regarding the issue of good governance, and increasing attention is being paid to the ability of the governance approaches to address modern technological challenges. As pointed out by Goujon and Dedeurwaerder “it has to be accepted that in order to face these challenges and the risks and dangers attendant upon the spectacular growth of the techno-sciences, we need to rethink our modes of governance in science and technology” (Goujon & Dedeurwaerder, 2009, p. 1). Since ethics is related to values, this is clearly not an easy task. As we shall demonstrate throughout our work, there is a marked ethical dimension within ICT research⁵.

The deliberation on the ethical framing of the EU policy making inside the European Commission⁶ shows that there is a strong awareness of the ethical challenges that need to be addressed, but the real challenge, as it seems to us, is how to translate this awareness and understanding into practice⁷, due to various legal, economical, political, social and other constraints. To do this, commitment is necessary not only from technology development teams but equally, or even more, from policy makers. As public

³ Understanding Public Debate on Nanotechnology. Options for Framing Public Policy, 2010.

⁴ For governance see Glossary in Annex 1.

⁵ The study of addressing ethical issues in emerging ICT (from a theoretical perspective and from the point of view of practical implementation) has been carried out within the EU 7th Framework EGAIS project. As we shall explain in greater detail in our work, our research has been carried out as part of the EGAIS project and consequently, the EGAIS project has a key importance to the present thesis. The role of the EGAIS project will be described in great detail in a subchapter of the Introduction.

⁶ Our analyses of the relevant reports by the European Commission are enclosed in Annex 5.

⁷ As had been pointed out by one of our interviewees professor Simon Rogerson (who was contracted by the European Commission as the external expert for drafting the FP7 Ethical Guidelines), ethical issue is now on the political agenda, now the task is to give it a content.

policy is accountable⁸ to society, it is also responsible for introducing mechanisms, including knowledge assessment mechanisms, in addressing challenges which are relevant to the society at large.

Thus, on the one hand, there is a need for a continuous shift for a real participatory approach in public policy making. Here we would like to refer to the current tendency in public policy making with the involvement of a broad spectrum of stakeholders, including the involvement of the wider public. On the other hand, there is a need for a political and policy deliberation, since these processes are interlinked and depend on each other⁹. As pointed out by Hajer and Wagenaar, “there is a move from familiar topography of formal political institutions to the edges of organizational activity, negotiations between sovereign bodies, and inter-organisational networks that challenge the established distinction between public and private” (Hajer and Wagenaar, 2003, p. 3).

However, regarding the governance of technological development, as we shall present further in the work, today we still have to speak about the currently predominating separation between scientific and ethical communities, with the scientific expertise often being the main source of normativity, where top-down approaches are still characteristic, and where there is no clear answer how to deal with multiple sources of normativity the public policy is facing today¹⁰. Moreover, the typical approach in the EU policy making in

⁸ The quality or state of being **accountable**; *especially* : an obligation or willingness to accept responsibility or to **account** for one's actions.

<http://www.merriam-webster.com/dictionary/>

⁹ According to Von Schomberg, there are three levels of deliberation regarding public policy. The first level concerns a broad political deliberation, which assumes a political consensus on the need for long term planning when it engages in foresight exercises. In the second level one can identify deliberation at the policy level which immediately builds upon outcomes of political deliberation. A third deliberation level, the science/policy interface, is of particular interest since it qualifies the input of a diverse range of knowledge inputs, e.g. those of the scientific community, stakeholders and possibly the public at large by applying foresight (scenario workshops, foresight techniques/ studies/ panels etc. In Von Schomberg, R., (2007) From Ethics of Technology to Ethics of Knowledge Assessment in Goujon et al. (eds) The information society: innovation, legitimacy, ethics and democracy (In honour of Professor Jacques Berleur s.j.). New York: IFIP, Springer Boston.

¹⁰ We have come to these conclusions through our empirical studies, when analysing the relevant EU reports and interviews with EU officials. We will refer to these aspects further in the work. |

addressing the ethical issues of technological development is by risk assessment and management.

Consequently, there is a risk that little space is left for genuine reflexivity¹¹ in dealing with technological development, and this concerns also the issue of ethics. Thus, answers should be sought how to create a comprehensive ethical governance framework for technology development, and what features of research policy would lead to such reflexive governance, the ultimate goal of this search being the interests of the society at large. In the present work we have studied this problem regarding the ethical framework in the policy approaches and implementation of the EU Seventh Framework Program¹² (FP7).

The FP7 has been recognized the need to pay attention to ethics in research - it has been made mandatory for all research projects to address ethical issues according to set guidelines. The Decision No 1982/2006/EC, Article 6 of the European Commission stipulates: “All the research activities carried out under the Seventh Framework Program shall be in compliance with fundamental ethical principles”. However, based on evidence available, there is a concern that not all FP7 technological projects sufficiently address the arising ethical issues¹³, and particularly governance of ethics is missing. Another concern is if reflexivity is part of the governance process, since without genuine reflexivity, true democracy cannot be implemented in a way that the interests of the society are addressed in an appropriate way, with the ethical imperative respected¹⁴.

¹¹ Reflexivity is an important term within our work, and we give it a specific meaning. According to Goujon and Dedeurwaerdere, reflexivity may be defined as the “capacity of actors and institutions to revise basic normative orientations in response to the evolution of economic, techno-scientific or political systems and to shortcomings in current modes of regulation (Goujon and Dedeurwaerdere, p.1). We will also refer to “first order reflexivity” and “second order reflexivity”. See Glossary in Annex 1.

¹² EU 7th framework program is one of the EU major research funding instruments with total budget over 50 billion Eur.

¹³ We will support this by our case study on the EU FP7 EGAIS project research

¹⁴ For ethical imperative see Glossary in Annex 1.

At the same time, as to our knowledge, there are no solutions provided how to secure that reflexivity becomes part of the governance approaches of the FP7 projects, and in particular with regard to ethical reflexivity. To have more insight into this, we see it important to investigate the ethical framing of the FP7 and its mechanisms for ethical reflexivity in the governance of the ICT research projects. This is important for addressing our actual research problem in relation to the conditions for ethical reflexivity¹⁵ within FP7 ICT research projects, as part of the respective EU policy.

The field of inquiry and research problem of the thesis

The focus of the current thesis will be in the analysis of the EU conception, implementation and assessment of ethical reflexivity in the governance of FP7 research projects. Taking into consideration that the FP7 research projects with their ethical framing represent the outcome of the implementation of the respective EU research policy, and in order to be able to have a critical perspective on the problem, the ethical reflexivity and its effectiveness will be studied at two levels:

1) at the level of EU research policy - with its normative¹⁶ conception and representation of this normative conception in policy and legal documents;

2) at the level of EU research projects. The second level will be used for testing how this normative concept is being translated into practice. Specifically we shall rely on the results obtained from the FP7 EGAIS¹⁷ (The Ethical GovernAncE of technologieS) project implementation. The EGAIS project will be used as a case study, since it has

¹⁵ For ethical reflexivity see Glossary in Annex 1.

¹⁶ Normative is contrasted here with its antonym, positive, when describing types of theories, beliefs or statements. A positive statement is a falsifiable statement that attempts to describe ontology. A normative statement, on the other hand, is a statement regarding how things “should or ought to be”. Such statements are impossible to prove or disapprove.

¹⁷ As we shall explain in greater detail further in the work – our research was carried out as part of the EU FP7 EGAIS project, and we also used the existing research results from the EGAIS project as our case study. For more information on EGAIS project see <http://www.egais-project.eu/>

produced an analysis of the effectiveness and reflexivity of ethics and governance in Ambient Intelligence projects of the EU Framework program.

The role of the EGAIS project in regard to the research and analysis

It should be specifically pointed out here that our present work is being carried out as part of the EGAIS project research¹⁸. Therefore, within our theses we will be relying on the same theoretical approaches and concepts, as developed and used in the overall EGAIS project (with the necessary adjustments regarding our own research problem), in order to secure the methodological consistency and comparability of results obtained. At the same time, it should be pointed out that this is an original and independent study. It is related to the domain that has not been studied within the EGAIS project itself, namely, the ethical framing of the respective EU policy and its governance arrangements.

Thus, on the one hand, by definition we have had to restrict ourselves to a certain theoretical approach in our work. On the other hand, we have been able to benefit from this situation, since the broader context of the EGAIS project and the availability of its research results so far (regarding the ethical framing in the implementation of FP7 projects) has enabled us to encompass a much broader scope for analysis than it would have been possible outside an actual project context. Thus, throughout our research we will be referring to the EGAIS project and pointing out the specific connotations and implications for our own research.

Within the present work we will carry out normative and descriptive analysis, as well as present a critical perspective:

¹⁸ It was agreed between the responsible representatives of Maastricht University and Namur University regarding the second semester placement of the author of the present work – that her research will be carried out within the framework of the EU EGAIS project which is currently being implemented by Namur University

1) in the normative analysis we shall rely on the relevant normative and policy documents, as well as empirical data that represent the conceived EU ethical governance framing itself;

2) in the descriptive analysis we will rely on the collected empirical data regarding the implementation of the relevant EU ICT research policy, as well as on the case study of the EGAIS project. By this we will aim at finding out how the EU normative framing functions in practice in EU ICT project implementation and assessment. This will be used for testing the efficiency and limits of the respective EU normative framing.

3) within the critical perspective we will analyze how normative and functional aspects of ethical governance relate and what are the outcomes of it. We will also see how the outcomes of our analysis relate to our theoretical framework and possibly see its limits. The contextualization of the ICT research projects as part of relevant EU research policy implementation framework will enable us also to draw some broader general conclusions. Based on the findings, we will present a critical perspective and, if not produce recommendations, then at least attempt to indicate some direction for improved EU policy approaches and procedures in relation to issues of FP7 ethical governance.

Being conscious of the enormous challenge of such a research, as well as being aware of the limited scope of the present work, we would like to point out that our aim is not to propose definitive answers to the questions of our research. Instead we are aiming at analyzing the conditions for a reflexive ethical governance in the respective EU policy and its implementation.

The aim and objectives of the thesis

Referring to the overall framework of the EGAIS project discussed above:

1) The field of inquiry of the thesis will be – the representation of ethics and governance reflexivity in technological research and development, as part of EU (FP7)

ICT research policy – with the FP7 ICT research projects¹⁹ as the testing field and actual result of the implementation of the EU (FP7) ICT research policy.

2) *The problem studied in the theses will be* - the effectiveness of ethical reflexivity in EU (FP7) ICT research projects, as part of the implementation of EU research policy.

The aim and objective of the theses will be to answer our research questions.

The key research question to be answered is: What are the conditions for ethical reflexivity in relation to the efficiency of an ethical norm in the context of EU (FP7) ICT research projects? The fundamental challenge to answer this research question will be to determine: What are the characteristics and limits of the proposed system, approaches and theory?

Relying on the produced normative and descriptive analysis, in the final part of the thesis we will:

- 1) have reflection concerning the limits of the actual representation;
- 2) develop critical perspective and will attempt to develop an insight on the conditions for ethical reflexivity and its efficiency;
- 3) develop applied field analysis;
- 4) propose certain guidelines.

Having presented the field and problem of our research, as well as the main aims and objectives, we would like to discuss the theoretical framework for our analysis.

The research approach and theoretical framework for analysis

Before discussing the theoretical framework of our analysis, we would like to point out that we will be relying on the same theoretical approaches as those used by the EGAIS project. Another important aspect we need to point out is the specificity of our overall

¹⁹ We refer to FP7ICT projects in the field of Ambient Intelligence. This was studied by the EGAIS project, and we will use the findings obtained by the case study of the EGAIS project.

research approach²⁰. Our research problem and approach to analysis will not be informed by our empirical studies. We have followed a different trajectory. In the first place we have constructed our research problem based on a theoretical approach. Afterwards we have tested this research problem within our empirical study. Thus, our research results and conclusions will be drawn from this kind of standpoint.

The theoretical framework used for our research will be based on the theory of governance developed by the Louvainist school²¹. The reason for this choice is determined by the used theoretical approaches within the EGAIS project, and is also directly linked to the specific features of our research problem. We were interested in the construction of an *ethical* norm and in the conditions of the application of an *ethical* norm, and the Louvainist school has developed a theory on the action of a norm²². This allowed us to adjust the concepts of the Louvainist school to our own research needs (in the development of the theoretical framework), since our research problem is exactly to address the conditions for a reflexivity which can have a real impact.

In other schools and theoretical approaches that we have identified²³, the primary concern is with the identification (not construction) of an ethical norm, and the conditions for ethical reflexivity are generally pre-supposed. In current more traditional approaches, expertise tends to be the indisputable source of normativity, and the existing and potential problems are often confined to the expert perspectives only. The ethical theoretical approach to be used is traditionally chosen by experts involved in the decision making

²⁰ Our research approach will be discussed in greater detail in Part 3 of the present work.

²¹ The Louvainist school is linked to the Catholic University of Louvain, it is currently a well known and recognised school of governance. Our theoretical approach is based on the large amount of work done by Lenoble and Maesschalck in the Centre de Philosophie du Droit (CPDR) at the University of Louvain. According to Lenoble and Maesschalck, “every norm aims to institute a way of life that is judged to be rationally more acceptable” (Lenoble and Maesschalck, 2003, pp.91-93).

²² The term “action of a norm” is being used according to Lenoble and Maesschalck, specifically referring to “Toward a theory of governance: Action of norms, Kluwer Law International, 2003.

²³ We will refer to these approaches when discussing the theoretical framework of our research in the context of the EGAIS project

process, and the (cognitive) framing²⁴ is determined by their specific field of expertise. If reduced in such a way, the issue of ethical acceptability is transformed to the mere social acceptance of the technology. Therefore, there is a need to investigate and reflect on the governance conditions that allow for an ethical reflexivity inside the project itself, and thus allow to overcome the limits of the existing ethical offer with its endeavour to give answer to the ethical demands.

The theory of governance developed by the Louvainist school directly addresses the problem of the conditions for the effectiveness of a norm expression. Therefore, it will be used as a theoretical background for our approach in the analyses regarding the conditions for the effectiveness of the ethical norm expression, which is the central problem of this thesis. Our proposed framework allows us to investigate and reflect on the ethics and governance conditions inside the project, seeing the process of the production of an ethical norm and its further application within the context of the project itself.

Moreover, this approach enables us to integrate “learning”²⁵ throughout the process of technological development and allows for the broadening of views beyond the technical aspects, raising also the questions regarding values. It should also allow for the suppression of the boarder between the technological and ethical communities, so that there is a relationship between the context and the construction of the ethical norm in technological development. We will attempt to demonstrate that by such an approach an impact to ethical reflexivity can be assured. The use of the above mentioned theoretical framework will also enable us to determine and critically address the drawbacks of the current ethical approaches and allow for the proposition of a more reflexive ethical governance approache.

²⁴ For cognitive framing see Glossary in Annex 1. In general terms, this refers to the individual conception of the world which is connected to some specific framing, e.g. political, economic, technical and other.

²⁵ For learning see Glossary in Annex 1.

Additionally it should be noted that the present thesis does not aim at an in-depth analysis of the theory of governance developed by the Louvainist school. Instead, we will refer to it to justify our theoretical standpoint in the analyses of our research problem on the conditions for the effectiveness of the ethical norm expression.

The research methods

In order to carry out our analysis, we will be using the following methods:

1. Literature search and analyses - for the development of the theoretical framework. After the identification our theoretical framework, our research problem has been constructed within this framework.
2. Application of the theoretical framework - for the construction of the analytical grid. The analytical grid is necessary for the development of the questionnaire (according to certain parameters) for the empirical field study.
3. Textual analysis – legal and policy documents, reports and other documents - for generating normative analysis. By normative analysis we mean the analyses of the conceived respective EU policy.
4. Empirical data gathering and analysis - interviews with EU officials - for generating normative and descriptive analysis). This is necessary for relating policy making to its actual implementation, as conceived by the EU officials.
5. Case study of FP7 EGAIS project (based on questionnaire survey analysis from existing EU project data) - for structured input. This is relevant for testing the results of the implementation of the respective EU policy - from the perspective of perceived governance ethical framing of existing EU Framework program projects.

6. Methodological approach based on the key premises of the SCOT theory²⁶ - for the interpretation of certain conclusions of our research. We will explain in greater detail the reasons for the need to use such an approach further in the work.

Thesis outline

The thesis consists of the introduction, six parts, the conclusions, the bibliography, and the annexes.

In the first part “Science, society and ethics” the ethical issues of technological development will be raised in the context of the modern technological culture, showing that technological developments, societal processes and respective public policy are mutually contingent and cannot be viewed separately from each other. This will serve as a background for a subsequent focus on EU ICT research policy framework regarding ethics and governance issues in FP7.

In the second part “Ethics and governance” background for the theoretical framework of the current thesis will be provided and the theoretical framework itself presented. This will be linked to the issue of governance of ICT projects, and more specifically, to reflexive governance which includes reflection and deliberation on ethics in technological development. The constructed analytical grid for the development of the questionnaire for the interviews with EU officials will be explained.

In the third part “Ethics in governance - from theory to practice. Study of the EU 7th framework program” the empirical analysis will be carried out regarding the FP7 approaches in relation to ethics in the governance of technological projects. The textual analysis and interviews with present and former EU officials will allow us for a deeper insight into our research problem.

²⁶ SCOT is a sociological theory – social construction of technologies. We will refer to this approach in greater detail further in the work.

In the fourth part “Reflecting on the results of the empirical analysis and the critical perspective” we will be reflecting on the results and relation of the empirical data analysis at project and policy level. The analysis of the relationship between the theoretical framework and empirical study results will be presented. Limitations to the proposed model will be outlined.

In the fifth part “Outcomes, proposed guidelines and lessons learnt” we will develop upon our findings and research results in relation to our theoretical framework and from a wider policy perspective.

In the sixth part “Implications for EU research policy” key challenges to be addressed by the EU research policy regarding ethics in the governance of FP7 will be presented. Some fundamental conditions that are to be met to this end will be proposed. Ways will be suggested how the theoretical conclusions could be translated into practice – in a form of recommendations.

In the Conclusion key findings and critical remarks will be enclosed.

List of literature will comprise books, reports, articles and e-resources.

The Annexes will comprise:

Annex 1 Glossary

Annex 2 The analytical grid and grid for data analysis - description

Annex 3 Template (questionnaire) for interviews (within empirical study)

Annex 4 Interviews with present and former EU officials

Annex 5 Analysis of relevant EU reports and working documents

Annex 6 Documents and procedures relevant to the FP7 ethical framing

Annex 7 Analysis of empirical findings according to parameters within the analytical grid

Annex 8 Analysis of identified governance arrangements according to the grid

Annex 9 Case study of the EGAIS project

1. Science, society and ethics (*Ethics in trouble*)

Abstract

In this part challenges of technological development for society will be analyzed. Justification will be presented why ethics regarding scientific and technological development is increasingly important today. The general tendencies in EU policy making and governance approaches regarding ethics in science and research will be identified and outlined in order to set a general background for a further focused analysis regarding the ethics and governance issues within FP7 in relation to our specific research problem.

1.1. The double edged scientific advances of modern society

We live in a culture where the technological developments, the societal processes and respective public policy are mutually contingent and cannot be viewed separately from each other. It is a new “technological culture”, as pointed out by Bijker, and it is “so permeated by science and technology that it cannot be properly understood without a careful analysis of the particular roles of science and technology” (Bijker, 2009, p.7). Moreover, the older assumptions on science as essentially progressive and beneficial no longer hold true, and “there is concern in society that scientific advances have become double-edged; ...there is also fear that science based technology is running out of control” (Ravetz, 2008, p.11).

Ravetz here evidently refers to the increased level of risks and inherent uncertainty related to technological development, with its potential threats (and respective impact to the modern society). In recent decades these issues have widely been represented in academic and political discourse. Since risks and uncertainties in technological development can potentially affect people and their values, this issue clearly has an ethical dimension. To justify this, we shall rely on some academic and political discourse on it (showing that technological development may representing the source of ethical challenges

for the society as a whole). As pointed out by Bijker “risk and scientific uncertainty are central characteristics of technological cultures” (Bijker, 2009, p. 158).

Although the issues of ethical governance as part of modern technological policy making will be addressed in the second part of the work, already in this part we wish to introduce ethical governance as a notion and object within the deliberation processes of EU research policy. By doing so our aim is to contextualize our research questions regarding determining the conditions of ethical reflexivity in the governance of the respective EU research policy from the very start. Here we will refer to the Report of the Expert Group²⁷ “Global Governance of Science”:

“The loss of deference to expertise reinforces the need to construct new models of governance for a more skeptical age. Finding ways to involve the public and other stakeholders across a spectrum of activities – including the assessment and management of risks, uncertainties, ethics and the funding of research – is key to the construction of successful governance. Connections with the public should no longer be viewed as exercises in better communications from a privileged elite. Policy makers increasingly recognize that deliberation is a cornerstone of good governance. What global deliberative governance might look like nevertheless remains unclear” (p. 27).

Thus, the task of the development of a deliberative and reflexive governance in the EU ICT research policy must be viewed in the context of the challenges the modern society and technological culture presents. Therefore, based on our textual analysis, we will attempt to identify and outline these challenges, as the overall background and context for modern policy making and governance. In other words, we will highlighting these “double edged scientific advances of modern society”²⁸.

We will attempt to show that in the respective academic and policy discourse, risk and uncertainty (with its inherent dangers) are being viewed as the key factors causing

²⁷ Report of the Expert Group on Global Governance of Science to the Science, Economy and Society Directorate, directorate-General for Research, European Commission “Global Governance of Science”, European Commission, 2009.

²⁸ “Double edged scientific advances of modern society” is a citation from Ravetz (2008, p. 11).

concerns, ethical concerns including. Beck²⁹, for example, states that alongside with the growth of uncertainties of scientific judgment, also the grey area of unrecognized suspected risks grows. He argues that “if it is impossible anyway to determine causal relationship finally and unambiguously...then where does anyone derive the right to believe only in certain risks (Beck, 1992, p.71).

In the same line of argumentation Nowotny et al claim that the time of predictability is gone, when we believed in simple cause-effect relationship with the implicit assumptions of linearity; instead it is argued that many - perhaps most - relationships are non-linear and subject to ever changing patterns of unpredictability (Nowotny et al, 2001, p.5).

It is no surprise, therefore, that these societal concerns are addressed in political discourse as well. As pointed out, for example, in the Communication of the European Commission³⁰ “decision-makers are constantly faced with the dilemma of balancing the freedom and rights of individuals, industry and organizations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health”. As pointed out by Beck “in the future it will become a central insight for the role of *all* sciences that one requires an institutionally strengthened and protected moral and political backbone in order to be able to conduct respectable research at all” (Beck, 1992, p. 82).

Given the complexity of the task, it is no surprise that the policy makers may be running short of backup in finding approaches for addressing the new ethical challenges in technological development. As pointed out by Goujon and Lavelle, we should realize the failure of a method that consists of basing every ethical problem on a sociological analysis

²⁹ Beck refers to risk as an inherent part of technological development and similarly stresses the uncertainties which are to be faced globally regarding technological development and its implications. He speaks about “consequences which relate to the threatening force of modernization and to its globalization of doubt”.

³⁰ Communication from the Commission on the precautionary principle.
http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf

of the functioning of a techno-scientific system and decision making, all of which is related to a unified and reconciled normative framework where scientific truth founds good ethics (Goujon and Lavelle, 2007, xviii). Clearly, new governance approaches are needed in order to address these complex challenges of modern technological culture, its ethical challenges including.

The above analysis has been done in order to present a general background regarding the non-ambiguous nature of modern scientific development with its risks and uncertainties, and to show that these developments also create ethical challenges for the modern society. We have demonstrated that the global risk and uncertainty, not exclusively, but to a high degree can be viewed as the source of these new ethical challenges. Therefore, further on we will attempt to justify more specifically why ethics in technological development matters.

1.2. Justification – why ethics in technological development matters

It is already a common knowledge today that the globalization, digital convergence, nano and biotechnologies may be offering new unprecedented benefits. We can follow in media and academic research that these new technologies can potentially solve problems related to our employment, security, health and leisure. At the same, it is a common knowledge that this innovative research can potentially affect the human health, welfare, security and even life in certain detriment ways or ways yet unknown to us. Since these technological developments refer to our values, they are coloured with ethical implication (as ethics inherently refers to values)³¹.

We will specifically refer in our justification to the ethical aspects in the emerging information and communication technologies, since these technologies are affecting almost all of us in our everyday life and since our research is also restricted to this field (as we have mentioned before, our research is part of the EGAIS project which has

³¹ For ethics and its implications see Glossary in Annex 1.

specifically focused on FP7 projects dealing with ambient intelligence³²). Moreover, it has been recognized in various studies that these new technologies imply complex ethical, legal and societal issues³³.

The awareness of ethical implications of the emerging technologies is manifested also as a public concern, which we have witnessed over the past decades. People are becoming increasingly aware that the applications of new technologies are already having or can have impact on human lives in ways that are yet unknown to us (as we have indicated already regarding the well known GMO case).

Regarding ICT, the realization is coming in people of not a far away future when the environment around us will include various devices capable to detect human presence or collect data without us being aware of it, and “unwanted data matching with detriment effects on privacy may take place due to digital convergence coupled with the ever-increasing tracking and collecting of data about individual European citizens, through online activities, ambient technologies, RFID and biometrics³⁴”.

There are more examples that show – today’s technologies are not neutral, they have and potentially can have increasing effect on human integrity, security and welfare. It is therefore not surprising that the Charter of the Fundamental Rights of the European Union³⁵ addresses the rights of European citizens regarding physical and mental integrity, security and personal data protection³⁶. This makes us increasingly aware of the existing

³² Projects on ambient intelligence are being funded under the FP7 program, and the EGAIS project has been doing research on these particular projects, more specifically regarding their ethical framing.

³³ SWAMI (Safeguards in a World of Ambient Intelligence) which aim to identify and analyse the social, economic, legal, technological and ethical issues related to identity, privacy and security in the forecasted but not yet deployed Ambient Intelligence (AmI) environment <http://swami.jrc.es/pages/index.htm>.

³⁴ As pointed out in the publications of the European Group of Ethics in Science and New Technologies (which is an advisory body to the European Commission) “Ethically speaking” http://ec.europa.eu/european_group_ethics/publications/index_en.htm

³⁵ Charter of the Fundamental Rights of the European Union (2000/C 364/01), Official Journal of the European Communities C 364/1.

³⁶ Article 3 of the Charter stipulates that “everyone has the right to respect for his or her physical and mental integrity”, Article 6 stipulates that “everyone has the right to liberty and security of person”, addresses the rights of the European citizens also in a new and more specific way (Article 8 stipulates that “everyone has the right to the protection of personal data concerning him or her; such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid

and potential ethical aspects in technological development. This also makes us look for ways to deepen our understanding of these challenging and their possible solutions. Brey claims “it is critical to ‘disclose’ and make visible the values at stake in the design and use of computer technology”; he urges for a “disclosive computer ethics”. (Brey, 1999).

We must be aware of the complicated nature of the task of addressing the impacts of the new technologies, as “ICT does not only involve technological aspects, but also epistemology, since the main component of ICT is information which represents data, information, and knowledge” (Sembok, 2003, p. 244). We find us in a completely new environment. A comprehensive approach needs to be found in dealing with new technologies and their ethically often ambiguous nature. Therefore we shall show that technological developments not only create challenges for the society but also contribute to new forms of societal involvement in addressing these arising ethical challenges.

1.3. Ethics in technological development - implications for society and new forms of governance

Today’s society is frequently called the information society³⁷, knowledge society³⁸ (or even risk society)³⁹. The new order of economic, social and political arrangements that has emerged over the past two decades, are highly related to the production, organisation, as

down by law; Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified”).

³⁷ The notion information society: “In 1973, United States sociologist Daniel Bell introduced the notion “information society” in his book *The Coming of Post-Industrial Society* [1], where he formulates that the main axis of this society will be theoretical knowledge and warns that knowledge-based services will be transformed into the central structure of the new economy and of an information-led society, where ideologies will end up being superfluous.” (Sally Burch: “The Information Society/ the Knowledge Society” on <http://vecam.org/article517.html>).

³⁸ The notion “knowledge society” (“sociedad del conocimiento”) emerged toward the end of the 90s and is particularly used as an alternative by some in academic circles to the “information society”. For example, Abdul Waheed Khan (general sub-director of UNESCO for Communication and Information) writes [3]: “Information society is the building block for knowledge societies. Whereas I see the concept of ‘information society’ as linked to the idea of ‘technological innovation’, the concept of ‘knowledge societies’ includes a dimension of social, cultural, economical, political and institutional transformation, and a more pluralistic and developmental perspective. In my view, the concept of ‘knowledge societies’ is preferable to that of the ‘information society’ because it better captures the complexity and dynamism of the changes taking place. (...) the knowledge in question is important not only for economic growth but also for empowering and developing all sectors of society.” (Ibid).

³⁹ The notion of risk society has been developed upon by Ulrich Beck.

well as exchange of knowledge. Already Beck almost two decades ago points to the importance of analysing the social and political dynamics of ... society alongside with its technical, chemical, biological and medical expertise (Beck, 1992, p. 51).

Previously we have discussed ethical implications of technological development and their effects on individual members of the society and society as a whole. Now we would like to point to the changing role of society in regard to the technological development. We have traced from various sources that society has become increasingly distant from idealistic perceptions of science, and instead has become more aware of its “incorporated”⁴⁰ nature. The discovery has come that “science is to a great extent motivated by power and profit, where eventual societal benefit is mediated through those primary goals” (Ravetz, 2008, p. 11).

The public debates on contradictory technological developments⁴¹ show that societies are not indifferent or neutral towards the new technological developments and actively react towards the potential threats or identified risks to human health, security, dignity or even life - “there are some fundamental aspects of social experience that lie at the centre of public unease with science in Europe” (TEKSS⁴², p.10). The above mentioned “social experience” (science having become a socially sensitive issue⁴³), in our

⁴⁰ According to Ravetz (in Ravetz, 2008).

⁴¹ Like debates on GMO, genetic engineering, nanotechnologies and other research.

⁴² As pointed out by Expert group on science and governance to the Science, Economy and society Directorate of the Directorate-General for Research in the European Commission in its report “Taking European Knowledge Society Seriously” (TEKSS report).

⁴³ Indeed, “science and technology must be at the service of safeguarding the human heritage, and science and technology should not introduce new constraints or discrimination”, as pointed out in the Report by the European Group of Ethics in Science and New Technologies “Citizens rights and new challenges: a European challenge”(pp. 3., 4). Thus, one of the key challenges regarding technological development and its ethical implications is – how to find a balance between the useful aspects to the benefit of society and the detriment effects that may harm people, or, in other word, how to be wise enough not to hinder development in the name of unknown threats (which may also never become existent). According to Jasanoff, the question is not only “whether we will get affected and under what conditions but also ... how we should live with uncertainty and ignorance” (Jasanoff, 2003, p. 224). Being aware of the important role of the conditions of uncertainty and the increased risks in relation to current technological challenges, it should be pointed out, however, that ethics cannot be reduced to risk assessment or management. In addressing the current technological challenges, ethics needs to be part of the process. At the same time we need to address the question if we can limit ethics to rational choice only. It is much debated if risk assessment is an effective measure to address ethical challenges in technological development. As pointed out in the Report from the European Commission Services on Options for Framing Public Policy “in the development of ...

opinion, has preconditioned the developments we see today - the emerging implicit and explicit demand for new modes of governance. As these new forms of public response emerge⁴⁴, one should ask - by whom and in what way these sensitivities are to be addressed, because of “the rapidly-changing context of global science and the pressing need for new forms of dialogue, across border, between disciplines (scientific and non-scientific) and countries (developed and developing)”⁴⁵.

As part of these new forms of governance of science, we can refer also to governance of *ethics* in science, since “given the power of science to influence human affairs in general, the broader society has a vested interest in insuring sound governance”⁴⁶. At the same time, there is one fundamental novelty in the situation, which related to the field of our research - “public policies are faced with the problem of regulation and social order in a society characterised by the multiplication of sources of normativity” (Goujon and Dedeurwaerder, p.2). The fact that today’s research cannot any more rely on a clear source of normativity⁴⁷ has promoted also our interest in the present research, and this question, due to its complexity, can be seen as a real challenge to any researcher⁴⁸.

technologies, there is not yet a shared understanding of how we might define the acceptability of possible risks, or of how we would weight them against possible benefits” (p. 10).

⁴⁴ Bucci, for example, argues that “various forms of public mobilisation have arisen in relation to specific scientific and technological initiatives, and, in general, there is increasing concern over the unforeseen and unwanted effects of scientific and technological progress on the environment and human health (Bucci, 2004, p.139).

⁴⁵ Global Governance of Science. Report of the Expert Group on global Governance of Science to the Science, Economy and Society Directorate, Directorate-General for Research, European Commission. European Communities, 2009, p.26.

⁴⁶ Global Governance of Science. Report of the Expert Group on global Governance of Science to the Science, Economy and Society Directorate, Directorate-General for Research, European Commission. European Communities, 2009, p.25.

⁴⁷ Here we are referring to formerly accepted various sources of normativity, e.g. religion, scientific expertise etc. which were considered as authoritative and which is not the case any more.

⁴⁸ While recognizing society as an important actor in the debate on research and development, we have to point to several important aspects of general nature that create difficulty in addressing the potential ethical issues. Deriving from what we have discussed previously – the new global risks and the unprecedented degree of uncertainty – people find it difficult to position themselves regarding what is an ethical action or approach in relation to technological development, and in what way and how far our individual responsibility reaches. Consequently we are faced with the dilemma of our individual versus collective role responsibility. These are the two sides of the dilemma – to face the inherent potential uncertainty of the effects of technological developments and to chose the best possible way for action at individual and also societal level. As argued by Kimppa, it is important to address these issues in order to preserve an ethically viable society: “The unintended consequences of rapid technological development and explosive knowledge

Society and public policy needs to find the right approaches for deliberation on what is the meaning of ethics in today's technological society, and what are the means and tools for making ethical approaches and frameworks function effectively and to the purpose. Although the question of governance of technological development will be addressed in greater detail in the second part of the present work - in relation to the ethical aspects of technological development and in the light of our research question - we would like to introduce already here the issues that are relevant to our research in the context of emerging modes of governance in relation to the changing role of society in this process.

Through our textual analysis we have been able to identify the following challenges: 1) dealing with increased risk and uncertainty; 2) dilemmas of individual and collective choices – as, for example, regarding how to define what is ethics and an ethical norm in technological development (given that the new developments have deprived us of clear normative horizon and we can speak of multiple sources of normativity); 3) who is an expert on ethics in technological development; 4) how to come to a decision over a contradictory issue and what stakeholders and in what ways should be involved; 5) what are the general implications for a sound governance.

These questions are not easy to answer, since the (impact of) technologies and the development of society, being mutually contingent, today have contributed to the increased difficulty in finding a clear source of normativity. Therefore, now we need to question the more traditional perception that “ethics refers to well-based standards of right and wrong that prescribe what humans ought to do, usually in terms of rights, obligations, benefits to

creation have decreased the area of personal ethical choice by directing the possibilities open to us and at the same time closing other possibilities. Personal and institutional changes – increases in roles and in institutions – have also decreased opportunities for personal ethical choice. Since role responsibility – which follows from these – is clearly not enough for the new technologically and socially complex times, we need an ethics of collective responsibility. Discourses, fact analysis, foresight, even constitutional change may be needed to ensure an ethically viable society” (Kimppa, 2007, p. 37).

society, fairness, and specific virtues” Sembok, 2003, p.243)⁴⁹. Are these traditional sources of normativity helpful when dealing with ethics of technological development in modern technological cultures? In our understanding, ethics cannot be reduce to mere standard application, but instead should be related to the issue of ethical imperative and reaching the “normative horizon”, since these questions are related to human conception⁵⁰.

In the following chapter we will outline key identified relevant response of public policy regarding these identified challenges, also to provide a general background for a further more specific analysis of ethics and governance aspects in the EU FP7.

1.4. The responses and responsibilities of public policy regarding ethics in science and technological development

In seeking to understand the complex processes in science, society and technology, we have to recognize that “institutional practices in science and technology are tacitly shaped and framed by deeper social values and interests”⁵¹, or, proceeding from a similar line of argumentation, that “technologies are socio-technical systems; they are systems of artifacts together with social practices, social relationships, social institutions and values (Johnson, 2007, p.5). For this reason we would like to outline the responses and responsibilities of public policy making within the context of research and technological development, since the public policy is responsible for addressing the needs, concerns and rights of the individual members of the society. This will also serve as a background for our further focused analysis of ethics and governance aspects in the EU FP7, as part of EU research policy.

⁴⁹ These approaches since long has been rooted in our conscience and social experience, and it well reflected in classical ethical theories.

⁵⁰ The ethical imperative is related to the notion of “normative horizon” (that is, the ideal goal for how the world should be) and the relationship of ethics with context. It is supposed that ethics should be free of any contextual constraints, so that it can aim at an ethical normative horizon.

⁵¹ Report by Expert group on science and governance to the Science, Economy and society Directorate of the Directorate-General for Research in the European Commission in its report “Taking European Knowledge Society Seriously, p. 9.

The relationship between ethics and public policy has a long tradition in Western philosophy and culture, going back to classical approaches by Aristotle. Public policies in various branches since long have been aware of the need for certain ethical norms or standards⁵². However, these culturally rooted attitudes towards ethical issues, as discussed previously, face new challenges. Today the modern technologies not only themselves are being subject to ethical reconsideration by various stakeholders, but as such have challenged the deliberation on technological development, as well as the basic moral presuppositions and assumptions regarding ethics (and deliberation on ethics) in public policy⁵³. According to Goujon and Dedeurwaerdere “if one takes as given the functional differentiation of society and the multiplication of sub-systems, each employing its own rationality and each running the risk of closing in on itself, the question arises not only of communication between these sub-systems, but of where the legal system stands in relation to them (Goujon and Dedeurwaerdere, p.2)⁵⁴.

Ethics today has become part of public discourse – as political, legal and social debate, and “the rise of ethics as a public discourse may be interpreted as a symptom of

⁵² Historically in Europe the first ethical code of conduct has been known as Oath of Hippocrates – an ethical standard for practicing medical science. Since then the idea of a professional code of ethics are deeply rooted in the European culture, and the Oath of Hippocrates serves as a model for other professional domains, scientific society including

⁵³ Alongside with the questions and arguments presented, we would like to argue additionally that today a new an important institution has gained force and power – the global digital medium or digital environment. Some authors claim today that the public policy making has changed in a fundamental way due to the introduction of digital media, and due to the impact of modern technologies on the society as a whole. Consequently, the public policy making cannot be viewed separately from this particular impact, and technological development, society and public policy making are mutually contingent, including the ethical dilemmas that emerge. Capurro, for example, points to Internet as a decentralized digital and global media, a digital networked environment that “creates new opportunities for ethical, legal, and political discourse as well as for individual and social political action” (Capurro, 2005, p.22). Similarly, McLaren points out that that public opinion on ethics in science and technological development “is affected by the availability of information, the existence of at least some honest and intelligent media, and the level of public discussion” (McLaren, 2005, p.33).

⁵⁴ Winner, for example, points to the distinction between “conditions that are *internal* to the workings of a given technical system and those that are *external* to it” (Winner, 1980, p. 130). When deliberating on the proposed scholarly approaches on “conditions internal to the system or external to it (or both)” he argues that “arguments in this general category do have an important presence in modern political discourse” and further on puts the important question: “Does this state of affairs derive from an avoidable social response to intractable properties in the things themselves, or is it instead a pattern imposed independently by a governing body, ruling class, or some other social or cultural institution to further its own purposes?” (Winner, 1980, p. 131).

the moral crisis arising in complex modern societies that can neither be solved by an implicit or explicit moral tradition nor by state policy alone”⁵⁵. The novelty of the present situation is that “ethics is considered to belong to the public debate at an institutional political level”⁵⁶. Thus, we can see that ethical discourse on science and technologies is not any more a prerogative to any particular social, religious, academic or political group, but has become contingent on multiple stakeholders.

According to Capurro⁵⁷, “political ethics conceived as a discourse in between public policy and society opens possibility not only to reflect publicly on the foundations of morality including its legal fixation, but also to give politicians a space of reflection beyond the constraints of political parties” (Capurro, 2005, p. 19). Consequently, it follows that ethics today is becoming an indispensable part of public policy deliberation and governance, and good governance today cannot be void of ethical consideration.

Having presented the overall societal background, in the following part of the work we will introduce the issues of ethics and governance in relation to our actual research field and problem.

⁵⁵ As pointed out in the General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission 2000 – 2005

⁵⁶ Here we are referring to arguments by Capurro within the General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission 2000 – 2005, p.19.

⁵⁷ It should be noted that Dr Rafael Capurro, Professor em, is the former member of the European Group of Ethics and has published extensively on the issues of ethics in research and technological development. Rafael Capurro also kindly agreed for an interview in the framework of our research. For interviews see Annex 2.

2. Ethics and governance

Abstract

In this chapter we will introduce ethics and governance as part the new normative discourse in the EU policy making and as a response to the new challenges in technological development. As relevant to our research problem and research questions, our analytical approach will be to see this in relation to the effectiveness of ethical norms (from the conditions of their emergence to their implementation).

We will refer to the analysis of the current ethical offer, and will point out the limitations of the existing approaches. The outlined shortcomings of the current ethical theory will serve as a justification for a need of a new theoretical framework in addressing ethics in the governance of technological development. The underlying concepts and approaches in our proposed theoretical framework regarding the construction and efficiency of an ethical norm in a specific context, as well as reflexive approaches to ethics in governance will be presented.

2.1. Ethics and governance as part of the new normative discourse

As discussed in the previous chapters, the new societal developments have been reflected also in public policy making. In its turn, the public policy making has evolved accordingly - “a new range of political practices has emerged between institutional layers of the state and between state institutions and societal organisations” (Hajer and Wagenaar, 2004, p.1).

At the same time, it is argued by Hajer and Wagenaar that “one of the most striking developments in the analysis of politics and policy making is the shift in vocabulary⁵⁸ that

⁵⁸ Some scientists argue that today a whole ‘language of governance’ or ‘vocabulary of governance’ has emerged, and claim that it “opens up the cognitive commitments implicit in thinking about governing and political decision making” (Hajer and Wagenaar, 2004, p.2). It is also argued by Hajer and Wagenaar that “the language of ‘governance’ seems to help practitioners and theorists alike to unlearn embedded intellectual reflexes and break out of tacit patterns of thinking. This stimulates them to re-think governing, politics and administration against the backdrop of these changing societal processes” (Hajer and Wagenaar, 2004, p.2). Thus, we can see that the shifts in the language are not to be seen as a mere linguistic

has occurred over the last ten years” (2004, p.1). This new vocabulary is reflected in European policy documents as well⁵⁹, and, as we will show, the implications of this new vocabulary and its content are relevant to our present work. Thus, for example, the phrasing “normative discourse” is increasingly used to substitute the previously used term of “legal discourse”⁶⁰, thus reflecting the content of the changing modes of regulation in society⁶¹.

This chapter will specifically deal with some new developments in governance, and according to our findings from textual analysis, will represent ethics as part of good governance. It is being argued that less formal and less obvious normative domain of initiatives and practices have been extended in Europe “by a broad shift away from direct and explicit modes of regulation towards ‘soft’, non-legally binding instruments, such as codes of practice, fiscal incentives, audit and reporting measures – in short, by the shift from legislatively authorised *government* to administratively implemented *governance*”⁶².

Moreover, the very term of “governance” has arisen from the growing awareness that “keeping a country ‘governed’ involves more than the various traditional branches of ‘government’ doing their things” and that in governance “command-and-control was replaced by negotiation and dialogue”⁶³. The governance-based approach, according to Tait, has been promoted to achieve “more democratic and more robust political processes

phenomenon. Instead, it should be viewed as a meaningful signal on shifts in the very process of our thinking in regard to regulatory processes in society.

⁵⁹ Already the titles of various EU policy documents represent this shift, and certainly the content of these documents. For example, we can trace it in Von Schomberg, R., Pereira, A.G. & Funtowicz, S. (2005). *Deliberating Foresight-Knowledge for Policy and Foresight-Knowledge assessment*. European Commission.

⁶⁰ According to the report “Taking European Knowledge Society Seriously. Report of the Expert Group on Science and Governance to the Science, Economy and Science Directorate, Directorate-General for Research, European Commission. European Communities, 2007” (TEKSS Report) – the shift from the term “legal discourse” to the term “normative discourse” represents normative developments that have a legal or quasi-legal function, but that are easily missed if we look for them under the conventional heading of the “legal”. The word “discourse” in its turn is used in order to include the ways in which important but implicit shifts in normative orientations are shaped not just by deliberate regulatory initiatives, but also by language and practices which appear to have no regulatory dimension (p.43).

⁶¹ See footnote 57.

⁶² TEKSS Report, p. 43.

⁶³ Here we are referring to the EU Research in Social, Sciences and Humanities. *Science, Governance and Society*. Policy Review Series No12. European Communities, p.8.

and decisions, distributing power more equitably across societal groups” (Tait, 2009, xiii). Since science and technology are so crucial elements in policy making⁶⁴, the ethical aspects of science, as an inseparable and inherent part of it, are also to be viewed with an increased attention and sense of responsibility⁶⁵.

Although ethics and governance as notions, as well as the actual content of them (as elusive as it sometimes is) have become an indispensable part of today’s European policy making, and ethics discourse is being viewed as an important mechanism in governance to secure sound relationship between science and society, the actual application of ethics in practice, as we have seen through our textual analysis⁶⁶, still tend to be viewed as a sort of control mechanism which often has little to do with real ethics. There is some indication in the present research policy discourse that the well established legal mechanisms, even when combined with the democratic debate methods, can hardly give meaningful answers how to deal with ethics in practice.

According to the TEKSS report⁶⁷, ethics on the one hand, “has become a self-legitimizing way to serve the same functions as politics and law”, but, on the other hand, has “neither the democratic deliberative mechanisms nor warrants required by legal systems to protect citizens against state power” (TEKSS Report, p. 47). Thus, there is an

⁶⁴ We have argued already previously that today’s European policy making not only depends on science and technology, but science and technology has become an integral part of it. According to Wynne et al. “science and technology do not simply represent one among many tasks for policy and law, but are a founding political principle of the European knowledge-based society that provides the means and frames the ends of policy” (Wynne et al., 2007, p. 46).

⁶⁵ However, as our analysis shows, the ethical issues in political discourse regarding science and technology has become sort of a ‘stumbling block’ or a particularly challenging issues, and there are no clear answers so far, how these issues should be dealt with. There are many reasons for this, which we have already pointed out and will discuss further on. However, clearly it is not satisfactory any more to use ethics as a ‘label’ to make science socially acceptable, and there must be much more to it.

⁶⁶ For example, we might refer to Von Schomberg, R., (2002). *The Erosion of Our Value Spheres: The Ways in which Society Copes with Scientific, Moral and Ethical Uncertainty*. Publishes in: “Discourse and Democracy. On Habermas ‘Between Facts and Norms, ’edited by Rene von Schomberg and Kenneth Baynes, chapter 10, p. 219-245 Albany: Suny press, ISBN: 0-7914-5498-3

⁶⁷ Taking European Knowledge Society Seriously. Report of the Expert Group on Science and Governance to the Science, Economy and Science Directorate, Directorate-General for Research, European Commission. European Communities, 2007” (TEKSS Report).

inherent weakness in the very approach when dealing with ethics in public research policy making, at least with regard to the balance of the capacity of various actors⁶⁸.

We need to keep in mind that “the domains of ethics, and also of risk, uncertainty and precaution, are key European arenas in which scientific and ethical expertise, normative issues, and questions of public deliberation, are intersecting in new ways” (TEKSS Report, p. 46). According to our understanding, however, the real challenge is not only in the identification of the ethical challenges and the new patterns how these challenges arise, but also in thinking of a comprehensive and flexible ethical frameworks⁶⁹ to deal with these challenges in practice⁷⁰.

Consequently, in order to seek solutions to the identified problems, first we should look at the current ethical offer at theory level. Further we will present analysis of the current ethical offer and point to the limitations in regard to the ability of these approaches to address the new needs of ethics in technological development.

2.2. The current ethical offer and its limit

In the previous part of the work we analyzed the ethical challenges as part of the political,

⁶⁸ There are various aspects to the problem regarding legitimation, as related to the non-ambiguous roles and capacities (mandates) of various stakeholders (even if the democratic procedures are well established and properly functional). As pointed out by Von Schomberg, regarding the negotiation processes with social groups as recognised stakeholders, “not much can be expected in terms of quality of these consensuses that arise in the context of strategic action and under the conditions of unequal power (Von Schomberg, 2002, p.231). Moreover, as argued by Von Schomberg, problems arising by legitimation processes are characterised by a state which “on the one hand, in its planning, cannot concur with opposing interest groups on how to interpret situations, and on the other hand, it is confronted by citizens who are protesting against being overwhelmed by innovation processes which they are not allowed to decide upon” (Von Schomberg, 2002, p. 31). Thus, we can see that the very democratic procedure may not any more be an answer in principle regarding the various interests of stakeholders.

⁶⁹ Regarding the development of an ethical framework -we would like to point to the distinction between the legitimation and application of an ethical norm. The legitimation of a norm cannot be effective without taking into account the context of its application. This, however, can be secured only if true ethical reflexivity takes place.

⁷⁰ Although the rise in institutional ethics as a mode of EU governance is an important development, and there are many instruments and approaches put in place, like risk management, application of precautionary principle and other, we must be aware that ethics is not limited only to the issue of risk or to any sectorial approach, neither its is sufficient to just identify the potential ethical issue and then deal with it according to the existing legislation, since that is usually not a solution to the problem. We will attempt to justify it throughout our work.

as well as scientific discourse. Now we need to look if the current ethical offer in principle can address these problems⁷¹. This will allow us to point out the limitations of the current ethical offer with regard to our identified challenges and needs, as well as justify the need of a new theoretical approach in addressing ethics in today's governance of technological development.

Here we are “stepping back” for clarification purposes. Since we are aiming at the analysis of the actual ethical framing of the EU ICT research policy and the instruments for implementing this policy, we will need a theoretical framework for it. However, in order to create such a theoretical framework, we must analyze the present ethical offer and base our proposed framework on its identified limitations. At the same time, when analyzing the limits of the current ethical approaches and in formulating our own theoretical framework, we need to keep in mind the new ethical challenges discussed previously. Only by such a methodical approach we will be able to carry out relevant analysis of the ethical framing of the EU research policy and its implementation, and further on propose potential solutions to the identified problems⁷².

Based on the fact that our research is being carried out as part of the EGAIS project⁷³, in our study of the current ethical offer and its limitations, we will have to be consistent and to a certain degree rely on the analysis carried out by this project, in order to secure a uniform methodological approach within the whole of the EGAIS project, also for

⁷¹ In order to analyze the current ethical offer and point out its limitations with regard to the current ethical demands, we need to see it from a certain theoretical perspective. We are basing our approach on the standpoint that most theoretical approaches explicitly or implicitly presuppose that the conditions that determine the effectiveness of the implementation of a norm are supposed to be linked to rules within mind, and therefore are supposed to be a function of mental capacities (EGAIS deliverable 2.1.).

⁷² As we have discussed above, the current governance approaches cannot or can only partly address the ethical issues of new technological development in regard to sound research. There is clearly a need for a new ethical approach that would address the new problems more effectively. By analyzing the existing ethical offer from a more theoretical perspective we will be able to see the underlying mechanisms of current ethical practice, as well as the ability or inability of these mechanisms to precondition solutions in principle. In other words, we will analyze the current ethical offer and point out its limitations with regard to the current ethical demands, in order to justify the need for a new theoretical framework concerning ethics in the governance of ICT research projects.

⁷³ For more details on the role and meaning of the EGAIS project see the information presented in the Introduction of the present work.

the comparability of results. The analysis of the current ethical offer and its limitations, and the obtained results and conclusions from the analysis within the EGAIS project will serve us as a platform for proceeding with our own research question⁷⁴.

As a result of the analysis carried out within the EGAIS project⁷⁵, it can be concluded that most of the existing theoretical approaches to ethics are concerned with the ethical issue determination, but do not propose how the ethical issues could be resolved. Most of these theoretical approaches presuppose – the conditions that determine the effectiveness of the implementation of a norm are supposed to be linked to rules within the mind and therefore are supposed to be a function of mental capacities which are independent of the external subjects' context and presuppose the context as given⁷⁶. In other words, in the existing theoretical approaches, the conditions of ethical thinking are not addressed, and no solution is offered how to overcome the contextual limits. This has been the key aspect in the critique by the EGAIS project and thus presents the main limitations of the current ethical offer⁷⁷.

⁷⁴ As pointed out previously – the EGAIS project envisages to carry out the analysis at two levels – at the level of EU 7th framework program technological projects and at the level of EU 7th framework program policy making level. The author of the present work is conducting her research exclusively on the second level regarding EU research policy. At the same time, the available results of the technological project analysis completed by the EGAIS project will serve us as a case study, and more importantly, also as a test for the efficiency of the implementation of the EU research policy. Therefore, it is essential that the same theoretical approaches are used for the analysis at both levels of the EGAIS project research – on the level of EU ICT project implementation and at the level of EU ICT research policy. The identified limitations of the current ethical offer are relevant for us in the construction of the theoretical framework for our research.

⁷⁵ Our analyses of the EGAIS project reports has shown that in terms of the current ethical offer, the main philosophical approaches identified as relevant to our research problem and as analysed by the project are - analytical, pragmatic, contextualist and semantico-symbolic. These philosophical approaches have been studied regarding their pretension to address the diversity of ethical demands of society and individuals, as we have described these above. However, more importantly, the analysis has been done proceeding from the overall research interest of the EGAIS project and bears relevance to our present research - regarding the conditions for effective integration of ethics in an actual context (in our case, the context is the EU ICT research projects as the result of the implementation of respective EU research policy).

⁷⁶ EGAIS project deliverable 2.1.

⁷⁷ According to the EGAIS project, the conclusion is that contemporary ethics keeps its diversity, with the diversity of tendencies hiding some of the specificity and its consequences. Ex-analytical ethics (Rawls) and pragmatics ethics (Habermas) postulates a semantic indetermination. Semantic ethics (Ricoeur) finds that the legitimisation process of the norm does not belong to ethics, but that the real ethical question is the response to the injunction of the suffering of others. Contextualist ethics (Taylor) proposes a realistic ethics of the way that the subject assumes its cultural space. The semantico-symbolic approach appears to be a connection between ethical efforts and life in itself, with the openness of the structure constitutive of the subjection to the injunction of historical reality. The problem is, however, the necessity of the voluntary disposition of the actor, under the law that the actor gives to itself. Ethics meets its main challenge when it confronts human

Consequently, the highlighted limitations have determined the aspects that need to be addressed by new and more adequate frameworks. A potentially more suitable approach - the proceduralism⁷⁸ – had been identified. There are certain general features in the proceduralist approach that allow to address the question of the contextual limits (which has been identified as the main limitation with the other analysed ethical theories)⁷⁹. For this reason proceduralism was identified as potentially useful for our research purposes, especially due to its dialogical approaches. Yet, the dialogical procedures, while being means to avoid pitfalls of both, deontological and teleological⁸⁰ theories, face at least on some crucial points – on the same kind of limit regarding the justification of the norm and the context of application⁸¹. As a potential solution to the critique of the limits of the proceduralism and as a potential answer to our search for an adequate theoretical framework, the theory of governance, developed by the previously mentioned Leuvinist school, had been identified⁸².

In the following part of the work we shall refer to the key concepts regarding the construction of a norm and its relationship to context, as proposed by the Leuvinist behaviour with rational choices for the management of human responses. Thus, if ethics is to assert a normative authority, which is a fundamental characteristic of ethics, since ethics concerns the relationship between what is and what should be, it is necessary to question the condition for its effective integration in the context of technical projects (EGAIS deliverable 2.1).

⁷⁸ For proceduralism see Glossary in the Annex 1.

⁷⁹ The procedural approaches are often viewed as an alternative to the classical version of rational choice theory, as pointed out, for example by Lenoble and Maesschalck (In Toward Theory of Governance: The Action of Norms. Lenoble, J.& Maesschalck, M., 2003, Kluwer, Law International, p. 19).

⁸⁰ In contemporary moral philosophy, deontology is one of those kinds of normative theories regarding which choices are morally required, forbidden, or permitted. In other words, deontology falls within the domain of moral theories that guide and assess our choices of what we ought to do (deontic theories), in contrast to (aretaic [virtue] theories) that — fundamentally, at least — guide and assess what kind of person (in terms of character traits) we are and should be. For more information see Glossary in Annex 1.

Teleological moral systems are characterized primarily by a focus on the consequences which any action might have (for that reason, they are often referred to as consequentialist moral systems, and both terms are used here). For more information see Glossary in Annex 1.

⁸¹ According to the EGAIS project - the relationship between the rational justification of norms and the context of application of norms. There must be something more than a mere procedural discussion to elaborate a rational justification of a norm and almost simultaneously adapt it to the specificity of a social and cultural context (EGAIS project, p. 19).

⁸² By this approach, the rationality of norm depends on “a ‘return’ to the context of the life world within which the norms are to be applied. This dependence of the justification of the norm on its contexts of application thus requires...reversibility (or reciprocal dependence) of the operations of justification and of application within all production of social norms to be taken into account ((In Toward Theory of Governance: The Action of Norms. Lenoble, J.& Maesschalck, M., 2003, Kluwer, Law International, p. 30).

school. By adapting these concepts to our research needs, we will propose a theoretical framework regarding the efficiency of a *ethical norm* in a specific context. Our theoretical framework will concern the construction of *an ethical norm* and its relation to context, as well as the concept of the efficiency of an ethical norm in a specific context.

We will attempt to overcome the main limits of the current ethical offer – the key concern of these theories with the ethical issue determination and the attempts to address the ethical issues after the development of the new technology (thus, decontextualising it). We, instead will attempt to propose a framework that can address the ethical issues in the process of the technological development, and thus, contextualise it. █

2.3. Viewing an ethical norm and its efficiency in a specific context

Having discussed the limits of the current ethical offer, we would like once again to point out - most of the current ethical approaches tend to be concerned with the identification of an ethical issue, but pay little attention to the actual resolution of the ethical problem. In other words, no solutions are offered how to act in practical terms, given the various inherent contingencies we described in part one. Therefore, in this part of the work we will develop upon the proposed approach regarding the contextualisation of an ethical norm, the main premise of this approach being that an ethical norm regarding technological development cannot be viewed in an abstract way, but instead must be related to a specific context⁸³.

In order to address the problem of the functioning of an ethical norm and its efficiency in a specific context, it is essential to understand how a norm is constructed. As indicated previously, we will base our theoretical approach on the governance theory

⁸³ We will be using this theory to construct our research approach and the understanding of our research problem. Our research approach will be described in greater detail in part 3.1. of the present work. However, we would like to point out that our overall research approach is to construct our research problem based on a specific theoretical framework. Further on our aim is to test our research problem in concrete policy context through the empirical studies. Therefore we need to explain in more detail our theoretical approach to the construction and functioning of an ethical norm in a specific context.

developed by the representatives of the Leuvainist school Lenoble and Maesschalck. More specifically, we will deal with the notion of the “action of a norm”⁸⁴. We will adjust this concept to the needs of our research question in relation to the action and efficiency of an *ethical* norm inside a specific context. This will enable us, at a later stage of the work, to analyse the efficiency of an ethical norm inside a specific context, by determining the conditions that make for this efficiency⁸⁵.

2.3.1. Some perspectives on the development of an ethical norm

Having discussed the relevance of the actual implementation of an ethical norm, we consider it important to look at the approaches to the development of an ethical norm. It is also necessary to see and analyze if the existing approaches regarding the development of an ethical norm give answers to the ethical challenges of technological development in the modern society. As we shall demonstrate by our case study (see Annex 9) - ethical thinking traditionally is applied after the development of the technology. Ethical thinking is reduced to the question of justification (legitimation) of ethics, but hardly to provide a real solution (to a certain extent we found it also during our empirical field study through textual and interview analysis). Thus, we can conclude that currently the norm is conceived without taking into consideration the problem of its application⁸⁶.

⁸⁴ After Lenoble and Maesschalck, *Toward a Theory of Governance: The Action of Norms*, Kluwer Law International, 2003.

⁸⁵ Given the complexity of the issues, we will present the process of the construction of an ethical norm as a series of actions or stages, in order to produce a methodological approach regarding ethical issue determination and resolution. We will be discussing the construction of an ethical norm, the construction of the context, the implementation of an ethical norm and the possible change of trajectory as a result of the implementation of an ethical norm. In doing this, our aim is not purely theoretical. We want to relate this to actual practices of ethical governance of technological projects as part of the ethical framing of EU research policy, and further on propose ways how to avoid the limitations of the current EU governance practices in this respect. To do this, we will also use the case study from the EGAIS project further in the work. This will allow us to see how to respond to the emerging conditions concretely, but with solid theoretical foundations. This will also allow us, by using our theoretical framework, to further on analyse ethics as part of governance procedure in relation to ethical framing of the EU ICT research policy making and implementation which is the field of study of our actual research.

⁸⁶ To refer to our research problem and research questions – it implies that the issue of the norm construction needs to be taken into consideration. The Louvainist school which is at the bases of our theoretical framework determines that a norm, in order to have an impact and be effective, must be constructed by taking into account its foreseen contextual insertion and taking into account the normative (ethical) horizon.

Furthermore, we have found (based on our case study of the EGAIS project) that ethical thinking is often reduced to the use of ethical guidelines or deontological codes for the evaluation of the emerging technologies. This is usually done without any substantial background or contextual analysis. We are arguing however, that the ethical thinking should be integrated into the very process of technological development. By our theoretical approach and subsequent analysis we will try to see how such an approach would function in practice.

Within the very technology development, the need for ethical consideration prior to the funding or implementation of the project today is not the current practice. We have seen this during our empirical analysis of the EGAIS case study, through the ICT project results analysis - concerning the values and scientific rationality⁸⁷ and concerning the traditional sectorial ethics approaches⁸⁸.

Thus, in order to propose the possible ways of integrating ethics into the design and development of technology and securing the possibility of various external and alternate framings (thus avoiding the traditional⁸⁹ internal and specific framing for moral problems),

⁸⁷ There are problems associated with our traditional value system, and so far there has been a tendency for technological and scientific rationality to impose its value system also regarding ethics in technological development. Scientific experts often are the main and often indisputable source of normativity, and potential ethical problems are somewhat confined to a scientific perspective alone (EGAIS deliverable 2.1). However, we do not have an answer what is an expert on ethical issues today, since scientists traditionally base their expertise on the principles of strict scientific rationality. This may prove to be a somewhat limited approach regarding ethical issues, based on individual responsibility, and any democracy regarding decision taking confiscated. Such an approach would attempt to objectify the world we experience in order to predetermine the form of the world we share. There is a big risk that the possibility of genuine reflexivity will be stifled, as a result of a dismissal of the role of moral reason in favour of purely technical rationality.

⁸⁸ Various sectorial ethics increasingly reinforce social differentiation characteristics of modernity (here the EGAIS project is referring to the multiple subsystems of society such as justice systems, scientific systems, etc. as discussed by Niklas Luhmann in *Observations on Modernity*, (1998), Stanford University Press and *The Differentiation of Society*, (1982) Columbia University Press) by proposing an internal and specific framing for moral problems. This carries the risk of exclusion of other external and alternate framings. As a consequence, ethics is generally disconnected from the design and development of technology. The issue is further reinforced by lack of a concrete grid of assessment concerning the embedding of ethics in technological development. As a result, ethics is often an “add-on”, a sort of accessory and instrumentalised guarantee, not properly integrated or understood in its methods and objectives, which are radically different from the methods and objectives of science and technology development

⁸⁹ In current more traditional approaches, expertise tends to be the indisputable source of normativity, and the existing and potential problems are often confined to the expert perspectives only. The ethical theoretical approach to be used is traditionally chosen by experts involved in the decision making process, and the (cognitive) framing is determined by their specific field of expertise. If reduced in such a way, the issue of

the analyses on the construction and contextualisation of an ethical norm will be presented in the following chapters. Being too much concerned with the ethical issue determination, the many existing approaches overlook the actual application of an ethical norm and its efficiency in a specific context. These are important factors for the resolution of an ethical issue.

Apart from the above mentioned arguments, we will also attempt to show further on that often the underlying reason for the problems with the current ethical approaches is the existing separation between the technical and ethical communities⁹⁰, which is gradually becoming an acknowledged fact in scientific and partly also political discourse, and also this problem needs to be addressed by alternative ethical framings.

2.3.2. The efficiency of a norm inside a specific context

To understand the construction of the norm, and further on the conditions for its application, we will structure the problem in a series of stages. These stages will allow us to have a better understanding of the overall complexity of the issue and its different components, and represent the trajectory of the different issues and conditions related to the ethical issue determination and resolution. We will differentiate between 7 steps or stages in this process: 1) cognitive framing; 2) capacitation of actors; 3) acknowledgement of cognitive condition for ethical reflexivity; 4) determination of an ethical issue; 5) search for a resolution; 6) determination and specification of the solution; 7) acknowledgement of the fact that a solution is a solution. For more detail of this approach see footnote⁹¹. This

ethical acceptability is transformed to the mere social acceptance of the technology.

⁹⁰ In an implicit and also explicit way we noted this problem also during our interviews with relevant EU officials.

⁹¹ According to the theoretical approach elaborated within the EGAIS project, the seven stages represent the following:

1) The first stage in this problem is the issue of cognitive framing. Obviously each conception of the world is related to a specific framing, so when one tries to analyse an ethical issue, they do so within some preconceptions. Through the framing concept, we can highlight the necessary contextualisation of every judgement and how it relies on the routines that an interpretive approach will continually adapt to new contexts. Cognitive framing consists of the way the actors see the situation. Framing constraints could be economic, scientific, technical, or similar, and have a major effect on the decisions made by the actor

approach will bear relevance to our analysis of the ethical governance arrangements in the EU research policy implementation. Especially we would like to point to the neologism ‘capacitation’, since it is key to the understanding of the important notion of reflexivity⁹².

Having discussed in a systematic way how an ethical norm is being constructed, we would like again refer to the main purpose of our research – ethical governance of EU ICT projects, as part of the implementation of the ethical framing of the EU ICT research policy. Since ethics today is viewed as part of good governance, in our research we will be concerned with the determination, addressing and assessment of ethical issues in a way that there is an ethical reflexivity present (for this reason we were dealing with the approaches to the concept of the construction of an ethical norm). Consequently, as a next step in the present study we see the discussion of the approaches to reflexive governance. Our approach to the construction of an ethical norm alongside with the key concepts for ethical governance will allow us to formulate the main aspects and preconditions for the development of the theoretical framework of our research.

2.4. On reflexive governance

As discussed previously, there is a growing desire and need by citizens to be involved in

involved. These framing issues are fundamental, because, as we will demonstrate in the next sections, ethical reflexivity requires an opening of the framing.

2) The second stage is the problem of reflexivity, with its related issue, the problem of capacitation of the actors. Capacitation is the process by which the actor acquires a new capacity (in this case the capacity of being reflexive upon their own framing and the requirements for ethical reflexivity). This stage is a questioning of the mental position of the actors by the actors themselves.

3) The third stage is the requirement that there be an acknowledgement of the cognitive condition for an ethical reflexivity. This stage relates to the conditions for the ethical will.

4) The fourth stage is the determination of ethical issues (related to ideal, normative, and contextual constraints).

5) The fifth stage is the search for a resolution.

6) The sixth stage is the determination and specification of the solution.

7) The seventh final stage of the problem is the recognition and acknowledgement of the fact that the solution is a solution. It should be noted that a solution could arise but be unrecognised by those involved as being a solution.

⁹² According to Lenoble and Maesschalck, “the only way to respect ... reflexivity is to construct reflexively the ‘capacities’ of the actors to be gathered, that is, to reconstruct collectively the contextual stakes of the problems to be dealt with in order to ‘adapt’ their ways of life so as to overcome the perceived shortcomings. It is in order to take account of this degree of additional reflexivity... that we use the neologism ‘capacitation’ (In Lenoble and Maesschalck, *Toward a Theory of Governance: The Action of Norms*, Kluwer Law International, 2003, p. 23).

decision making, especially in situations which are perceived as presenting risk. At the same time, as we have discussed before, ethics in technological development is related to a whole spectrum of issues, and risk is only one aspect of it. Also the application of the precautionary principle⁹³, as argued by Goujon and Dedeurwaerdere, can only partly offer effective solutions⁹⁴.

At the same time, we have shown (chapter 2.1) that ethics is an inherent part of good governance. We have also shown that the older modes of governing by top-down control and command methods are not only morally out dated, but more importantly, cannot provide the needed answers to the current ethical challenges, as there is no clear source of normativity available to guide these actions. One could even argue that there are plenty of sources of normativity⁹⁵, and the challenge is how to come to terms with this situation.

Thus, an approach is needed which, on the one hand, would involve participatory approaches, and on the other hand, would enable the involved stakeholders to cope with the absence of clear source of normativity. We can see that, as a reaction to this situation, more participatory and cooperative ways of governance have evolved⁹⁶ over the past

⁹³ This has been argued by Goujon and Dedeurwaerdere (UCL, Louvain-la-Neuve) in “Taking precaution beyond expert rule. Institutional design for collaborative governance. The Genetically Modified Organisms controversy case, p. 3.

⁹⁴ According to Stirling, the precautionary principle does not of itself purport to provide a detailed protocol for deriving a precise understanding of relative risks and uncertainties, much less justify particular detailed decisions. Instead, it provides a general normative guide to the effect that policy-making under uncertainty, ambiguity and ignorance should give the benefit of the doubt to the protection of human health and the environment, rather than to competing organizational or economic interests. This, in turn, holds important implications for the level of proof required to sustain an argument, the placing of the burden of and the performance of analysis. This is useful because none of these are matters on which there can be a uniquely firm 'sound scientific' position (Stirling, 2007, p. 312).

⁹⁵ To exemplify, we would refer to various sub-systems, like techno science sub system, law sub system, economic sub system and other. Or in broader terms, we would refer to the national state, the United Nations Organisation, the European Union, certain international organisations or agreements etc.

⁹⁶ According to Lenoble and Maesschalck, concerning the new forms of public intervention, “. . . at the level of administrative authority, the conditions of rationality (legitimacy and efficiency) of a public policy are presumed met by the chance given to concerned interest groups to participate in the public decision” (In Lenoble and Maesschalck, *Toward a Theory of Governance: The Action of Norms*, Kluwer Law International, 2003, p. 23).

decades - starting from the new institutionalist economic approaches⁹⁷ and evolving further to theories of governance based on deliberation and collective action⁹⁸. Here we would like to refer to the notion of reflexive governance – an emerging new mode of governance⁹⁹. Alongside with its other features it implies a particular distinctive aspect – it is based on the presence of learning (as well as on the success of this learning operation).

As argued by Lenoble, this learning can occur only as a result of genuine reflexivity, and by reflexivity the transformation of given context (as well as that of the identities of ‘actors’) is implied¹⁰⁰. In this mode of governance particular attention is being paid to the institutional mechanisms whose existence is necessary to the success of the learning operation, on which in turn rests the success of a collective action (Lenoble, 2010, p.2). According to Lenoble, this approach envisages that a practical acceptance of a shared norm depends exclusively on the proliferation of mechanisms that are assumed to foster cooperation and participation by citizens in the process by which these norms are developed and applied (p.2).

Furthermore, as pointed out by Goujon and Dedeurwaerdere, reflexivity may be defined as the “capacity of actors and institutions to revise basic normative orientations in response to the evolution of economic, techno-scientific or political systems and to shortcomings in current modes of regulation (Goujon and Dedeurwaerdere, 2009, p. 1). At the same time, it should be reminded that our interest lies in the issue of the ethical norm in

⁹⁷ The neo-institutionalist approaches are concerned with the role of institutions in the construction of the efficient governance of the market.

⁹⁸ Theories of governance based on deliberation and collective action primarily agree that the efficiency of an organisation will depend on its capacity to implement a deliberative approach containing the conditions of collective learning.

⁹⁹ For reference on the term see Glossary in Annex 1.

¹⁰⁰ According to Lenoble, transformation of the given context requires that the actors involved divide their attention between the anticipation of consequences and a specific operation: that of re-examining “accustomed competencies and behaviours” in order to acquire new competencies (Lenoble, 2010, p.2). He also claims that this operation of re-examination would require specific institutional mechanisms (Ibid, p.2). “At this stage the assumption is made that the conditions for transforming the identities of participating citizens – that is, the conditions for transforming the way these citizens conceive themselves and the world – emerge solely from the pragmatic conditions presented by the cooperative and participatory models” (Ibid, 2). In a sense, the transforming of ‘actors’ identities occurs.

this context. Therefore, in the next part of the work, when dealing with the issue of reflexivity in governance approaches, we will also introduce the notion of the ethical norm in a specific context. Based on this, we will present the proposed theoretical framework of our research.

2.5. Theoretical framework for analysis

Having analysed the current ethical needs and challenges regarding modern technological development, and having analysed the limited capacity of the existing ethical approaches to address these new challenges, we will present a theoretical framework which, in our opinion, may address these ethical challenges in a more effective way¹⁰¹. As discussed before, we will base our approach on the concept of the construction and the efficiency of an ethical norm in a specific context. Our theoretical framework will be rooted in the theory of governance developed by Leuvainist school which we presented in the previous chapter, and we will attempt to adjust its main theoretical approaches to the needs of our specific research objectives.

By our theoretical framework we aim to address the question of the effectiveness of *ethical* norms – from the conditions of their emergence to their implementation. To our knowledge, this effectiveness has not been questioned or discussed before, especially in regard to the existing practices in research policies. The currently predominant theoretical approaches, at least implicitly, presuppose - the conditions that determine the effectiveness of the implementation of the norm are linked to rules within the mind, and therefore are supposed to be a function of mental capacities (which are independent of the external

¹⁰¹ As previously discussed – in our theoretical approach we have been constrained by the approaches implemented by the EGAIS project. Thus, we will develop upon and refer to the main approaches by the EGAIS project, however, adjusting it to our specific research problem

subjects' context)¹⁰². However, our interest lies specifically in the development and implementation of an ethical norm in relation to context.

To avoid being purely theoretical, and will link our theoretical approaches to practice. We will analyse the existing governance practices in the light of our theoretical framework – thus addressing the existing conditions with a solid theoretical foundation. This will further on allow us to propose ways to overcome the identified limitations of the actual governance practice.

We have already explained in chapter 2.3.2. our approach regarding the stages in the production of an ethical norm within a concrete (social) context, as well as the process of its application. We have also shown that these two processes are related, and for them to be effective, the norm has to be constructed, taking into account the conditions for its application, which, as the actual practice shows, is still a major challenge¹⁰³.

As our case study on the findings of the EGAIS project shows (EGAIS deliverable 2.1. p. 12) – currently, by the predominant positivist approaches, ethics is reduced to risk analysis, and risk analysis is traditionally addressed by scientific methods. This reductionist approach (in this case, reducing ethics to risk assessment or management) also reduces reflexivity to a first –order reflexivity (by first order reflexivity we refer to reflexivity that does not question its own framing, in contrast to second order reflexivity which addresses the condition that allow for questioning of the framing).

The problem with first order reflexivity is that – the fields of analysis are determined or conditioned by that particular framing. Consequently, specific problems (also ethical problems) are ‘identified’ and ‘addressed’ within a specific framing, with the

¹⁰² This approach has been extensively studied by the EGAIS project. Here we are referring to EGAIS project deliverable 2.1. p.3.

¹⁰³ This has been identified as a challenge by the EGAIS project. It is being argued that one of the reasons is the existing separation between the technical and philosophical communities, (with their “experts”), exacerbated by the “top down” approach (favoured for risk management in particular). According to the EGAIS project, this limits the debate to positivist, reductionist approach that in its turn leads to cognitive closure (EGAIS deliverable 2.1. p.12). We have found during our empirical study (interviews) that implicitly (not explicitly) this is considered to be a challenge also by the respective EU officials.

subsequent cognitive closure¹⁰⁴ taking place. This excludes any reflection on the construction of that particular framing (instead, the reflection on the existing framing and on the conditions that allow to put in question the existing framing we would refer to as second order reflexivity)¹⁰⁵.

With these problems in mind, we need to ask the following question: how can we elicit the opening up of this cognitive closure, so that we can have a genuine ethical reflexivity. According to our analysis of the approaches within the EGAIS project – a potential solution might be a reflexive governance process that integrates “learning” through the process of technical development. This would allow for the broadening of views beyond the technical ones, and would open up debate (or raise questions) regarding values. In other words, it needs to allow the ‘capacitation of actors’ (as discussed in chapter 2.3.2.). It should also allow for the suppression of the border between the communities (as referred to previously), so that there is a relationship between the context and the construction of a norm. Only by this, according to our theoretical approach, we can assure an impact of ethical reflexivity¹⁰⁶.

We must acknowledge here that in compliance with the EGAIS project approaches – the background we use and build on refers to the contextual pragmatics and the theory of governance developed by the Louvainist school, as it offers a solid, theoretically founded framework (which ensures the above requirements). The justification for using this theory as our starting point is that it directly addresses the problem of the conditions for the

¹⁰⁴ For ‘cognitive closure’ see p. 50.

¹⁰⁵ The second order reflexivity can be characterised as a self-critical reflection on the process used to determine problems encountered within a project, and an assessment of the usefulness of the such processes in changing the ethical trajectory of a project (EGAIS project). The issue of first order reflexivity and second order reflexivity in relation to the development and implementation of an *ethical* norm has been extensively discussed within the EGAIS project, based on the approaches of the Louvainist school. This has been referred to the approaches on the development and implementation of norm according to J.Lenoble and M.Maesschalch (J.Lenoble & M.Maesschalch. *Toward a Theory of governance: the action of Norms*, Kluwer Law International, 2003).

¹⁰⁶ According to our findings on the case study of the EGAIS project (Deliverable 2.1. p.12). For ethical reflexivity See Glossary in Annex 1.

effectiveness of norm expression (which is at the heart of our research). It does this from a theoretical perspective and using an applied set of studies. It also addresses the limits of the current ethical approaches – where ethics is restricted to a categorical field and where answers are given without a particular context of application in mind¹⁰⁷.

In this context, expertise, be it philosophical, scientific, economic, or other, becomes the indisputable source of normativity¹⁰⁸, and the problems revealed are confined to these expert perspectives alone. As a result, ethics becomes kind of an accessory, without a proper integration or understanding of its objectives (and also methods). But we have to keep in mind that these objectives and also methods are not the same as those of the science or technological development, and also approaches therefore should be different¹⁰⁹.

Consequently, there is a strong need to investigate and reflect on the governance conditions that allow for an ethical reflexivity inside the project and for the effectiveness of that reflexivity. In other words, ethics must not reduce itself to a means to satisfy the contextual constraints, such as economic, political, or scientific constraints. By this the question of the ethical acceptability would be transformed into the question of the social acceptance of the technology, which is easily addressed by sociological enquiry. Such governance conditions also need to allow for the inclusion of ethical consideration before, during, and at the end of technological and scientific projects. The ethical aspects should

¹⁰⁷ We base our theoretical standpoint in the EGAIS project. According to the EGAIS project - deontological codes and ethical guidelines are good examples of this because they answer to issues that are, most of the time, sectorially defined, with a theoretical approach that is chosen by “experts” employing a decisionist process, with their own specific framing, determined by their field of expertise. This sectorial ethics reinforces the social differentiation characteristics of modernity by proposing both internal and specific framing for moral problems. The risk, here, is that the possibility of genuine reflexivity will be stifled by a technological and scientific rationality imposing its value system. Sectorial ethics tends to also propose an internal and specific framing for moral problems, risking the exclusion of other alternative framings (according to EGAIS deliverable 2.1.)

¹⁰⁸ Normativity - a careful, rigorous account of the meanings of basic normative terms like good, virtue, correct, ought, should, and must (see Glossary in Annex 1).

¹⁰⁹ We base our theoretical standpoint in the EGAIS project.

be addressed throughout the conception, development, and implementation stages of a technological project¹¹⁰.

Within a regulation framework, for ethical integration to be successful, it firstly needs to be considered for inclusion in that framework, and ‘to be accorded a certain status which acknowledges and respects its fundamental epistemological and methodological characteristics and requirements’¹¹¹.

To study how such requirements are being satisfied in practice, we developed an analytical grid (based on our theoretical framework), in order to prepare bases for our empirical field study, including the questionnaire for the interviews with EU respective EU officials. Our analytical grid was based on the approaches used by the EGAIS project (since our own research is part of this project), but adjusted specifically to our own research problem and needs.

Furthermore, in order to interpret the data obtained through our field study, and in compliance with our theoretical framework and the EGAIS approaches, we developed a grid for data analysis. In this respect, we would like to introduce the notions we will be describing in greater detail in the following chapter. These notions refer to the models of governance¹¹², as well the various governance arrangements and their underlying pre-suppositions¹¹³.

In the following chapter we will represent the approaches to the development of :

1) our analytical grid and 2) our grid for subsequent empirical data analysis. We will also

¹¹⁰ The EGAIS project has used this standpoint in the analysis of the FP7 projects. We will, however, examine these approaches in the context of EU research policy making.

¹¹¹ Here we are referring to the analysis carried out within the EGAIS project (based in the approach by Ladrière), “The ethical dimension [...] manifests itself when it exercises and founds an authority under an unconditional and, in a certain way, intemporal form (according to J. Ladrière, *Philosophie politique et philosophie analytique*, in J. Ladrière and Ph. Van Parijs, *Fondements d’une théorie de la justice. Essais critiques sur la philosophie politique de John Rawls*, Louvain-la-Neuve, Éditions de l’Institut Supérieur de Philosophie (1984), p. 222).

¹¹² In line with the EGAIS approach, we will be referring to the following models of governance: standard model; consultation model; 3) revised standard model; 4) co-construction model.

¹¹³ In line with the EGAIS approach, we will be referring to the following presuppositions: intentionalist, schematising, mentalist.

show how our theoretical approach feeds the development of these grids, and this will subsequently enable us to analyse our actual research problem.

2.6. Implementation of the analytical grid

The analytical grid was constructed according to our theoretical framework described in the previous chapter of the work and by taking into consideration the following approaches: one cannot merely look at the ethical norms identified or used, instead one needs to look at the construction of the norms, taking into consideration the issue of their relationship to the context. The main premises implied, in accordance with the overall EGAIS approach¹¹⁴, were:

- 1) there exists a separation between the ethical and technological communities;
- 2) there exists a separation between the context of application of the norm and the context of legitimisation of the norm; and
- 3) there exists a problem with the reflexive relation between the construction of the norm and the context.

With these premises in mind, further on our focus was on:

- 1) how contexts and norms are constructed, how they are applied, and the relationship between the norms and contexts and
- 2) how this relates to the respective governance arrangements that are being implemented in FP7.

Based on the overall EGAIS approaches, our task was to develop an analytical grid and a respective questionnaire - to be used for data collection regarding specifically the ethical framing of the FP7 research policy. With our research problem in mind, our focus was on the qualitative aspects of the respective governance arrangements in FP7 ethical

¹¹⁴ Here we are referring to the EGAIS deliverable 2.1 which presents the overall EGAIS approach to the analysis of the ethical framing of FP7.

framing. To be more specific, we focused on 1) how ethical norms are being constructed in FP7; 2) how/if they relate to the actual context of their application 3) how the existing FP7 governance arrangements and the contextualisation of ethical norms in the respective FP7 research relate to each other.

Our analytical grid, due to the word number constraint, will be presented in greater detail in Annex 2. However, in this chapter we will outline the key issues we needed to address in the development and implementation of our analytical grid;

- 1) firstly, we had to determine the domains for analysis¹¹⁵;
- 2) secondly, we had to specify the parameters¹¹⁶ we are interested in within the particular domain;
- 3) thirdly, we had to formulate the questions for the questionnaire (for interviews) – in order to yield answers (material) in compliance with our parameters in each specific domain for analysis;
- 4) fourthly, we had to create a grid for analysis¹¹⁷ of our empirical findings.

Regarding the grid for analysis of empirical findings (which we will present in Annex 6) - taking into consideration our field of inquiry¹¹⁸, our research problem¹¹⁹, as well as the focus of the present thesis on the governance arrangements in the implementation of the FP7 ethical framing – within the framework of our theoretical approach, we were interested to represent the following:

¹¹⁵ By domains of analysis we mean the aspect of FP7 ethical framing that is relevant for the analysis of our research problem. In order to avoid a specific framing for our subsequent analysis, we did not intend to have an exhaustive description of the scope or content of the particular domain. Instead, we intended to give an overall orientation. Thus, we were interested in 5 domains of analysis: 1) ethical issue identification and specification; 2) governance arrangements; 3) implementation; 4) ethical approach; 5) reflexivity.

¹¹⁶ By parameters we mean: what we want to specifically look at and find out within the particular domain.

¹¹⁷ By grid for analysis of empirical findings we mean a frame of analysis according to certain pre-determined parameters based on our theoretical framework.

¹¹⁸ As stated in the Introduction of the present work – our field of inquiry is the representation of ethics and governance reflexivity in technological research and development, as part of EU (FP7) ICT research policy within the EU 7th Framework Program.

¹¹⁹ As stated in the Introduction of the present work – our research problem is the effectiveness of ethical reflexivity in FP7 ICT research projects as part of the implementation of EU research policy.

1) how ethics in governance relate to context¹²⁰ - if the respective identified governance arrangements are decontextualised¹²¹, if the context is restricted¹²², or if they are fully contextualised¹²³;

2) what models of governance predominate – how the respective identified governance arrangements relate to the four governance models as part of our theoretical approach referred to in chapter 2.5 and presented in greater detail in Annex 2¹²⁴: standard model¹²⁵; consultation model¹²⁶; revised standard model¹²⁷ and co-construction model¹²⁸;

¹²⁰ The approaches by these models have been elaborated by the EU EGAIS project, based on Callon, M., (1998), Des différentes formes de démocratie technique, *Annales des Mines*, January 1998, pp 63-73, Joly, P.-B. (2001) Les OGM entre la science et le public? Quatre modèles pour la gouvernance de l'innovation et des risques, *Economie Rurale*, , 266, pp. 11-29.

¹²¹ Decontextualised – refers to the situation where the ethical norm is seen outside the context of its application.

¹²² Context restricted - refers to the situation where the ethical norm is seen restricted in the context of its application.

¹²³ Fully contextualised - refers to the situation where the ethical norm is seen fully inside the context of its application.

¹²⁴ The approaches by these models have been elaborated by the EU EGAIS project, based on Callon, M., (1998), Des différentes formes de démocratie technique, *Annales des Mines*, January 1998, pp 63-73, Joly, P.-B. (2001) Les OGM entre la science et le public? Quatre modèles pour la gouvernance de l'innovation et des risques, *Economie Rurale*, , 266, pp. 11-29.

¹²⁵ *Standard Model*: In this model, the disagreements between the experts and the public are perceived as irrational due to the public's lack of knowledge. This model fits perfectly into the classical distinctions between facts and values. Experts have an objective ethical approach to risk whereas the risks perceived by the public are marked by a greater degree of subjectivity.

¹²⁶ *Consultation Model*: This model brings into question the fundamental thesis of the standard model, namely the opposition between the irrational public and the rationality of the experts. The distance between experts and non-experts is not connected with the level of knowledge, but with the difference in the perception of risk.

¹²⁷ *Revised Standard Model*: In this model, which is the extension of the standard model, the emphasis is placed on the interaction between the regulation process, social groups and media. Risks are often overestimated, however the efforts to educate the public about scientific risks have failed and will fail in future. Consequently, responding to public attitude, legislature itself will exaggerate the risks. As a result, the public will feel unprotected by law and decision-makers, which will lead to more political pressure to take action. In this model, public influence and participation in risk management are considered with great suspicion.

¹²⁸ *Co-construction Model*: This model distinguishes itself by questioning the way in which technological development projects use experts. Representations of technology come from numerous collected case studies. The works of the new sociology of sciences have progressively come to blame the traditional conception of science as a revelation of universal, independent truths of the social system they produce.

2) what are the underlying pre-supposition in the use of the particular governance arrangements – in compliance with our theoretical framework we refer to such presuppositions as intentionalist¹²⁹, schematising¹³⁰ and mentalist¹³¹.

Regarding the identified governance approaches used within the respective EU policy making – we were interested not only in what governance approaches were used but also: in what way they were used. In other words, we assumed that these governance approaches could be used as tools for achieving various purposes, namely, that one and the same governance tool, if used in a different way, could yield a different result. Therefore, to secure a comprehensive approach, we used in our analytical grid the uniform term ‘governance arrangements’ – by this implying a type of governance tools regardless the content of its application.

While the actual analytical grid and the grid for empirical data analysis and the analysis itself will be presented in Annex 6, we would like to point out that the results of the analysis will enable us to draw the necessary conclusions regarding our research question on ethical reflexivity in relation to the efficiency of an ethical norm in the context of EU (FP7) ICT research.

In order to be able to test our theoretical approaches in practice, in the following part of the work we will introduce, justify and describe our empirical field study.

¹²⁹ According to the intentionalist pre-supposition, the norms effects are supposed to be deducible from the simple intention to adopt the norm. Additionally, there is the presupposition that the actors in a participatory approach will have capacity and intention to contribute to the participatory discussion.

¹³⁰ The schematising pre-supposition involves Kantian schemes (rules), in which the operation of the application of a norm is a simple formal deductive reasoning on the basis of the rule itself. The determination of the norm is linked to these rules, such as ethical guidelines, or laws, or other external sets of rules.

¹³¹ The mentalist pre-supposition is named so because it relies on the mind having a set of rules (or schemes, in Kant’s words), that predetermines the effect of a norm, and does not depend on any exterior context (to that of the thinker). This is commonly seen when participants in a participatory approach come to the setting with their own particular ethical framing, or with some preconceptions as to what ethical issues might arise.

3. Ethics in governance - from theory to practice. Study of the EU 7th framework programme

Abstract

In this part of the work will proceed from the previously discussed theoretical approaches in ethics and governance to the practice, in regard to the implementation of ethical governance in the EU research. In the first place we will justify why an empirical study was needed in our research - in relation to our overall research approach. We will also present and justify our research methods.

We will contextualize our research problem from three main aspect – historical, normative and process aspect. We will look at the implementation of the ethical framing in practice from two sides - from the EU officials' perspective and from the perspective of existing EU Framework ICT research projects, as a case study and will be able to compare them.

3.1. Outline and justification of the methodological approach

In the previous parts of the work we have presented our research problem regarding the effectiveness of ethical reflexivity in FP7 ICT research projects, as part of the implementation of the relevant EU research policy. As indicated before, within our work we are aiming at answering several research questions. Our main research interest refers to the conditions for ethical reflexivity in relation to the efficiency of an ethical norm in the context of FP7 ICT research projects. In previous parts of the work we have also presented the theoretical framework for our research, as well as the analytical grid for analysis which has been developed on the basis of our theoretical approach. Now, in order to address our research problem, we will study and test how our research problem is being

translated into practice. Only this will allow us to answer our research questions and analyze the characteristics and limits of the proposed system, approaches and theory.

In this part of the work we will proceed from the theoretical approaches in ethics and governance to the practice, in regard to the implementation of ethical governance in FP7 ICT research. We will carry out an empirical study, with the aim of an actual contextualisation of our research problem. The empirical field study will allow us to construct the context for the analysis of our research problem.

As we have pointed out previously, we have used a specific research approach – our research object was constructed from the epistemological point of view, based on our theoretical background. Our approach was also pre-determined by the EGAIS project, since our research is part of this project. Thus, our overall analysis was not based on a specific method, vice versa – we constructed our research object and tested it in practice through our empirical studies.

3.1.1. Justification for the need of an empirical study

In order to justify the importance of the empirical field study for our research, we need to outline the overall approach to our research process in greater detail. As we have mentioned previously, it has not been the field studies that have directed our theory, but vice versa, the theory has directed our field studies. Based on our theoretical approach, we constructed our research object. Based on the theoretical approach, we also constructed our grid for analysis, in order to analyse the political context.

Thus, our scientific research process is not being led by pure induction, which would by itself be impossible, since to see a scientific object, a theoretical background is needed that allows to construct it. We needed a theory in the first place, and based on this theory, we were able to define our research object and problem. Thus, the object and the problem of our research had been constructed from the position of a certain theoretical

background. Further on, our theoretical approach was used to construct the analytical grid for analysis, not to give the answer.

In order to avoid a purely theoretical analysis, which might lead to too many presuppositions, we considered an applied approach necessary. We used our theoretical framework as a starting point, 1) to construct the problem; 2) to be able to construct the analytical grid for analysis. Further on, based on the identified research problem, we carried out relevant field analysis. In this way we have addressed the problem of our research interest within an actual context, and more specifically, in the context of the ethics and governance issues EU ICT research policy conception, legitimation and implementation. Consequently, the results of our field study will be used to test the theoretical framework of our research and to draw the respective conclusions.

3.1.2. The research methods used

Based on our overall research approach, we have identified appropriate research methods, in order to be able to translate and test our theoretical approach in practice, that is, contextualize it. In terms of research methods, in the first place we have used textual analysis and interviews. In addition to this, we have also used a case study of the EGAIS project (see Annex 9), since within the EGAIS project a research was carried out on the implementation of the EU Framework program ethical framing from the perspective of EU Framework program projects themselves. This allowed us to view the implementation of the ethical framing from two different perspectives – from the perspective of the EU officials (via textual analysis and interviews) and from the perspective of EU Framework program projects themselves (from the deliverables of the EGAIS project, based on a survey of interviews).

At a later stage of our research, however, we came across a problem that not all our findings could be analysed and interpreted by using the theoretical framework of our

research. Our theoretical framework clearly allowed us to analyse our research problem in the specific context (the conception and implementation of the FP7 ethical framing), but this theoretical framework did not allow us to interpret some of our findings in a broader socio-political context. Therefore we needed to identify additional research methods to deal with the problem. Clearly, we needed a sociological theory or approach, in order to interpret these above mentioned findings. To this end, we identified the SCOT¹³² theory.

It was not, however, our intention to submit ourselves to use SCOT for the overall analysis in our work, instead, we used the approaches of this theory in the interpretation of some of the limitations that we identified to our theoretical approach in the analysis of the findings of the conceived, legitimised and implemented FP7 research policy. This enabled to draw some more comprehensive conclusions of our study.

3.1.3. Rationale and procedure for empirical field study and data collection

Our data collection strategy was aimed at identifying relevant materials on the ethical framing of the FP7 research policy, in regard to its 1) conception, 2) legitimation and 3) implementation. Our data collecting process was carried out through textual analysis and through questionnaire based interviews – in complacence with the theoretical background presented. Additional data were collected through a case study.

The data were collected to enable us to answer our research questions - on the EU conception, legitimation and implementation (as well as the assessment) of the ethical reflexivity in the governance of FP7 research projects. These data served us to identify, classify and describe models of strategies for addressing ethical issues in FP7.

In the textual analysis and through the interviews with the EU officials we identified:

1) the conceived EU research policy approaches regarding ethics in FP7 (in terms of policy papers, reports and views expressed during the interviews);

¹³² SCOT – social construction of technology

2) the legitimation (actual legal and policy framework) of the FP7 put in place (in terms of institutions, primary and secondary legal acts and other binding documents) and

3) the results of the actual implementation (as well as the assessment) of the FP7 ethical framework from the perspective of EU officials.

Through the EGAIS project case study we identified the implementation of the FP7 ethical framework from the perspective of EU Framework program projects. We will be reporting our findings in the light of the theoretical background and the presented epistemological standpoint which we have described in previous parts of the work. In this light, we will attempt to analyse the conceived or existent institutional arrangements and governance approaches regarding the ethical framing of EU Framework program. Given the limited scope of the work, part of our actual analysis will be enclosed in the annexes, and the main body of the thesis will represent the key findings and conclusions of our analysis.

Regarding the identification of materials for textual analysis, see footnote¹³³.

Regarding the approach to interviews with EU officials and experts, see footnote¹³⁴

¹³³ The identification of materials for our textual analysis were based on our own search of relevant documents, as well as based on the information on the relevant documents which we obtained during the interviews with EU officials. Our search was based on the information enclosed in the relevant web pages of the European Commission – regarding ethics in EU research policy and regarding ethics in FP7. These documents comprised:

- 1) policy documents and reports on the conceived EU approaches to ethics in EU research in broader terms and more specifically regarding FP7;
- 2) legal documents and informative documents on the normative and institutional approaches for the implementation of ethics in EU FP7 research;
- 3) reports and other documents and informative materials on the implementation of ethical approaches in FP7.

¹³⁴ The candidates for the interviews were selected in relation to their present and former involvement in ethics and governance issues in EU research policy making or implementation, and specifically, with regard to the EU Framework Programme.

In order to carry out the interviews we needed to prepare a questionnaire – list of questions relevant to our theoretical framework and object of research. To do this we had to develop an analytical grid comprising key domains and parameters for analysis. We would like to point out once again that our research approach was pre-determined by the framework of the EGAIS project – as our study is part of this project. Thus, the concept of the analytical grid was derived from previous developments within the EGAIS project, but our actual grid for analysis was constructed and adjusted to the specificity of our research problem (object of analysis). The approaches to the development of the analytical grid were already presented in greater detail in the second part of the work. For information purposes, the analytical grid is enclosed in annex to the present work. The questionnaire (template) which we used for the interviews is also enclosed in annex to the present work. Due to the restricted volume of the present work, in the main body of the thesis we will

It should be pointed out that the interviews were not intended to be as the key source of information (given the fact that the information on the legal and institutional frameworks and actual FP7 procedures is publicly available), nor as a source for collecting a broad and representative material for quantitative analyses. This would not be necessary, given the overall aim of the work, and would not be feasible, given the available time frame, as well as the access and availability of EU officials and experts.

Instead, we were aiming at obtaining a varied representation regarding roles and competences of the interviewees in the implementation of the respective EU research policy. We saw it as a supportive resource for a deeper and more comprehensive understanding¹³⁵ of the conception and actual implementation of the respective EU research policy¹³⁶.

Another specific feature in relation to the interviewees – our intention was to select a target group which is not homogeneous as to their status, roles and responsibilities, as well as their competence and functions. The differences were regarding:

- 1) *present or former* involvement with the EU policy making or implementation regarding ethics in science and technology;
- 2) *status* as an EU official or contracted expert, or member of relevant EU body;
- 3) *function and role* regarding the particular aspect in implementation of the relevant EU policy.

include our key findings and conclusions of the analysis of the interview relevant to our research problem.

¹³⁵ By the interviews and their analysis we intended to go beyond the available written documents and have a deeper insight into the actual problem. Our interest was directed towards the reflection of the interviewees on the relevant questions included in the questionnaire (these questions, as mentioned before, were bearing links to the theoretical background of our research). We were looking for information that would allow us, according to our theoretical framework, interpret the conceived and implemented ethical framework in the respective EU research policy, as well as identify challenges as seen by the EU officials and experts themselves.

¹³⁶ To analyse our research problem of the conditions for ethical reflexivity in the governance of the EU FP7 ICT research projects, we had to comply, as already mentioned before, to the general approaches of the EU EGAIS project. Further on we had to relate the theoretical framework of our research to the actual ethical framing of the European Commission within the FP7, by using certain criteria within our analytical grid. Further on, in order to make the association between the components of our theoretical approach and the form and content of the actual approaches in practice, the analytical grid was used for the analysis of the obtained results from the interviews.

Below is enclosed a more detailed information regarding the representation¹³⁷ of the interviewees¹³⁸.

By the case study of the EGAIS project we were aiming at obtaining data on the perception of the implementation of the EU Framework program by the actual EU Framework program ICT projects¹³⁹ – via the analysis of the research findings within the EU EGAIS project on the ethical governance models within of the FP7 projects – as part of the implementation of relevant EU policy.

3.1.4. The construction of context for empirical analysis

In order to construct the context for our analysis, we needed a method to do it. The rationale behind our method was that: 1) first, we need to look at the relevant policy developments in research ethics from a historical perspective, in order to see the roots of

¹³⁷ Our analysis of the interviews was not aimed at quantifying the responses according to certain uniform criteria (although the questionnaire, as we mentioned before, was constructed with a specific theory and criteria in mind). Our target group was selected in order to present as broad panorama as possible of relevant stakeholders, thus providing a maximum comprehensive spectrum of views regarding the conceived and actual ethical framework of the governance in EU ICT research policy and its implementation. Further on we will present the aims of our study.

¹³⁸

1. A researcher formerly contracted by the European Commission to draft the Ethical Guidelines of the EU 7th Framework program;
2. A current EU official from the Evaluation and Monitoring Unit, European Commission, Information, Information, Society and Media, formerly responsible for the process of the adoption of the Ethical Guidelines of the EU 7th Framework program ;
3. An ethicist, former member European Groups of Ethics in Science and New Technologies – an advisory body to the European Commission
4. A former project officer of the Information, Information, Society and Media DG and former observer of the European Groups of Ethics in Science and New Technologies;
5. The current Head of the Ethics Review Sector in the Unit of Ethics and Governance of the Directorate L: Science, Economy and Society of the European Commission; former scientific secretary of the European Research Advisory Board (EURAB)
6. The former Head of the Ethics Review Sector in the Unit of Ethics and Governance of the Directorate L: Science, Economy and Society of the European Commission
7. A project officer from Unit of Ethics and Governance of the Directorate L: Science, Economy and Society of the European Commission, responsible for the monitoring of the EU 7th framework projects
8. A project officer from Unit of Ethics and Governance of the Directorate L: Science, Economy and Society of the European Commission, responsible for drafting policy research documents on behalf of the European Commission, by involvement of experts and expert groups.

¹³⁹ As we have indicated previously – our research is being based on two levels of analysis – regarding the EU ethical framework for the governance of the EU framework program projects and the actual implementation in practice at ICT project level. Thus, the results of the EGAIS case study will serve as a test for our findings on the EU ICT research policy ethical framing – on how it relates to actual practice.

the issue; 2) secondly, based on this, we saw it important to analyse the specific ethical framing of the FP7 from the perspective of the normative approach – how the EU policy makers conceive “it should be”; 3) thirdly, as a logical sequence, we saw it important to analyse the actual implementation of the respective policy, in order to be able to compare the conceived ethical framing and the actual outcome.

Thus, correspondingly, in regard to constructing the context of our analysis, we will analyse our research problem by: 1) historical contextualisation¹⁴⁰; 2) normative contextualisation¹⁴¹ and 3) process contextualisation¹⁴². This analysis will allow us to determine how efficiently the respective normative framing functions in practice from the perspective of impact analysis by relevant EU reports, as well as from the point of view of EU officials and experts involved in the practical implementation of the ethical framework of the FP7.

3.2. Historical contextualization – development of relevant EU policy

In this part of the work we will present the general landscape on why and how ethics became part of the EU policy agenda regarding science and technological development,

¹⁴⁰ By the historical contextualisation we intend to draw the general landscape of the emergence and legitimisation of ethical framework as relevant to the overall EU research policy. We will present our vision of why and how the issue of ethics became part of the EU political agenda. To this end, we will carry out textual analysis (relevant legal and policy documents regarding ethics in relation to EU research and technological development) and analysis of the interviews with EU officials. We would like to point out here that our aim is not an in-depth analysis of the EU policy developments regarding ethics in the governance of EU research. Instead, our aim is to have a glimpse at the historical roots and the broader landscape, in order to present a general background for our in-depth analysis of the conceived and implemented EU ethical and governance framing of the 7th framework program. The results and key findings of the exercise of the historical contextualisation will be presented in the thesis, whereas the information on the documents and their analysis will be enclosed in annex to the present work. |

¹⁴¹ By the normative contextualisation we intend to present the EU vision of how the ethical issues should be addressed in the implementation of the actual EU research policy, and more specifically, regarding the EU 7th Framework programme. In other words, we will analyse the relevant legal framework, as well as related reports, statements and other documents and interviews with EU officials. With this we will present the conceived EU policy approach how things regarding ethics in the governance of EU research “should be”. More specifically, we will analyse both, the binding legal framework and relevant procedures, as well as well refer to policy documents and expert reports. The interviews with EU officials and experts will be analysed for in-depth understanding of the conceived EU policy.

¹⁴² By the process contextualisation we intend to present our findings on how the actual implementation of the respective EU research policy concerning ethics in the governance of the EU 7th framework programme functions in reality, and what are the actual results of this policy implementation. To this end we will use textual analysis (reports and other documents), as well the analysis of the interviews with EU officials

and what the general ethical framing of EU science and research policy is – as a historical contextualisation for the analysis of our research problem. Our intention is not to carry out an in-depth historical analysis of the respective EU policy framing. Instead, we intend to look at the reasons why ethics became part of EU research policy, what were the main impetus and key cornerstones of the process, what is the overall institutional and legal framework for addressing ethical issue in science and technologies, and most importantly, what implications all this has for our research question. Regarding the approaches to this part of our study see footnote¹⁴³. Regarding the identified main reasons for ethics becoming part of EU research policy agenda, see footnote¹⁴⁴.

We could clearly see that the overall ethical framing of the EU research policy in terms of its sources and causes implies the respect and dignity of an individual. In legal terms this issue is being addressed by the Charter of the Fundamental Rights of the European Union (CFREU)¹⁴⁵. In most interviews that we carried out, reference was being made to the traditional European values in general, and, in legal terms, to the CFREU as a

¹⁴³ We will base this study on the textual (report) analysis and on the information obtained during our interviews, since one of the questions presented to our interviewees was - why and how the issue of ethics in EU research appeared in the political agenda. We will produce a synthesis of our empirical findings – both, from the reports and from the interviews, and by that will draw a broader panorama which goes beyond a mere report analysis and is enriched by the relevant views of the responsible EU officials. We will present our key findings and conclusions in the main body of the present work – as relevant to our research problem, and due to the limited scope of the work, include other relevant materials and their analysis in the annex to the present work.

¹⁴⁴ According to the analyzed reports and interviews we were able to identify the main reasons - why and how the issue of ethics in EU research appeared in the political agenda. We have to acknowledge that the reasons presented and mentioned have been varied, and they range from broadly general to strictly specific. However, there is one key unifying reason highlighted both, in texts and interviews. Reference has been made to the classical European ethical values and approaches. It has been indicated that the relationship between ethics and public policy also has a long tradition in Western history and philosophy.

Thus, in addressing the question – why a greater emphasis on ethics is so essential to Europe – the Report “Citizens Rights and New technologies: a European Challenge. Report of the European Group of Ethics in Science and New Technologies on the Charter on Fundamental Rights related to technological innovation as requested by President Prodi on February 3, 2000 (EGE Report) states that the contemporary European civilization is at the same time based on science, technology and multiculturalism, and the multiculturalism in its turn is moderated by the Graeco-Latin and Judeo-Christian tradition. These are referred to as the historical sources of European values, modern science and technology, and as “the roots of human rights, which ordains the respect of all individuals” (EGE Report, p. 3).

¹⁴⁵ Charter of the Fundamental Rights of the European Union (2000/C 364/01) has become part of the Lisbon Treaty.

primary legal source for sustaining these values, also specifically in regard to ethics in EU research¹⁴⁶.

All this we could trace and verify in our empirical analysis. In general terms, the overall challenge was identified as - the consequences of the new societal developments and a new technological culture which, among other things, is being characterised by an unprecedented degree of risk and uncertainty. An increasing concern and evidence have been identified that the basic human values, as the respect, dignity and even security of an individual, might be threatened in an unknown and often unpredictable way.

Through our empirical work we identified the awareness among the EU policy makers - to address these new challenges (with their implicit and often already explicit effect on human values), new conceptual and policy approaches had to be promoted and discussed, and a new institutional and legal framework had to be sought¹⁴⁷.

We could see this awareness also through our interviews when questioning our interviewees specifically on the main reasons for ethics becoming part of the EU research policy agenda. We were able to trace numerous causes and reasons, quite general or more specific in nature (see footnote 145), in some sense overlapping, but the message was one – all the reasons derive from the interests or concern of the society at large, thus, also the respective policy making cannot be the sole responsibility of a single stakeholder. For a

¹⁴⁶ Thus, on the one hand, the overall aim of ethics in EU research policy, as our empirical analysis has shown, is to secure the fundamental European human values. On the other hand, there have to be specific reasons that have made the EU policy makers to become aware that these fundamental human values might be challenged through modern research and technological development. If so, the EU policy makers must have had certain presuppositions regarding the threats and risks related to these challenges, and further on, a vision on how these challenges ought to be addressed.

¹⁴⁷ We found the new conceptual and policy approaches widely represented in the policy papers, opinions and reports of relevant EU bodies that we will refer further in the text. From the empirical analysis we could conclude that ethics today has become part of public discourse – as political, legal and social debate. As pointed out in the General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission 2000 – 2005: “the rise of ethics as a public discourse may be interpreted as a symptom of the moral crisis arising in complex modern societies that can neither be solved by an implicit or explicit moral tradition nor by state policy alone”, and further on concluded in the report that the novelty of the present situation is that “ethics is considered to belong to the public debate at an institutional political level” (Capurro, 23).

better overview we made a synthesis of the presented causes and reasons, and grouped them in some principal clusters¹⁴⁸. At the same time we could trace something of a contradiction - that the actual institutional and legal framing for addressing ethical issues (discussed further on in this chapter) not always corresponded to the high degree and specificity of awareness that we could identify in the relevant policy documents, opinions, reports and interviews. This is an important issue we will return later in our work. █

¹⁴⁸ Through the analysis of our interviews we have been able to make the synthesis of our findings on the causes and reasons for ethics becoming part of EU research policy agenda. Since the presented reasons have been varied and have ranged from broadly general to strictly specific, we have attempted to highlight the principal clusters of causes and reasons (occasionally mutually complementary or overlapping) for ethics becoming part of EU research and technological development policies:

- 1) culturally and historically rooted reasons – in the context of traditional European values;
- 2) as a result or by impact from broader international processes, debates or internationally binding documents;
- 3) as a result of the work and opinions of institutionalised bodies dealing with ethics – like EGE, national ethical committees and other;
- 4) as a result of academic research presented to politicians at various historic periods of time and for various reasons;
- 5) as a result of consequences of controversial research;
- 6) as a spin-off effect, e.g., in ICT research, following controversial research consequences in other research domains (especially following research on humans);
- 7) as a result of overall societal and technological developments and newly identified challenges of society at large;
- 8) as a result of society driven processes, especially following controversial research issues;
- 9) as a result of broader public involvement in governance and the overall change of the modes of governance;
- 10) as a result of specific individual cases – like the unprecedented case of the rejection of a EU Framework research project due to ethical reasons, with a subsequent involvement of a high level EU official (European Commissioner) and later on leading to certain policy decisions regarding the ethical framing of EU research policy

We could trace that there is an ongoing political discourse regarding the ethical framing of the EU research policy (see Annexes 4 and 5). We could see that ethical discourse on science and technologies is not any more a prerogative to any particular social, religious, academic or political group, but has become contingent on multiple stakeholders, and there is a tendency for ethics in public policy to become part of a broader discourse. According to Cappuro¹⁴⁹ “political ethics conceived as a discourse in between public policy and society opens possibility not only to reflect publicly on the foundations of morality including its legal fixation, but also to give politicians a space of reflection beyond the constraints of political parties” (Capurro, 2005, p. 19).

Therefore, it is important to outline and analyse the institutionalisation and legitimisation of the ethical framing of the EU research policy – how this new ethical challenge for public research policy has been addressed in practical terms. We saw it relevant to link the relevant EU bodies and structural units of EU institutions with their respective functions and competences to the process of legitimisation¹⁵⁰ of ethics in EU research policy. Thus, we are linking the issue of institutional framework with the issue of the legal framework - the EU and member state bodies with their relevant and respective authority¹⁵¹.

We will highlight further on the main bodies and their competence with regard to respective policy issues with the aim of presenting the overall EU approach to the

¹⁴⁹ (Professor em. Rafael Capurro is the former EGE member, and he also kindly agreed to an interview in the framework of our research).

¹⁵⁰ Here we will not be dealing with the role of the Council of the EU or the EU Parliament as the legislative institutions in EU, instead we will refer to the key bodies that are authorised to pass an opinion or decision on ethical issues in the implementation of European research and technological development issues as part of the respective EU policy.

¹⁵¹ By the bodies and structural units we are primarily referring to:

- 1) European Group of Ethics in Science and New Technologies to the European Commission with its Secretariat;
- 2) European Research Advisory Board;
- 3) Unit of Ethics and Governance within Research DG with its Ethics Review Sector (European Commission),
- 4) National Ethics Committees (Councils);
- 5) Forum of National Ethics Councils;
- 6) European Research Advisory Board.

institutionalization and legitimation of ethics – as a background for a more specific EU FP7 ethical framing. Before this, however, it is important to clarify the distinction between what we would call ‘legally binding documents’¹⁵² (in our context we primarily refer to the CHREU and to three EU directives¹⁵³) and ‘legally non - binding documents’, as both these types of documents have a key importance for the implementation of the ethical framing of the EU research in their own specific way¹⁵⁴.

Thus, in order to link the institutional and legal framing, we would refer:

- 1) to the reports and opinions¹⁵⁵ by EGE, especially to their latest report of activities 2005 - 2010;
- 2) to the policy papers and reports drawn on behalf of the EU Commission as managed by the Unit of Ethics and Governance (UEG) within Research DG with its Ethics Review Sector (ERS) within the European Commission. Through our empirical analysis

¹⁵² Here by legally binding sources we are primarily referring to the Charter of Human Rights in the European Union (which has acquired its legal status since 2009 as part of the Treaty of Lisbon), with its implicit or explicit reference to ethics for science and technological development. █

In the second place we are referring that are, in their turn, translated accordingly to the legislation of individual member states. Having said this we would like to specify that our interest primarily lies in the EU Directive 95/46/EC of 1995 on data protection, requiring that member states protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data we would like to point out that this directive with its specific reference to the data protection is rooted in the above mentioned Charter of Human Rights in the European Union.

¹⁵³ Here we are referring to the following areas covered by specific directives: 1) data protection – with the supporting EU Directive 95/46/EC of 1995 on data protection, requiring that, member states protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data;

2) clinical medicine – with the supporting EU Directive 2001/20/EC of 2001 on clinical medicine, harmonising the provisions governing clinical trials and fostering and facilitate multinational clinical research;

3) animal welfare – with the supporting EU Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.

¹⁵⁴ Thus, in more general terms, in regard to the legally binding relevant documents we primarily refer to primary and secondary EU legal acts and decisions; in regard to the non-binding relevant documents we primarily refer to 1) opinions and reports of relevant bodies – having advisory role, primarily for the use of the EU Commission, but also for other EU institutions and bodies; 2) policy documents and reports – mostly representing the strategic planning and strategic visions of professionals of the field (also as a resource for future policy making or as a normative vision – “how it should be” in an ideal situation), but also including assessments and impact analysis.

¹⁵⁵ These are usually opinions, reports and analysis drafted on behalf or by order of the European Commission or some other EU institution, or alternatively, by the initiative of the EGE itself. Although these documents do not represent the official EU policy, they should be considered as an important source of information regarding the deliberation on existing and potential EU policy aspects on ethical framing in EU in research and technological development.

we identified the UEG and the ERS as one of the key actors within our field of studies, and the reports and policy documents produced by UEG and ERS as key to the strategic approaches in the development and implementation of the overall ethical framing of the EU research and development;

3) to the opinions and other documents produced by the National Ethical Committees (NECs) which in themselves may not be legally binding but a) have been drafted taking into consideration respective the legally binding national legislation; b) serve as a basis – as we shall demonstrate further in the work – for the respective EU bodies (e.g. EU Commission) to take a legal decision on the conditions of funding an EU research project (taking into account its ethical aspects) or rejecting the project proposal as ethically unsound, for example.

More specifically, regarding the issue of legitimation, it is important for our research problem to point out that:

1) there is no and cannot be a uniform EU ethical framing or legislation, in terms of certain rules or legal norms, primarily due to the reason of the diversity of European values (since ethics is linked to values); at the same time, there should be and there are certain principles that refer to the whole of the EU, and they are legally binding; these principles have been enclosed in the CFREU which is part of the Lisbon treaty and thus binding to all of the EU member states;

2) one of the key legal principles, as stipulated by the primary legal sources of EU, is the principle of subsidiarity; thus, when decisions have to be taken on activities (including research activities and their ethical aspects) that are to be performed in a particular member state, in principle the decision is to be taken by the respective member states¹⁵⁶.

¹⁵⁶ There are a few exceptions to this overall approach, especially regarding research on humans. For example, there is a uniform EU approach regarding human cloning

These findings and conclusions bear relevance to our analysis regarding the role and impact of the relevant bodies and relevant legal and policy documents for the implementation of ethical approaches in EU research, and specifically the FP7 research. In the subsequent chapters of the present work we will show in what way these legal aspects and legal and policy documents, as well as their hierarchy is relevant for taking decision on ethical aspects of FP7 research projects. We will try to analyse the role of these documents not only regarding their capacity to cause respective consequences and regarding the effectiveness of this process in relation to policy implications, but also regarding the inherent question - whether ethics can be reduced to law, and if not, if there are also alternative approaches for ethics to be effectively implemented in practice. We will analyse it in relation to our research problem on the conditions of ethical reflexivity in the governance of FP7 ICT research.

However, in order to analyze this, we will have to keep in mind our research problem with its theoretical approaches - as to the issue of the development, implementation and efficiency of ethical norms with regard to technological developments¹⁵⁷.

Based on our textual (report) and interview analysis we have come to the following conclusions:

¹⁵⁷ Thus, we will have to analyse our empirical findings on how decisions on ethics are being made within the existing institutional and legal framing in EU research domain, since, as we could conclude from our empirical study, the widely discussed separation between the technological and ethical communities has not yet been overcome, and the issue of expertise in ethics remains a challenge to be addressed. We will have to analyze in the further parts of the work what is the role of the current EU ethical framing in facilitating ethical thinking and reflexivity at early parts of technological development, and not reducing ethics to pure checking of certain legal compliance or individual expert opinion. In other words – we will have to verify if the institutional practices in EU have reference to “deeper social values and interests” – as was represented in the TEKSS report – a policy report on “how things should be”. As pointed out by Sembok, reflexive ethics also means the continuous effort of studying of our own moral beliefs and conduct, and striving to ensure that we, and our community and the institutions we help to shape, live up to standards that are reasonable and solidly-based for the progress of human beings. Sembok, 2003, p. 244)

1) the society, the public policy makers in research, as well as the academic society are aware of the impending ethical problems in technological development;

2) there are certain institutional measures and policy instruments put in place to address ethical issues regarding technological development in EU, still, the question is, how effectively the respective ethical challenges are addressed in terms of the implementation of the respective EU policy;

3) there is no and cannot be a uniform EU policy regarding ethics in technological development, since the moral and ethical issues are contingent to the national tradition and legislation; at the same time, there are common European values as part of the European cultural heritage, and for this reason we can speak of certain universal principles addressing general human values;

4) in practical terms, the key challenges today are - making relevant information more accessible; promoting European dialogue on ethics in science; promoting awareness and integrity of researchers; facilitating exchange between NECs;

5) on the operational side – we have found ethics has been closely related to law;

6) the divide between the scientific and ethical communities still exists and needs to be addressed; this bears relevance to the issue of ethical expertise;

7) the principle of subsidiarity is important in dealing with ethical issues in EU research and technological development; since ethics is related to values, we have to count with the diversity of European values;

Further on in the work, we will have to see and analyse how the existing conceptual, institutional and legal framework is being put to practice specifically in FP7 (how law, ethics and politics is being connected). We will have to see whether ethics is not being reduced to a purely operational positivist approach¹⁵⁸, since such an approach could

¹⁵⁸ Positivism is any philosophical system that confines itself to the data of experience, excludes a priori or metaphysical speculations, and emphasizes the achievements of science. Positivism is closely connected with empiricism, pragmatism, and logical positivism. For more information see Glossary in Annex 1.

not be viewed as truly ethical approach (keeping in mind that the task of ethics is to test and show the difference between the “ideal” and the actual practice). We will have to see the actual regulatory framework, the role of EU and member state institutions, as well as experts in regard to decision making on ethics in FP7 ICT research. At the same time, we will have to see the role of the broader spectrum of stakeholders, the public opinion and the EU citizenship at large. Thus, further on, we will present our empirical findings regarding the normative conception of the ethical framing of the FP7.

3.3. Normative conception – the conceived approach

Having discussed in the previous chapter the historical context for ethics becoming part of EU research policy, in this part of the work we will be analysing the normative conception of the P7 framing and see our research problem in this particular context. Firstly, we will identify the respective governance arrangements and their application. Secondly, we will analyse them in compliance with our theoretical framework and the constructed grid for analysis. To this end, the information from our textual analysis and interviews will be used. The relevant documents¹⁵⁹ and information on general rules for EU research¹⁶⁰ will be referred to in footnotes and analysed in annexes, respecting the length criteria of the present work. In the main text, however, we will present our key findings, as relevant to our research problem.

¹⁵⁹ By relevant documents we refer to:

- 1) European Parliament and Council Decision 1982/2006/EC of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013). Its Article 6 stipulates: "All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles".
- 2) Annex 5 to the FP7 ICT research Guide for Applicants “Ethical Guidelines for undertaking ICT research in FP7”.
- 3) Ethics check-list
- 4) Ethics Review procedure and Ethics Review report.

¹⁶⁰ General rules in EU research - first of all, participants in FP7 projects must conform to current legislation and regulations in the countries where the research will be carried out. They must seek the approval of the relevant ethics committees prior to the start of the research activities, if there are ethical issues involved. Participants should respect [international conventions and declarations](#). In accordance with the [Amsterdam protocol on animal protection and welfare](#), animal experiments must be replaced with alternatives wherever possible. The suffering of animals must be avoided or kept to a minimum. This applies in particular to animal experiments involving species which are closest to human beings.

We were viewing the normative conception of the ethical framing of FP7 in context with its institutional framework within the EC. We attempted to see how the organisational and institutional aspects contributed to the initiation and implementation of specific relevant governance arrangements. Regarding the relevant structural units in the European Commission we are referring to: 1) the Unit of Ethics and Governance (UEG) with its Ethics Review Sector (ERS) within Research DG; 2) the Evaluation and Monitoring Unit (EMU) in the Information, Society and Media DG. Regarding the institutional approaches with implication to the decision making process for ethics in FP7 (as part of governance arrangements), our attention was targeted at:

- 1) experts and expert panels;
- 2) NECs;
- 3) various other relevant governance arrangements and tools¹⁶¹.

The above mentioned structural units were relevant for our research in the first place because of their particular competence and functions in relation to FP7 ethical framing. However, further on it turned out during our empirical study that these units apart from their function in the implementation of the FP7 ethics normative framing, have also a significant role in the policy deliberation process on ethics in EU research, (FP7 including), as well as in search of innovative policy solutions¹⁶².

¹⁶¹ As we found out during our empirical study, although there is a clear and precisely defined institutional and legal framing with regard to the decision making procedure on ethics in FP7, the decision making procedure involves various arrangements and tools that go beyond the strictly defined legal and institutional framing. Therefore we would like to note – in the context of the present work by governance arrangements we will be referring to any institutional arrangement, approach or tool which we identified as relevant to our research problem. Consequently, in our analysis, we will be dealing with such identified governance arrangements as: National ethics committees; FP7 Ethical guidelines Annex on Ethics with the Ethical Check list; Expert panels; Ethical review procedure with ethical review report; Ethical audit; Impact assessment; Learning function between different stakeholders; Public consultation; Expert studies on behalf of the Commission

¹⁶² Thus, for example, the UEG among other functions, manages the production of high level expert reports regarding the policy approaches to EU research ethical framing, FP7 ethical framing including. The preparation of many of the reports that we have analysed in annex, have been managed by the UEG, and a considerable input here has been by the UEG project and policy officer Dr Rene Von Schomberg who kindly agreed for an interview during our empirical study process. The ERS, in its turn, apart from the implementation of the ethics review in FP7, apart from its basic function of ethics review, has taken the initiative and lead in the implementation of communication and exchange of opinion among the National

In the analysis of the normative framing of FP7 (according to the parameters within our analytical grid¹⁶³ regarding the ethical approach) we have found that:

1) on the one hand, the FP7 ethical framework is being implemented by means and within the legal framework of EU and the EU member states); the responsible EU officials explicitly referred to this legal framework, when discussing the decision taking procedure for ethical compliance of FP7 projects; thus, in general terms, we could conclude that ethics in FP7 is being implemented by means of law;

2) on the other hand, as we found out during our empirical study¹⁶⁴, in practice, in the decision making procedure, various tools and approaches that go beyond the existing legal framework are widely used; these approaches and tools can also be tacitly shaped through experience, exchange and mutual learning; awareness was explicitly shown among the EU officials on the complicated nature of decision making regarding ethics in research (that ethics cannot be equated with legal or moral authority, and that clearly there is much more to it); for example, it was mentioned in one of the interviews that the borderline between the research with potentially negative impact and an ethically unsound research is thin, and purely legal instruments in such cases may not be effective enough; moreover, given the fact that cases differ greatly each from other;

3) thirdly, we came to the conclusion that there is a clear awareness and definite opinions among the EU officials regarding both, the successful aspects and the limitations of the existing ethical framework of the FP7¹⁶⁵; regarding the successful aspects, reference was often being made to the raised awareness among the relevant stakeholders; regarding

Ethics Committees and other relevant bodies, in order to facilitate a more uniform approach to the implementation of ethics in EU (FP7) research. The EMU according to our empirical findings has been responsible for the drafting and final adoption (with the relevant public discussion process in between) of the Annex on Ethics as part of Guidelines for FP7 applicants.

¹⁶³ The analytical grid and its parameters have been described in chapter 2.6 and Annex 2.

¹⁶⁴ The various governance approaches and arrangements were discussed during the interviews with EU officials and described in relevant reports. For interviews see Annex 4. For relevant reports and report analysis see Annex

¹⁶⁵ For reference see Annex 7

the limitations, these were being interpreted as challenges to be addressed by future policy making and as part of the current policy deliberation process (including the reports prepared on behalf of EC by groups of relevant experts¹⁶⁶, and, as we mentioned above, on many occasions managed by the UEG).

As a result of our empirical study we were able to identify the normative framing and the governance approaches of ethics in FP7 and further on, by the analysis of them, produced material for the interpretation of these findings with respect to our research problems. This interpretation will be presented in the following parts of the work.

However, in order to summarize our actual findings on the normative framing of FP7 and the relevant governance approaches, we would like to present our key observations, based on our interview and textual analysis:

1) ethical issues are present in FP7 research projects and they need to be addressed, as evidenced by the rules and procedures for ethical evaluation introduced and implemented by the relevant authorities;

2) the key approach for the evaluation procedure is based on respective EU and member states' legal framework and expert evaluation;

3) the key documents and procedures used during the ethical evaluation are the Ethical guidelines, the Checklist and Ethics review (with ethics review report);

4) expert evaluation depends to great extent on the scientific and professional background of the particular expert, and ethical expertise is much related to the approaches within risk assessment;

5) NECs have the key deciding role as to the ethical compliance of the particular research to the national legislation;

6) The awareness among the NECs is raising regarding their role to promote public discussion and policy deliberation on ethics in EU research policy

¹⁶⁶ For reference on relevant reports and report analysis see Annex 5.

7) various relevant stakeholders are being involved in the decision making process, if necessary;

8) the public debate is part of the ethical framework implementation.

These findings (the details are to be found in the texts of our interviews) will serve further on as a basis for analysis of the existing EU ethical governance approaches from the point of view of our theoretical approach. This will allow us to categorise the FP7 institutional and legal framing and the respective governance arrangements accordingly. We are interested to see the relevant governance arrangements in relation to context (if these are contextualised or de-contextualised), as well as to see if the governance arrangements comprise or lack the elements of reflexivity. In this way we attempted to address our actual research question regarding the ethical reflexivity in the FP7 governance procedures.

3.4. Ethics in practice

3.4.1. Implementation of the ethical framework of FP7

Through our interviews during our empirical study we were aiming at obtaining the opinions and analysis by the respective EU officials (present and former) regarding the results of the implementation of the ethical framing of FP7. We were particularly interested in their opinion on the success in the implementation of the FP7 ethical framing, as well on the perceived drawbacks and challenges. Furthermore we were interested in their opinions regarding the relevant governance procedures and the presence of reflexivity in their implementation. We received a wide variety of answers, ranging from broadly general to strictly specific¹⁶⁷. We carried out the analysis of our empirical findings according to a set of parameters developed within the analytical grid (enclosed in Annex

¹⁶⁷ For a general insight we will represent the key types of answers in Annex 7.

2). Following our analysis of the findings (enclosed in Annex 7), here are our main conclusions:

1) the respective EU officials regard the implementation of the FP7 ethical framework as a success, however, the arguments are basically related to the organisational, managerial, statistical and legal aspects (see Annex 7);

2) there is clear evidence on the respective governance arrangements put in place for the implementation of this ethical framework (see Annex 8);

3) there is awareness present among the respective EU officials on the necessity for reflexivity within these governance arrangements. There has been an explicit reference to the policy deliberation procedures, involvement of stakeholders, public discussion and the function of learning. There was also clear reference made on the complicated nature of the issue of “ethical expertise” – in terms of non-existence of clear “ethical authority”¹⁶⁸;

4) the respective EU officials have explicitly referred to a range of challenges to be addressed regarding the ethical framing of FP7 and its implementation, and these challenges mostly concern the problems raised by the diversity of European values, by the difficulty to translate normative assumptions into policy and legal documents, by the complexity of the issue of “ethical expertise”, the coordination of approaches among various structural units of the EC and expert panels and the difficulty to secure a continuous and effective policy deliberation and public discussion process with the involvement of multiple stakeholders, with the implicit learning function (See Annex 7).

¹⁶⁸ We would like here to refer, for example, to the interview with the ex-member of the European Group of Ethics Rafael Capurro regarding the role of ethics councils: "Ethics councils within the sphere of public policy have the function of reflecting on the moral and legal foundations of specific controversial issues without being itself neither a legal nor a moral authority. Their task is reflection, not decision-making or dogmatic proclamation. They should counterbalance ethical arguments and give an opinion on matters that remain controversial and subject to revision. Today's public policy has a need for such counsels particularly with regard to new developments in science and technology".

Following the main conclusions regarding our empirical findings, in the following parts of the work we will refer to our cases study and further on reflect on our empirical findings in relation to the theoretical framework of our research.

3.4.2. Case study. Analyses of ethics in the governance of technological projects

In order to see how the conceived ethical framing of the EU Framework (EU FP) program is being translated into practice, we performed a case study on the findings of the EGAIS project concerning the ethical approaches used by the EU Framework program ICT projects. We were interested in the actual governance arrangements and tools used by the EU FP ICT projects, as well as in their opinion on the effectiveness of the process. The findings of our case study on the EGAIS research are enclosed in Annex 9.

4 Reflecting on the results of the empirical analysis and the critical perspective

Abstract

In the previous part of the work we discussed our empirical study. In this part of the work we will be reflecting on the result of the empirical data analysis at project and policy level. We will attempt represent how the conceived EU policy is translated into practice. Further on we will reflect on our empirical findings in relationship to our theoretical approach.

Referring to our theoretical approach and the proposed ethical framework which was based on the notion of contextualization of an ethical norm, as well as on the approaches for ethical reflexivity in relation to the efficiency of an ethical norm, we will identify problems within our theoretical framework and our empirical data and critically evaluate them. This will enable us to determine the possible limitation of the proposed theoretical approach.

4.1. Reflecting on the empirical data analyses

As part of our research we saw it relevant to relate the findings of the case study (at project level) to our findings at policy implementation level. From the analysis of the case study of the EGAIS project we have seen that the projects adhere to the formal requirements in terms of checklists and other procedures. However, the performed analysis within the EGAIS project - on the implemented governance approaches - show that ethical reflexivity in most cases is missing (see Annex 9). There are instances of first order reflexivity, however second order reflexivity is rarely met. Thus, we could conclude that adhering to the formal requirements by itself does not lead to the implementation of ethics in EU FP7 ICT research from the point of view of our theoretical approach.

At the same time, when reflecting on the results of the empirical data analysis at policy level, we have come to a particular finding - that there are two mutually contradictory sides of the issue (see Annex 7). On the one hand, based on the findings of our FP7 normative analysis, we have seen (see footnote 171) that ethics in its implementation (though to a varying degree and occasionally in a relative way) is subject to certain limits. We will justify our argument regarding the limits as follows - since there is no and cannot be a uniform and absolute definition on what ethics is, also with regard to ethics in EU research¹⁶⁹, we have proceeded from the opposite approach by the negative definition of what ethics “is NOT”. We have borrowed this approach from the field of law¹⁷⁰, where the application of negative definitions is a common practice, e.g., in administrative law, once a comprehensive or exhaustive positive definition is not possible or feasible¹⁷¹.

On the other hand, however, our empirical text analysis and interview materials indicate to the EU policy makers awareness of these limitations, and to their awareness that ethics cannot be reduced to a mere moral or legal authority. Moreover, that policy discourse and involvement of various stakeholders not only are an inherent part of the ethical framework of EU research today, but must include the element of reflexivity and continuous learning (if ethics is to be taken seriously). To justify this awareness, we will refer to the findings of our empirical study with regard to existing challenges or drawbacks

¹⁶⁹ Cultural disagreements do not only have their source in difference in values. Different cultural frameworks may assign various problems or issues to different forms of reason; these disputes are about justification and adjudication themselves and thus give rise to the need for the exercise of public reason (Public deliberation, p.90).

¹⁷⁰ The author of the work in 2009 has obtained a qualification in legal science, and her thesis (qualification work dealing with EU education rights) was promoted for publication and published in 2010. Since our work is aiming at the analysis of EU policy implications, and not specifically analysing ethics as a philosophical category, we saw it appropriate to apply a varied spectrum of approaches, including also those typical to the science of law.

¹⁷¹ In administrative law, when it is necessary to qualify a certain action, on certain occasions a clear distinction between various types of actions can be achieved only through applying a negative definition.

in the EU (FP7) research ethical framing¹⁷². We will also refer to justification of this from relevant policy documents and reports analysed during our empirical study¹⁷³.

Consequently, we would like to argue that alongside with the above mentioned awareness on the complicated nature of ethics in EU research, in practice in the implementation of this framework, there are traces of certain limitations (as related to our previously discussed challenges in public policy and deliberation)¹⁷⁴.

¹⁷² The key challenges and drawbacks referred to by EU policy makers in their interviews are:

- 1) The unprecedented level of uncertainty in research has created a new technological culture and also ethics needs to be addressed in a new way;
- 2) Ethics is being seen as a questionable field for legally binding norms;
- 3) The historically novel contradictions that exist between the value spheres cannot simply be eliminated through political decisions, and political system must react independently of the subjective will of political actors;
- 4) Limitations by individual decision making;
- 5) Limitations of collective decision making;
- 6) Negotiations with social groups under the conditions of unequal power;
- 7) The question of the relationship of ethics and the effectiveness of respective legally binding norms regarding ethics remains open;
- 8) Non-ambiguous roles and capacities (mandates) of various stakeholders;
- 9) The very democratic procedure may not any more be an answer in principle regarding the various interests of stakeholders;
- 10) The divide between the ethical and scientific communities;
- 11) The current mode of institutionalisation of ethical expertise.

¹⁷³ For example, according to Von Schomberg “The need for a differentiation of authorized discourses stands at odds with the impossibility of such differentiation on the level of actual problems” (Von Schomberg, 2002, p. 231). Thus, clearly, there is an indication that the problem of ethics cannot be addressed purely on the level of content, but structurally new solutions need to be sought. Furthermore, according to Schomberg, the major ethical challenge we face today is that “techno-scientific applications can remain ethically problematic even in cases where scientists and engineers have the best possible intentions and users have not conscious intention to misuse or abuse” (Schomberg, From Ethics of Technology Assessment to Ethics of Knowledge Assessment, p.11). As pointed out by Schomberg, “as a minimum we would require an ethical framework that addresses both the aspect of unintended side consequences (rather than intentional actions) and the aspect of collective decisions (rather than individual decisions) with regard to complex societal systems” (Schomberg, (From Ethics of Technology Assessment to Ethics of Knowledge Assessment, p.5). According to Von Schomberg “a successful response to uncertainty is not a question of what the better political option might be, but rather a structural reaction to the growing problem of uncertainty, which could usher in a new evolutionary stage of social development (Von Schomberg, 2002, p. 231).

¹⁷⁴

- 1) Implementation of ethics in FP7 is carried out by means of the relevant legal framework, thus, in general terms, we can evaluate that ethics is being reduced to law;
- 2) The favoured methods used are technology assessment and risk assessment with expert involvement (ethics being reduced to risk assessment);
- 3) Ethics tends to be separated from the technology itself, that is, the technological communities and the philosophical communities are not integrated (ethics being reduced to scientific expertise under respective cognitive framing, with second order reflexivity missing);
- 5) There is a tendency to involve various stakeholders in decision making, however, the stakeholders’ debate is often reduced to positivist reductionist approach, in the sense that the experts tend to base their opinion on the existing legal framing
- 6) The public debate is part of the ethical framework, however, it is often reduced to social acceptance instead of social acceptability, by social acceptance we mean approaches where a consensus is reached without second order reflexivity being present.

Based on our empirical findings, we can conclude that there is a high awareness among EU research policy makers that ethics cannot be reduced to scientific expertise or legal frameworks only (See Annex 7). Consequently, scientific expertise is not an answer, legal frameworks cannot guarantee ethically sound research. We have found evidence also on the increasing awareness on the existing divide between the scientific and ethical communities, which on many occasions preconditions that ethics is addressed in a fragmentary way or by a purely sectorial approach, also regarding the issue of expertise¹⁷⁵. We have also found evidence that key classical ethical theory approaches are increasingly unable to give answers to the ethical challenges of today, and clearly there are new needs regarding adequate ethical frameworks.

Moreover, in our analysis of the policy deliberation on ethics in technological development, we have found evidence of opinions (especially in report analysis) that risk assessment is just one aspect (and often incomplete) in ethical issue determination which often is not sufficient to offer solutions¹⁷⁶; and technology users are also frequently not aware of the potential ethical aspects in new technologies or of ethical aspects in their use of these new technologies¹⁷⁷.

¹⁷⁵ Regarding the role of experts - there is a growing uncertainty regarding who are the ethical experts regarding technological developments, and “the move towards participation in science recognizes the limits of experts”, as pointed out in the Report on Global Governance p. 28. The question is whether ethics can be reduced to mere consequences of risk and uncertainty in technological development, or is there more to it.

¹⁷⁶ Here we would also like to refer to the findings of the EU FP7 ETICA project, arguing that most forms of technology assessment have some sort of stakeholder input, using various tools to gauge the concerns of users, stakeholders, interest groups and other. However, it is indicated by the ETICA project, the norms constructed by the experts and stakeholder participants are in no way required to be ethical norms, and in fact they are most likely to be societal norms and expectations of the target groups (ETICA, deliverable 4.1).

¹⁷⁷ In terms of justification that ethics cannot be reduced e.g. to risk assessment - as stated in the TEKSS Report, “ethics has become an important political resource in the European Union” and at the same time, further on, it has been argued that “ethical discourse has been introduced in Europe as a warrant for, and a putative regulatory control over scientific and technological power – and as a means to establish a closer link between science and society” (TEKSS Report, p. 47). This is statement which requires some analysis, since, on the one hand, it is implied that ethics is being addressed by the politicians in order to respond to the societal needs. On the other hand, in referring to ethics as a ‘warrant’, there is no indication in what way this warrant actually functions or how effective it is, moreover, ‘putative regulatory control’ implies that we can hardly speak of a real impact at all. Proceeding from this we can see, that the very awareness of ethical issues at public policy level does not provide automatic solutions, and the very awareness of ethical issues in science and technological development can hardly be regarded as a ‘warrant’ or ‘regulatory control’. By such an approach ethics would be reduced to a simple risks management or a similar issues, which ethics is clearly not.

For this reason, the traditional sociological approaches, although highly relevant, in addressing the ethical issues, alone may not be able to give all the answers, and alternative approaches might be needed to see ethics from some different or alternative complementary perspective.

Following our reflection on the empirical findings and the conclusions drawn based on these findings, further on we performed the analysis of our empirical findings from the theoretical perspective of our research.

4.2. Relationship between theoretical framework and the results of empirical analyses

Regarding the analysis of the results of our empirical data analysis in relation to our theoretical framework, we were interested in certain aspects of the identified governance arrangements.

In the first place we were interested in what way these governance arrangements are being used (see Annex 8). For example, these applications might include the securing of ethical compliance or legal compliance, avoiding future obstacles, consulting, restriction of framing, social acceptance, identification of ethical issues, ethical management and other.

Secondly, we were interested in how these arrangements relate to the previously discussed modes of governance within our theoretical framework (for more details see Chapter 2.6 and Annex 8) - standard¹⁷⁸, consultation¹⁷⁹, revised standard¹⁸⁰, co-construction¹⁸¹ mode.

¹⁷⁸ Standard model - disagreement between the experts and the public are perceived as irrational due to public's lack of knowledge. Rational experts and irrational public

¹⁷⁹ Consultation model - Difference between experts and non-experts is in the perception of risk. Public have valid views. Voluntary and involuntary exposure to risk, the unknown character of risk, the number of people affected by risk

¹⁸⁰ Revised standard model – interaction btw regulation process, social groups and medias. Public attitude, exaggerated legislation, consequently irrational law-making. Technocratic vision, top down approach

¹⁸¹ Co-construction model – Questions the way in which technological development projects use experts. Based in Latour. Facts and values are being taken into account. Stirling - not only a democratic matter but a matter of analytical rigour. Why withdraw from debate which will discuss what may eventually be changed.

Thirdly, we wanted to see how these governance arrangements relate to context (see chapter 2.6. and Annex 8) – if they are decontextualised¹⁸², if context is restricted¹⁸³, or if they are fully contextualised¹⁸⁴.

Fourthly, we were interested in what was the underlying pre-supposition in the use of the particular governance arrangement (intentionalist¹⁸⁵, schematising¹⁸⁶, mentalist¹⁸⁷).

Fifthly, we were interested in the presence of reflexivity within these arrangements. We have performed our analysis by using the grid for empirical data analysis which we have discussed in chapter 2.6. and enclosed in Annex 2, alongside with the respective analysis in Annex 8. In this part of the work we will include our key findings and conclusions after analyzing the respective FP7 governance arrangements according to our grid for data analysis:

1) regarding the modes of governance as relevant to our research (described in chapter 2.6. and analyzed in Annex 8), we have found that in most cases the standard,

¹⁸² Decontextualised - refers to the situation where the ethical norm is seen outside the context of its application

¹⁸³ Restricted context - refers to the situation where the ethical norm is seen partly inside the context of its application

¹⁸⁴ Fully contextualised - refers to the situation where the ethical norm is seen fully inside the context of its application

¹⁸⁵ Intentionalist pre-supposition - according to the intentionalist pre-supposition, the norms effects are supposed to be deducible from the simple intention to adopt the norm. additionally, there is the presupposition that the actors in a participatory approach will have capacity and intention to contribute to the participatory discussion, in line with Habermas (1981/1984) proceduralism. For example, an ethical committee may produce a set of guidelines for the technological developers to implement. However, they do so without thinking about what actual effect the norm will have in the implementation; they simply assume that the developers will have the will and intention to implement the norm, and thus the norm will be implemented.

¹⁸⁶ Schematising pre-supposition - the schematising pre-supposition involves Kantian schemes (rules), in which the operation of the application of a norm is a simple formal deductive reasoning on the basis of the rule itself. The determination of the norm is linked to these rules, such as ethical guidelines, or laws, or other external sets of rules (Such as Human Rights act, e.g., etc.) in order to determine the effect of the ethical norm. The schematising presupposition also involves preconditions about how the norms might be addressed, and is most commonly seen in expert panels, advisory boards and committees.

¹⁸⁷ The Mentalist pre-supposition - the mentalist pre-supposition is named so because it relies on the mind having a set of rules (or schemes, in Kant's words), that predetermines the effect of a norm, and does not depend on any exterior context (to that of the thinker). This is commonly seen when participants in a participatory approach come to the setting with their own particular ethical framing, or with some preconceptions as to what ethical issues might arise. This is also commonly seen within expert opinion committees, with each expert having their own preconceived idea about the ethical issues before consulting any of the people that technology might impact. Such an expert may also have a idea about what effect the norm might have before fully exploring the contextual, social, cultural and other sides of the problem.

consultation and revised standard modes predominate, with some cases of the co-construction (or partial co-construction model);

2) regarding the relationship to context, we found that in most cases the context is either ignored, or restricted contextualisation is present. Full contextualisation could hardly be traced (see Chapter 2.6. and Annex 8);

3) regarding the governance arrangements and their underlying pre-suppositions – we have found that the FP7 governance arrangements suffer from the three presuppositions, as discussed in our theoretical framework – the intentionalist, the mentalist and the schematising presupposition (see Chapter 2.6. and Annex 8).

Thus, for example, the Ethics check-list and Ethical Guidelines pre-supposes the capacity of relevant stakeholder to identify the ethical issue and does not take into account the actual addressing of the ethical issue. The same problems refer to the Ethics review process which is used for projects that raise ethical issues, if it has been identified by the check-list procedure or as envisaged in certain cases by the Ethics Review procedure itself. These approaches do not facilitate the opening up of the cognitive framing by any stakeholder involved. We found that most of the governance arrangements within the ethical framework pre-suppose normative criteria for evaluation.

We have also found that a pre-supposition seems to exist regarding what ethics is – since otherwise a generalised requirements for an ethical approach would not be possible. Thus, reducing ethics to check-lists, guidelines or certain ethical concepts or formal norms can hardly mean approaching ethical with full awareness and responsibility. According to our findings, these documents can secure the acceptance or compliance of these technologies to certain defined criteria or standards (e.g., normative), but not the ethical acceptability (which in our understanding is the true meaning of ethics).

At the same time, as we have mentioned already before, the analysis of the policy documents and reports, as well as the analysis of the interviews show a clear awareness among policy makers regarding the complex nature of ethics in governance, including the issues of governance approaches, the various uses of governance tools and also the many and various underlying pre-suppositions¹⁸⁸ (see Annex 7). There is also a clear awareness on the need for reflexivity - not only within the specific mental framing (as a first order reflexivity¹⁸⁹) but also regarding the reflection on the mental framing itself (as a second order reflexivity¹⁹⁰) – especially in the context of policy deliberation.

At the same time, regarding the implementation of respective governance approaches, we could see that the ethical approaches are partially or fully de-contextualised, that the first order reflexivity was still predominant, at least in terms of the actual decision taking process.

Further on we will discuss our assumptions regarding these conclusions. We will attempt to identify the problems within our theoretical framework and our empirical data. In this way we will be able to generate a critical perspective – both, on the positive aspects of our theoretical approach and also regarding its limits. We will analyze the outcomes and propose solutions within the context of our theoretical framework.

4.3. Identified problems within the theoretical framework and empirical data analyses

The above mentioned findings make us assume that our theoretical framework has allowed us to identify problems within the FP7 ethical framing with regard to the reflexivity within the relevant governance approaches. At the same time, our empirical data indicate that our

¹⁸⁸ This refers to the contradiction we described above – regardless of the limits we identified within the ethical framing of FP7 (as described in p.83), in most interviews with the EU officials we identified a clear awareness regarding the complicated nature of ethics in research and technological development, and a clear awareness for the need of reflexivity and continuous learning.

¹⁸⁹ First order reflexivity implies cognitive framing, analysis of the world with some pre-conception

¹⁹⁰ Second order reflexivity implies capacity to reflect on ones own mental framing

theoretical framework does not allow us to analyze the implications of our findings from a broader policy perspective. We had to conclude that there should be some additional unidentified factors at work, as we have found a clear discrepancy between the conceived (ideal) ethical framing in the governance of the FP7 and the actual normative framing and its implementation (including the actual procedures put in place).

We have concluded that according to our theoretical approach, there is no fundamental problem with the conceived approaches to ethics in EU policy making, but there are challenges present regarding the actual implementation and function of ethics. There is evidence that ethics is basically being reduced to law (in order to secure legal compliance and in such a way in fact losing the true normative function of ethics), and there is some evidence that ethics might become subject to the interests of various stakeholders or used for achieving political aims (as in a democratic discussion there can never be a guarantee that the various opinions are based solely on values and not interests) (See Annex 7). Consequently, ethics might be reduced to a purely formalistic approach – for securing some form of compliance or compromise (we will refer to the issue of compromise further in the text).

Thus, by our theoretical approaches we were able to evaluate the existing governance arrangements in the conception and implementation of the ethical framework of the FP7, but not fully able interpret them in the actual policy context (e.g. the contradictory process on the adoption of the ethical guidelines of FP7, as presented in our interviews). This makes us think on the limits of our theoretical approach and makes us also apply the second order reflexivity regarding our own theoretical framing. Consequently, we had to identify additional approaches for a full interpretation of our empirical findings. To this end we identified the SCOT and adjusted it to our own needs as a method of analysis (see 5.3.1).

Further on we will point out more specifically the limits to our theoretical model.

4.4.Limitations to the model

Before discussing the limits to our model, in the first place we would refer to the success of our theoretical approach in proposing a way for addressing ethics as part of technological development and thus proposing a solution to the drawbacks of the more traditional ways of addressing ethics after the development of a technology.

Regarding the limits to the model, we have identified its inability to address wider societal implications regarding the role of the various actors and stakeholders involved in the policy deliberation and public discussion process, as part of modern technological culture.

As a consequence of this finding, we would like to underline the role of our theoretical approach for the promotion of reflexive governance with its inherent learning function. Thus, despite of its identified limits, we would like to view our theoretical approach as a meaningful contribution to the overall policy deliberation procedure, and regarding the promotion of institutional and legal frameworks that promote the integration of ethical reflexivity into the technological development at an early stage of the process.

Proceeding from this, we would like to discuss the outcomes of our research, the proposed guidelines and the lessons learnt.

5 Outcomes, proposed guidelines and lessons learnt

Abstract

In order to discuss the outcomes of our study and propose guidelines, as well as to present lessons learnt, we will refer to the key research issues we were addressing in our study.

According to our research problem and research questions, we were concerned with the

the conditions of ethical reflexivity in specific context. We were interested in the conditions of ethical reflexivity in relation to the efficiency of an ethical norm, as well as in the conditions that will allow for the efficiency of this theoretical approach. Based on the identified outcomes, we will propose solutions and discussed the lessons learnt.

5.1. Outcome and guidelines - on the conditions of ethical reflexivity in relation to the efficiency of an ethical norm

As a result of our study and analysis, we have found that the predominant approach to ethics in FP7 technological development tends to respond to “ad hoc” problems, namely, when an ethical problem appears (for example, when evaluating an FP7 project, it is being screened for ethical problems and if such are identified, respective measures are taken). In our research however, it was important to understand how effective the ethical norms are and under which conditions they emerge and are being implemented. Thus, a special emphasis was put on addressing the conditions for the effectiveness of ethical reflexivity within technological development.

As we pointed out already in the previous parts of the work - in most theoretical approaches to ethics, the conditions that determine the effective implementation of a norm are considered to be presupposed by rules of our minds (mentalist pre-supposition). Most of these approaches tend to undermine the role of external contexts within which the norm is to be constructed and operated. Moreover, these approaches usually take the context as given. Therefore, by attempting to underline the role of the conditions of the construction and implementation of the norm in a specific context, in our opinion, has help us demonstrate the limitations of the theoretical approaches in question.

We have also attempted to show the problem of “cognitive closure” (as discussed in the second part of our work) which lies at the heart of these limitations - in relation to the many specific cognitive framings with their characteristic constraints, such as

technical, political, cultural or other constraints (this issue is also related to the problem of expertise with its own specific cognitive closure). Our concern has been that technical and scientific value systems might dominate over the moral reason. These value systems might undermine the other external framings that are relevant to the construction of the norm regarding the technological development.

We have also attempted to show that the divide between the ethical and technological communities still is strong. Thus, genuine reflexivity can be easily suppressed by a rational technological approach, with its own specific values system. This value system typically tends to reduce or even undermine other alternative framings. But these alternative framings may be relevant to the construction of the specific ethical norm. Therefore we have attempted to point out the significance of opening up such framings, in order to create a genuine ethical reflexivity. As indicated by our empirical analysis, the ethical reflexivity is well present in the policy discourse, but faces certain challenges regarding its actual implementation.

We encounter the same problem - when ethical governance is being reduced to sectorial ethics – in regard to the work of experts (usually with a specific professional background and therefore having a specific framing). These experts (according to our empirical findings) often find it difficult to go beyond the boundaries of their own cognitive framing, and this again leads to a cognitive closure.

Our empirical research has helped us to explore what types of cognitive framing have affected the ethical governance approaches of FP7 (see Annex 8). By understanding these cognitive framings and the potential cognitive closures, we attempted to understand the ways how to possibly open up such cognitive closures.

Our key findings regarding this are:

- 1) in order to address the issue of cognitive closure, we need a reflexive

governance process; this reflexive governance process would consist of a learning process among actors (or stakeholders) - to use the vocabulary of our theoretical approach, that would lead to the capacitation of actors;

2) such an approach would only be possible if the stakeholders are prepared to learn; this involves readiness on their part to review their current opinions or framings, or, if to use the vocabulary of our theoretical framework and that of the EG AIS project, to be prepared for the “destabilisation of the *a priori* frame of contextualisation”; only this would lead to the opening up the cognitive closure.

3) The learning needs to be integrated into the ethical governance process throughout the technology development process; this should involve the investigation of the conditions on how to effectively insert an ethical norm into a context from the beginning of technological development.

Here we need to refer to the notion of the second-order reflexivity which means that the existing cognitive framing itself is being questioned and reflected upon, as well as the conditions that allow for putting this in question). Our approach is that ethical governance cannot be limited to an approach where it is sufficient to provide a justification how a decision on ethical issues is being made (for example, by referring to specific legal norms or procedures). Neither can it be limited to a consultation process which would reduce any ethical issue to the question (or condition) of (social) acceptance - instead of real (social) acceptability¹⁹¹. In most cases of our analysis we have seen this specific approach.

But ethics should be considered as a normative authority (referring also to the ethical imperative), as we have discussed before, and thus free of any contextual constraints. Otherwise ethics would be equated to, or would have to obey, for example, economic, political and other constraints, which would reduce ethics to mere need for

¹⁹¹ For social acceptability see Glossary in Annex 1.

consultancy (as giving means to reach objectives that are not ethically defined, and that would contradict to the very function of ethics).

Our empirical analysis helped us to identify the ethical approaches used by FP7, the governance arrangements that are being used, the conditions in which ethical issues arose, and the implementation processes and tools of ethical governance. Based on this, we had been able to develop on our research question - on the conditions of ethical reflexivity in relation to the efficiency of an ethical norm.

5.2. Outcome and guidelines – on the conditions that will allow for the efficiency of the theoretical approach

As we have discussed before - every norm aims to create a better or more acceptable way of living together (or at least aims in an ideal situation). At the same time, when making their choices, people tend to use rationality which under the present conditions cannot guarantee the optimal result and consequently does not lead to the “ethical ideal”. Thus, the rules that have been put to place (or more concretely, the fact that these rules are valid and operational) cannot guarantee that ethics in its true sense is being implemented.

For this reason, reflexivity is necessary regarding the perceptions of the way of life – in relation to those to whom the norm is being addressed (more generally we could refer to this as the construction of the context). However, in this context, by reflexivity we do not mean a process by which the dominant perception or views are adopted - in relation to the acceptability of the norm. From a more theoretical perspective we would define this as the main limitations of proceduralism (which we referred to in the second part of the work). The question still remains how to organise the relevant actors and their capacity for reflexivity, so that they could identify the various useful possibilities for the identification or selection of a specific norm. We see that the procedural mechanisms and rational approaches in the determination of a norm cannot by themselves alone assure the

modification of the way of life in relation to the "ethical ideal" (how things ideally should be).

However, our aim is to look for ways - how to increase the capacity for reflexivity of actors (with regard to the conditions to the production of the norm and the effectiveness of the norm expression). According to our approach, the capacity for reflexivity needs to be built in such a way, as to not presuppose it already exists by itself. It is therefore important to make sure that 1) every application of a norm presupposes possibility to choose its acceptable normative constraints, 2) and also presupposes the option of the selection of the various possibilities according to the acceptable way of life within the specific target group or community itself.

Having said this, we would like to point out our awareness of the limitations of our approach – it potentially being theoretical to a comparatively high degree, its actual implementation might present further challenges (this is still to be tested in practice). We are aware that institutional arrangements are necessary (indispensable) for the effectiveness of the expression of norms in concrete situations, as well as for the legitimisation process for the norm. We are aware that we can hardly escape these contextual limitations in actual life situations¹⁹².

Thus, within the FP7 project implementation, the policy approaches might further enhance the deliberative processes on technological development within the FP7 projects themselves – based on our approach that an ethical norm has to be constructed, taking into account from the very start the conditions required for its application (that is, the actual context). Taking into account the existing institutional and legal framework, more

¹⁹² Thus, we have to see the outcomes of our theoretical approach in the actual contexts, including the context of our research field – the FP7 ethical framing. At the same time, we have to bear in mind that any theoretical approach alongside its limitations (frequently for their direct application in practice (may have useful implications for the existing approach of framing – as a change of perspective or facilitator for second order reflexivity, for example. Thus, to speak in concrete terms, the existing institutional and legal frameworks not only have certain elements of first (and at some instances) also second order reflexivity as part of their procedures (as our empirical findings show), but they could possibly enhance this reflexivity by the application of elements of our theoretical approach.

emphasis might be put on the deliberative procedures by the various project partners and project ethical advisory boards (ethical committees) – the role of these boards¹⁹³ or committees being to keep the respective deliberation relevant to the ethical imperative¹⁹⁴.

Furthermore, referring to the existing FP7 procedures, we see it feasible to develop upon these procedures – regarding, for example, the monitoring of the projects, the follow up of the projects, the impact assessment, the various governance arrangements within the project (stakeholders’ consultation, contextual study - with the help of technology assessment), ethical framing, deliberation on the so called ethical horizon – insured by the ethical committee, and other) – all these procedures can be reviewed in the light of our theoretical approach in relation to the enhancement of first and second order reflexivity. We see it as the main result of our theoretical approach regarding its implementation in practice. We will develop upon this also in Chapter 6.2.

Referring to more theoretical considerations and the challenges for implementation, the appropriate institutional arrangements must be established for such reflexivity to become possible. The fundamental limitations of these existing ethical approaches should be addressed and overcome. Primarily it concerns the actual moment of the application of the norm. Determining these arrangements will allow actors and institutions, when confronted with an ethical issue, to go through a learning process. Moreover, after reflection on the learning process and its results, to reframe the context of the situation. This would allow to speak of inserting a norm into a context. This would also allow to assess the effectiveness of the result of that process.

As we discussed within our theoretical framework – in order to more effectively incorporate ethical norms into contexts, we need to construct the framing of the context in

¹⁹³ Regarding the role of the ethical councils and committees – our empirical study showed that their role is recognised both, within the existing institutional and legal framework, and also with regard to the deliberation on ethical imperative. The latter was frequently referred to as the “ideal case” which is still not the common practice.

¹⁹⁴ For ethical imperative see Glossary in Annex 1.

relation to the norm (i.e. not presuppose it). Afterwards this context should be opened up - so that we can have a reflexivity on the opening of this framing (that is, to have a feedback mechanism). Concerning research projects, ways (instruments) should be sought how research projects should reconstruct the two-way relationship between the norm and the context and thus achieve a second-order reflexivity.

Our collected data and their analysis allowed us to build a landscape of ethical governance approaches and tools, and an assessment of the reflexivity present. This also allows us to speak of certain outcomes and some lessons learnt.

5.3. Outcomes from a policy perspective and lessons learnt

Here we would like to refer to the outcomes of our study from the policy perspective. As mentioned previously, during our study we came across the fact that not all our findings could be meaningfully interpreted by the use of our theoretical framework. Especially it refers to the identified contradiction between the conceived and implemented FP7 ethical framing. This made us search for other theoretical approaches to secure a comprehensive interpretation of our findings.

5.3.1. Additional methods needed for interpreting policy implications

As mentioned before, we identified the key concepts of SCOT as suited for the analysis of our empirical findings from a broader policy perspective (not the theory as such but its certain aspects in relation to our identified need)¹⁹⁵. It was not our aim to use this theory for analysis for the whole of our work. Instead, we found it relevant to adjust its key concepts to be applicable as a method for the interpretation of our findings¹⁹⁶. This approach allowed us to explain why under the conditions of respective cognitive framing (with elements of second order reflexivity) being present among EU officials regarding the conceived ethical framing of FP7, the implemented procedures to a varying degree suffered from various limitations in this respect¹⁹⁷.

According to the key premises of SCOT, “the technology does not follow its own momentum nor a rational goal directed problem-solving path but is instead shaped by social factors” (Bijker, 2001, p.27). The key concepts within this approach are the

¹⁹⁵ According to Bijker and Law “technology and its shaping has to do with the historical, the economic, the political, and the psychological, as well as with the sociological” (Bijker, W. and Law, J. General Introduction. In *Shaping Technology/ Building Society. Studies in Societal Change.* (Eds Bijker, W. & Law, J.), p. 5.

¹⁹⁶ The social construction of technology (SCOT) model developed by Bijker and Pinch is often contrasted with the theory of technological determinism. In SCOT, relevant social groups play a key role in determining the meaning and function of technology. Variant relevant social groups will have problems associated with a particular technological artifact, as well as various solutions to these problems. The ability of an artifact to manifest various meanings from differing social groups is attributed to its interpretive flexibility. Ultimately, certain interpretations or solutions will become more widely accepted than others, and the significance of the artifact can be said to stabilize. One of the main concepts in SCOT is that of relevant social groups. According to Bijker and Pinch, relevant social groups are organized based on their collective approaches to various problems. Relevant social groups can be “institutions and organizations, as well as organized or unorganized groups of individuals with a key requirement that all members of the social group share the same set of meanings, attached to a specific artefact.” <http://www.newinfluencer.com/mediapedia/social-construction-of-technology/>

¹⁹⁷ As a concrete example we would mention the adoption of the Ethical Guidelines of FP 7. We had been able to interview the key experts who drafted the actual guidelines. According to their opinion and analysis, regarding the actual outcome of the document – the draft had gone through a lengthy consultation procedure with around 17 subsequent drafts, and the final document differed from the initial concept in a fundamental way, on many occasions not containing the initial approaches.

‘interpretative flexibility’, ‘closure’ and ‘relevant social groups’¹⁹⁸. With regard to politics, “the constructivist perspective provides a rationale for a politics of technology” (p.27).

We have found these premises key and relevant to our findings of the policy context. Thus, Bijker points out that “demonstrating the interpretative flexibility of an artifact makes clear that the stabilization of an artifact is a social process, and hence subject to choices, interests and value judgments – in short, to politics” (p.27). Indeed, we have seen that the political process follows its own logic, and the very fact of awareness by officials of certain alternative approaches (alternative cognitive framings) itself does not predetermine opening up of some existing and/ or established framing also regarding ethics in technological development, even though relevant public discussion takes place (see footnote 186).

5.3.2. Is compromise at moral level a solution

To develop on it further more (as being aware that processes in society cannot be controlled or directed by arbitrary means and being aware of a need for a comprehensive and in a sense “realistic” approach), we would like here to bring in the notion of ‘compromise’ with all its implicit positive and negative connotations. In the context of public deliberation, according to Bohman, “compromise in an ordinary sense is all about coming to an accommodation or making concessions”. It involves tradeoffs and balances of interests – making concessions of one’s own for equal by others. If these interests are backed by moral reasons, we often evaluate such tradeoffs or concessions as involving “compromising” ones beliefs or losing integrity. (Bohman, 1996, p. 88.) At the same time Bohman points out that “in cases where ‘common human reason’ gets us no further, there is no other choice but to reach a compromise at moral level. (p.90).

¹⁹⁸ According to W.E.Bijker, W.E., Hughes, T.P. & T.Pinch. (1987). *The Social Construction of Technological Systems. New Directions in the Sociology and History of Technology*. Cambridge MA.: MIT Press., p.4. One of the central tenets of this approach is the claim that technological artefacts are open to sociological analysis , not just in their usage but especially with respect to their design and technical “content” (p.4).

Moreover, for deep conflicts Bohman sees some form of public compromise as inescapable. He argues that “cultural disagreements do not only have their source in difference in values. Different cultural frameworks may assign various problems or issues to different forms of reason; these disputes are about justification and adjudication themselves and thus give rise to the need for the exercise of public reason” (p. 90). Consequently, we can conclude that the complexity of the issue of ethic is not rooted solely in the difference of values (which by itself is an important aspect in the overall EU policy), but is heavily rooted in the potentially different forms of reasoning. This should be taken into account also when deliberating on the various forms of governance, also with regard to ethics in research and technological development.

5.3.3. Capacitation of actors versus moral compromise and the role of learning

Once again reflecting on the policy deliberation and public discussion in the context of the governance in technological cultures, we should recognize the role of knowledge and the role of learning regardless of the status of the actor or stakeholder, or more precisely, regardless the role someone might wish to ascribe to the particular actor. As pointed out by Bijker, “citizens, stakeholders, patients, and users all have their own views, opinions, and knowledge of this society with its science and technology (Bijker, 2009, p.167).

Democratic governance of technological cultures requires that those forms of knowledge and experience are recognized and allowed to play a role, together with the specific – but in a newly recognized sense limited – expertise of scientists and engineers (Bijker, 2009, p.167). This bears relevance also with regard to our theoretical approach – that all these actors and stakeholders are relevant also regarding the actual construction of an ethical norm – bearing in mind the actual context of its application.

In the framework of our theoretical approach, after having seen the strengths, as well as identified the limits of our approach and after having analyzed the broader policy implications, our lessons learnt imply that not a single theoretical approach can provide a comprehensive answer, and various theoretical approaches can be and are mutually complementary and enriching. To be more specific, and in regard to the above argument by Bijker, we would like specify one of our key findings regarding the role of learning in the process of the implementation of ethics. Within democratic governance, in order to minimize the need for the unavoidable moral compromise (as cited above), the ways for “capacitation”¹⁹⁹ of the various actors and stakeholders should be sought, thus promoting the implementation of the second order reflexivity in the process of the construction and implementation of ethical norms in respective context.

¹⁹⁹ For capacitation of actors see chapter 3.2.3.

6. Implications for EU research policy

Abstract

In this part of the work we will discuss the main challenges to be addressed, as well as suggest ways for addressing these challenges in the form of recommendations. We will also refer to suggested future research.

6.1. Key challenges to be addressed

As a result of our research we have identified the main challenges in the implementation of the ethical framing of FP7, as part of the findings from our theoretical approach:

1) the existing separation between the ethical and technological communities, as a result of which sectorial approaches are predominant with the respective ethical framings;

2) the existing separation between the context of the application of the norm and the context of the legitimisation of the norm, as a result of the more traditional top-down approaches in the development and implementation of the respective legal framework;

3) the existing problem with the reflexive relation between the construction of the norm and the context, as a result of the predominant approaches that ethics is being addressed well after the development of the technology.

Furthermore, as part of our overall research, we have identified the following challenges with regard to the FP7 ethical framing and its implementation:

1) awareness raising on ethics should be further promoted among the scientific, academic, policy making communities, as well as among other relevant stakeholders, including the general public;

2) reflexivity, and especially second order reflexivity should be promoted to become an inherent part of the policy making and policy implementation process;

3) learning should be implemented at all levels and stages in addressing ethics in EU research;

4) new mechanisms should be sought that would allow for comprehensive governance approaches with an effective stakeholder involvement, taking into consideration the above mentioned challenges and their addressing.

As pointed out in the Policy Synthesis of EU Research, Results on Science, Governance and Society²⁰⁰: “With all its [science] great benefits, and its central role in ‘the knowledge economy’, it is recognised to need something for its control and governance, external to its own institutions, and more effective than the existing governmental institutions have hitherto provided. This other force we call, for lack of better term or idea, ‘society’” (p. 11). Thus, society can be viewed as a powerful force in today’s technological culture, provided the key challenges are being adequately addressed to capacitate this powerful actor in relation to the existing cognitive framings.

6.2. Suggested ways of addressing – recommendations

Having carried our respective research and analysis, we do not have the pretension here to advise the European Commission on the approaches to the ethical framing of FP7. On the contrary, being aware of the complexity of the task and having observed the high level of the policy deliberation and the clear and well functioning legal framework with respective procedures put in place for the implementation of the respective EU policy, in the first place we would like to recognize the enormous commitment on the part of the respective EU institutions and their structural units in securing a smooth and well justified implementation of the FP7 ethical framing.

However, based on our theoretical framework and our respective research, we would like to present the following suggestions²⁰¹:

²⁰⁰ EU Research in Social Sciences and Humanities. Policy synthesis of EU Research Results. Series No 12: Science, Governance and Society. Directorate-General for Research Citizens and Governance in Knowledge based Society. European Communities, 2008.

²⁰¹ Here we would also like to refer to the main challenges identified by the EU officials during our interviews: 1) lack of awareness among various stakeholders; 2) indifference among various stakeholders; 3) lack of knowledge among various stakeholders; 4) need for an increased collaboration on ethics in research

At the level of EU Commission

1) to review and reconsider the role and functions of NECs, given the fact that historically these committees were established primarily in the context of medical research; today the scope of the activities of NECs is much broader, and thus the member states should be encouraged to reconsider their scope of activity, paying much more attention to ethics in research in general (also the titles of these committees should not be medicine or biomedicine specific, as is the case in many member states). Also regarding the functions of NECs, apart from securing the compliance to the national legislation, more reflexive and deliberative approaches should become part of the activities of NECs;

2) new approaches to the issue of scientific and ethical expertise should be sought, in order to address more effectively the recognized gap between the scientific committees and NECs, and to promote deliberation on the issue of what ethical expertise means in the context of today's technological culture;

3) the FP7 projects should be more encouraged to have ethical advisory boards as part of their projects ethics institutional aspect; more encouragement should also be given to projects to envisage specific ethical components in their work packages (as well as an assessment mechanism of their ethical reflexivity impact). This would promote the reflexive and deliberative processes as well;

4) more cooperation should be encouraged between the FP7 projects which are specifically dealing with ethical issues. This could generate high level discussions on innovative ethical frameworks in EU research policy;

among member state; 5) the diversity of European values versus the need for a uniformity of approach to ethics at the EU level.

Ethics specialised knowledge not always helpful in expertise; 6) ethical issues do not easily fall under strict legal frameworks, therefore broader general principles need to be attributed; 7) differences in the national legislation in member states; practice of case to case approach due to lack of relevant standards

5) new and realistic approaches should be sought to institute ethics also beyond the well established and possibly indispensable legal frameworks;

At FP7 project level

6) by bottom-up approach and pro-activity, to stimulate discussion with the European Commission regarding the implementation of ethics in FP7 as a meaningful process (as opposed to fulfilling formal requirements), as well as discussion with NECs;

7) to stimulate relevant discussion within project consortiums, with an involvement of various stakeholders in order to raise awareness and stimulate pro-activity and mutual learning.

As an integrating element to these two levels, the learning function might become of key importance (learning as a potential “solution” was also mentioned in most of the interviews with the EU officials). Possibly, the “learning operation” could take the form of joint workshops among EU officials, academic representatives, project researchers, experts, general public and other stakeholders, and would concern specific case studies in order to ground the learning in actual practice and promote the implementation of the second order reflexivity approaches among the participants.

More specifically, we would suggest that:

1) the role of NECs should be promoted in safeguarding the deliberation (and the corresponding conditions for deliberation) at national level (with respect to the subsidiarity principle). Given the existing good co-operation links between the European Commission and NECs, more “uniform”²⁰² approaches might be promoted in the EU and among various stakeholders;

2) the role of ethicists in various institutional contexts should be reconsidered and enhanced, given the need to adhere to a normative horizon (with the ethical imperative in

²⁰² By uniformity we imply the similarity in conceptual and methodological approaches in dealing with ethics in EU research, and not so much regarding the actual content

mind) during the discussion or deliberation process. By this also the impact of ethical reflexivity could be assessed more effectively;

3) the approaches to technology assessment should be reviewed in the above mentioned context, in order to avoid misinterpreting and replacing ethics by social acceptance;

4) the status of ethics in EU research should be promoted through empowering the role of ethics in the decision making on EU research. This is, however, feasible only through a continuous awareness raising and integrated endeavours at the level of governments of EU member states at the EU level.

It should be pointed out that our pretension is not to resolve the issues, which is clearly the question of high level policy and research agenda. At the same time, we would like to point out that the increasing tendency for the involvement of various stakeholders, including the civil society, in EU funded research (both, as an object and subject for research), is an indicator that public discussion and policy deliberation approaches are a force to be counted with in future²⁰³.

²⁰³ As pointed out in the Work program 2011 "Science and Society, (European Commission C(2010)4903 of 19 July 2010), in the terms of the Seventh Framework Programme, activities in the field of Science in Society aim to "*stimulate, with a view to building an open, effective and democratic European knowledge-based society, the harmonious integration of scientific and technological endeavour, and associated research policies in the European social web, by encouraging pan-European reflection and debate on science and technology and their relationship with the whole spectrum of society and culture*".

Concerning recommendations in terms of suggested future research see below²⁰⁴.

Further on we will present our conclusions regarding the research work carried out.

Conclusion

Before drawing the final conclusions, we would like to recall the key cornerstones of our research. Our aim was to investigate the ethical framing of the European Union research policy in regard to the 7th Framework program, and our intention was to do it from a certain theoretical perspective. Proceeding from the identified limits of the current ethical offer, and by applying the key concepts of the Louvainist school of governance, we developed our own theoretical framework for analysis²⁰⁵.

By using our theoretical approach, we constructed accordingly our research problem and defined our research questions. Our principal research interest lay in the relationship between the construction of an ethical norm and the context of its application. More specifically, we were interested to analyse the conditions for ethical reflexivity in relation to the efficiency of an ethical norm in the context of EU (FP7) ICT research

²⁰⁴ Based on our reflection on the empirical findings, we see the necessary future research regarding the role of and relationship between the scientific and ethical expertise – since this problem has a high degree of capacity – it comprises many other problems we have discussed above, and thus, also potentially comprises solutions to these problems. In this respect the research would also refer to the institutional and normative aspects of the problem, and might suggest new solutions to the problems of the new technological culture we are living in. By saying this we do not intend to undermine the role of the wider policy and public discourse. Vice versa – as argued by Bijker “the role of scientific advisory institutions is thus different from what it was centuries ago, when they were government’s one and only window to the truth about scientific matters. But they are still crucially important as one element in the broader governance of technological cultures. (Bijker, 2009, p.167).

Thus, by being able to determine the new role of scientific (and/or ethical) expertise, also the new approaches to democratic governance of new technologies and their ethical frameworks will be enhanced and enriched greatly. As argued by Bijker “...relation between scientific advice and the wider democratic governance of technological culture – more specifically, about how to characterize concrete risk situation in which political decisions are needed and scientific advice is called for. This characterization is an important element in the articulation of the public issues, and it will constitute to the shaping of political objects Bijker, 2009, p. 166, 167).

Furthermore, we see that the issue of scientific/ ethical expertise could be viewed as potentially contributing to our theoretical approach regarding the construction of the ethical norm in relation to the context of its application. In our opinion, it would be research on innovative approaches to expertise in ethics which would contribute to improved governance approaches in the ethical framing of the EU research policy.

²⁰⁵ As discussed throughout our work, our key theoretical approaches were based in the conceptual framework developed by the EGAIS project, and our research was also carried out as part of this particular project.

projects, as part of the respective EU policy. We wanted to determine the characteristics and limits of the proposed system, approaches and theory.

Based on our critique of the existing ethical offer which primarily view the construction of an ethical norm outside the context of its application, by our research we wanted to addressing the limits of the predominant ethical standpoint and propose an alternative framework. Our theoretical approach had to be tested in practice, therefore an empirical study was needed.

Our empirical study had to be linked with our theoretical framework, therefore, based on our theoretical approaches, we developed an analytical grid with specific parameters and constructed a respective questionnaire to interview the EU officials with relevant competence. We also constructed a grid for data analysis, in order to see how the identified governance arrangements in the FP7 ethical framing relate to our theoretical standpoint.

It was important for us to see how the existing FP7 governance arrangements deal with the determination, addressing and assessment of ethical issues. We wanted to see also if ethical reflexivity is present and if the context for the application of an ethical norm is taken into account²⁰⁶. We were also interested to see if the existing institutional mechanisms secure the implementation of the learning operation which is an indispensable part of a truly reflexive processes.

Moreover, we wanted to see it in the context of the overall regulatory framework, including the role of EU and member state institutions, as well as experts in regard to making decisions on ethics in FP7 ICT research. Besides, we were also interested in the

²⁰⁶ According to Lenoble, the approach envisages that a practical acceptance of a shared norm depends exclusively on the proliferation of mechanisms that are assumed to foster cooperation and participation by citizens in the process by which these norms are developed and applied.

role of the broader spectrum of stakeholders, the public opinion and the EU citizenship at large.

Having carried out our research, we have arrived at particular conclusions:

1. Our theoretical approach has allowed us to analyse the ethical framing and governance approaches of the European Union 7th framework program. With our research we have been able to answer our research questions 1) on the conditions for ethical reflexivity in relation to the efficiency of an ethical norm in the context of EU Framework Program ICT research projects and 2) on the characteristics and limits of the proposed system, approaches and theory. We have also determined the limits of the actual representation and developed a critical perspective on the conditions for ethical reflexivity and its efficiency.

2. We have found that our theoretical approach has allowed us to go beyond the scope of the more traditional sociological approaches regarding the analysis of certain aspects in policy making regarding research and technological development. This has proved to be both, the strength and the weakness of our theoretical approach.

3. As a strength of our theoretical approach we see our demonstrated process of integrating ethical governance and ethical thinking into the process of technological development, instead of the current traditional approaches when ethics is being addressed after the technological development, primarily as risk assessment by expert evaluation.

4. As a weakness of our approach we see its inability to address the various policy issues in a broader societal context, given the many and varied roles of relevant actors and stakeholders in the democratic processes within the new technological cultures.

5. By analyzing the strengths and weaknesses of our theoretical approach to the problem of ethical framing in the governance of FP7, we have concluded that there is no

one uniform solution to this problem, and that various approaches are mutually complementary.

6. Since ethics cannot be reduced to moral or legal authority, and given the conditions of the high degree of risk and uncertainty of today's technological culture, the role of policy makers is to secure adequate reflection on the legal and moral foundations of controversial issues in today's scientific and technological developments.

7. Acknowledging the role of policy deliberation and public discussion as part of the democratic process, a special emphasis should be put on the operation of learning, since without learning, a true reflexivity cannot be implemented.

The above mentioned conclusions are of a general nature. However, we would like to present also more specific conclusions, which relate more directly to the implementation of our theoretical approach. When analyzing the existing FP7 governance arrangements, we have seen that the governance models used in most cases do not take into consideration the trajectory of norm in a specific context. Thus, the ethical norm is de-contextualised or only partly contextualised, and answers are traditionally being sought by reducing everything to reason. However, regarding ethics – is not possible to limit everything to a rational positivist approach²⁰⁷, since by such an approach the true meaning of ethics is missed.

We are aware that our proposed theoretical framework does not provide an immediate practical solution to the problem. However, our standpoint, based on the Louvainist approach to the problem of norm and context, is important at problem level. Even though clear cut answers are certainly not possible, we should seek answers why such limits in the development and implementation of the present ethical framing exist and why there are such limits to the system.

²⁰⁷ For positivism see Glossary in Annex 1.

The current EU approach to a considerable degree is rooted in the expert approach, including the European Group of Ethics which is the key advisory body to the European Commission regarding ethics in research and technological development. The ethical expertise in general terms is the key source recognised in the process of the implementation of the FP7 ethical framing (within the existing legal framework), and top-down approaches are still predominant.

Nevertheless, having found and being aware that a comprehensive and well functioning system has been put in place in the European Union with regard to the development and implementation of the ethical framing of FP7, and recognising that one cannot overlook the need for the conventional institutional and legal mechanisms to secure a sound operation of this system from the juridical and managerial point of view, as well as from the point of view of European democratic tradition, we would like here to refer to one of the key terms within our research – the second order reflexivity. No system can be perfect, and in our opinion, the relevant issue is to secure a continuous discussion and deliberation on this system with the involvement of a broad spectrum of stakeholders. Only in such a way we can speak of foresight knowledge²⁰⁸, as well as colour positively the term of ‘moral compromise’ and the make an attempt to approach the desired moral horizon as closely as possible.

Our research with its rich empirical material has shown us that the ethical framing of the EU research policy is a broad and fascinating field for future studies. Given the limited scope of the present work, we have been able to analyse this field within our set limits in regard to our specific research problem. At the same time, the collected empirical

²⁰⁸ According to Von Schomberg, the foresight knowledge allows us 1) to explore futures and develop a vision on such futures; 2) to identify impacts on society and implications for policy and particular stakeholders or sectors of society; 3) to guide and support the policy process; 4) to timely mitigate negative impacts to new situations and exploit positive outcomes; 5) to deepen dialogue with society; 6) to improve governance (Von Schomberg, 2005, p.3).

material and the acquired competences and skills is a good precondition for relevant future studies.

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Annex 1 Glossary

Cognitive framing

A frame is a psychological device that offers a perspective and manipulates salience to influence subsequent judgment. By inviting to view the topic from a certain perspective it not only offers a perspective but manages the observer's alignment in relation to the subject. In a visual field some objects are perceived as prominent while others recede in the background. Directing the viewer to consider certain features and to ignore others, perception is organized around the frame and may be resized to fit within the constraints of the framework. By implying a certain organization for the information it co-creates the picture and influences judgment and information received. Influencing the way a problem is perceived can lead to radically different solutions. According to Prospect Theory, humans give priority to not loosing. Gains are secondary to "no loss". Framing a decision in terms of possible loss should motivate more than framing the same decision in terms of possible gain, a person is more likely to follow conservative strategies when presented with a positively-framed dilemma and choosing risky strategies when presented with negatively-framed ones.

All variants of the Frame Problem in a theory of mind are special cases of the problem of complete description. It not only appears within the situation calculus for representing a constantly changing world, closely related to the general problem of the "laws of motion" which can adequately describe the world, but also in prediction, induction, reasoning, natural language understanding, learning and other problems. It is generally not possible to specify the necessary and sufficient conditions for anything and it is even unknown what is meant by "a complete description" of, for example, everything that is relevant for a particular action in a particular situation in view of a particular goal. A prevailing framing effect is in media itself where news programs may even try to follow the rules for objective reporting and yet inadvertently convey a dominant framing of the news that prevents most audience members from making a balanced assessment of a situation. (Tactical Reality Dictionary, <http://world-information.org/trd/06>)

Context

Context in the respective theoretical framework:

Is not a set of factual constraints; Is not a false representation or a framework offering resistance; Is not a particular culture which cultural anthropologists can identify and which can be found in the minds of individual actors as continually adaptable conventions that can serve as capacitating structure for the actor. (Lenoble & Maesschalck, 2003).

Context is not just what we see outside, i.e. the environment in which the decision is to be made, and it's not just the problem of what one can perceive as the environment, since even when you address the environment, you address it from your own perspective and framing, so the context is reduced to being part of your framing. Context is also your framing, background, and stock of knowledge. In contemporary approaches, context is generally assumed as given, and not treated as a problem. Maesschalck & Lenoble's approach treats the context as something to be explored and constructed in a complex process rather than taken as given (Lenoble & Maesschalck, 2003). (EGAIS project Glossary).

Deontological ethics

The word deontology derives from the Greek words for duty (*deon*) and science (or study) of (*logos*). In contemporary moral philosophy, deontology is one of those kinds of

normative theories regarding which choices are morally required, forbidden, or permitted. In other words, deontology falls within the domain of moral theories that guide and assess our choices of what we ought to do (deontic theories), in contrast to (aretaic [virtue] theories) that — fundamentally, at least — guide and assess what kind of person (in terms of character traits) we are and should be. And within that domain, deontologists — those who subscribe to deontological theories of morality — stand in opposition to *consequentialists*. From Stanford Encyclopedia of Philosophy <http://plato.stanford.edu/entries/ethics-deontological/>

Discourse ethics

Jürgen Habermas' theory of discourse ethics contains two distinctive characteristics: (I) it puts forth as its fundamental tenet a prerequisite of participation in argumentation for testing the validity of a norm and (ii) it transforms the individual nature of Kant's categorical imperative into a collective imperative by reformulating it to ensure the expression of a general will and by elevating it to a rule of argumentation. The proceduralism of the first characteristic sets Habermas' discourse ethics apart from the moral theory of John Rawls. The second characteristic differentiates it from Kantian moral theory and, again, from Rawls' theory of justice.

Habermas' moral theory is grounded in the principle of discourse ethics, which can be viewed as a principle of argumentation. It stipulates that "only those norms can claim to be valid that meet (or could meet) with the approval of all affected in their capacity as participants in a practical discourse."

This practical discourse, Habermas writes, is "a procedure for testing the validity of hypothetical norms, not for producing justified norms." In this way Habermas' discourse ethics guarantees that the process of making judgements is carried out impartially, in contrast to Rawls' theory of justice, which seeks to make impartial the orientation of an individual making a moral judgement. Unlike Rawls' (and Kant's) theory, Habermas' principle of discourse ethics ensures that the universalist principle can be interpreted only as expressing the normative content of a procedure, not the normative content of the argument. Indeed, Habermas makes it clear that his theory contains no hint of substantive moral content. (EGAIS project Glossary).

Ethics

The field of ethics (or moral philosophy) involves systematizing, defending, and recommending concepts of right and wrong behavior. Philosophers today usually divide ethical theories into three general subject areas: metaethics, normative ethics, and applied ethics. *Metaethics* investigates where our ethical principles come from, and what they mean. Are they merely social inventions? Do they involve more than expressions of our individual emotions? Metaethical answers to these questions focus on the issues of universal truths, the will of God, the role of reason in ethical judgments, and the meaning of ethical terms themselves. *Normative ethics* takes on a more practical task, which is to arrive at moral standards that regulate right and wrong conduct. This may involve articulating the good habits that we should acquire, the duties that we should follow, or the consequences of our behavior on others. (Internet Encyclopedia of Philosophy).

<http://www.iep.utm.edu/ethics/> author James Fieser

Deriving from the analysis within the EGAIS project - ethics keeps its diversity, with the diversity of tendencies hiding some of the specificity and its consequences. Ex-analytical ethics (Rawls) and pragmatics ethics (Habermas) postulates a semantic indetermination. Semantic ethics (Ricoeur) finds that the legitimisation process of the norm does not belong

to ethics, but that the real ethical question is the response to the injunction of the suffering of others. Contextualist ethics (Taylor) proposes a realistic ethics of the way that the subject assumes its cultural space. The semantico-symbolic approach appears to be a connection between ethical efforts and life in itself, with the openness of the structure constitutive of the subjection to the injunction of historical reality. The problem is, however, the necessity of the voluntary disposition of the actor, under the law that the actor gives to itself. Ethics meets its main challenge when it confronts human behaviour with rational choices for the management of human responses. Thus, if ethics is to assert a normative authority, which is a fundamental characteristic of ethics, since ethics concerns the relationship between what is and what should be, it is necessary to question the condition for its effective integration in the context of technical projects (EGAIS deliverable 2.1).

Ethical imperative

This term is linked to the issue of “normative horizon” (that is, the ideal goal for how the world should be) and the relationship of ethics with context. It is supposed that ethics should be free of any contextual constraints, so that it can aim at ethical normative horizon. This is being referred to as the “ethical imperative” (ETICA project, deliverable 4.1., p.4).

Ethical reflexivity

Ethical reflexivity: “an uncomfortable reflexivity that ‘seeks to go beyond the confession/absolution tendencies of some forms of reflexivity, and, in acknowledging the impossibility of a thoroughly transparent and nameable knowledge of oneself, accepts “the uncomfortable task of leaving what is unfamiliar, unfamiliar”’ (Ellwood, 2006, p. 5, citing Pillow, 2003, p. 177). The full knowledge of self that is implicated in humanist ideals of ethical practice, must, in this understanding, be put aside in favour of an awareness of the emergent process of mutual formation”

(Bronwyn Davies, *University of Western Sydney, Australia, British Journal of Sociology of Education*

First order reflexivity

First order reflexivity: “the unanticipated feedback effects of modernity (modernity undermining itself)” (National sustainable development strategies: features, challenges, and reflexivity. James Meadowcroft, Carleton University < <http://www2.carleton.ca/sppa/ccms/wp-content/ccms-files/meadowcroft4.pdf>>)

Governance

Governance is “the reflexive self-organisation of independent actors involved in complex relations of reciprocal interdependence” (Jessop, 2003), with more recent EU developments further qualifying the mode of co-ordination as democratic, participative, and pragmatic, and recommending support for collective action (Maesschalck, 2007). The concept of governance is defined by Jessop as “the reflexive self-organization of independent actors involved in complex relations of reciprocal interdependence” (Jessop, 2002, p.1). The most recent developments of the concept, in the context of the European Union for example, qualify this mode of coordination as democratic, participative and pragmatic, with a focus on supporting collective action (Maesschalck, unpublished, p.3-4). According to Jessop, governance is now seen as an “important means to overcome the division between rulers and ruled in representative regimes and to secure the input and commitment of an increasingly wide range of stakeholders in policy formulation and

implementation" (Jessop, 2002, p.3). This new governance model requires both groups (rulers and ruled) to engage in a social learning process (Schön, 1983). Indeed, joined participation in collaborative problem-solving can lead to critical scrutinizing of governing variables: goals, values, plans and rules. In this perspective, "reflexive governance" (Lenoble and Maesschalck, 2003) reviews its own mechanisms to insure institutional learning. Hence, it results in the co-design of institutions and the elaboration of common social representations.

In addition, Maesschalck's *pragmatique contextuelle* (contextualised pragmatic approach) (Maesschalck, 2001) stresses the importance of taking into account the specificities of contexts when creating norms. He recommends that, in lieu of the democratic apparatus set by authorities in which community members are invited to participate (school councils, for example), the actors' ability to participate is mistakenly taken for granted. Therefore, existing cooperative networks should be exploited and supported. Moreover, he suggests that implementation of norms is more likely to be feasible when norms are created in collaboration with the actors in context, since they are the most knowledgeable about the particularities and limits of this context. (EGAIS project Glossary).

Learning

“Argyris (1976) proposes double loop learning theory which pertains to learning to change underlying values and assumptions. The focus of the theory is on solving problems that are complex and ill-structured and which change as problem-solving advances. Double loop theory is based upon a "theory of action" perspective outlined by Argyris & Schon (1974). This perspective examines reality from the point of view of human beings as actors. Changes in values, behavior, leadership, and helping others, are all part of, and informed by, the actors' theory of action. An important aspect of the theory is the distinction between an individual's espoused theory and their "theory-in-use" (what they actually do); bringing these two into congruence is a primary concern of double loop learning. Typically, interaction with others is necessary to identify the conflict. There are four basic steps in the action theory learning process: (1) discovery of espoused and theory-in-use, (2) invention of new meanings, (3) production of new actions, and (4) generalization of results. Double loop learning involves applying each of these steps to itself. In double loop learning, assumptions underlying current views are questioned and hypotheses about behavior tested publically. The end result of double loop learning should be increased effectiveness in decision-making and better acceptance of failures and mistakes.”

<http://tip.psychology.org/argyris.html>

Norm

Norm: “a culturally established rule prescribing appropriate social behaviour. Norms are relatively specific and precise and elaborate the detailed behavioural requirements that flow from more general and overarching social values. A norm fixes the boundaries of behavior. However, a rational person only acts according to the rule if only it suits her. A norm gives an expectation of how other people act in a given situation. In order for a norm to be stable, people's actions must reconstitute the expectation without change. A set of such correct stable expectations is known as a Nash equilibrium. Thus, a stable norm must constitute a Nash equilibrium.”

(Sociologyindex < <http://sociologyindex.com/norm.htm>>)

Normativity: “a careful, rigorous account of the meanings of basic normative terms like good, virtue, correct, ought, should, and must”

(From an upcoming article by Gilbert Harman, Professor of Philosophy at Princeton University < <http://www.princeton.edu/~harman/Papers/Thomson.pdf>>)

Public accountability: “the obligations of persons/authorities entrusted with public resources to report on the management of such resources and be answerable for the fiscal, managerial and programme responsibilities that are conferred”. (The Tokyo Declaration of „Guidelines on Public Accountability”
http://www.asosai.org/asosai_old/R_P_accountability_control/appendix1.htm

Positivism

Any philosophical system that confines itself to the data of experience, excludes a priori or metaphysical speculations, and emphasizes the achievements of science. Positivism is closely connected with empiricism, pragmatism, and logical positivism. More narrowly, the term designates the philosophy of Auguste Comte, who held that human thought had passed inevitably through a theological stage into a metaphysical stage and was passing into a positive, or scientific, stage. Believing that the religious impulse would survive the decay of revealed religion, he projected a worship of mankind, with churches, calendar, and hierarchy.

From Encyclopedia Britannica

<http://www.britannica.com/EBchecked/topic/471865/positivism>

Proceduralism

Jürgen Habermas' proceduralist paradigm is derived from his discourse-theoretical approach to ethics, law, and politics. Habermas agrees with Luhmann that law must stabilize expectations but goes further and insists that legal interpretations must be right. In other words, for Habermas justice according to law must be predictable but also consistent with justice beyond law. Habermas' toward legal proceduralism is his conclusion that alternative approaches to legal interpretation cannot successfully overcome the crisis in legal interpretation. Noting that natural law is not a viable option for a society with competing gods and demons Habermas also finds legal hermeneutics, legal realism, and legal positivism inadequate. (Just Interpretations, Law between Ethics and Politics, Michel Rosenfeld University of California Press, Berkeley · Los Angeles · Oxford © 1998 The Regents of the University of California , p 114-115)

Reflexivity

The notion of reflexivity refers to "the operation by which a social group seeks to respond to its perception of the need to adjust its capacities for action" (Lenoble & Maesschalck, 2006). A reflexive governance must be able to think about the normativity inside the practical contexts. The link between the ethical aspects and the governance of the general interest is the reflexivity.

Reflexive governance

Reflexive governance is not an easy term to pin down. Its ambiguity stems largely from the multiple faces of reflexivity. ‘To be reflexive’ in its most elementary meaning is the capacity to turn or bend back on oneself. Reflexivity, then at least in a methodological sense, refers to ‘the mutual interdependence of observer or knower to what is seen or known’ (Johnson, 1977: 172). When reflexivity is taken beyond the individual and applied to larger sociological phenomena, its meaning becomes more slippery. For Beck (1994), reflexivity is used to describe a phenomenon of late modernity, when society begins to accept that we cannot control our development path and that many of the premises,

structures and institutions taken for granted in first modernity are questioned and reconsidered. For Latour (2003), reflexivity is interpreted more narrowly as the recognition in society that we cannot control the intractable problems that modern societies produce.

Governance has come to take on a particular meaning, one that is best appreciated by Voß and Kemp's (2005) distinction between first-order and second-order reflexivity. Under this schema, first-order reflexivity refers to the continuous cycle of side effects from simple modernity. Reflexivity of this kind is 'reflex like'. For example, Stirling (2006) takes to term reflexive Governance "to imply the exercise ex ante of deliberate agency, rather than to describe ex post unintentional reflexes in the face of unpredicted consequences". (EGAIS project Glossary).

Second order reflexivity

Second order reflexivity: "self-critical and reflective practices that contribute to the conscious re-ordering of social life"

(National sustainable development strategies: features, challenges, and reflexivity. James Meadowcroft, Carleton University < <http://www2.carleton.ca/sppa/ccms/wp-content/ccms-files/meadowcroft4.pdf>>

The second order reflexivity can be characterised as a self-critical reflection on the process used to determine problems encountered within a project, and an assessment of the usefulness of the such processes in changing the ethical trajectory of a project (EGAIS project).

Social acceptability

A condition that results from a judgmental process by which individuals incorporate the perceived reality with its known alternatives; and decide whether the 'real' condition is superior, or sufficiently similar, to the most favourable alternative condition." This definition highlights key aspects of social acceptability: it is a judgmental process involving comparisons of known alternatives, it implies judgments are influenced by a suite of factors, and it has a behavioural component that reveals itself at multiple levels. The idea of a judgment implies an assessment, estimation, and inference about the occurrence of events and the relation of outcomes to these events. It is fundamentally normative since it refers to the condition that allows social acceptance (in includes also the ethical acceptability). Although the definition focuses on how individuals make judgments, the adjective social implies that what matters is some aggregation of individual judgments. Such aggregated measures can range from an informal consensus among participants at a public meeting to formal, codified expressions (e.g., laws). The multidisciplinary roots of a social-acceptability concept mean that various approaches exist for its study (e.g., interest politics, decision theory). Contemporary investigations of the acceptability judgment process, however, have relied primarily on belief-attitude-behavior models of social, Psychology. (from Bruce Shindler, Social Acceptability in Forest and Range Management, , in Chapter 14 in Society and Natural Resources: A Summary of Knowledge. 2004. M.Manfredo, J. Vaske, B. Bruyere, D. Field, and P. Brown (eds.). Modern Litho Press: Jefferson, MO)

SCOT

SCOT - the social construction of technology model developed by Bijker and Pinch is often contrasted with the theory of technological determinism. In SCOT, relevant social groups play a key role in determining the meaning and function of technology. Variant

relevant social groups will have problems associated with a particular technological artifact, as well as various solutions to these problems. The ability of an artifact to manifest various meanings from differing social groups is attributed to its interpretive flexibility. Ultimately, certain interpretations or solutions will become more widely accepted than others, and the significance of the artifact can be said to stabilize. One of the main concepts in SCOT is that of relevant social groups. According to Bijker and Pinch, relevant social groups are organized based on their collective approaches to various problems. Relevant social groups can be “institutions and organizations, as well as organized or unorganized groups of individuals with a key requirement that all members of the social group share the same set of meanings, attached to a specific artifact.” <http://www.newinfluencer.com/mediapedia/social-construction-of-technology/>

Teleology and Ethics

Teleological moral systems are characterized primarily by a focus on the consequences which any action might have (for that reason, they are often referred to as consequentialist moral systems, and both terms are used here). Thus, in order to make correct moral choices, we have to have some understanding of what will result from our choices. When we make choices which result in the correct consequences, then we are acting morally; when we make choices which result in the incorrect consequences, then we are acting immorally.

The idea that the moral worth of an action is determined by the consequences of that action is often labeled consequentialism. Usually, the "correct consequences" are those which are most beneficial to humanity - they may promote human happiness, human pleasure, human satisfaction, human survival or simply the general welfare of all humans. Whatever the consequences are, it is believed that those consequences are intrinsically good and valuable, and that is why actions which lead to those consequences are moral while actions which lead away from them are immoral.

The various teleological moral systems differ not only on exactly what the "correct consequences" are, but also on how people balance the various possible consequences. After all, few choices are unequivocally positive, and this means it is necessary to figure out how to arrive at the correct balance of good and bad in what we do. Note that merely being concerned with the consequences of an action does not make a person a consequentialist - the key factor is, rather, basing the morality of that action on the consequences instead of on something else.

From About.com

http://atheism.about.com/library/FAQs/phil/blfaq_phileth_teleo.htm

Value

Value: “Relatively general cultural prescriptions of what is right, moral and desirable. Values provide the broad foundations for specific normative regulation of social interaction. Personal values are based on the influence of external world and can change over time. Personal values are related to choice and are generally influenced by groups or systems, such as culture or religion.”

(Sociologyindex < <http://sociologyindex.com/values.htm>>)

Annex 2 The analytical grid and grid for data analysis - description

1. Analytical grid (based on the theoretical framework)

A. Approach to the development of the analytical grid

The overall approach to the development of the analytical grid has been discussed in chapter 2.6. Here we will describe the actual content of the analytical grid. The analytical grid was necessary for the development of the questionnaire for the field study (interviews). The questionnaire had to be based on a solid theoretical background, in order to collect data for analysis regarding the ethical framing of the FP7 research policy.

The key steps in the development and implementation of the analytical grid were:

- 1) determining the domains for analysis: a) ethical issue identification and specification; b) governance arrangements; c) implementation; d) ethical approach; e) reflexivity;
- 2) specifying the parameters within each particular domain;
- 3) formulating the questions for the questionnaire (for interviews) – in order to yield data and material in compliance with our parameters in each specific domain for analysis;
- 4) creating a grid for analysis of our empirical findings by taking into consideration: a) our field of inquiry - the representation of ethics and governance reflexivity in technological research and development, as part of EU (FP7) ICT research policy within the EU 7th Framework Program; b) our research problem - the effectiveness of ethical reflexivity in FP7 ICT research projects as part of the implementation of EU research policy; as well as the focus of the present thesis on the governance arrangements in the implementation of the FP7 framing.

B. Domains of analysis and parameters

The parameters we were interested in were organised according to the domains (aspects) of analysis outlined above. We do not intend to give an exhaustive description of the content within each domain, but instead we intend to give an orientation by presenting the parameters as basis for our questionnaire.

1. Ethical issue identification and specification

This domain envisage to look at how policy makers determine what ethical issues to look for and how to identify them in general terms. Our interest lies in – what sort of framework is used to decide what issues are ethical.

2. Governance arrangements

This domain envisages to look at the governance arrangements and approaches. Our interest lies in – what institutional arrangements were implemented within FP7 to deal with ethical issues. The key institutional arrangements we were potentially implying were:

- *Ethical guidelines (See Annex 6)*

a) to assist proposers in identifying potential ethical issues arising from the proposed ICT research

- *Ethics check list (See Annex 6)*

a) identifies the main ethical dilemmas that arise in research and indicates how each topic might be addressed to ensure compliance.

b) promotes identifying the expert(s) within project promoter's organisation or consortium that can provide further advice.

- *Experts and expert panels*

The experts evaluate the projects as to the existence of ethical issues.

Expert panels come to a uniform approach

- *Ethical Committees*

a) These are National Ethical Committees which verify the compliance of the research to the specific national legislation

b) Ensure ongoing discussion and deliberation on ethics and ethical framework in research

- *Ethical Review procedure and Ethics Review report (See Annex 6)*

a) a procedure to secure compliance with the FP7 ethical framework

b) assistance to project promoters

- *Ethical follow up and audit*

a) a monitoring and preventive measure

b) assistance to projects

- *Public consultations*

a) carried out in the process of adoption of certain relevant documents within the FP7 ethical framing. For example, when adopting the Ethical Guidelines

b) used when discussing controversial research issues

3. Implementation

This domain envisages to look at the implementation of the FP7 ethical framing. Our interest lies in – in what way the FP7 ethical framing is being implemented in practice and if the results of implementation are in compliance with the intended effect.

4. Ethical approach

This domain envisages to look at the theories, approaches or principles that have been used in the development of the FP7 ethical framing. Our interest lies in – what have been the underlying assumptions when developing the specific ethical framing.

5. Reflexivity

This domain envisages to look at the different levels of reflexivity existing within the respective institutional settings and in the development and implementation of the ethical framing (if there is also second order reflexivity present). Our interest lies in – not only in the way how ethical issues are being determined but also in there is reflection on the very process of determining of what an ethical issue is (what is the role of experts and ethical committees, should ethical guidelines be used etc.). Our interest also lies in determining if the governance arrangements are suited to address potential ethical issues before they arise and are there arrangements that allow the involved actors (stakeholders) to overcome the presuppositions of specific framings.

C. The questionnaire

The questions that arose within the domains according to the parameters were incorporated into the questionnaire. The questionnaire potentially involved responses allowing for analysis of the nature of the construction of the ethical norms and the existence of ethical reflexivity in the respective EU research policy and within its governance arrangements.

D. Implementation of the analytical grid

By the implementation of the analytical grid we understand the yielding of data and material from our field study (results of the analytical grid). After the results have been obtained, we have to assess these results, so that we can determine the effectiveness of addressing ethical issues in EU research policy regarding FP7. We also wish to assess the effectiveness of institutional governance arrangements.

2. Grid for data analysis (regarding governance arrangements in FP7 and data analysis

Since in our research we were not aiming at a scientific representative analysis, we will primarily analyse the obtained data from the qualitative point of view in relation to our theoretical approach. However, since the governance arrangements in the implementation of the FP7 framing are a key aspect of our research, a specific grid for data analysis was developed in order to analyse these governance arrangements in the light of our theoretical approach.

Approach to the development of the grid for data analysis

The identified governance approaches were analysed by the grid of data analysis. Afterwards and accordingly, the responses were analysed for the existence and use of governance arrangements and tools, and the existence of reflexivity within them.

Based on our research problem, more specifically and in greater detail we had to concentrate on the construction of the ethical norms and their relation to context and the governance arrangements used in the respective EU policy making. Since in general terms we had to use the same approach as used by the EGAIS project (regarding the approaches to the construction of an ethical norm and its context and with regard to the governance approaches:

Since in general terms we had to use the same approach as used by the EGAIS project (regarding the approaches to the construction of an ethical norm and its context and with regard to the governance approaches:

1) regarding the construction of the ethical norm and its context, we were interested if the policy makers, in order to attain reflexivity, construct within the governance arrangements the ethical issue that might be encountered; subsequently, we were interested if the respective governance arrangements were decontextualised²⁰⁹, if the context is restricted²¹⁰, or if they are fully contextualised²¹¹;

²⁰⁹ Decontextualised – refers to the situation where the ethical norm is seen outside the context of its application

²¹⁰ Context restricted - refers to the situation where the ethical norm is seen restricted in the context of its application

²¹¹ Fully contextualised - refers to the situation where the ethical norm is seen fully inside the context of its application

2) regarding the governance approaches, within our study we were interested in the following (mostly concerning risk assessment) four models²¹²: 1) standard model²¹³; consultation model²¹⁴; 3) revised standard model²¹⁵; 4) co-construction model²¹⁶.

²¹² These four models have been studied and respectively elaborated by the EU EGAIS project

²¹³ *Standard Model*: In this model, the disagreements between the experts and the public are perceived as irrational due to the public's lack of knowledge. This model fits perfectly into the classical distinctions between facts and values. Experts have an objective ethical approach to risk whereas the risks perceived by the public are marked by a greater degree of subjectivity. The difference in perceptions between experts and the public can be reduced by means of education. It is supposed that people who have more advanced knowledge, especially in ethical disciplines, understand better and adopt experts' arguments. In this model, risk communication plays an important role. It is related to a one-way method of communication since the experts have little to learn from the public. The objective is to reassure the public to perceive the benefits concealed behind the risks.

²¹⁴ *Consultation Model*: This model brings into question the fundamental thesis of the standard model, namely the opposition between the irrational public and the rationality of the experts. The distance between experts and non-experts is not connected with the level of knowledge, but with the difference in the perception of risk. The public asks wider questions with regard to risk because they are no longer confronted with abstract scientific theoretical risk, but with real risk. It is no longer correct to consider that only experts are rational. Moreover the experts' perception of risk takes into account their connections with industry and commercial interests etc.

The solutions of this model are different from those of the first. Risk communications and risk management are based on a two-way process. Both the experts and the public have valid views and opinions to contribute. Each side respects the opposition's insights. In this model, trust is incompatible with a closed, confined, or secretive attitude. To establish trust the public needs to participate in the decision process. Only by engaging the public can regulatory institutions gain legitimacy. In practice, there is a clear distinction between public opinion and the ethical opinion of experts. The public, still seen as irrational, is engaged only in risk management but not in risk definition.

²¹⁵ *Revised Standard Model*: In this model, which is the extension of the standard model, the emphasis is placed on the interaction between the regulation process, social groups and media. Breyer's model of vicious circle of risk regulation is a good illustration of this model. For him, the legislative process is caught in a vicious circle with the source of the problem being the public attitude towards risk and uncertainty created by the media. Breyer claims that public perception of risk is usually inadequate. Risks are often overestimated, however the efforts to educate the public about scientific risks have failed and will fail in future. Consequently, responding to public attitude, legislature itself will exaggerate the risks and "... combined with an institutional inability to set detailed, scientific standards, will cause inconsistent, random, and often irrational ...lawmaking". As a result, the public will feel unprotected by law and decision-makers, which will lead to more political pressure to take action.

In this model, public influence and participation in risk management are considered with great suspicion. Accordingly, risk management includes the following elements:

1. Delegation of risk management to a competent and independent administrative body (in order to avoid the influence of media, pressure groups and politics)
2. Clear distinction between risk assessment and risk management.
3. Risk cannot be measured in an abstract way but rather analysed, comparing various action scenarios, respecting the general principle of coherence and introducing the economic dimension.
4. Trust is not connected with openness, but rather with reputation and competence.

3) regarding the governance arrangements, we were interested in what was the underlying pre-supposition in the use of the particular governance arrangement (intentionalist²¹⁷, schematising²¹⁸, mentalist²¹⁹).

The assessment of governance arrangements used within the respective EU policy making was related to the way these governance arrangements were used. In other words, we saw these arrangements as tools that could be used for various purposes (in various ways). One and the same governance arrangement, if used in a different way, from our point of view, could yield a different result (from the practical point of you and also when analysed from the theoretical perspective which is our current interest).

Additional emphasis on the analysis of reflexivity

Consequently, this model corresponds with the technocratic vision. The bias against industrial lobbying, polarisation of public opinion and groups of interests, and reinforcement of independent scientific expertise, represent the elements of the traditional top-down approach.

²¹⁶ *Co-construction Model*: This model distinguishes itself by questioning the way in which technological development projects use experts. Representations of technology come from numerous collected case studies. The works of the new sociology of sciences have progressively come to blame the traditional conception of science as a revelation of universal, independent truths of the social system they produce. This important work results from taking the methodological path proposed by Latour. It is therefore a criticism of sound science, which ‘melts’ the analysis of risks in the preceding models, and which invites us to place it into a pragmatic perspective.

In this model, both facts and values being taken into account, as underlined by Stirling, is not only a democratic matter; it is a matter of analytical rigor because it is the only way of treating these essential points seriously. If not, how can we criticise and validate the framing? Why hide and withdraw from the debate which will discuss what may eventually be changed?

²¹⁷ According to the intentionalist pre-supposition, the norms effects are supposed to be deducible from the simple intention to adopt the norm. additionally, there is the presupposition that the actors in a participatory approach will have capacity and intention to contribute to the participatory discussion, in line with Habermas (1981/1984) proceduralism. For example, an ethcial committee may produce a set of guidelines for the technological developers to implement. However, they do so without thinking about what actual effect the norm will have in the implementation; they simply assume that the developers will have the will and intention to implement the norm, and thus the norm will be implemented.

²¹⁸ The schematising pre-supposition involves Kantian schemes (rules), in which the operation of the application of a norm is a simple formal deductive reasoning on the basis of the rule itself. The determination of the norm is linked to these rules, such as ethical guidelines, or laws, or other external sets of rules (Such as Human Rights act, e.g., etc.) in order to determine the effectof the ethical norm. The schematising presupposition also involves preconditions about how the norms might be addressed, and is most commonly seen in expert panels, advisory boards and committees.

²¹⁹ The mentalist pre-supposition is named so because it relies on the mind having a set of rules (or schemes, in Kant’s words), that predetermines the effect of a norm, and does not depend on any exterior context (to that of the thinker). This is commonly seen when participants in a participatory approach come to the setting with their own particular ethical framing, or with some preconceptions as to what ethical issues might arise. This is also commonly seen within expert opinion committees, with each expert having their own preconceived idea about the ethical issues before consulting any of the people that technology might impact. Such an expert may also have a idea about what effect the norm might have before fully exploring the contextual, social, cultural and other sides of the problem.

According to the developed theory, we were assessing not only the governance arrangements themselves but also the reflexivity present within them (if there was any), as well as its impact. Firstly, we were interested in the degree of reflexivity²²⁰. Thus, the relevant stakeholder, in order to attain reflexivity, must construct within their policy context the normative ethical issues that might be encountered. This should also envisage the potential ‘destabilisation of context’, i.e. possible new and unexpected aspects to the potential ethical issues²²¹.

For example, a different culture might be additionally taken into consideration, which is a typical situation in the context of the EU member states. Such a situation would also require to recognise the need to ‘reframe’ the problem to take the new culture into consideration and also to implement the reframing, which might be a particular challenge. By doing so, the relationship between the context and the norm is being re-defined, and the application of the norm to the context is being carried out.

Regarding the construction of the ethical norm – a concrete solution needs to be found to solve a particular problem. However, the sought solution should ‘optimise’ something that is ideal. However, this relies on the selection of various possibilities that cannot exhaust the possibilities of the given context (within which the ideal world the norm is chosen from takes place). It is impossible for one solution to exhaust all possible solutions, because the diversity of the context of the ideal world needs to be taken into account within the construction. For example, nothing in a formal mechanism of discussion can guarantee that the choice of possibilities (within the context) can correspond to the full perception of the actors concerned. Trying to tell people how they should conceive of life does not work; rather it would be a reintegration of the suggestion into their conception of life, but not the transformation of their conception. This

²²⁰ Reflexivity is defined by Lenoble and Maeschalsk as “the operation by which a social group seeks to respond to its perception of the need to adjust its capacities for action” (Lenoble and Maeschalsk, 2006).

²²¹ Here and further we are referring to the approaches elaborated by the EGAIS project

asymmetry (and reversibility) is important to examine, because it affects the implementation of norms in the concrete field.

What we wish to discover is the extent of reflexivity in the respective governance arrangements, specifically, how the framing of the problem is being addressed and whether reflexivity is present. We are also interested whether there is reflexivity on the conditions of discussion and whether there is reflexivity of the reversibility of the construction of the norm (i.e., the construction of the parameters that will condition the insertion of the norm into a concrete world). Finally, we wanted to see if the relationship between the context and the norm is being constructed, and what are these relationships.

We will try to see if in the governance approaches by the European Commission a particular issue had any a particular effect on the ethical framing (ethical trajectory change) or changed the way the governance procedures were enacted (governance change).

We would like once more to point out that our analysis is rather qualitative than quantitative. Therefore we will much rely on the empirical material obtained through our interviews in order to: identify the various governance tools; assess their effectiveness; see how justified is the use of these tools. Thus, we will see how ethical issues are being determined, how the problems are framed, and how change in the framing (as a response to the destabilisation) is carried out. All of these results will be assessed against our theoretical background. The template of the grid for data analysis and the analysis according to the grid is enclosed in Annex 8.

Annex 3 Questionnaire template for interviews within empirical study

TEMPLATE

for interviews with EU officials (based on the analytical grid according to theoretical framework of research)

The questionnaire, as discussed in Annex 2, is based on our theoretical concept. In the framework of our theoretical concept, the domains and parameters of analysis were determined, and the questions in the questionnaire is a response to this. The questionnaire has enabled us to yield the necessary empirical material for analysis (according to our theoretical framework).

I. Ethical issue determination

1. Why and how did the issue of ethics appear in the political agenda?
2. What were the reasons, aims and needs for making the decision to create a framework for addressing ethical issues in the projects of the 7th Framework program?

II. Governance arrangements

3. What governance arrangements or tools are being used to ensure ongoing discussions and deliberation on the existing ethical framework?

III. Implementation

4. In your opinion, has the existing ethical framework been successful from the point of view of implementation?
5. Have any parts or procedures been particularly successful, and do you see any drawbacks or needs for improvement?
6. Do you see any limits or insufficiencies in the system?
7. Are there any analyses or studies on the results of the implementation?

IV. Ethical approach

8. What principles and approaches were used in the development of the ethical framework?
9. What were the main steps in the process?
10. What were the main challenges and difficulties during this process?

V. Reflexivity

11. Are there mechanisms that allow for flexibility, reflection and revision of the ethical framework, taking into account the changing political, social and technological contexts?

Annex 4 Interviews with present and former EU officials
with competence to ethical framing of EU research policy

THE INTERVIEWS WITH THE FORMER AND PRESENT EU OFFICIALS, WITH THEIR KIND CONSENT, ARE TO BE CONSIDERED EXCLUSIVELY AS A RESOURCE FOR RELEVANT ANALYSIS WITHIN OUR THESIS (AND NOT AS A SOURCE FOR ANY FURTHER REFERENCES). THE AUTHOR OF THE THESIS IS GRATEFUL TO ALL THESE PROFESSIONALS FOR THEIR KIND AND GENEROUS SUPPORT, THEIR COMPETENCE AND TIME.

Interview with Isidoros Karatzas, 12.05.2010

Dr Isidoros Karatzas is Head of the Ethics Review Sector in the Unit of Ethics and Governance of the Directorate L: Science, Economy and Society of the European Commission. He is responsible for the ethics review process for projects that raise ethics issues and are selected for FP7 funding. Dr Karatzas has his research background in biochemistry. He has been the scientific secretary of the European Research Advisory Board (EURAB). Dr Karatzas has been presenting extensively to relevant stakeholders and other target groups regarding the role and opinions of the European Commission on ethics in European and global research.

I. Ethical issue determination

1. Why and how did the issue of ethics appear in the political agenda?

The issues raised by ethics is deeply rooted in the European culture and conscience. This refers also to the issue of ethics in science. When analysing, for example, the Greek mythology, we can easily find examples which we today would refer to as cases of perceived reality and scientific reality, and thus having links to the issue of values.

Also the political process of the post-war period of the 20th century presents us examples of addressing ethical issues in a scientific context: The Nuremberg code (1947) includes such principles as [informed consent](#) and other; The Declaration of Helsinki (1964 – 2008) details ethical principles related to the protection of the life, privacy, health and dignity of the human subject.

The European Charter of Fundamental Rights (2000) is an important document that tried to combine and declare all the values and fundamental rights to which EU citizens should be entitled, and this serves also as a basis for various policy initiatives regarding ethics in science and research.

Historically many initiatives regarding ethics in science have originated within member states. At the same time, various initiatives have also found their origin in the European Commission. The European Commission interchangeably with the EU national states leads or follows developments regarding ethics in science. It should also be noted that civil society is quick to identify ethical issues in scientific research.

Public opinion is and important driver in EU policy making. Any “organized” opinion from society would be taken as relevant public opinion. Society never remains silent. Consultations are being carried out, and controversial issues put “on the table” for

discussion before any important issue is being passed over to the European Parliament or Council. On some occasions the society remains relatively passive regarding certain controversial issues, and the discussions go on primarily in scientific circles. Thus, for example, regarding nanotechnology, in scientific circles and among various stakeholders from industries the discussion has been ongoing for 10-15 years, whereas the public has not shown an equal degree of interest or concern.

The approach of the European Commission is - discuss potential ethical issues in science and research as early and as widely as possible. This has been prompted by lessons learnt from the history, especially from the case with genetically modified foods (GMO). It is always a good time to start a discussion. The later the discussion is being started, the more problems and worries might emerge.

There are 3 major categories of ethical issues, and they are related to three corresponding directives, which are translated into national law of member states:

These categories are:

- 1) data protection – with the supporting EU Directive 95/46/EC of 1995 on data protection, requiring that, member states protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data;
- 2) clinical medicine – with the supporting EU Directive 2001/20/EC of 2001 on clinical medicine, harmonising the provisions governing clinical trials and fostering and facilitate multinational clinical research;
- 3) animal welfare – with the supporting EU Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes.

2. What were the reasons, aims and needs for making the decision to create a framework for addressing ethical issues in the projects of the 7th Framework program?

It was clearly the reaction to technological development. Within the Framework program a major impetus was the controversial issue of human embryonic stem cells. It became broadly discussed and was put on political agenda. The discussion lasted till the very last in the Parliament. A special Statement by the Commission is attached to the FP 7 Decision. It became evident soon that an increasing number of controversial issues ask for a specific framework to address the inherent ethical aspects. The research funded by the European Commission has to comply with the fundamental values and rights of the EU citizens, thus, existing and potential ethical issues need to be addressed in any research funded by the EU research programs.

II. Governance arrangements

3. What governance arrangements or tools are being used to ensure ongoing discussions and deliberation on the existing ethical framework?

The national ethical committees play a major role in the discussions and deliberation on ethics and ethical frameworks in research.

Regarding the procedures within the ethical framework of the EU 7th framework program - since 2007 there have been several major innovations as a result of deliberation of existing approaches. The ethics review procedure is of major importance.

Expertize and learning from each other

Learning from each other is an important aspect regarding governance arrangements, since expertise in ethics is a complicated issue (due to the underlying uncertainty). More discussion on possible “standard” in ethics is necessary. Scientific community that deals with ethics should come up with procedures and codes that standardize the process of ethics review as much as possible. This is a major challenge, since there are different people (with various professional and cultural backgrounds) in different panels. At the same time the European Commission should secure that a similar proposals or issue is being addressed in the same way, and the decisions on these issues should be similar in different panels. The process should be steered through rational decision making, as far as possible. A scientific method should be developed and implemented. Ongoing discussions with scientific community and society at large are necessary. This is also important from the point of view of public image and good name of the European Commission.

The diversity of European values vs need for uniformity of approach to ethics at EU level
There is a challenge regarding the variety and richness of European values. The question is how to bring it to the European level and how it would affect the overall ethical framework. It is important to respect diversity, but still a discussion is necessary how to arrive to a greater uniformity of approach at European level.

Public participation as a major source of good governance

Public participation to any research is important. Today it is not possible to know the “right” answer to an ethical challenge, so, a discussion is always necessary to address a problem and in order to get a variety of opinion. Tolerance is also important, taking into consideration the diversity of interests and values.

Major obstacles and challenges to good governance

Indifference, lack of awareness, lack of knowledge. Member states should increasingly go on with collaboration on ethics in research.

4. In your opinion, has the existing ethical framework been successful from the point of view of implementation?

The current ethical framework has been well thought over and has a clear and effective procedure.

Ethics review

Ethics review which started in 2001 as a procedure. The implementation of ethics review is a clearly and well organised procedure, it functions well and has a clear distinction of roles and responsibilities.

Ethics review report

The Ethics Review Report is an important document that becomes part of the contractual obligations, thus, the scientific consortium has specific demands to comply with regarding ethics. The project officers follow the process, to secure that projects do not find themselves in administrative difficulties in fulfilling the obligations.

There are three main purposes of the review: 1) help the scientists in a practical way and contribute to the overall development of ethical research; 2) political reasons – to secure that the European Commission addresses potential risks at an early stage (partly a risk management issue). This allows to avoid needless negative publicity from media.

3) this also allows the European Commission to continuously follow the developments and be informed on what is going on.

Follow up and audit

From 2010 (officially, before were pilots and preparation) monitoring of the ethical part has been started. This consists of the ethical follow up and audit within 18 months of the project. This is being done by project officers and also by contracted experts. (More details in the attached documents I.B.) Apart from the ethics reviewers others can notify for the need of a follow-up/audit: other partners in a project; project officers who follow the developments in projects; advisory board of a project (an internal body).

Help desk

Help desk is being offered to researchers. It is possible to call the head of the Ethics Review sector for ethical guidance.

Internal reflection

Internal reflection is also being organized. First in the world to organise ethical workshops starting from 2010. Ethics review impact will be estimated. In 2010 possibly two workshops will be organised in 2 countries. Later on workshops will be organised country by country. What ethics means to a scientist? Talking to people is important. Scientists appreciate the help, even in the medical field.

5. Have any parts or procedures been particularly successful, and do you see any drawbacks or needs for improvement?

The initiative of the Ethics Review Sector is pioneering at European and world level with its procedure of ethics review and audit, and the up-coming ethics workshops in different EU countries.

6. Do you see any limits or insufficiencies in the system?

Standardized methodology in Europe (following a discussion at the European level of what ethics in research covers, what it needs to achieve, what are the tools available, how it can maximize its effectiveness, what scientists mean and need and want, what policy makers want to achieve, what administrations need to do to fulfill the promise of ethics. Also, training of all involved and more discussion/exposure at the formative years at the university. Continuous training for ethics committee members

7. Are there any analyses or studies on the results of the implementation?

Not many at EU level. Some at the national levels, many articles in refereed journals.

IV. Ethical approach

8. What principles and approaches were used in the development of the ethical framework?

Ethics Review legal basis is:

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

The principles and approaches defined in the European Charter of Fundamental Rights (articles 1,2,3,4 for example in Chapter 1)

9. What were the main steps in the process?

The starting point regarding the Seventh Framework Programme - (Decision N° 1982/2006/EC), Article 6 (1§) stipulates: “All the research activities carried out under the Seventh Framework Programme shall be in compliance with fundamental ethical principles”

A case-to-case review is being carried out of all research proposals submitted in FP7 and have been selected for funding and raise ethical issues. Organisation of the Ethics Review is being carried out in two stages: Ethics Screening and Ethics Review. It involves 1) appointment of the members of the Ethics Screening and Review panels; 2) procedural coordination of the entire evaluation process. From 2010 there is a new procedure - an ex-post evaluation (ethics follow-up/audit)

Functions of the Ethics review panel

The ethical review panel discusses the following elements:

- Whether the researchers respect the FP7 ethical standards;
- Whether the relevant EU legislation is taken into account in the design of the proposed research frame;
- Whether the applicants have sought/ are planning to seek the approval of relevant local/national (ethics) committees;
- The awareness of the applicants on the ethical aspects and the social impact of the research they propose;
- Whether the relevant International Conventions, Treaties and Declarations are followed;
- The balance between the research objectives and the means to be used;

New procedure from 2010

Starting from 2010 all proposals that raise ethical issues and are selected for funding are screened by the programmes. The process is common for the DGs in the research family and the Agencies. Screening covers all ethics issues raised by an application and separates:

- 1) All proposals that are covered by European law go to national bodies (CT, data protection, animal welfare, human tissue directive)
- 2) proposals that raise ethical issues in three categories (hESCs, interventions on humans, non human primates) go automatically to ETHICS REVIEW by the DGRTDL3- the Ethics Review Sector

The Ethics Review stage - more details can be found in Annex A of the rules for submission of proposals for this. As a general framework:

- Individual reading of the proposals
- Meeting as an ethical review panel: discussion for a consensus
- Production of an Ethical Review Report (sent to the participants)
- 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.

What happens after the formulation of the 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 Review Sector is also organising Ethics Audits / Follow-ups

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

Objectives of the Ethics Audit/follow-up

- 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)

10. What were the main challenges and difficulties during this process?

The main challenges have been:

1) awareness rising on ethics procedures of the program, there is low awareness among some research communities; 2) different legislation in different EU countries; this is challenging for the stability of the system; 3) experts have to make very general statements, sometimes too general; ideally would be to refer to concrete legal text; would be much better to be concrete; 4) problems with implementation research in non-EU countries. When projects are funded in non-EU countries, EU standard applies. Article 6 makes reference to Human Rights Charter; 5) Additional efforts needed to improving contacts with other DGs, e.g. Health, Justice (data protection), environment (animals), enterprise (security); 6) more ethics training necessary: for national contact points; administrators, for scientific community; 7) how to secure researchers start early and build ethics into their into research from the very beginning.

V. Reflexivity

11. Are there mechanisms that allow for flexibility, reflection and revision of the ethical framework, taking into account the changing political, social and technological contexts?

Relevant stakeholders - National Ethical Committees, Workshops in EU countries, Public debates, European Parliament, Council, European group on Ethics, Patients' organizations, Industry groups and other have a role in it.

Interview with Peteris Zilgalvis, Brussels, 4.06.2010

Background

Dr Pēteris Zilgalvis received his JD from the University of Southern California Law Centre in 1990. He has been a member of the California State Bar since 1991. From 1993 to 1996, he was a regional environmental specialist at the World Bank. He has also held positions at the Latvian Ministry of Foreign Affairs and the Latvian Environmental Protection Committee (now the Ministry of Environment). He has acted as a consultant on environmental law for the European Commission.

From 1997 till 2005 Pēteris Zilgalvis had been holding the position as the deputy head of the Bioethics Department of the Legal Affairs Directorate-General at the Council of Europe. During his period in the Council of Europe he has also been participating in the drafting of the explanatory Memorandum of the Oviedo Convention (1997)²²².

He has also been secretary of the Working Parties on Biomedical Research, on Biotechnology, and on Research on Human Biological Materials. Pēteris Zilgalvis has written articles and papers on bioethics and environmental law in specialist journals, as well as magazines and newspapers.

From October 2005 till May 2010 Pēteris Zilgalvis had been holding the position of the Head of Unit of Ethics and Governance of the Directorate L: Science, Economy and Society of the European Commission.

I. Ethical issue determination

1. Why and how did the issue of ethics appear in the political agenda?

The political and legal process of the post-war period of the 20th century raised new ethical issues in a scientific context. Following the legal trials on the experiments with human beings, the Nuremberg code²²³ (1947) was an important historic document, representing such relevant principles as [informed consent](#) and other.

In the United States of America, and later on in Europe, various ethical committees started emerging as a response to scientific and industrial developments, for example, in pharmaceutical industry. These ethical committees initially were dealing with the rights of customers etc.

In Europe, alongside with the broadening of the European Union in 2004, ethics committees gained more authority and status in national states. The responses to activities with implications to fundamental rights of citizens had to be coordinated at European level, therefore instruments were sought to facilitate such coordination.

This growing awareness regarding ethics in science is represented also in the EU legislation. For example, the [Directive 2001/20/EC](#) – the Clinical Trial Directive - sets

²²² The Oviedo Convention (1997) is an international convention, signed by most of the European States. It sets out the fundamental principles applicable in day-to-day medicine as well as those applicable to new technologies in human biology and medicine

²²³ The Nuremberg Code (1947) is a set of [research ethics](#) principles for [human experimentation](#) set as a result of the [subsequent Nuremberg trials](#) at the end of the [Second World War](#).

out requirements for the conduct of clinical trials in the European Union. Good clinical practice is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

It should be noted that the awareness of ethical aspects of scientific research was growing in the society in general over the past decades, and the legal instruments put in place represented and addressed the actual processes in the society. At the same time, it is important to mention that apart from the major political and legal responses, like relevant conventions, declarations and directives, also minor political initiatives could produce significant impact. Thus, for example, the DEBRA co-operation program of the Council of Europe (initiated and managed by Dr Pēteris Zilgalvis), with the limited budget of 600 000 ECU, made an impact on the ethical awareness raising in science at that time and facilitates further developments in the field.

2. What were the reasons, aims and needs for making the decision to create a framework for addressing ethical issues in the projects of the 7th Framework program?

The EU 5th and 6th framework programs were already addressing ethical issues, since there was clear awareness in the European Commission that not a single research should violate fundamental rights of people and the basic ethical principles.

Dr Zilgalvis joined the Unit of Ethics and Governance towards the end of the 6th Framework program. The ethical approach (philosophy) that was applied during the 5th and 6th Framework program, basically remained the same also during the 7th Framework program.

The main difference is that in the 7th Framework program every proposal is being evaluated from the ethical perspective, and those proposals that are “flagged” by scientific experts are being examined more closely, in case a full ethics review might be needed. The procedures for addressing ethical issues are much more elaborated than previously, and the Ethics review sector has been created within the Unit of Ethics and Governance in order to coordinate the process. Another important development and difference is the introduction of the audit of project proposals. Around 10% of the funded projects are being examined during their lifetime and after their completion as well. Measures have been taken to raise the general awareness of researchers regarding ethical issues.

In the last five years only three proposals have been rejected due to “ethical reasons”, which is a comparatively small amount if compared to the total number of (rejected) project proposals.

II. Governance arrangements

3. What governance arrangements or tools are being used to ensure ongoing discussions and deliberation on the existing ethical framework?

Relation between society, scientists, policy makers and those who implement the policy are the cornerstones of good governance. This has been implemented by: choice of adequate legal instruments; methods used in the dialogue with scientists and the society;

obtaining the societal opinions via the European Parliament; when addressing controversial issues, discussing them with Parliament committees, NGOs, advisors, so that a potentially ethically unsound project proposal may not be financed; using foresight – to understand the future societal developments through dialogue of scientists with society, sociological studies, discussions with policy makers, so that policy making and legislation can be in harmony with the existing and potential societal processes. Discussions in various circles allowing to take into consideration the rights of individuals and new societal needs. Increased co-operation with national ethical committees in member states.

III. Implementation

4. In your opinion, has the existing ethical framework been successful from the point of view of implementation?

This question should be viewed in context with the set aims and objectives. By actual the implementation of the Framework program, its main aims regarding ethics in science have been addressed. Thus, the framework can be evaluated as successful. These main aims have been: to support science, in a way that the researchers and their teams are aware of the broader ethical principles and approaches, in line with the fundamental rights of European citizens, in accordance with responsible science, and so that the society can view and regard the science as being ethical; to protect the fundamental rights of European people, and that no research that might affect their fundamental rights is being financed – in accordance with the principles incorporated in the Charter of Fundamental Rights of the European Union.

Thus, this framework has been supporting ethical science. Moreover, the proposed framework itself excludes that a clearly ethically unsound research proposal is being funded. However, there is still a challenge – what (legal) instruments to use in identifying and differentiating between the proposals of a potentially negative ethical impact and those that are violating fundamental rights of citizens. In other words - where the borderline starts when we can already speak of the breach of fundamental rights.

5. Have any parts or procedures been particularly successful, and do you see any drawbacks or needs for improvement?

The overall organisation and management of the cycle of ethical evaluation of project proposals is a success. The system is well functioning and effective.

The most important developments have been the introduction of the full ethical review and the introduced ethics audit. The introduction of the audit has been a fundamental change – ethical evaluation of proposals not only before funding but also during and also after the implementation of the funded project. Around 10% out of all funded projects are selected for ethics audit. The choice is being made: 1) from projects which have been dealing with sensitive ethical issues; 2) when there is indication that a project might be having ethical problems during its implementation; 3) by random choice.

In order to further evolve the system, the challenges to be addressed are:
 the audit procedures should be elaborated;
 the too many bureaucratic procedures need to be eliminated. Procedures need to be simplified, so that fewer proposals are being sent for full ethical review (potential ethical challenges should be addressed and managed in the process of evaluation);

The subsidiarity principle should be applied as much as possible, letting the national authorities deal with more cases. This would allow for the reduction of human resources involved in project monitoring. The budgetary savings could be re-allocated for actual research.

6. Do you see any limits or insufficiencies in the system?

Sometimes there is a very thin borderline between the violation of fundamental rights or just an ethically non-acceptable activity. There is a legal justification to reject a project that violates the fundamental rights, and it is sometimes challenging to find legal justification for rejecting a potentially ethically non-acceptable proposal (where there is not 100% proof of the violation of the fundamental rights). In such situations the case is brought to the attention to the particular Directorate to which the project proposal “belongs”, and the decision is taken at the level of the particular Directorate, or could also be taken at the level of the Commission, if necessary.

In dealing with biomedicine, there is a fairly precise legal regulation (addressing human rights, informed consent, bioethics). However, in dealing with ethics in ICT research, there are more problems to be encountered, since there are regulations regarding data protection but not on some other aspects of what might be acceptable in ICT research etc.

7. Are there any analyses or studies on the results of the implementation?

There are numerous studies and reports available on the relevant topic. The project officer Rene Von Schomberg should be addressed for more specific information.

IV. Ethical approach

8. What principles and approaches were used in the development of the ethical framework?

The philosophy of the ethical framework is rooted in the approaches implemented by the Council of Europe and UNESCO and from the existing relevant EU and national legal framework. Further on much has been derived from the existing approaches in the member states, as well as from the existing expertise (with multiple stakeholders involved in the process).

The main instruments applied have been: European legislation; national legislation of the member states; international treaties.

The proposed ethical framework should be in compliance with the needs of a competitive society from the point of view of scientific development, and at the same time promoting critical perspective and deliberation on the existing framework, in order to keep it up-to-date and able to continuously address the new ethical challenges of technological development.

These needs have been addressed by the 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). It envisages that: the general competitiveness of the European science and research should be enhanced; research policy should be developed –

also from the critical point of view – deliberation should take place, so that the policy up-to date and addresses the real situation

9. What were the main steps in the process?

10. What were the main challenges and difficulties during this process?

From the point of view of procedures, it was a new challenge to introduce the full ethical screening and the ethical audit of projects. This is a great achievement at European level and beyond. Another challenge has been to implement more decentralised approaches in decision making – delegating more responsibility to respective Directorates. By retaining the same philosophy in ethical framing, the approaches to procedures changed and were made more effective. Many things had to be re-thought, and the principle of subsidiarity was applied more commonly.

From the point of view of human resources – there had been lack of administrative staff before. Through exercise in administration and management, as well as by introducing more staff, this had been solved.

Dialogue with and among scientists has to be enhanced. If a completely new and unprecedented situation occurred (that had not previously been addressed) – a political opinion and solution was sought. In such situations usually the respective Directorate had to be involved, and in, if necessary, an issue could also be brought to the Commission level.

The issue of ethical expertise is another relevant question. Involvement of representatives (experts) from various domains – who have thought about ethics in research - is important. Lay people must also be involved. Often these are members from society within national Ethical Committees. Experience shows that these lay people gradually obtain capacity for relevant expertise. All those involved usually act to the best of their knowledge. It becomes a pool of knowledge and expertise.

V. Reflexivity

11. Are there mechanisms that allow for flexibility, reflection and revision of the ethical framework, taking into account the changing political, social and technological contexts?

The national ethical committees are an important stakeholder. Common reflection on the arising ethical issues by these committees (by pooling of resources), as well as common discussions and reflection by experts from various branches of science are important. Thus, the background information for relevant policy making in Europe is being enriched.

Other important developments and activities are increased synergies between research on ethics in science, research on governance and scientific advice, research on fundamental rights and citizenship, as well as involvement of civil society. The activities of the European Science Foundation are also important in this respect.

Interview of Mr Frank Cunningham, 29.04.2010.

European Commission, Information, Society and Media DG, Evaluation and Monitoring Unit

Frank Cunningham has been working in the European Commission for 20 years – for 12 years in management of research projects, and for more than 7 years on program evaluation, assessment of impact, as well as ex-post, ex-ante evaluations. Frank Cunningham has a degree in physics and a Master degree in digital engineering. He has overall experience in work with ICT for more than 30 years. His previous professional experience is from private and public sector in UK and Ireland, he has also spent 6 months in the USA.

I. Ethical issue determination

1. Why and how did the issue of ethics appear in the political agenda?

During the implementation of the 6th Framework new ICT research areas and results kept emerging, and it became evident that they had impact on human life and human privacy. Two basic patterns were observed how these new ethical issues kept appearing: through more frequent application of ICT in everyday life, with subsequent issues of privacy being involved; e.g., through tracking (overt and covert) becoming routine procedures; new research on human brain, e.g. cognitive systems, having major effect on human life and privacy. It became clear that the newly emerging ethical issues that came parallel to the new ICT research, will have to be addressed at policy level.

2. What were the reasons, aims and needs for making the decision to create a framework for addressing ethical issues in the projects of the 7th Framework program?

Experience in ICT calls in FP6 demonstrated a growing number of ICT RTD proposals with ethical issues, which required ethical review, and which led to one proposal being not funded for ethical reasons. This proposal passed scientific evaluation, but potential misuse of result was identified - experiments on humans (memory recall). It was withdrawn due to ethical concerns. The fact that it is tax payers money was also to be taken into consideration. It was suggested by senior management that better grounded project screening is developed. This led to creating ICT research and technological development specific Ethical Guidelines and clear and simple instructions to applicants on how to include information on ethical issues in ICT research proposals. Also clear and transparent proposal screening and ethical review process was developed. The guidelines were drafted by an independent ethics expert after consultation with research stakeholder groups (including program advisory group members). These Ethical Guidelines include guidance on: conduct of research; privacy & informed consent; use of animals; ICT implants & wearable computing; eHealth and genetics and ICT & Bio/Nano electronics. The Ethical Guidelines form Annex 5 of ICT Guides for Applicants. Ethics 'Check-list' (Ethical issues table) are in Annex 4 of Guides for Applicants.

II. Governance arrangements

3. What governance arrangements or tools are being used to ensure ongoing discussions and deliberation on the existing ethical framework?

Main governance issues are linked to the clarity of the process and division of responsibilities, including the role of senior management. Results of the calls are being

analyzed in this respect as well, in order to improve the procedures. Integrity of the staff is an important issue, and it has links with the learning process, as well. Since the environment is dynamic, the implementation process is being closely observed and major gaps identified. The hope is for the collective knowledge as a source. It is resulting from a joint work by staff, evaluators, researchers. Eyes are being kept open. Discussions in internal networks regarding ethics are also important for subsequent governance arrangements.

III. Implementation

4. In your opinion, has the existing ethical framework been successful from the point of view of implementation?

It has been successful. First of all, an efficient and well functioning ethics screening process of ICT research and technological development proposals was established. Many ethical issues are now being dealt with at grant contract negotiation stage (without carrying out ethics review). Ethics review requirements are effectively dealt with by consortium during the project implementation stage and reported on during technical reviews as a monitoring procedure. One of the major achievements has been awareness of ICT ethical issues raised among researchers, evaluators and European Commission staff. Steady reduction in numbers (and percentage) of proposals requiring ethics review from 6th FP to 7th FP and from Call 1 to Call 3 is being observed and considered as an indicator for successful addressing of ethical issues in ICT research and development projects. A framing has been created to address sensitive areas. It has enabled to capture many potential ethical issues from arising and producing unwanted consequences. In cases of not serious ethical issue the process allows to address them during the project implementation, making it a contractual obligation. Through monitoring the project officers follow the processes.

5. Have any parts or procedures been particularly successful, and do you see any drawbacks or needs for improvement?

The very fact that it was possible to draft and formalize the Ethical Guidelines has been a great success, given the fact that they had to be circulated to many other stakeholders and parties internally and externally for comment and approval. The Ethical Guidelines are concise and well grounded (referenced) in legal documents and opinions of the European Group of Ethics – there are 16 references all in all. That gives a good basis for communication with project promoters in case of negotiations or in other situations that may arise. The Ethical Guidelines address potentially ethically sensitive areas, but in a broad way (not pre-defining anything), so that the document could be used for a possibly longer period of time and did not ask for serious update in the near future. There has been collective and complementary input in the process in adopting the Guidelines – people and experts with different backgrounds participated in the process. Unless there is some specific turn of events that asks for changes, the present intention is to keep the Ethical Guidelines stable and as they are. These Guidelines help to promote ethically sound research. Raising ethical awareness among the researchers, the evaluators, the staff and policy makers has been one of the major achievements. There is also learning taking place during the process of identifying and addressing ethical issues - among the Commission staff, researchers, evaluators and other involved persons and parties (stakeholders). Ethical expertise today is much linked to learning from each other. People learn from situations, from each other, from various new experiences and exercises. That has made the screening process more effective. Many things are being managed at negotiation stage, without reviewing process. It is also important from the point of view of effective

management of human resources. One of the main results generally - enforcement and awareness raising has taken place, and raised awareness pays off. People act ethically, and it has impact on research society at large.

From the implementation point of view: 1) reduced number of projects going for ethical review; 2) research is being dealt with sufficiently well regarding ethics.

6. Do you see any limits or insufficiencies in the system?

No system can be perfect. Since the environment is dynamic, the implementation process is needs to be continuously observed and major gaps identified. The hope is for the collective knowledge as a source. It is resulting from a joint work by staff, evaluators, researchers. Awareness raising exercise needs to be ongoing. Expertise is not an easy question. It is not easy to define who is an ethical expert today - someone with ethical academic training or specialist in a particular field. Ethical expertise today is much linked to learning from each other. People learn from situations, from each other, from various new experiences and exercises. These are some of the ways to address challenges.

Further and continuing awareness raising exercise is needed. Ethics should be integrated from beginning into research. Researchers (and those associated with management of research programmes) should think and act both with integrity and look upon ethics in the research objectives and the conduct of the research as being just as important (of not more so) than research approaches/methodologies, finance, project management etc.

7. Are there any analyses or studies on the results of the implementation?

Regarding the results of the implementation, there are several studies and analysis:

Ethical Issues Statistics – for FP 6 Calls 4, 5 and 6

Ethical Issues Statistics – for FP 7 ICT Calls 1 to 3

Overview of Proposals For ethics review in FP7 in Call 1, Call 3 and Call 3

Analysis on implementation of Ethical Review Requirements (Negotiation of Contract)

Analysis on implementation of Ethical Review Requirements (During Project)

IV. Ethical approach

8. What principles and approaches were used in the development of the ethical framework?

The draft framework was developed by an external expert. The guidelines, which can be considered along with the ethical screening process, as a framework for addressing ethical issues in the ICT research program were drafted in collaboration with an independent external expert with a thorough knowledge of ICT linked ethical issues. Senior management looks upon dealing with ethics partially at least from a risk management perspective (top- down). The 'bottom-up' aspects were instilling an 'ownership' of ethics by ALL stakeholders, researchers, Commission staff, evaluators etc

9. What were the main steps in the process?

The draft framework was developed by an external expert. The development of the framework mainly consisted of the development of: guidelines; the process of screening. These were circulated for comment to other relevant institutions, units and stakeholders internally and externally. The process of application of the framework procedures:

1) Applicants flag ethical issues; 2) Evaluators are invited to flag any (above-threshold) proposal they consider requires ethical review and also to flag ethical issues needing attention at contract negotiation phase for those proposals considered not to require ethical

review; 3) INFISO Directorates screen ‘flagged’ proposals which are in Implementation Plan/Reserve list and decide which require full ethical review. In rare cases of very serious concerns expressed by ER Panel the responsible ICT Director may request DG RTD to hold a hearing between the ER Panel and applicants. If, following the hearing, the ER Panel’s concerns can still not be adequately addressed then the ICT Director Responsible will propose to reject proposal and withdraw it from the Implementation Plan. All Proposals Requiring Ethical Review transmitted to DG RTD which co-ordinates the Ethical Reviews by independent ethics experts. Requirements and Recommendations from the Ethical Review Panel are transmitted to the INFISO Director concerned and are implemented in project negotiations.

10. What were the main challenges and difficulties during this process?

It was a rather demanding process to coordinate all the opinions during the development process of the Ethical Guidelines. The internal process was more complicated if compared to the external process of consultancy and co-ordination. .

It is important to note that – when asked for an opinion on the Ethical Guidelines, initially there was a general tendency among people to point out that they were not professionals in ethics and for this reason not always having real grounds to express opinion ways for addressing ethical issues. There are certain issues that can or have to be addressed by subsidiarity approach – national states can often deal with certain ethical issues more specifically or adequately.

V. Reflexivity

11. Are there mechanisms that allow for flexibility, reflection and revision of the ethical framework, taking into account the changing political, social and technological contexts? Currently there is no formal procedure for reflecting on the existing ethical framework. One must beware not to make the process too bureaucratic if additional formal procedures were invented. However, the importance of reflection should be acknowledged and therefore worth while consideration.

Ethical approach should be a bottom up process. Look at real world and situations gives material for policy making. Reflection comes from evaluation.

Any additional comment to be made. Issues for concern regarding ethics.

There is a major concern regarding privacy issues – increasing and ubiquitous use of identification tools, their complexity. Increasing capability to be able to intrude personal lives. This may have an increasing impact on the ethical issue evaluation in ICT research projects. However, this is a broader issue and falls outside the exclusive competence of DG Information, Society and Media. One possible solution for addressing future challenges is to ask for the opinion of the European Group of Ethics. However, it is always a lengthy procedure and may take up to 2-3 years. Important developments and links to ethics. Innovation and innovation networks are of major importance today. Links between innovation and research is an important topic. Innovation underpinned by ICT presents ethical issues. General developments and policy instruments
Social networks’ analysis based knowledge hubs have been identified. There are special tool created to feed in data and quantify. The position of institution, density of networks is being determined. SMEs are found to be chronically weak players. New methods of assessing systemic impacts. Colleagues in the operational side balanced it out. Better critical mass in some areas is being achieved. This characterizes the power of approach. Another study – to simulate future networks. A policy instrument. Results of the new instrument: larger integrated proposals and networks.

Interview with Diane Whitehouse, 6.05.2010

Background

Diana Whitehouse is a former project officer in the DG Information Society and Media, European Commission. During her period in the European Commission she was responsible for two fields – eInclusion and eHealth. In both the fields the focus of her work was on social implications. Her background is in social sciences (including political science). She also dealt academically with information systems, organisational and behavioural sciences. For 25 years she has been a member of the Working Group on Social Accountability and Computing, and for 20 years a member of the Special Interest Group on a Framework for Ethics, of the International Federation for Information Processing (IFIP). She was one of the early members of the British Computer Society's forum on ethics in its start-up phase (1996/97). At that time the Society was discussing the implications of its Code of Practice and Code of Conduct (a debate that continues until the present day), as well as on ethical implications of technologies. Her interest throughout this whole period is in the social and the ethical implications of information and communication technologies (ICT). Around 2001, and again around 2004-2005, for a limited period of time Diane Whitehouse attended several meetings of the European Group of Ethics (EGE) as either an observer or an external guest. Two Opinions were voiced/published that she had a "watching brief" over: first, the ethical implications of eHealth and, second, nanotechnologies. Currently Diane Whitehouse works with The Castlegate Consultancy on issues that relate to eServices (including eHealth, eGovernment, and eInclusion) but e.g., as chair of the IFIP working group on social accountability and computing she continues also to focus on issues that relate to the social implications and social impact of ICT.

I. Ethical issue determination

1. Why and how did the issue of ethics appear on the political agenda?

The intellectual foundations for ethical concerns in terms of ICT go back at least already to mid seventies of the twentieth century²²⁴²²⁵. Ethical methods were much studied at the Copenhagen Business School, Denmark²²⁶, Manchester Business School, UK²²⁷, London School of Economics and Political Science²²⁸ and – more recently with the arrival of Simon Rogerson on the scene in the mid-1980s, at De Montfort University in the UK. These academics were always very applied and would raise the same sorts of issues in political/policy-making circles.

The process was speeded up by the introduction of internet in mid-nineties. Already at that time there was concern regarding the application of internet for inappropriate purposes (see e.g., the concerns of the British Computer Society in the UK at that era) and there frequent broadsheet newspaper articles in e.g., the International Herald Tribune, Le Monde or in magazines also with the launch of Wired. This facilitated the process of ethical discussion of technological developments in the public arena and in political circles.

In European terms, it is important to refer to the early work of the European Group of Ethics (EGE) throughout the 1990s – and e.g., regarding their opinions on ethical issues in

²²⁴ E.g., Mowshowitz, A. (1976). *The Conquest of Will: Information Processing in Human Affairs*. Reading, MA: Addison-Wesley.

²²⁵ Weizenbaum, J. (1976) *Computer Power and Human Reason: From Judgement to Calculation*. San Francisco: WH Freeman

²²⁶ Professor Niels Bjorn Andersen

²²⁷ Professor Enid Mumford

²²⁸ Professor Frank Land

the FP5²²⁹. In Diane Whitehouse's case, she became aware of the work of the Group with their preparatory work on the quality related aspects of eHealth websites and ICT for health (published in 1999).

Another important factor was the general concern in the European Commission that EC co-financed activities should be sound and well-grounded, and – where technologies are concerned – for them to be socially and ethically appropriate. There has always been high level policy making attempts to ensure that ICT addresses 1) economic, legal, social challenges; 2) respects EU values; 3) involves European citizens (e.g., focus on accessibility and inclusion). Policy makers always try to act to the best of their knowledge.

The EU programme “Science and Society” was created in the DG Research as a response to the current processes that are under development.

The current and ongoing activities of the European Group of Ethics with its new agenda (in 2010+) is important for the development of the field. There is a general impression that the EGE activities are becoming more integrated in terms of what the EC does, and that there is a maturation of the field taking place. The Group was attempting to liaise with what the different Member States are doing in terms of committees of ethics on research relating to science and technologies. The fact that the EGE reports to the Commission President is important.

There is an increasing awareness of social implications and ethical implications in relation to science and technology. The problem of expertise – in ethics – and how to transmit that expertise is also raised.

It should be noted that not all social issues are in fact ethical, and similarly not all ethical issues are social.

2. What were the reasons, aims and needs for making the decision to create a framework for addressing ethical issues in the projects of the 7th Framework program?

As technologies start to converge and as they become closer to human beings (e.g., health, body, brain, being²³⁰) wider concerns started to become manifest. Also data privacy concerns emerged. The European Commission wanted to be seen as an institution to be doing the appropriate thing and to ensure that it was NOT co-financing projects that were in some way inappropriate.

The experience emerging from the 5th and 6th framework programmes indicated that ethical issues would have to be addressed more in the future. In the 6th framework programme there were certain challenges in the evaluation of the proposals regarding the ethical aspects of projects (which were largely organisational and/or process-related), Ordinary evaluators (e.g., with scientific, technical, or organisational competences) would claim that ethics was not their competence or responsibility. This issue had to be addressed more specifically by the 7th Framework Programme. Thus, special information was already created for the 6th Framework Programme proposers, and further Guidelines were created for the 7th Framework Programme and an ethical statement had to be submitted by Call applicants. Forms in relation to ethical issues will also have to be completed by projects at the end of their projects.

²²⁹ http://ec.europa.eu/european_group_ethics/avis/index_en.htm

²³⁰ <http://www.ctc-2010maribor.org/>

DG Information Society and Media in its first years (as DG 13) was very technological- and engineering-oriented. Later it became aware of societal and ethics issues. Until the late 1990s, there were relatively few members of staff in the DG who had a social science background. Internal personnel who had some more knowledge or background on relevant social and ethical issues started internal discussions on these matters in the early part of the first decade of the twenty-first century. During the period 2003-2005, an internal working group was started that involved project officers interested in the ethics of ICT. About once in a month these people met to discuss very generally and informally the ethical implications of technological development. Small scale investigations were done. Attempts were made to find out what the current body of knowledge was and what concerns there were by holding two workshops that were attended by distinguished scholars²³¹. Thus, the pool of knowledge was gradually formed – both internal and external, and the preconditions were created to start dealing with the questions concerned in a systemic way.

It should be noted, however, that issues that related to ICT projects were not treated specifically; the conversation were very general about technology and ethics. There was no particular investigation of any ICT projects. ICT projects co-financed by the EC are funded essentially (eventually) through taxpayers money, and hence ethical responsibilities have to be taken seriously.

Based on the discussions of the informal internal group, discussion started on what the mechanisms or guidelines to address the ethical challenges might be. In 2006-7 (possibly earlier) potential Guidelines for proposals were developed. The Commission tendered the early drafting process out to external consultancy and experts. Professor Simon Rogerson was one of the chief authors of the draft Guidelines. However, such drafts are used as drafts only; the Commission revises and uses them according to its own needs. The eventual draft Guidelines had to go through a long and complicated process of consultation with the member states and within the Commission and Council procedures.

The EC became aware that a mechanism was needed to assess/evaluate proposals for projects also regarding ethics²³² – in order to see what is being co-financed in terms of ethics, as well. No particular triggers could be identified for this: there were no specific concerns, no difficult issues. It just reflected the developments in society at large: a kind of precautionary principle.

Possible some more political/policy-oriented reasons enhanced this process – ethical responses to the needs of society were necessary. Several issues were raised at political level. What in the eHealth field, purely as an example, is an appropriate use of health data and other sensitive data.

From 2003/ 2004, in particular, policy makers started to think about these issues more intensely. Latterly, in societal terms, various technological developments have also been accompanied by various errors leading to the potential threat of the loss of citizens' trust²³³. Is the current legislation (and the way in which it is applied in the various Member States) up to scratch? Some foresight was necessary. Also it became increasingly important e.g.,

²³¹ Attendees included e.g., Jacques Berleur, Penny Duquenoy, Jeroen van den Hoven, Simon Rogerson.

²³² Proposals are always evaluated e.g., for their scientific and technical qualities and their organisational and leadership competences.

²³³ E.g., in the UK, sensitive data lost in transmission (via the physical postal system) or e.g., USB sticks left in compromising circumstances.

via public relations to convey public policy concerns and the measures taken to address these concerns.

II. Governance arrangements

3. What governance arrangements or tools are being used to ensure ongoing discussions and deliberation on the existing ethical framework?

The activities of the European Group on Ethics is ongoing, its mandate is in the process of/has been renewed. The ethics evaluation of proposals for projects is continuing through FP7.

Internally in the EC, I understand that there is a cross-DGs initiative to enable project officers to be aware of ethical issues in relation to technology and science projects.

In the development of any programme or policy at a European level, there are always such organisational activities as – 1) gaining expert input, guidance, information; 2) consultation with stakeholders; 3) lobbying by stakeholders (of a wide diversity of sorts) 4) consultation with society at large (e.g., via submissions, via reports, now also via websites) 5) expert focus groups, expert committees 6) by asking relevant research projects, 7) expert studies done on behalf of the Commission. 8) high level expert groups whose members give advice at a high level of policy making.

Reflexive governance today is a major challenge. Not everyone, however, sees the world through the “glasses” of ethics – and ethics experts also need to be aware of this limitation. It is important to consider how to transpose ideas about ethics and ethical principles into ways in which more ordinary people can understand them. People with broad educational background can and should be involved in deliberation on ethics in technological development today – domains like law, political science, business, culture, social studies and others are relevant and need to be represented.

Every European Commission framework programme has both an ex-ante and ex-post evaluation as well as an interim one at its mid-point. It possibly, however, gives more emphasis on quantitative parameters and not so much on qualitative (which can be far more difficult to ‘investigate’). A small portion of today’s evaluations concerns also ethics (see the final forms that FP7 projects will have to fill in at their end). Specific FP7 projects that deal with ethical issues, like ETICA and EGAIS, are also being financed and will potentially contribute to the deliberation on ethics in technological development.

In terms of governance, it is useful to consider in what ways strategy or policy is actually developed. It can be appropriate to look at the work of Henry Mintzberg, Emeritus Professor, McGill, Montreal. He theorised about how top down and bottom up approaches can come together; his work also enables a focus on process and organisation²³⁴.

III. Implementation

4. In your opinion, has the existing ethical framework been successful from the point of view of implementation?

Reasonably so. The reasons for this are:

- a) there is an awareness of the programme on the outside, and a growth in various ethics of computing initiatives;
- b) research proposals and applications apparently appear to fill in forms appropriately.

²³⁴ E.g., <http://cas.uah.edu/berkowd/webpage/mgt690/mintzbergandwaters.pdf>

It has been a great achievement that:

- a) there is an awareness of the ethical aspects of FP 7, also outside purely theoretical ethical field;
- b) proposal forms are filled out better;
- c) a set of evaluators who are available to do the evaluating.

All in all the programme that relates to ethics in projects has been reasonably successful. Idealistic hopes need to be viewed in the context of realistic possibilities and actual outcomes.

Of course, this relative success is not without certain difficulties. Organisationally, it has been said that there has been a deluge (flood) of needs for evaluation (as could have been predicted); this has apparently placed substantial pressures internally on the EC staff who organise the specific ethics evaluations and therefore on the science/ethics Unit in DG Research. The flood is not necessarily because there are actually ethical issues in the proposals themselves, but because ordinary evaluators can find it difficult to ascertain what an ethical issue is and I suspect that they will want to ensure that the ethical evaluations are undertaken by people who are experts in ethics.

There are some indications that the ethics evaluation has been the single element that has held up the mechanisms that enable the official go-ahead of project negotiation and acceptance. This is not necessarily because there are real ethical issues, but because there is a logjam of evaluations to be done on the proposals' ethical elements. There would therefore be a need internally inside the European Commission to re-think how these evaluations are being handled organisationally.

Historically, going back even to the 5FP and 6FP, excellent project proposals have always generally had excellent treatment of the ethical issues in respect of what they are planning to do (e.g., upholding their nations' scientific ethics principles, involving their university/industry ethics committees, knowing what the underpinning theories and principles are). Good science is ethical science!

However, even some otherwise very good project proposals have handled ethics of computing issues in a symbolic and superficial manner.

5. Have any parts or procedures been particularly successful, and do you see any drawbacks or needs for improvement?

Organisational things are apparently still a problem. Many proposals for projects at the evaluation stage have been sent for ethical evaluation, but – even before this stage, at the ordinary evaluation stage – there is often lack of expertise or knowledge what ethics in research is, and who are the experts. Also which people to invite as experts.

There is a lot of appropriate precaution, but at the same time measures have to be taken to ensure that a proposal for a project can pass the ethical evaluation smoothly without unnecessary delays and set-backs. Organisationally, overload takes place; there is a bottleneck effect.

A potential solution could be to start dealing with ethical challenges at an earlier stage. Measures could be taken to make evaluators and project officers feel more reassured. The procedural problems could be dealt with.

It could mean re-thinking the check list and the guidelines; organisation of information days; discussing the limits and insufficiencies of the 5th, 6th and now the 7th Framework Programme at a stage when enhancements could still be made (2011-2013). There could be more training on proposal writing, capacity building for organisations with regard to research proposals; it could be about drawing people's attention to ethical guidelines and templates; also, include in (research) journals, an awareness of ethical issues.

But also the issues need to be raised in an appropriate way in the broader means of communication (e.g., television; newspapers; websites; blogs; social networking). Even among the so-called “chattering classes” there is huge debate about HOW to do this – there is not a clear answer to “what is ethics”? Possible channels include e.g., Science or The New Scientist or Wired. Social media too. Even if the original was not a spoof, e.g., a PhD student created a Twitter site for Habermas²³⁵, it raised considerable levels of interest in forums for discussing ethics.

There needs to be a community dialogue on how to discuss ethics. Conventional, orthodox approaches. Classical scientific approaches. Radical versus conservative approaches. There are many interpretations: forums are always needed.

6. Do you see any limits or insufficiencies in the system?

See above.

7. Are there any analyses or studies on the results of the implementation?

There are:

- evaluations of every evaluation of proposals-submissions and also of every FP programme – pre-, interim, and post evaluation of the implementation.
- perhaps EGE-reform/revision might include assessment of how the ethics-in-research initiative has taken place?
- deliverables of individual projects that are dedicated to ethics (and also forms to be completed at the end of every FP7 project).

IV. Ethical approach

8. What principles and approaches were used in the development of the ethical framework?

EC looked to expertise from external experts, e.g., drafting of guidelines for FP7; some forms of external focus groups to gain input (circa 2003-2004); gradual incremental employment of persons internal to the EC (e.g., in DG RTD and DG INFSO with social science or with ethical expertise); ethics evaluation of proposals (identification of which proposals include an ethical challenge) and assessment by recognised committees on ethics.

9. What were the main steps in the process?

It is too grandiose to call it a “process”.

10. What were the main challenges and difficulties during this process?

The main challenges probably included that:

- (a) The process was starting from zero.
- (b) Being responsible generally!

²³⁵ http://cachef.ft.com/cms/s/0/eda3bcd8-5327-11df-813e-00144feab49a,dwp_uuid=a712eb94-dc2b-11da-890d-0000779e2340.html

(c) The issue of the selection of experts. How should we define and “improve” the experts?

(d) How to ensure that project officers/policy officers in the different relevant DGs in the European Commission, especially those responsible for areas relating to informatics, have some form of understanding of the procedures that relate to ethical evaluation/analysis?

Take as a parallel the situation e.g., how to include gender issues in European research projects: this issue is still sensitive. Trying to include equitable inclusion is an immense challenge, and in Europe it has been on the agenda for a hundred+ years already.

The challenge with regard to ethics (in Europe) started 2500 years ago already. It will be an ongoing debate. It is essentially crucial to the human condition. So, why should we expect it to be solved – e.g., in terms of the ethics of computing as treated in European research projects “overnight”?

V. Reflexivity

11. Are there mechanisms that allow for flexibility, reflection and revision of the ethical framework, taking into account the changing political, social and technological contexts? In my opinion, the approach in its own right is not so inflexible that changes cannot be taken on board (as part of customary assessment of how the research co-financed by the European Commission works).

Dialogue by “clever people” should be enhanced. But anyone can do a “wrong thing”, since there is so much uncertainty and so many blank spots in life, work, and research. “Every great man can stub his toe in the middle of the night.” Policy-makers really try, in my opinion, to do their best possible.

The important thing with regard to “an ethical framework” for research proposals is to get somewhere near to a usable method of assessment. Less focus on the metaphysics, than what would improve the mechanisms. It is helpful if people can understand and know that they are improving ethical development of technologies. It is all about social shaping of society.

There is always (not constantly) deliberation about policy development and programme development/implementation. Ex-ante, mid-term, and ex-post evaluations. Programmes last on average 3-7 years; they are always evaluated. Perhaps a budget mechanism could be explored for very specific evaluations e.g., an evaluation of the ethical evaluation of project proposals that has taken place in FP7?

New programmes and activities can always be set up. Some of them very applied and practical. E.g., the Ambient Assisted Living (AAL) programme. It is a joint research and development funding programme implemented by 20 European Member States http://www.aal-europe.eu/about-aal - _ftn1 and 3 Associated States²³⁶ http://www.aal-europe.eu/about-aal - _ftn2. The programme receives a substantial financial support from the European Commission (based on article 185 (previous 169) of the EC Treaty). Or there is the Competitive and Innovation Programme. Already they can see how things are going, but are they yet in a position to evaluate fully?

Evaluation repeatedly and “constantly” need to take place.

²³⁶ www.aal-europe.eu

We are currently living in a challenging context. There is not a clear future for Europe. Sustainability and the economic condition of Europe are major challenges. In the middle of this, how will the “ethics of computing” fare? I.e., is it more applicable once one gets to the implementation/application stage of a technology?

It would be interesting to see – empirically – whether there is also any correlation between economic trends or waves and the growth/decline of ethical concerns. Are there waves of interest in ethics that run parallel to developments in society; does this interest go in phases? In 2010, the very sustainability of the European idea itself is being tested. It is all about balance and yet conflict in society.

Currently, “ethics in computing” in Europe is thriving. There has been a rapid growth in faculties in Europe. ETHICOMP started fifteen years ago and is still continuing. But “ethics” needs to become embedded per se. How can you be “qualified” in ethics of computing. Is there anything the European Research Council can do?

With regard to the European Commission and the Science and Society Programme. Programmes come to an end; or the orientation of programmes change.

Can the continuation of these programmes and these endeavours continue? Or will the economic crisis cause a re-orientation towards other subjects or new subjects?

Post-interview (June 6, 2010): In addition, we might ask about the challenges of ensuring ethical understanding and behaviour among the ‘Me Generation’.²³⁷

Finally, the mechanism is human existence itself.

²³⁷ <http://www.psychologicalscience.org/observer/>

Telephone interview with Professor Simon Rogerson, 04.04.2010.

Professor Simon Rogerson currently is the Director of the Centre for Computing and Social Responsibility, De Montfort University, Leicester, United Kingdom. He joined De Montfort University in 1983, following a successful industrial career which culminated in being the Computer Services Manager for Thorn EMI. Now Professor Rogerson combines lecturing, research and consultancy in the management and ethical aspects of computing. He has published and presented papers in many countries about these issues. In 1995 he became the Director of the newly formed Centre for Computing and Social Responsibility. He also conceived and co-direct the ETHICOMP conference series on the ethical impacts of IT. He is a member of the Parliamentary IT Committee in the UK, a Fellow of the Institute for the Management of Information Systems and a Fellow of the Royal Society for the encouragement of Arts, Manufactures and Commerce.

Among other issues, his interest lies in: Computer Ethics as a discipline; Ethically sensitive information systems development approaches; Codes of Ethics. Professor Rogerson has been involved in drafting the Guidelines for applicants in the EU 7th framework program

I. Ethical issue determination

1. Why and how did the issue of ethics appear in the political agenda?

Already during the 6th Framework program (FP6) started the evaluation procedure as two reviews – scientific and ethical review. In general the Framework program started to put greater emphasis on social impact. The panels of experts were rather superficial regarding ethical issues. Ethical issues were never going to stop a project. However, one FP6 project got rejected on grounds of ethics. This fact came to the attention by Commissioner Viviane Reding. That single event changed the impact. The first and only project to be rejected on the grounds of ethics. This changed the emphasis – as a policy. There was a desire to ensure that it never happens again. With that officials started looking at the ethical issues in the EU framework program more seriously – in FP7 more explicitly. Now ethics has been over – politicized in the European Commission. Mrs. Viviane Reding, European Commissioner for Information, Society and Media, launched a public debate on RFID.

2. What were the reasons, aims and needs for making the decision to create a framework for addressing ethical issues in the projects of the 7th Framework program?

Professor Rogerson himself was involved in drafting the FP7 Ethical Guidelines. That was challenging and problematic, 17 drafts prepared all in all. The process took around 12 months. The final draft was looking very different from the initially conceived, after it had gone through circulation in the European Commission and external circulation in compliance with relevant procedures. Various members of various DGs were involved. Professor Rogerson was the rapporteur. Different additional things had to be incorporated. Also things like animal testing (the guidelines were concerning ICT specifically).

III. Implementation

4. In your opinion, has the existing ethical framework been successful from the point of view of implementation?

The ethics review is an important development - projects are being carefully manage, so that there is explicit reference to ethics given. Commission insisted on a stronger ethical review panel. Ethics review panels are associated with funded research – are involved in

decision making. Ethical dimension is present. Given the number of problems, more projects specifically dealing with (addressing) ethics are being funded! Even more over 5 years. Inclusive information society. Quite a high number of excellent proposals. Awareness of research community is being raised. Pragmatic approaches are still predominant.

V. Reflexivity

11. Are there mechanisms that allow for flexibility, reflection and revision of the ethical framework, taking into account the changing political, social and technological contexts? The European Group of Ethics is an important and influential stakeholder – their independence is an important factor.. They produce opinions and advise primarily the European Commission.

Project officer in the European Commission. Interview held 11.06.2010.

Upon mutual agreement, the personal details are not being disclosed.

I. Ethical issue determination

1. Why and how did the issue of ethics appear in the political agenda?

From the historical point of view, regarding the more recent history - medical experiments on humans served as a trigger. Here reference should be given to the Nuremberg process. Later on the Helsinki declaration should be referred to. The human related issues served as triggers for subsequent related concerns in other domains. Regarding ICT research – it is especially sensitive where human body is involved. Thus, regarding ethics in ICT – it could be viewed as a spin-off effect from other fields. Such issues as GMO, human cloning have increased the awareness of general societal risks. Risk management has become increasingly important with the related ethical aspects. There are ongoing debates about risk management – guided by ethical principles.

2. What were the reasons, aims and needs for making the decision to create a framework for addressing ethical issues in the projects of the 7th Framework program?

The EU 6th and 7th framework programs are much the same in regard to addressing ethical issues. In the 6th framework program more accent was on ethical issues in biomedical field. Now it is extended to all fields. In ICT privacy, security are of major concern. General awareness is raised to a higher degree, it is also related to wider social applications of technologies (various internet sites with implications for privacy, security, etc.). Regarding legislative aspects, important issues are: 1) adoption of the framework program; 2) references to international legislation; 3) specifying ethical principles.

3. What principles and approaches were used in the development of the ethical framework?

4. What were the main challenges during this process?

5. In what way is the existing framework used to assess the ethical characteristics (nature) of the 7th Framework projects?

Procedures have become much more matured, ethical review sector has enhanced its activities. Governance arrangements are being considered continuously. Projects are bound by regulation. The stakeholders have to adhere to international declarations, Oviedo declaration and other. It is not possible to give specific guidance, but instead, general principles are provided. Networks of ethics committees is being supported, following the member state presidency. The European Commission is providing guidance to these national ethical committees. Ethical review comprises recommendations of general character. End report and follow-up are also relevant instruments. Some general guidance to national ethical committees as to European and international approaches to ethics is being given. The European Commission has a limited mandate, principle of subsidiarity is important.

Why approaches are not specified: the decision is made on case by case basis, since the legislation is general, based on principles; local ethical committees have a role to verify that national legislation is being observed. The only exception is research on stem cells, where there is a strict EU policy (since this is a contentious area. Also parliament opposition was strong in this question - FP6 and FP7 could only be adopted with stem cell question respectively addressed. Regarding cloning – there is a UN declaration.

II. Governance arrangement

6. Are there any specific ethical governance arrangements that the projects are encouraged to follow? If yes, are there specific guidelines or procedures to apply?

Good governance is based on the principles included in the Oviedo and Helsinki declarations. The difficulty still is how to implement it in practice. Code of conduct. Precautionary principle. How do you accept the risk? Self regulation. Governance and ethics are strongly linked. Value view point is important. Who benefits from what. Governance and risks are being linked. More Western world approach – a utilitarian approach to issues. Benefits and harms. How practices go together with values and the notion of good life. Quantitative assessment vs qualitative assessment is an important aspect. Western approach to governance in a clear qualified risk opinion, often narrowed down to concrete risk. The approach in a sense is limited, and a more holistic approach would be beneficial.

III. Implementation

7. How is monitoring of 7th Framework projects regarding ethics being carried out?

1. Monitoring by the EU Commission project officers - carried out every 18 months in projects. This is general monitoring, but can become aware of ethical issues during general monitoring.

2. Monitoring by national ethical committees – they ask the projects to implement certain approaches and report back to the ethical committees. Some projects have packages specifically on ethics. A group of experts working on it. Can be on a controversial issues within the project. Research on ethics in the concrete field is being carried out. Ethics advisory boards in the projects. Good will and chance.

8. On what basis is monitoring done and what are the instruments for possible amendments?

No specific procedure envisaged in EC to bring out some findings, just the pro-activity of the officer. No special requirement, but would be good if a formal requirement existed regarding identified ethical challenges.

IV. Ethical approach

9. What devices and methods are being used in the assessment of the projects from the ethical perspective?

Expert in ethics. There are two sides – ethicists (moral philosophers) and ethical committees. The values of citizens should be taken into account. Informed decision in scientific expertise is necessary – an enlightened scientific expertise. Deeper insights in wider implications and context should be sought. Scientists often leave out the wider societal context. Example – genetic testing. It potentially makes control on human life. What are the wider consequences in society, ethical implications. More stakeholders should be involved in the discussion. Local ethical committees, social scientists and many more. Recommendations by the European Group of Ethics are important in EU policy making.

10. What were the main steps in the process? What were the main challenges and difficulties during this process?

Audit could be improved, more than the present 10% would be good, but the question of human resources. Robust follow up for recommended approaches. Informally project

officers talk to projects, guidance on ethical issues is being provided. But more generally – Code of Conduct for Commission officials. Integrity issue.

V. Reflexivity

11. Are there mechanisms that make or allow the projects to address ethical issues throughout the life of the project depending on the social or technological context? In what way?

Reflexive governance. Learning effect. Feed-back loops. Learning is present , but could do better. How to deal with problematic issues, to force a certain change. The limited mandate of the EC is a problem. Infrastructure for governance is imbalanced in Europe. Fairly well functioning in the UK, Nordic countries, however in Southern Europe not so effective. Good governance – good integrity in the system. It is linked to the mind set. Top down approaches still to be observed. Feed-back and general principles need to be strengthened. At juridical level not always possible to pay adequate attention. Weakness in the system is sometimes on the implementation side due to various reasons. Political will is needed, which is not always the case. New plants keep appearing in Europe, where clearly there are ethical implications. Conceptual framework is being continuously revised. This leads to further research. Expert groups are being formed, new procedures implemented and approaches sought how to use the obtained results.

Interview with Professor em. Rafael Capurro, interview by e-mail

Background

Prof.em. Dr. Rafael Capurro Hochschule der Medien (HdM), Stuttgart, Germany
 Director, Steinbeis-Transfer-Institute Information Ethics (STI-IE), Karlsruhe, Germany
 (<http://sti-ie.de>)

Distinguished Researcher in Information Ethics, School of Information Studies, University of Wisconsin-Milwaukee, USA

President, International Center for Information Ethics (ICIE) (<http://icie.zkm.de>)

Editor in Chief, International Review of Information Ethics (IRIE) (<http://www.i-r-i-e.net>)

Homepage: www.capurro.de

Question 1. I quote myself from: Ethics between law and public policy

First published in the Journal of International Biotechnology Law (JIBL)

<http://www.degruyter.de/rs/280_7046_DEU_h.htm> Vol. 1, Issue 2, 2004, 62-66.

See online at: <http://www.capurro.de/jibl.html>

"In December 16, 1997 the European Commission set up the EGE for a three years mandate to succeed the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB 1991-1997). During its first mandate the EGE (1998-2000) provided Opinions on subjects as diverse as human tissue banking, human embryo research, personal health data in the information society, doping in sport and human stem cell research. At a specific request of the President of the Commission, Romano Prodi, the Group also wrote the "Report on the Charter on Fundamental Rights" related to technological innovation. By a decision of March 26, 2001 the Commission adopted a revised mandate for the EGE with a duration of four years and amended the EGE remit."

"Ethics councils within the sphere of public policy have the function of reflecting on the moral and legal foundations of specific controversial issues without being itself neither a legal nor a moral authority. Their task is reflection, not decision-making or dogmatic proclamation. They should counterbalance ethical arguments and give an opinion on matters that remain controversial and subject to revision. Today's public policy has a need for such counsels particularly with regard to new developments in science and technology. This is the case since twenty years or so in the field of biology (bioethics) (2) but it becomes more and more obvious also with regard to the new information and communication technologies (information ethics) (3). Of course, such ethics bodies are not unproblematic not only concerning their legitimating body -- in some cases it is the parliament, in other cases the executive --, but also with regard to possible controversial standpoints that may differ with present laws and/or directives. In other words, it is important that such bodies are politically independent, pluralist, and multidisciplinary and that they view themselves not just as guarantee of an established morality or of current law, but as a critical space where an open debate on legally and morally controversial issues can take place. Although they might look for consensual opinions, consensus should not be a *conditio sine qua non* of their proposals. It is also not their function to make public policy 'more moral,' but to encourage ethical reflection within the public sphere.

See also these references:

"(2) The first opinion of the French ethics committee (Comité Consultatif National d'Ethique/CCNE: <http://www.ccne-ethique.fr/>) dates from 22.5.1984: "Opinion on

sampling of dead human embryonic and fetal tissue for therapeutic, diagnostic, and scientific purposes." Most European and non-European national and international ethics committees have been created in the nineties. UNESCO's International Bioethics Committee (IBC) was created in 1993. The Steering Committee on Bioethics of the Council of Europe dates from 1992. US President George W. Bush created The President's Council on Bioethics on the basis of the Executive Order 13237 from November 28, 2001 (<http://www.bioethics.gov/>). Most ethics committees are in fact committees on bioethics. See the web site of the European Group on Ethics in Science and New Technologies (EGE) of the European Commission: http://europa.eu.int/comm/european_group_ethics/index_en.htm

(3) The EGE is the first international body to address ethical issues in such a broad context. With regard to information ethics see /International Center for Information Ethics/ (ICIE): <http://icie.zkm.de> <<http://icie.zkm.de/>>

See also (in German): Ethik in Europa zwischen Forschung und Politik. Vortrag im Rahmen der Abschlußveranstaltung des Verbundprojektes "Europäische Netze" im Wissenschaftszentrum Nordrhein-Westfalen <<http://www.wz.nrw.de/wz/veranstt.htm>> am 29. Oktober 2002. Erschienen in: Gert Kaiser (Hrsg.): Jahrbuch 2002/2003 des Wissenschaftszentrums Nordrhein-Westfalen (wz.nrw.de <<http://www.wz.nrw.de/>>), Düsseldorf 2003, 201-211.
Online at: <http://www.capurro.de/wznrw.html>

Questions 2-6 These are questions for Zilgalvis. I have worked inside (!) some EU projects dealing explicitly with ethics (such as Ethicbots and Etica) but I have no qualified information about how ethical issues are addressed in EU projects *in general*, or how the ethical framework for such projects was developed etc.

See my answers to these questions with regard to FP 5 and FP 6 in <http://www.capurro.de/wznrw.html>

Question 11: The ethical reflexivity in a project dealing with ethics itself such as ETICA (and also ETHICBOTS) was/is based on

- academic contributions and public discussions at international conferences organized within these projects
- original contributions by the persons involved in these projects. See for instance my: Ethics and Robotics

This paper was a contribution to the workshop "L'uomo e la macchina. Passato e presente (Pisa 1967-2007)" organized by the Università di Pisa, Dipartimento di Filosofia <<http://www.fl.unipi.it/>> Pisa, May 17-18, 2007. Published in Italian: Etica e robotica. I robot, maschere del desiderio umano <http://www.unipi.it/athenet/20/art_2.htm> in: I quaderni di Athenet. La rivista dell'Università di Pisa. No. 20, July 2007, 9-13. Published in: Rafael Capurro and Michael Nagenborg (Eds.). Ethics and Robotics. Heidelberg: Akademische Verlagsgesellschaft 2009, 117-123. The ideas developed in this paper were discussed at several meetings of the EU Project ETHICBOTS <<http://ethicbots.na.infn.it/index.php>>.

- interviews with experts in the field(s) (See the documents of ETHICOBTS <http://ethicbots.na.infn.it/documents.php>

Especially the ones dealing with the

- Deliverable 2: Methodology for the identification and analysis of techno-ethical issues

- Deliverable 4: Analysis of national and international EU regulations and ethical councils opinions related with technologies for the integration of human and artificial entities
- Deliverable D5 - Techno-Ethical Case-Studies in Robotics, Bionics, and Related AI Agent Technologies

<http://www.capurro.de/ethicsandrobotics.html>

- Study of the scientific and academic literature on ethical issues dealing with the matter at stake

- Internal workshops and discussions between the members of the projects and... as a result also the publication of the contributions on the Internet as well as in printed form such as (in my case)

Etica e robotica. I robot, maschere del desiderio umano

<http://www.unipi.it/athenet/20/art_2.htm>. In: I quaderni di Athenet. La rivista dell'Università di Pisa. No. 20, July 2007, 9-13.

Ethik in Europa zwischen Forschung und Politik. <<http://www.capurro.de/wznrw.html>>

In: Gert Kaiser (Hrsg.): Jahrbuch 2002/2003 des Wissenschaftszentrums Nordrhein-Westfalen (wz.nrw.de <<http://www.wz.nrw.de>>), Düsseldorf 2003, 201-211. Erschienen auch in: Wechselwirkung <<http://www.wechselwirkung.com>> Nr. 125, 25. Jg. (2004), 45-52.

Ethical Issues of Online Communication Research <<http://www.capurro.de/onres.htm>> (R. Capurro, Christoph Pingel). In: Ethics and Information Technology

<<http://www.springer.com/sgw/cda/frontpage/0,,5-40385-70-35553605-0,00.html>> (2002) Vol. 4, Issue 3, 189-194.

and as a book:

Rafael Capurro and Michael Nagenborg (Eds.): Ethics and Robotics. Heidelberg: Akademische Verlagsgesellschaft / IOS Press <<http://www.iospress.com/>>, 2009.

- public discussions on the matter at stake through interviews (TV, printed, etc.) See (in my case)
- but also peer-review articles

Interview with René Von Schomberg 14.06.2010.

Dr. René von Schomberg is at the European Commission, Directorate General for Research, Governance and Ethics unit. His background is in agricultural science (Agricultural University Wageningen), philosophy (Ph.D, J.W Goethe University, Frankfurt am Main) and science and technology studies (Ph. D Twente University). He has been teaching argumentation theory, ethics, philosophy, science and technology studies at Dutch universities for about a decade prior to joining the European Commission where he held various positions. He has been an EU Fellow at George Mason University, School of Public Policy, Arlington, USA during the 2007 Fall semester where he taught on the social and ethical aspects of the EU's science and technology policies. He has been working at the Unit of Ethics and Governance for 5 years.

Following a very informative interview, it has been agreed with Dr Von Schomberg that explicit reference to his opinion regarding relevant issues will be used in form of citations. In our research we have enclosed citations from Dr Von Schomberg's published work.

Annex 5 Analysis of relevant EU reports and working documents
(with regard to ethics in science and technological development)

Reports and Working document	
	Citizens Rights and New technologies: a European Challenge. Report of the European Group of Ethics in Science and New Technologies on the Charter on Fundamental Rights related to technological innovation as requested by President Prodi on February 3, 2000. Brussels, May 23, 2003
	General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission (2005 – 2010)
	Science and Society Action Plan. European Communities, 2002
	Codes of Conduct, Standards for ethics in Research, European Communities, 2004
	Taking European Knowledge Society Seriously. Report of the Expert Group on Science and Governance to the Science, Economy and Society Directorate, Directorate-General for Research, European Commission. European Communities, 2007
	Global Governance of Science. Report of the Expert Group on global Governance of Science to the Science, Economy and Society Directorate, Directorate-General for Research, European Commission. European Communities, 2009
	Ethics for Researchers. Facilitating research excellence in FP7. European communities, 2007.
	Facing the Future Together. Proceedings of the Conference on Research Ethics Committees in Europe. European Communities, 2005
	European Perspectives on Science and Technology Policy. Preliminary outcomes from policy research and debates generated by the STRATA projects (1999-2002). European Communities, 2004
	From ethics of technology towards an ethics of knowledge policy and knowledge assessment, 2007
	Deliberating Foresight Knowledge for Policy and Foresight knowledge Assessment, 2005
	Science, Society and Politics. Knowledge Societies from an Historical Perspective. Report to the Science, Economy and society Directorate, European Commission. European Communities, 2007
	European Group of Ethics Newsletter” Ethically speaking”. A newsletter providing information on the activities of the National Ethics committees compiled by the Secretariat of the European Group of Ethics in Science and New Technologies to the European Commission. European Communities, 2007.

Analysis

Citizens Rights and New technologies: a European Challenge. Report of the European Group of Ethics in Science and New Technologies on the Charter on Fundamental Rights related to technological innovation as requested by President Prodi on February 3, 2000. Brussels, May 23, 2003. It is pointed out in the report that the respect of the dignity of the human person is at the root of the ethics of science and new technologies as well as of human rights (p.10). A strong emphasis in the report is put on the opinions and reports by the national ethics committees in the member states or other relevant national bodies. It is pointed out that the work carried out by these committees on a wide range of issues constitute a useful source of inspiration for deliberation on ethics, and contributes to define ethical norms to be taken into account in national regulations or national policies (p.6).

General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission 2005 – 2010. European Union, 2010. It is pointed out in the report that in the European Union moral beliefs are often surveyed via empirical analysis, in order to identify the views held by citizens. The results of such empirical research are sometimes used as a basis for political decision making procedures, without the intermediate step of ethical analysis based on values (p.20). Further on it is stated that – despite the references to the European values, it is not clear whose morality (or moralities) and which ethical approaches are put into action in the different policy-making procedures. Ethics can be used to highlight the pluralism in value traditions, it can help to clarify the basic ethical concepts that play a role in different practical contexts; to synthesise the methods of ethical assessment; and to assess the beliefs and convictions in the light of the principle of human dignity and human rights (p.21). The European Group of Ethics calls for more efforts to establish theoretical ethical deliberation and analysis routinely and on multiple levels as a complement to the dialogue of science and society (p.22). As to the institutional aspects, it is pointed out in the report that the national Ethics councils' role is to stimulate general public debate, address ethical pluralism and to be consulted by political actors, whereas the latter are the ones who have to implement ethics provisions in local policies (p.22).

The action plan “Science and society”. Luxembourg, 2002. This document calls for putting responsible science at the heart of policy making, and since most policies have a scientific and technological dimension, decisions must be supported by transparent, responsible opinions based on ethical research (p. 8.) There is a separate part regarding the ethical dimension in science and the new technologies, among other things calling for 1) making information more accessible; promoting European dialogue on ethics in science; 3) promoting awareness and integrity of researchers; 4) facilitating exchange between Ethics Committees. Among the 38 actions suggested, six were aiming at improving the understanding and awareness of ethics in research.

Taking European Knowledge Society Seriously”. Report of expert group on science and governance to the Science, Economy and society Directorate of the Directorate-General for Research, European Commission. Luxembourg, 2007. A whole chapter is dedicated to new normative discourse in European science and governance in relation to ethics. It is pointed out in the report that European policy making on science and technology often “inadvertently suppresses full-fledged expression of normative questions, political values and democratic aspirations”. It is indicated in the report that in

both areas, this occurs most centrally through the assumption that expert discovery can reveal objective truths, which then determine proper policy, and that democratic input is valid only after factual truths have been revealed. Further on it is noted that “this institutional focus on post-innovation, ‘downstream’ or output questions as the only ones of interest to publics marginalises legitimate democratic concerns about the inputs (such as imagined social purposes, needs, benefits and priorities) that drive innovation research in the first place.

The report goes even further, from statement of a problem to proposing the actual direction of action: “An important change in the governance of innovation would be strategic development of improved European institutional capacity to deliberate and resolve normative questions concerning the prior shaping of science and innovation: over their directions as well as their scale and speed. Put simply, we recommend the introduction of structured ways of appraising the projected benefits of innovation. This means a shift from expert-dominated to more open deliberative science-informed institutions on ethics, risk and innovation”.

Regarding relationship between law and ethics, it is pointed out that “the ambiguous relationship between law and ethics, and the institutional treatment of ethics as a mode of expert discovery akin to scientific expertise, effectively extends these problems into new arenas of science and technology governance (p.46). Thus, apart from the relationship between the ethics and law as such, the relationship between the so called ethical and scientific communities, or rather the divide between them, and the current mode of institutionalisation of ethical expertise is an important challenge to address. Fundamentally, not only because ethics (and also culture) might be or seem a “questionable field for legally binding norms” (p. 48).

Global Governance of Science. Report of the Expert Group on global Governance of Science to the Science, Economy and Society Directorate, Directorate-General for Research, European Commission. European Communities, 2009. In discussing the issues of ethical governance, it is pointed out that the move towards participation in science recognizes the limits of experts – a recognition that applies as well to alleged ‘ethical experts’ (p. 28). It is also pointed out in the report that national ethical councils are typically independent and interdisciplinary, but their variation between countries indicates something about the uncertainties of democratic governance (p. 28). It is pointed out that national ethical councils often reflect a national political context – some aim for consensus and direct impact on decision making while others present a more complex picture of uncertainties and available options (p.29). Regarding the composition of these councils it is indicated that the composition varies from state to state. Some include a wide range of stakeholders – scientists, lawyers, philosophers, psychologists, religious leaders, journalists and lay members, while others have a much narrower composition (p. 28).

Code of conduct. Standards for ethics in research. Brussels, 2003. This documents aims to provide a systemic information facility of ethical issues in science that would help promote the awareness of and consistency in the use of existing codes of conduct and other ethical standards for science, and increase the understanding of problems they address (p. 9). This Code gives a survey of the existing public and written ethical norms across Europe, and also analyses the arguments of international debates concerning the positive or negative value of adopting ethical standards that regulate scientific research. One of the arguments mentioned in the survey – the argument of awareness – brings us close to the topic of our interest regarding ethics in technological development and its relation to society today.(p. 11).

Ethics for Researchers. Facilitating research excellence in FP7. European communities, 2007. It is pointed out in the document that ethics is context-dependent and consequently definitive mathematical outcomes are rare. The document refers to the legal basis of ethics review in the 7th framework program, and primarily to the European Charter of Fundamental Rights. It provides recommendations for the optimal composition of ethics review panels and points out that experts in the ethics review have the same status as experts in scientific evaluation (p. 12). It also addresses ethics review procedure and ethics review methodology at the same time pointing out that ethics is a state of mind and it is important to consider the social implications of the research results (p.20).

Facing the Future Together. Proceedings of the Conference on Research Ethics Committees in Europe. European Communities, 2005. It has been pointed out in the document that that even after the 20 years of ethical review, many of the fundamental questions about the role, scope and structure of ethical committees remain a matter of debate rather than of consensus (p. 8). Regarding the ethical expertise – it is pointed out that ethicists have the role not of saying what is right, but of clarifying the process of deciding what is right (p. 14).

European Perspectives on Science and Technology Policy. Preliminary outcomes from policy research and debates generated by the STRATA projects (1999-2002). European Communities, 2004. Regarding the governance of technological development, it is pointed out that risks need to be dealt with. In this respect the emergence of the precautionary principle may be seen as a further element of reflexivity, especially when actors anticipate on the eventual application of a precautionary principle by being more precautionary themselves (p. 11).

From ethics of technology towards an ethics of knowledge policy and knowledge assessment. European Communities, 2007. The document that develops upon the claim that the contemporary ethical theories cannot capture adequately the ethical and social challenges of scientific and technological development. It discusses the controversial relationship of ethical theory versus ethical practice and develops upon the concepts of individual and collective role responsibility. Further on the role of foresight and knowledge assessment is being discussed and promoted. It is being stipulated that foresight knowledge can be understood as a form of “strategic knowledge” necessary for agenda setting, opinion formation and vision development and problem solving (p. 15). It is claimed that foresight activities should be adapted to processes of deliberative democracy of modern western societies. Referring to Cohen, it is being pointed out that deliberation goes beyond the meaning as simple discussions concerning a particular subject matter, and in broadest meaning can be understood as free and public reasoning among equals (p.16).

Science, Society and Politics. Knowledge Societies from an Historical Perspective. Report to the Science, Economy and society Directorate, European Commission. European Communities, 2007. It is pointed out in the report that science carries predefined categories and values are present in its language, tools and structure. It is pointed out that solutions proposed by science are also partial and partisan, and that the solutions are also part of the problem (p. 8.). it is pointed out in the report that due to the modern development also a new discursive order has emerged and spread, and it is organized around words like governance, responsibility, transparency, accountability, sustainability, precaution, consensus, ethics, risk society, knowledge society, civil society etc. (p. 15). The question is

raised to what extent knowledge varies according to context (p. 20). It is also asked what are the consequences of these differences and to what extent they matter when entering the phase of negotiation between groups. It is argued in the report that there is another group of notions that are equally important for science and for society, that simultaneously have techno-scientific meanings and moral/ ethical ones, namely 'code', 'standard' value', 'norm' 'measure', 'balanced'. These issues are linked to the notion of governance.

European Group of Ethics Newsletter" Ethically speaking". A newsletter providing information on the activities of the National Ethics committees compiled by the Secretariat of the European Group of Ethics in Science and New Technologies to the European Commission. European Communities, 2007. The analysis of the activities of the national ethics committees is presented. At the same time also writings by the officials of the European Commission are included, and more specifically, regarding the ethical aspects of personal data matching and its implications for European citizens in the context of the fundamental human rights and in the context of relevant national legislations.

Annex 6 Documents and procedures relevant to the FP7 legal framing

Ethical guidelines

Source: http://cordis.europa.eu/fp7/ethics-ict_en.html

Annex 5 to the FP7 ICT research Guide for Applicants “Ethical Guidelines for undertaking ICT research in FP7

1. Introduction

In recent years there has been an increase in the importance of ethical issues related to ICT research and technological developments. The decision of the European Parliament and the Council concerning FP7¹ states that research activities supported by the Framework Programme should respect fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union² and take into account opinions of the European Group on Ethics in Science and New Technologies (EGE)³. Article 15 of the FP7 draft rules of participation⁴ states that any proposal which contravenes fundamental ethical principles or which does not fulfil the conditions set out in the specific programme, the workprogramme or in the call for proposals shall not be selected and may be excluded from the evaluation, selection and award procedures at any time.

Applications for EU-funded research activities may, if appropriate, include specific tasks or a specific work package that explicitly addresses ethical concerns (in terms of the research, its conduct and outcomes) and outlines how ethical issues raised by the proposed research will be handled.

The purpose of this guidance is to assist proposers in identifying potential ethical issues arising from the proposed ICT research.

2. Conduct of ICT Research

All research areas within ICT of FP7 may raise ethical issues of varying seriousness. Some proposals will be more sensitive than others. It is likely that new, sensitive applications will come to the fore during the term of FP7.

2.1 A responsible approach

It is likely that most of the principles of the Charter of Fundamental Rights of the European Union⁵ will be relevant to the approach adopted by ICT researchers. These principles cover dignity, freedom, equality, solidarity, citizens’ rights and justice. Proposals must comply with Article 8 of the European Human Rights Convention⁶. In particular, given the pervasive and ubiquitous nature of ICT and the many opportunities it offers, researchers should consider the sensitive implications of their proposals for privacy and autonomy.⁷ However, researchers should recognise that new dangers associated with the process of ICT research can exist. They should carry out a prior assessment of risk and identification of precautionary actions proportional to the potential risk/harm. http://www.europarl.europa.eu/charter/default_en.htm

The EGE is an independent, multidisciplinary body, appointed by the Commission to examine ethical questions arising from science and new technologies and on this basis to issue Opinions

-http://ec.europa.eu/european_group_ethics/index_en.htm

The Charter of Fundamental Rights of the European Union -

http://www.europarl.europa.eu/charter/pdf/text_en.pdf

<http://conventions.coe.int/treaty/en/Treaties/Html/005.htm>

Opinion 10 of EGE - The Ethical Aspects of the 5th Framework Programme ,

http://ec.europa.eu/european_group_ethics/docs/opinion10_en.pdf

Opinion 20 of EGE – Ethical Aspects of ICT Implants in the Human Body -

http://ec.europa.eu/european_group_ethics/docs/avis20_en.pdf

Researchers have a duty to alert public authorities to the ethical and practical implications of the ICT research outcomes, as and when particular issues become apparent within the research process.⁷ Researchers should comply with national legislation, European Union legislation, respect international conventions and declarations and take into account the Opinions of the European Group on Ethics. However, consideration of ethical issues goes beyond simple compliance with current regulations and laws.

2.2 Privacy and informed consent

The right to privacy and data protection is a fundamental right⁵ and therefore applicable to ICT research. Researchers must be aware that volunteers⁹ have the right to remain anonymous⁷. Researchers must comply with Data Protection legislation¹⁰ in the Member State where the research will be carried out regarding ICT research data that relates to volunteers. Informed consent is required whenever ICT research involves volunteers in interviews, behavioural observation, invasive and non-invasive experimentation, and accessing personal data records. The purpose of informed consent is to empower the individual to make a voluntary informed decision about whether or not to participate in the research based on knowledge of the purpose, procedures and outcomes of the research. Before consent is sought, information must be given specifying the alternatives, risks, and benefits for those involved in a way they understand. When such information has been given, free and informed consent must be obtained. Depending on the nature of the research, different consent procedures may be used. Special consideration must be given when volunteers have reduced autonomy or are vulnerable.

The majority of European citizens view personal privacy as an important issue. Research, for example, on RFID¹¹ and ICT for healthcare¹², is likely to raise privacy issues. Therefore, researchers must ensure that the manner in which research outcomes are reported does not contravene the right to privacy and data protection. Furthermore, researchers must carefully evaluate and report the personal privacy implications of the intended use or potential use of the research outcomes. Wherever possible, they must ensure that research outcomes do not contravene these fundamental rights.

2.3 Use of animals in ICT research

In accordance with the Amsterdam protocol on animal protection and welfare, animal experiments must be replaced with alternatives wherever possible. Suffering by animals must be avoided or kept to a minimum. This particularly applies to animal experiments involving species which are closest to human beings¹³. Thus ICT research involving animals should conform to the ethical principles of replacement, reduction, refinement and minimisation of suffering.

Proposers must carefully justify animal experiments in cross-science proposals for non-medical objectives. Furthermore, they should identify the scientific areas which would benefit from knowledge gained through animal experiments. Proposers must be aware that Member States may have differing.

“Volunteers” is used to describe all those who are the subjects of research observations, experiments, tests etc.

National legislation transposing Directive 95/46/EC -

http://ec.europa.eu/justice_home/fsj/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf

RFID Technology - Results of the Public Consultation on Article 29 Working Document 105 on Data Protection Issues Related to RFID Technology Adopted on 28 September 2005

http://europa.eu.int/comm/justice_home/fsj/privacy/workinggroup/consultations/rfid_en.

Opinion 13 of EGE - Ethical Issues of Healthcare in The Information Society.-

http://ec.europa.eu/european_group_ethics/docs/avis13_en.pdf

Council Directive on Protection of Animals used for Experimental and other Scientific Purposes

http://europa.eu.int/comm/food/fs/aw/aw_legislation/scientific/86-609-eec_en.pdf

and possibly conflicting interpretations of animal welfare in research, and the research must meet regulations in the country in which it will be carried out.

3. Specific guidance in some current sensitive areas

3.1 ICT implants⁸ and wearable computing

- ICT implants should only be developed if the objective cannot be achieved by less-invasive methods such as wearable computing devices and RFID tags.
- To the extent that an individual, via an ICT implant or wearable computing device, becomes part of an ICT network, the operation of this whole network will need to respect privacy and data protection requirements.
- ICT implants in healthcare are, in general, acceptable when the objective is saving lives, restoring health, or improving the quality of life. They should be treated in the same way as drugs and medical devices.
- ICT implants to enhance human capabilities should only be developed: to bring individuals into the “normal” range for the population, if they so wish and give their informed consent; or to improve health prospects such as enhancing the immune system. Their use should be based on need, rather than economic resources or social position.
- ICT implants or wearable computing devices must not: allow individuals to be located on a permanent and/or occasional basis, without the individual’s prior knowledge and consent; allow information to be changed remotely without the individual’s prior knowledge and consent; be used to support any kind of discrimination; be used to manipulate mental functions or change personal identity, memory, self-perception, perception of others; be used to enhance capabilities in order to dominate others, or enable remote control over the will of other people.
- ICT implants should not be developed to influence future generations, either biologically or culturally.
- ICT implants should be developed to be removed easily.

3.2 eHealth¹² and genetics

Personal health data must be treated as ‘sensitive personal data’¹⁵. ICT researchers using it have a duty

of confidentiality equivalent to the professional duty of medical secrecy. Therefore:

- The use of personal health data in ICT research for the purposes from which society as a whole benefits must be justified in the context of the personal rights.
- The security of ICT in healthcare is an ethical imperative to ensure the respect for human rights and freedoms of the individual, in particular the confidentiality of data and the reliability of ICT systems used in medical care.
- Proposers should be particularly aware when ICT is linked to sensitive medical areas such as the use of genetic material.
- Proposers should access established general medical and genetics ethical guidance when formulating their proposals.

3.3 ICT and Bio/Nano-electronics

ICT-bio/nano-electronics has a strong potential for mis-use. Consequently, proposers should pay particular attention to the guidelines in Section 2 in this area.

Such research is partly covered by Council Directive 90/385/EEC relating to active implantable medical devices- http://europa.eu.int/eur-lex/en/consleg/pdf/1990/en_1990L0385_do_001.pdf

Directive 95/46/EC -

http://ec.europa.eu/justice_home/fsj/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf

- Researchers involved in ICT-bio/nano-electronics research proposals should be aware that certain applications, e.g. miniaturised sensors, may have specific implications for the protection of privacy and

personal data.

- ICT-bio/nano-electronics research may overlap with other scientific disciplines such as biology. In these situations proposers should draw upon the ethical guidance of that discipline. COM (2004) 338 final - http://ec.europa.eu/prelex/rech_simple.cfm?CL=en

Ethics check list

Source: http://cordis.europa.eu/fp7/ethics-ict_en.html

The information which follows identifies the main ethical dilemmas that arise in research and indicates how each topic might be addressed to ensure compliance. It is also advisable to identify the expert(s) within your organisation or your consortium that can provide further advice.

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 Involving 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

Ethics Review Procedures

Source: http://cordis.europa.eu/fp7/ethics-ict_en.html

Introduction

In order to implement Article 6 of the EC FP7, Article 5 of the Euratom FP7, Article 15 of the EC Rules for Participation, and Article 14 of the equivalent Euratom Rules for Participation, the scientific evaluation procedure includes an initial identification of ethical issues raised by the proposals followed by an ethics screening of all proposals that raise ethical issues.

An ethics review of proposals may take place after the ethics screening and before any selection decision by the Commission in accordance to the set rules. The ethics review is mandatory for proposals that involve intervention on humans²³⁸, research involving human embryonic stems cells and human embryos and non-human primates. The ethics screening and the ethics review (to be referred to jointly as Ethics Review Procedure) are carried out by independent experts with the appropriate skills in ethics.

The objective of the Ethics Review Procedure is to make sure that the European Union and Euratom does not support research which would be contrary to fundamental ethical principles set out in the relevant EU and Euratom rules and to examine whether the research complies with the rules relating to research ethics set out in the Decisions on FP7 and the Specific Programmes. The opinions of the European Group on Ethics in Science and New technologies are and will be taken into account.

Proposals

Where appropriate and/or required by the call, a proposal shall include an Ethics Annex which:

Identifies and discusses the potential ethical issues that the proposed research raises including, when appropriate, its objectives

Describes and justifies the design and methodology of the research project from an ethical viewpoint;

Discusses the potential implications of the results of the proposed research from an ethical viewpoint;

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

Indicates the timeframe for applying for the opinion of an appropriate ethics Committee and, when necessary, the approval by a competent authority at national level (such as the data protection authority, the clinical trials authority etc).

To this end, applicants should complete the "Ethical Issues Table" included in the Guide for Applicants.

General procedural modalities

For proposals involving the use of human embryonic stem cells (hESC), the Commission follows specific procedural modalities described later in this Annex.

Evaluation

The experts in charge of the scientific evaluation indicate if any ethical issues are raised by a proposal with reference to the "Ethical Issues Table" completed by the applicant. The experts identify those proposals which may require further assessment due to the importance of the ethical issues raised and/or the degree of adequacy of the way the ethical

²³⁸ Such as research and clinical trials involving invasive techniques on persons (e.g. taking of tissue samples, examinations of the brain).

issues are addressed in the proposal. If any ethical issue is raised by the proposal and/or identified during the evaluation, an Ethical Issues Report (EIR) should be produced by the experts at this stage alongside the Evaluation Summary Report (ESR). The ESR should include any comments of the experts concerning ethical issues raised by the proposal. At this stage only the ESR is sent to the applicant.

Where appropriate, the expert evaluation panels examining the proposal may include independent experts specialised in ethical issues.

Ethics Review

Following the scientific evaluation process, the Commission undertakes an ethics review of proposals that are in line for funding and raise ethical issues.

The ethics review process includes two phases.

Phase 1: Ethics Screening

All proposals that are in line for funding, and which raise ethical issues, undergo an ethics screening, taking into account any EIR (see above). The Commission services can also request an ethics screening of proposals that were not flagged by the experts in charge of the scientific evaluation. The screening process is undertaken by independent experts with the appropriate skills in ethics.

The ethics screening aims at:

a) Identifying proposals that fall under EU and Euratom law (data protection, clinical trials, animal welfare etc) and require, an approval and/or a positive opinion at the national level as specified by special clauses 15 and 16 of the FP7 Grant Agreement ;

And

b) Identifying proposals that in addition to national approvals, require an Ethics Review by the Commission due to the nature of ethical issues raised (primarily: intervention on humans, use of non-human primates in research, research on human embryos and human embryonic stem cells).

For each proposal screened, the experts prepare and sign an Ethics Screening Report which includes a requirements section. These requirements become contractual obligations. For proposals under category (a) above, the Ethics Screening Report is sent to the applicants without disclosing the identity of the experts. In its decision to fund a proposal the Commission takes into account the results of the ethics screening. This may entail changes in Annex I to the grant agreement following negotiation, or in certain cases termination of negotiations.

Proposals in category (b) are sent to the Ethics Review Sector of DG Research for Ethics Review (see phase 2 below). The Commission may decide to submit proposals in category (a) that raise new or challenging ethical questions, to an Ethics Review.

The experts involved in the screening process are bound by the Commission requirements concerning conflict of interest and confidentiality.

Phase 2: Ethics Review

Following the ethics screening process and taking into account the Ethics Screening Report (see above), the Commission may decide to submit proposals that fall under category (b) and proposals under category (a) that raise challenging ethical issues, to an ethics review panel. In addition to the three mandatory categories mentioned above (human embryos, human embryonic stem cells, non-human primates and intervention on humans), particular attention is paid to research involving children, research undertaken in developing countries, and security-related research.

Composition of the Ethics Review panel

Similarly to the Ethics Screening panels, the Ethics Review panels are composed of experts specialised in ethical issues, coming from a variety of disciplines such as law, sociology, psychology, philosophy, medicine, molecular biology, chemistry, physics,

engineering, veterinary sciences, etc.. The composition of each panel depends on the nature of the proposals under review and every effort is made to achieve a geographical and gender balance. Representatives of civil society may be invited.

The experts are bound by the Commission requirements concerning conflict of interest and confidentiality as defined in Annex F.

Ethics Review Report

The experts individually read the proposals, and then meet as a panel to discuss and produce the Ethics Review Report. They shall endeavour to arrive at a consensus. In case no consensus can be reached, the report reflects the opinion of the majority of the members of the panel.

The Ethics Review Report includes a list of ethical issues, an account of the way the issues are addressed by the applicants, and the requirements and recommendations made by the panel. The Ethics Review Report may indicate the need to organise an ethics audit at a later stage of the implementation of the project. The report is signed by the members of the panel.

The applicants are informed of the outcome of the ethics review through the Ethics Review Report. The Report is sent to the applicants without disclosing the identity of the experts.

National approvals of competent authorities and opinions of ethics committees

The Commission ascertains that the applicants have received appropriate approval of the national competent authority and/or favourable opinions of the relevant ethics committee before the start of the grant agreement or before the start of the corresponding research.

Negotiation

During the negotiation of the grant agreement, account is taken of the results of the ethics review. This may entail changes in Annex I to the grant agreement following negotiations, or in certain cases termination of negotiations. Insertion of the relevant special clause(s) in the grant agreement may here be envisaged.

Where the approval of the national competent authority and/or a favourable opinion of the relevant ethics committee is/are not obtained before the start of the grant agreement, the grant agreement includes a special clause(s) requiring that the relevant authorisation or opinion be obtained before the start of the corresponding research.

Ethics Follow-up and Audit

Proposals that undergo an Ethics Screening and/or an Ethics Review can be flagged by the experts as requiring an Ethics Follow-up/Audit (EFA). An EFA is conducted by experts specialised in ethical issues, not earlier than on the date of the first reporting period for the proposal. The objective of the EFA procedure is to assist the beneficiaries to deal with the ethical issues that are raised by their work and if necessary take corrective measures.

In extreme cases, the EFA process may result in a recommendation to the Commission to terminate a grant agreement. The organization and implementation of the EFA procedure are the responsibility of the Ethics Review Sector of DG Research mentioned above.

Implementation

The organisation and coordination of the Ethics Review process, Ethics Follow-up and Audit are the responsibility of the Ethics Review Sector of DG Research. This sector will also assess the impact of the Ethics Review and Audit procedures on the scientific community, the beneficiaries and the competent national authorities and relevant ethics committees. The objective of this procedure is to improve the Ethics Review process, maximise the positive impact of the FP7 ethics framework on the research community and contribute to the positive societal image of research.

Annex 7 Analysis of empirical findings according to parameters in the analytical grid

Analysis

In order to analyse the empirical findings according to the parameters within the analytical grid, first of all we will present the key empirical findings. Our aim, as we have mentioned before, was not to produce a scientific representative quantitative analysis, but instead our attention was targeted at the qualitative aspects of the FP7 overall ethical framing. We will be using the following approach: we will determine the key success and the key challenges to the development and implementation of the FP7 ethical framing, as seen by the respective EU officials during our interviews. This will allow us to:

- 1) to identify and evaluate the implications from what has been considered as ‘success’ by the relevant EU officials;
- 2) to identify and evaluate and the implications from what has been considered as ‘challenges’ or ‘drawbacks’ by the relevant EU officials;
- 3) to draw some conclusions regarding the relationship of what the present FP7 framing is and what it ‘should be’ in an ideal situation. This will allow us to assess the presence of absence of reflexivity regarding the current FP7 framing among the relevant EU officials

1. Key findings regarding success in the implementation of the FP7 ethical framing

Awareness raising and learning

- Awareness has been raised among the EU commission staff, researchers, evaluators and other stakeholders
- A learning process is taking place during identifying and addressing ethical issues – among the EU Commission staff, researchers, evaluators and other relevant stakeholders

Procedures and their implementation

- Since the question should be viewed in the context of the set aims and objectives, and in this sense the implementation has been successful
- The overall organisation and management cycle of ethical evaluation of project proposals has been successful
- Ethical components are more frequently included in various research projects, and projects more frequently have their own ethical advisory boards
- An efficient and well functioning ethics screening process has been established
- Ethical issues are mostly being dealt with at grant contract negotiation stage without a need for ethics review; thus also an effective use of human resources is being promoted
- Even serious ethical issues can be addressed during the project implementation stage as part of contractual obligation
- The ethics review has been introduced
- The ethics audit for 10% of financed projects has been introduced

Legal and ethical framework

- A framing has been created to address sensitive areas and enabling to capture potential ethical issues from arising
- Ethical framework is continually being improved as a result of deliberative approaches
- The drafting and formalisation of Ethical guidelines has been a success – after being circulated to many stakeholders internally and externally for comment and approval. These guidelines are concise and well grounded legally – with 16 legal references.
- The used ethical framework excludes that ethically unsound research is being funded
- Results of research on ethics can become a resource for new legislative initiatives

Statistics

- Steady reduction in numbers (and percentages) of proposals requiring ethics review has been observed if to compare the EU 6th framework program and FP7
- Numbers of ethics review fall

Research society

- Research societies and research teams are aware of the broader ethical principles and approaches
- More ethical science is being supported
- Ethically unsound research is not being funded

Society at large

- Society involvement, also via submissions, via reports, via websites
- Societies can view science as being ethical
- The public image of the European Commission is being sustained

Policy developments and governance arrangements

- The continuous impact assessment can be viewed as a resource for future policy making
- Impact assessment can produce new insights
- When attempting to integrate ethics in to some particular discipline, an attempt is always made to make it as part of governance process as such
- Expert studies done on behalf of the EU Commission; also high level expert groups whose members give advice to high level of policy making

Ethical Committees and expert advice

- There is a continuous support form the European Group of Ethics – their opinions can be important resources for proposing new legislation
- The cooperation between National Ethics Committees in gradually increasing

2. Key findings regarding the problems and challenges in the implementation of the FP7 ethical framing

Policy and normative framework, policy deliberation

- Difficulty to see and decide how various normative assumptions fit with broader policy
- When an ethical component is identified, it is challenging to decide how to deal with normative framing of policy, and for this new research is needed
- A challenge – how to translate research results into policy concepts and policy instruments
- Since ethics is about identifying normative issue and proposing procedures to solve them, and important task is to promote and maintain deliberative procedures
- During the developments at EU program or policy level, lobbying by stakeholders could be of various sorts
- During policy and public discussion, when taking into account too many interests and opinions, the very essence of the issue may be transformed too much (possibly, in the “negative” direction)
- Diversity should be respected and tolerance observed, but at the same time a greater uniformity at European level should be aimed at
- Today it is not possible to know the “right” answer, therefore discussion is necessary to obtain a variety of opinions

Scientific communities

- Scientific communities that deal with ethics should come up with procedures and codes that standardize the process of ethics review as much as possible, since in various panels there are people with various cultural and professional backgrounds, and for this reason it may be difficult to secure the same approach to similar problems within different panels

Communication issues

- Regarding communication and sustainability of established networks – how to implements effective communication between various EU Commission directorates and how to effectively convey relevant research results

Public debate

- How to secure the public debate within a flexible framework where there is space and time for public opinion to evolve
- How to secure constant feed-back from the public opinion, and secure a continuous dialogue
- Ongoing discussions with scientific community and society at large should be enhanced

Ethical expertise and ethical committees

- How to secure ethical expertise by involving various stakeholders given the fact that professional ethicists are not a solution to the problem; however, it is important to realise that professional ethicists have the important role to keep the discussion or deliberation within the domain of ethics and see that the right principles and criteria are being applied
- Occasionally it is difficult to identify the borderline between an ethically unsound project and one that is breaching the fundamental rights
- Expertise in ethics is a complicated issue
- The issue of “ethical expertise” as such

- It is a major challenge to see the world through the “glasses” of ethics for many researchers and also for ethics experts
- There should be more cooperation and exchange between the National Ethics Committees

Procedures

- More discussion on possible “standard” in ethics is necessary
- The evaluation procedures (ex ante, ex-post as well as the interim) can give more emphasis on quantitative parameters, and not so much on qualitative

3. Analysis of empirical data findings and key conclusions

The EU officials consider the development and implementation of the FP ethical framing as a success. This evaluation is based on the fact that there is relevant institutional and legal framework and procedures put in place, as a well functioning management system. Another indicator of success of the framework, according to the opinion of EU officials is that the numbers of ethical reviews fall, meaning that more sound research is being funded under FP7.

Also the system of experts and expert panels is being viewed as generally successful, but from the point of view of functionality, not so much regarding the actual addressing of ethical issues. There is an awareness among EU research policy makers and other officials that ethics cannot be reduced to scientific expertise or ‘ethical’ expertise only, that the existing divide between the various scientific communities still is a challenge and that ways need to be sought how to bridge this gap.

There is also an awareness present among EU officials that ethics cannot be reduced to legal frameworks as well. Not only because a case differs from a case, and there is also a variety of cultures in Europe which does not allow to assess various cases from the same perspective. But primarily – its has been indicated that legal instruments are useful to secure adequate procedures but not so adequate to evaluate ethical aspects.

Thus, we have seen that the involved EU officials, on the one hand, evaluate the existing FP7 ethical framework as effective and successful, but on the other hand, point out the problems and challenges to it. Consequently, we can see the awareness that scientific expertise is not an answer, legal frameworks cannot guarantee ethically sound research. There is growing awareness on the existing divide between the scientific and ethical communities, which on many occasions preconditions that ethics is addressed in a fragmentary way or by a purely sectorial approach, also regarding the issue of expertise.

At the same time we can see that no alternative solutions have been found, and ethics is basically being reduced to law (in order to secure legal compliance and in such a way in fact losing the true normative function of ethics), and during the various consultations interests of various stakeholders or used for achieving political aims or defending national, religious or other interests²³⁹. Thus, there is some evidence that a substantial problem of ethics on certain occasions might be reduced to a purely formalistic approach – for securing some form of compliance or compromise.

It was pointed out by the EU officials that learning is an important aspect, as part of policy deliberation and public discussion. Our conclusion here is that there is an awareness among the relevant EU officials that the success of the FP7 ethical framing cannot be based solely on the success of institutional, legal and managerial approaches, and that ways need to be sought to address ethics in research according to the true meaning of ethics.

²³⁹ During our interviews the process of the drafting and adopting the Ethical guidelines was mentioned. Also the political discussion regarding the stem cells was mentioned as an example.

Annex 8 Analysis of identified governance arrangements (according to the grid for data analysis)

1. Key findings regarding governance arrangements in FP7

Within our empirical study we have identified the following key institutional/ governance arrangements in the implementation of the FP7 ethical framing:

- 1) Ethical guidelines (Annex 5 to the FP7 ICT research Guide for Applicants “Ethical Guidelines for undertaking ICT research in FP7”)
- 2) Ethics check list
- 3) Experts and expert panels
- 4) National Ethical Committees
- 5) Ethical Review procedure and Ethics Review Report
- 6) Ethical follow-up and audit
- 7) Public consultations

According to our empirical study (interviews and textual analysis²⁴⁰), the respective institutional and governance arrangements have the following aims, functions and implications:

Ethical guidelines

- to assist proposers in identifying potential ethical issues arising from the proposed ICT research

Check list

- identifies the main ethical dilemmas that arise in research and indicates how each topic might be addressed to ensure compliance.
- promotes identifying the expert(s) within project promoter’s organisation or consortium that can provide further advice.

National ethics committees

- Ensure ongoing discussion and deliberation on ethics and ethical framework in research
- Verify the compliance of research to the national legislation

Experts and expert panels

- Expertise in ethics has become a “vague” and complicated term due to the underlying uncertainty and lack of ethical authority

²⁴⁰ Although we relied on both, interview material and textual analysis, we were particularly interested in the interview material, since this provides a more comprehensive understanding of the implications within the particular governance approach

- The role of experience and tacit knowledge increases the ability for “spotting” potential ethical issues
- More discussion is necessary for possible standard” in ethics – scientific community should come up with procedures and codes that standardize the ethics review
- The professional and cultural background of the experts is a major challenge
- The process of ethics review should be steered by rational decision making
- Ongoing discussions with the scientific community are necessary

Ethics review procedure and Ethics Review Report

Procedure

- A procedure with clear distinction of roles and responsibilities
- A procedure based in the EU legal framework
- A procedure verifying if the researchers respect FP7 standards
- A procedure verifying if the relevant EU legislation is taken into account in the design of the proposed research frame
- A procedure verifying if the applicants have sought or are planning to seek the approval of relevant local or national ethics committees
- A procedure determining the awareness of applicants on the ethical aspects and the social impact of the research they propose
- A procedure verifying if the relevant international conventions, treaties and declarations are followed
- A procedure verifying balance between the research objective and the means to be used

Report

- Practical recommendations to scientists in the implementation of ethics in research
- Contribution to overall development of ethical research
- A preventive measure, as part of risk management
- As part of monitoring procedure, allowing to follow the implementation of ethics in EU research
- As a political measure to prevent negative publicity on EU research regarding ethics

Follow up and audit

- A preventive measure
- A measure to assist the projects
- Projects chosen for audit through existence of relevant information from outside and inside specific project or by random choice
- Performed by a group of experts
- Advice to projects given and mutual learning

2. Key findings regarding obstacles to good governance in the implementation of the *FP7 ethical framing*

Although the EU officials evaluate the FP7 normative framework as comprehensive, several major challenges have been pointed out by them:

- Lack of awareness among various stakeholders
- Indifference among various stakeholders
- Lack of knowledge among various stakeholders
- Need for an increased collaboration on ethics in research among member states
- The diversity of European values versus the need for a uniformity of approach to ethics at the EU level
- Ethics specialised knowledge not always helpful in expertise
- Ethical issues do not easily fall under strict legal frameworks, therefore broader general principles need to be attributed.
- Differences in the national legislation in member states
- Practice of case to case approach due to lack of relevant standards

3. Use of the grid for data analysis for the interpretation of the empirical findings in relation to the theoretical framework

- 1) Further on we shall analyse and interpret our empirical findings regarding the relevant governance arrangements in relation to the theoretical framework of our research. The description of the approaches to the development of the grid for data analysis was presented in Annex 2. We will present the grid itself (template), and the actual analysis will be carried out by using this grid.

Grid for data analysis (TEMPLATE)

We have dealt in greater detail with the approaches to the development of the grid for data analysis in chapter 2.6 and with its content of the content of the grid for analysis in Annex 2. Here we are presenting the grid itself.

Tool or institutional arrangement	Use of tools E.g. ethical compliance, legal compliance, avoiding future obstacles, consulting, restriction of framing, social acceptance, identification of ethical issues, ethical management	Relation to context ²⁴¹ (context ignored, decontextualised, restricted context, fully contextualised)	Presupposition underlying the use of the tool ²⁴² (Intentionalist, Schematising, mentalist)	Governance approach (mode) ²⁴³ (standard, consultation, revised standard, co-construction)

²⁴¹ **Relationship to context**

Decontextualised – refers to the situation where the ethical norm is seen outside the context of its application

Context restricted - refers to the situation where the ethical norm is seen restricted in the context of its application

Fully contextualised - refers to the situation where the ethical norm is seen fully inside the context of its application

²⁴² **Underlying pre-suppositions**

Intentionalist pre-supposition - the norms effects are supposed to be deducible from the simple intention to adopt the norm. Additionally, there is the presupposition that the actors in a participatory approach will have capacity and intention to contribute to the participatory discussion.

Schematising pre-supposition - involves Kantian schemes (rules), in which the operation of the application of a norm is a simple formal deductive reasoning on the basis of the rule itself. The determination of the norm is linked to these rules, such as ethical guidelines, or laws, or other external sets of rules.

Mentalist pre-supposition is named so because it relies on the mind having a set of rules (or schemes, in Kant's words), that predetermines the effect of a norm, and does not depend on any exterior context (to that of the thinker). This is commonly seen when participants in a participatory approach come to the setting with their own particular ethical framing, or with some preconceptions as to what ethical issues might arise.

²⁴³ **Modes of governance**

The following governance approaches (modes) as identified in our theoretical framework, are mostly concerned with risk assessment.

Standard – Disagreement between the experts and the public are perceived as irrational due to public's lack of knowledge. Rational experts and irrational public

Consultation - Difference between experts and non-experts is in the perception of risk. Public have valid views. Voluntary and involuntary exposure to risk, the unknown character of risk, the number of people affected by risk

Revised standard – interaction btw regulation process, social groups and medias. Public attitude, exaggerated legislation, consequently irrational law-making. Technocratic vision, top down approach

Co-construction model – Questions the way in which technological development projects use experts. Based in Latour. Facts and values are being taken into account. Stirling - not only a democratic matter but a matter of analytical rigour. Why withdraw from debate which will discuss what may eventually be changed.

Tool or institutional arrangement	Use of tools E.g. ethical compliance, legal compliance, avoiding future obstacles, consulting, restriction of framing, social acceptance, identification of ethical issues, ethical management	Relation to context (context ignored, decontextualised, restricted context, fully contextualised)	Presupposition underlying the use of the tool (Intentionalist, schematising, mentalist)	Governance approach (standard, consultation, revised standard, co-construction)
Ethical guidelines	Legal compliance	Decontextualised	Schematising	Standard
	Identifying ethical issue	Decontextualised	Mentalist	Consultation
	Ethical compliance	Decontextualised	Intentionalist	Standard
	Avoiding future obstacles	Restricted contextualised	Intentionalist	Partly co-construction
	Legal compliance	Decontextualised	Schematising	Standard

1. Ethical guidelines

2. Ethical check-list

Tool or institutional arrangement	Use of tools E.g. ethical compliance, legal compliance, avoiding future obstacles, consulting, restriction of framing, social acceptance, identification of ethical issues, ethical management	Relation to context (context ignored, decontextualised, restricted context, fully contextualised)	Presupposition underlying the use of the tool (Intentionalist, schematising, mentalist)	Governance approach (standard, consultation, revised standard, co-construction)
Ethical check-list	Identifying ethical issue	Decontextualised	Mentalist	Standard
	Avoiding future obstacles	Decontextualised,	Mentalist	Standard

3. Experts and expert panels

Tool or institutional arrangement	Use of tools E.g. ethical compliance, legal compliance, avoiding future obstacles, consulting, restriction of framing, social acceptance, identification of ethical issues, ethical management	Relation to context (context ignored, decontextualised, restricted context, fully contextualised)	Presupposition underlying the use of the tool (Intentionalist, schematising, mentalist)	Governance approach (standard, consultation, revised standard, co-construction)
Experts and expert panels	Identifying ethical issue	Decontextualised	Mentalist	Standard
	Identifying ethical issue	Restricted contextualised	Intentionalist	Consultation
	Avoiding future obstacles	Decontextualised,	Mentalist	Standard

4. Ethical Committees

Tool or institutional arrangement	Use of tools E.g. ethical compliance, legal compliance, avoiding future obstacles, consulting, restriction of framing, social acceptance, identification of ethical issues, ethical management	Relation to context (context ignored, decontextualised, restricted context, fully contextualised)	Presupposition underlying the use of the tool (Intentionalist, schematising, mentalist)	Governance approach (standard, consultation, revised standard, co-construction)
Ethical committee	Legal compliance	Decontextualised	Schematising	Standard
	Identifying ethical issue	Decontextualised	Mentalist	Consultation
	Ethical compliance	Decontextualised	Intentionalist	Standard
	Avoiding future obstacles	Restricted contextualised	Intentionalist	Partly co-construction

5. Ethic Review procedure and Ethics Review report

Tool or institutional arrangement	Use of tools E.g. ethical compliance, legal compliance, avoiding future obstacles, consulting, restriction of framing, social acceptance, identification of ethical issues, ethical management	Relation to context (context ignored, decontextualised, restricted context, fully contextualised)	Presupposition underlying the use of the tool (Intentionalist, schematising, mentalist)	Governance approach (standard, consultation, revised standard, co-construction)
Ethical Review procedure and Ethics Review report	Legal compliance	Decontextualised	Schematising	Standard
	Identifying ethical issue	Decontextualised	Mentalist	Standard
	Identifying ethical issue	Restricted contextualised	Intentionalist	Consultation
	Avoiding future obstacles	Restricted contextualised	Intentionalist	Partly co-construction

6. Ethics follow up and audit

Tool or institutional arrangement	Use of tools E.g. ethical compliance, legal compliance, avoiding future obstacles, consulting, restriction of framing, social acceptance, identification of ethical issues, ethical management	Relation to context (context ignored, decontextualised, restricted context, fully contextualised)	Presupposition underlying the use of the tool (Intentionalist, schematising, mentalist)	Governance approach (standard, consultation, revised standard, co-construction)
Ethics follow up and audit	Identifying ethical issue	Restricted context	Intentionalist	Revised standard
	Avoiding future obstacles	Restricted context	Intentionalist	Revised standard
	Ethical management	Restricted context	Shematising	Consultation

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7. Public consulting

Tool or institutional arrangement	Use of tools E.g. ethical compliance, legal compliance, avoiding future obstacles, consulting, restriction of framing, social acceptance, identification of ethical issues, ethical management	Relation to context (context ignored, decontextualised, restricted context, fully contextualised)	Presupposition underlying the use of the tool (Intentionalist, schematising, mentalist)	Governance approach (standard, consultation, revised standard, co-construction)
Ethical public consulting	Identifying ethical issue	Restricted context	Mentalist	Standard
	Ethical compliance	Decontextualised	Intentionalist	Standard
	Avoiding future obstacles	Restricted context	Mentalist	Revised standard
	Consulting	Restricted context	Mentalist	Consulting
	Social acceptance	Decontextualised	Mentalist	Revised standard

2. Key conclusions from the analysis of governance arrangements

Our analysis of the empirical findings based on our theoretical framework show that the governance approaches are in most cases de-contextualised, and only on some occasions partly contextualised. Standard, revised standard and consultation models are predominant. The underlying presuppositions in most cases refer to mentalist and intentionalist approaches, with some cases of schematising approaches. Thus, the existing EU governance approaches do not take into consideration the trajectory of a norm in a specific context. Most things are reduced to reason, to a rational positivist approach.

At the same time it should be pointed out that, although the actual governance arrangements suffer from the above mentioned limits, the awareness of the need for a more reflexive approach is clearly indicated by the empirical data obtained from the interviews with the EU officials, and the awareness for the need to reflect on the very ethical FP7 framing was present.

Our interviews showed that not only there is awareness among the relevant EU officials on the need of a reflexive approach, but also the various procedures have elements of reflexivity (for example, within expert panels, within ethical committees, and especially within the ethical follow up and audit). Moreover, it was indicated on several occasions during our interviews that continuous learning is taking place among the relevant EU officials (both, internally from each other and externally from and among the various stakeholders).

Annex 9 Case study of the EGAIS project

In order to be able to compare the conceived FP7 ethical framing and its implementation (from the point of view of EU Commission) and the actual implementation as perceived by the FP7 projects, we carried out the case study of the EGAIS project which has carried out research on the ethical framing of the FP7 ICT projects in the field of ambient intelligence.

According to the EGAIS analysis we have found that in FP7 ICT projects ethical thinking in most cases is reduced to the use of ethical guidelines or deontological codes for the evaluation of the emerging technologies. This is usually done without any substantial background or contextual analysis. Within the very technology development, the need for ethical consideration prior to the funding or implementation of the project today is not the current practice.

EGAIS case analysis indicate that ethical thinking in FP7 ICT projects traditionally is applied after the development of the technology. Ethical thinking is reduced to the question of justification (legitimation) of ethics, but hardly to provide a real solution. Thus, we can say that the norm in these projects is conceived without taking into consideration the problem of its application. We have found that the projects adhere to the formal requirements in terms of ethical guidelines, checklists and other procedures, and ethical reflexivity in most cases is missing.

The key governance arrangements put in practice are ethical committees, expert panels, focus groups, hybrid panels. In all of these the issue of ethical reflexivity is problematic, and the first order reflexivity is predominant, with the characteristic sectorial ethical framing

The analysis of the level of awareness of ethical issues of the involved projects show that there is a varying degree of awareness. Also regarding the perception of these projects of the different governance arrangements, the results are non-homogenous. For

example, regarding the perception of the effectiveness of the work of the ethical committees, 13% of the representatives view them as not effective, 25% as not very effective, 13% as somewhat effective, 37% as effective, and 12% as very effective. Similarly, also the other ethical arrangements are evaluated regarding their effectiveness.

Given the fact that the national ethical committees is one of the key advisory (and also decision tasking) instruments regarding ethics in research and technological development, the given results need further analysis and consideration. The underlying presuppositions are linked to the mentalist and intentionalist approach, and the ethical norm is basically viewed outside the context of its application. Most of the governance arrangements are linked to top down and sectorial approaches and do not incorporate reflecting on their own framing (with a few exceptions).

Our general conclusion is that the awareness among the target group (FP7 ICT projects) regarding ethics in technological development are in most cases limited to legal or procedural compliance. The respective governance approaches should be an issue to be continuously addressed in future, so that second order reflexivity in the implementation of ethics in technological development is enhanced.