European Commission

Ethics

for researchers

Facilitating Research Excellence in FP7

Research and Innovation

EUROPEAN COMMISSION

Directorate-General for Research and Innovation
Directorate B – European Research Area
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Contact: Isidoros Karatzas

European Commission
B-1049 Brussels

E-mail: isidoros.karatzas@ec.europa.eu
RTD-PUBLICATIONS@ec.europa.eu

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Directorate-General for Research and Innovation
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Introduction

Designed for all researchers who are preparing an application to receive funding from the European Union for their research, this document describes the most important aspects of research ethics and indicates the main points of attention for the Ethics Review procedure as a part of the 7th Framework Programme (FP7). For research funded by the European Union, ethics is an integral part of research from beginning to end and ethical compliance is pivotal to achieve real research excellence.

After a briefly explaining the history and legal basis of research ethics (Chapter 1) it is illustrated how exactly the Ethics Review procedure is integrated in the application and evaluation process. (Chapter 2) Chapter 3 will help you to understand the core subjects of research ethics and provides a practical roadmap to help with the preparation of your proposal.

SCIENTIFIC MISCONDUCT

Scientific misconduct includes (negligent or intended) fabrication (making up data or results), falsification (changing or misreporting research data or improper manipulation of experiments) and plagiarism (using ideas or words without accurate reference).

These practices go against all scientific values and can undermine the scientific progress. Even more, it can cause harm.

The European Commission condemns all forms of scientific misconduct. There is no place for these practices in research funded by the European Union.

Chapter I: Research Ethics

True Research Excellence

Ethical research conduct implies the application of fundamental ethical principles to scientific research. All possible domains of scientific research can raise ethical issues. Ethics is not just about the theories and the complex philosophical reasoning. Ethics is everywhere. In everything we do there can be an ethical component. When conducting research, there is clear need to make a thorough ethical evaluation.

Ethics is often misunderstood by researchers as hindering the scientific progress. While it is true that research ethics intends to put boundaries to what is and is not possible (under a certain perspective), it does not intend to regulate research or go against research freedom. The way research ethics is interpreted at the European Commission, aims to be collaborative and constructive. Also, by considering ethics at the conceptual stage of the proposal, the quality of the research is enhanced.

THE NUREMBERG CODE[1]

The Nuremberg Code is one of the most important documents in the history of research ethics. The Code was formulated in 1947 in Nuremberg, Germany, by the American judges of the Nuremberg Tribunal, who had to judge doctors of the Nazi-regime accused of murderous and torturous human experiments. The Nuremberg Code, with principal focus on medical research, consists of only 10 rules, indicating the most basic and fundamental principles. Consent, proportionality, necessity and the right to withdraw are at the core of this document. Although the Nuremberg Code has never officially been adopted as law, it has had a major influence on human rights law and medical ethics. Previous ethics codes focussed on the obligations of the investigator towards the research subjects. The Nuremberg Code reverses that logic: The rights are directly awarded to the research subjects. This was, at that time, a fundamentally different view on research ethics.

History and Legal Basis of Research Ethics

For a good understanding of the field, it is important to take a look at the history of research ethics. Research ethics is most developed as a concept in medical research, but the general principles apply for all fields of research. Informed consent and confidentiality are as important for a sociological study as they are for clinical research.

As a reaction to malpractices that were revealed during the Nuremberg trials, the World Medical Association (established in Paris in 1947) adopted a declaration on research ethics in 1964, in Helsinki, Finland.[2] Since, *the Declaration of Helsinki* has been reviewed for several times, but the general focus and core ideas remain the same.[3] The *Declaration of Helsinki* sets forward ethical principles for the conduct of medical research on human subjects, including research on identifiable human material and data. The basic principle behind the declaration is that, for all research, the well-being of the individual research subject must take precedence over all other interests. The declaration sets principles for the conduct of medical research and additional principles for medical research combined with medical care.[4]

Although research ethics is most developed within the context of medical research, research ethics is of crucial importance for **all scientific domains**. Professional and academic associations have often provided guidance documents and ethics codes, adapted to the specificities of their research domains. Good examples are the *Code of Ethics* from the International Sociological Association, The

Code of Ethics and Conduct from the British Psychological Society and the ethics guidelines from the British Educational Research Association.[5]

There is a strong connection between **research ethics and human rights**. Both fields influence each other and there are significant overlaps. This is illustrated by the *Convention on Human Rights and Biomedicine* or the *Oviedo Convention*, adopted by the Ministers of the Council of Europe in 1996.[6] This convention is meant to address the ethical issues raised by research within the framework of the protection of human rights and sets common standards for all members of the Council of Europe.[7] The convention sets out the general fundamental principles, additional protocols provide standards for more specific types of research. These principles include the primacy of the interest and welfare of the human being, informed consent and privacy.[8] The *Oviedo Convention* also sets standards for the use of the human genome and research on human embryos.[9] The *Additional Protocol Concerning Biomedical Research*, signed by most members of the Council of Europe but only ratified by a few[10], confirms the general principles and provides more specific rules for the role of ethics committees in research, the conditions for adequate informed consent, confidentiality and the right to information.[11] Other important international declarations and conventions are the UNESCO's *Universal Declaration on Bioethics and Human Rights* and the Council for International Organizations of Medical Sciences' (CIOMS*) International Ethical Guidelines for Biomedical Research Involving Human Subjects*[12]

Within the European regulatory framework, research ethics is based on the explicit European commitment to human rights. Firmly enshrined in the treaties[13], compliance with human rights is pivotal for all European policy domains. To further strengthen this commitment, the European Union adopted its own human rights legislation, the *European Charter of Fundamental Rights.*

THE EUROPEAN CHARTER OF FUNDAMENTAL RIGHTS[14]

Taking into account the ethical aspects of research practices has a particular significance in the European legal framework as the European Union is founded on a common ground of shared values laid out in the European Charter of Fundamental Rights. The Charter recognises a range of personal, civil, political, economic and social rights. The Cologne European Council of June 1999 entrusted the task of drafting a charter to a convention. The Lisbon Treaty incorporates the Charter into the Treaty on the European Union, giving the charter an equal legal effect, and states that all European legislation needs to conform to the principles of the Charter. Consequently, this also applies to the European research policy. The European Charter of Fundamental Rights contains several principles which can be relevant in the context of research. These principles form the basis of important ethics guidelines but also support the conduct of research.

Article 3 – Right to the integrity of the person

Everyone has the right to respect for his or her physical and mental integrity.

In the fields of medicine and biology, the following must be respected in particular:

- the free and informed consent of the person concerned, according to the procedures laid down by law;
- the prohibition of eugenic practices, in particular those aiming at the selection of persons;
- the prohibition on making the human body and its parts as such a source of financial gain;
- the prohibition of the reproductive cloning of human beings.

Article 7 – Respect for private and family life

Everyone has the right to respect for his or her private and family life, home and communications.

Article 8 – Protection of Personal Data

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 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.

Compliance with these rules shall be subject to control by an independent authority.

Article 13 – Freedom of the Arts and Sciences

The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

Chapter II: The 7th Framework Programme: The Ethics Review Procedure

Ethics Reviews are an integral component of the research proposal evaluation procedure undertaken by the European Commission. The purpose of these Ethics Reviews is to ensure that all research activities carried out under the 7th Framework Programme are conducted in compliance with fundamental ethical principles.

The 7th Framework Programme is a significant source of public funding dedicated to supporting a sound research community for a better future for Europe. Through the Ethics Review, some concerns the public might have relating to scientific research, are represented and addressed. The 7th Framework Programme legislation explains in more detail the most important aspects for the Ethics Review at the European level.

The 7th Framework Programme: Article 6 – Ethical Principles

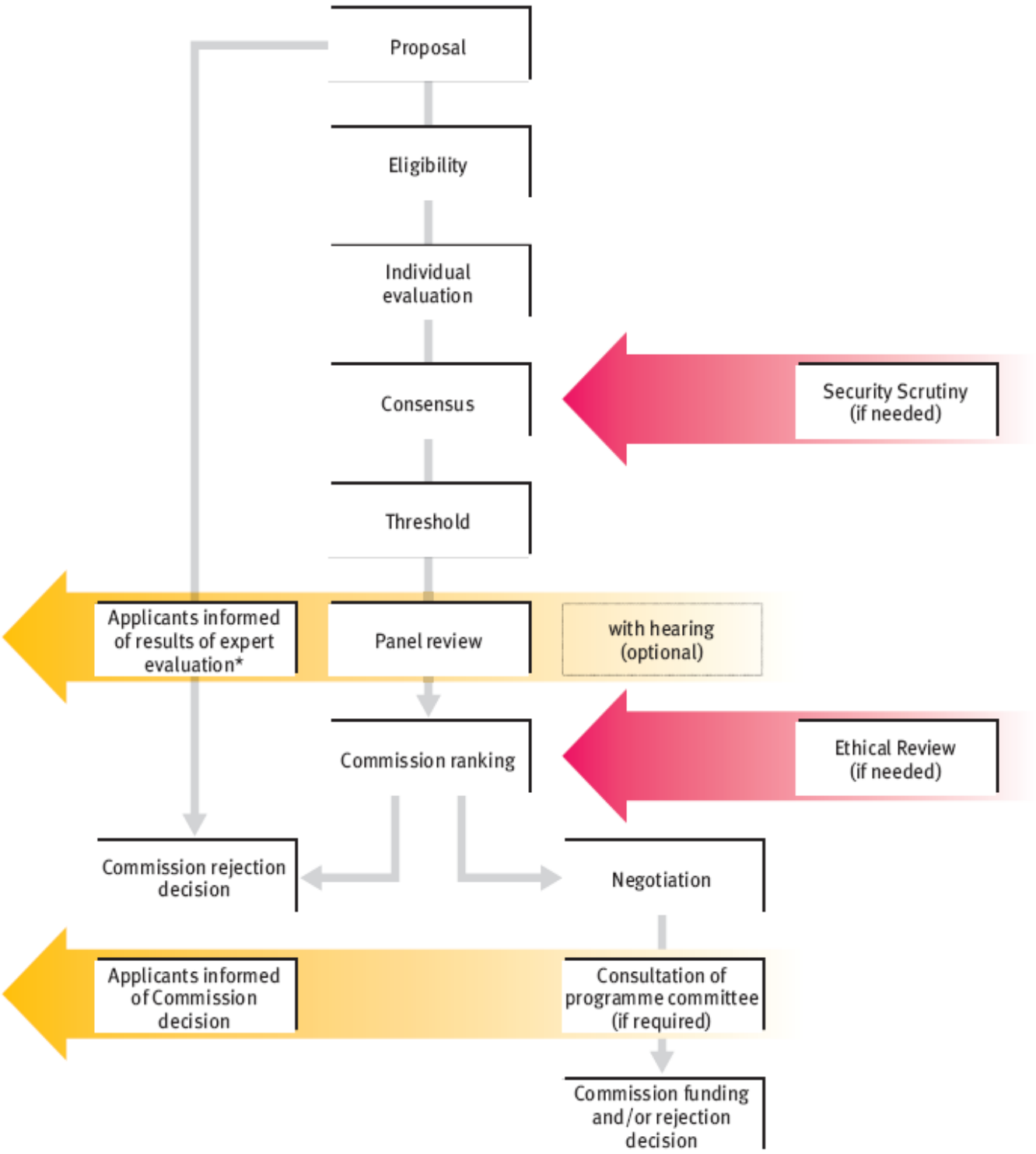
In compliance with the general obligations from the Treaties, the *7th Framework Programme Legislation*[15] sets general standards for all research funded by the programme. Article 6 of the decision comprises the applicable ethical principles:

1. *All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles.*
2. *The following fields of research shall not be financed under this Framework Programme:*
   - *research activity aiming at human cloning for reproductive purposes,*
   - *research activity intended to modify the genetic heritage of human beings which could make such changes heritable,*
   - *research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.*
3. *Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved.*

   Any application for financing for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approval(s) that will be provided.

   As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member State(s) involved.

The Ethics Review Procedure



Ethics Requirements

Both after the Ethics Screening and the Ethics Review, the experts can formulate recommendations and requirements. The requirements formulated in the Ethics Screening Report or the Ethics Review Report form the basis for specific obligations in the Grant Agreement. When national approvals of competent authorities and opinions of ethics committees are required, the European Commission ascertains that these authorizations and favourable opinions are in place before the start of the corresponding research.

The Optimal Composition of an Ethics Review Panel

Ethics Reviews at the European Commission are performed by a panel of experts from different disciplines such as law, sociology, philosophy, ethics, psychology, information technology, medicine, molecular biology, and veterinary science. Representatives of civil society may also be invited, such as representatives of patient organisations. The experts in the Ethics Review Panel have the same status as the experts performing the scientific evaluation and are bound by the European Commission obligations concerning conflict of interest and confidentiality. Ethics Review panel members are selected according their expertise, but also other criteria such as the gender balance of a panel group are taken into account. The overall objective is to include at least 45% of women in the panels. The Commission also makes constant efforts to recruit experts from all Member States.

All research proposals submitted to the European Commission are evaluated both on their scientific merit and on its ethical and social impact. When preparing a proposal, it can be appropriate or required to include an Ethics Annex with a completed Ethical Issues Table.[16] During the scientific evaluation of the proposals, *"the experts identify the proposals that may require further assessment due to the importance of the ethical issues raised by the proposal or the degree of adequacy of the way the ethical issues are addressed in the proposal."*[17]

The proposals retained by the experts with a view to funding, but identified as raising ethical issues, will be submitted to the Ethics Review.

Ethics Screening

The first phase of the Ethics Review, the Ethics Screening, is meant to identify all proposals that require (ethical) approval at the national level (e.g. with regards to data protection, the conduct of clinical trials and animal welfare) and identifies the proposals that require a full Ethics Review due to the ethical issues they raise (such as intervention on humans, use of non-human primates in research and research on human embryos and human embryonic stem cells).

Ethics Review

After the Ethics Screening process the European Commission may decide to submit proposals to a full Ethics Review. This is mandatory when the research involves intervention on humans, the use of non-human primates, human embryos or human embryonic stem cells.

After an individual assessment of the proposals, the experts meet as a panel and discuss and produce an Ethics Review Report. The Ethics Review Panel assesses the compliance with ethical rules and standards, relevant European legislation and relevant international conventions and declarations, national authorizations and ethics approvals, proportionality of the research methods and the applicants' awareness of the ethical aspects and social impact of their planned research.

Ethics Follow-up and Audit

During the Ethics Screening or the Ethics Review, the experts identify the projects that need a follow-up or audit. The follow-up and audit procedures are executed during the course of the research project and is meant *"to assist the beneficiaries to deal with the ethical issues that are raised by their work and if necessary take preventive and/or corrective measures."* [18]

This procedure is established by the *Commission Decision of 28 February 2011 amending Decision C(2008) 4617 related to the rules for proposals submission, evaluation, selection and award procedures for indirect actions such as the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) and under the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007-2011).*

Chapter III: Ethical Issues

Ethics might seem a very abstract concept, but, confronted with reality, ethics becomes the challenge to do what ought to be done. Although many of the rules and principles outlined above seem evident, several recent examples indicate we need to remain alert and cautious when it comes to research ethics. Often unintended, important ethics principles are violated.

CLINICAL TRIALS CASE[19]

In 2008 Nature reported a case of misconduct at the University of Innsbruck. The Austrian government Agency for Health and Food Safety stated that the clinical trials conducted to test the therapeutic efficacy of a stem-cell procedure for urinary incontinence had serious shortcomings. The agency reported a poor study design, inconsistent handling of patients and failure to randomize patients properly. Moreover, they failed to properly inform the patients about the nature of the intervention and the clinical trial was not approved by the relevant government authorities, nor by an ethics committee. Also the insurance certificates for the patients appeared to be dubious.

INDIAN TRIALS CASE[20]

In 2011, the British newspaper The Independent reported problems with the informed consent procedures applied by Western pharmaceutical companies for their clinical trials conducted in India. Because of its loose regulations for clinical trials, India has become a popular destination. These loose regulations and a lack of oversight led to situations where poor and illiterate people, who have little possibility of redress, are used in trials without giving proper informed consent. One example is the immunisation of hundreds of tribal girls without parental consent. This case was revealed because a young girl died after participating in the study. Although it is very unlikely that the girl died because of the vaccine, the parents only found out afterwards.

Any points raised in ethics reviews are not meant to be punishments or attempts to interfere with your research. Rather, they are requests for safeguards to ensure that human subjects, animals or the environment are protected and the public perception of research remains positive. If certain research methods may raise ethical concerns, you should take measures to ensure that widely shared societal values are not compromised. This is the human element that some researchers can easily overlook or downplay.

MMR AUTISM CASE[21]

In 1998 the medical journal the Lancet published a study linking the Measles, Mumps and Rubella (MMR) vaccine with autism and bowel disorders in children. Since, the research and the publication, leading to a public health panic, have been discredited. The General medical Council in the UK ruled that the responsible scientist acted "dishonestly and irresponsibly during his research and with callous disregard for the children involved in his study." Invasive tests were carried out without due regard for how the children might be affected and blood samples were collected paying children 8 $ at a birthday party. Also, there seemed to be a conflict of interest, because the responsible scientist was being paid by lawyers acting on behalf of parents who believe their children have been harmed by the MMR vaccine. The public health consequences of this fraudulent case continue until today. Due to the public health scare, thousands of children in the UK did not receive the MMR vaccine and remain unprotected. Recognizing that the MMR case exposed failings in the regulatory framework, the University College London revised its research governance framework. More robust procedures, properly embedded into the

management structure of research organisations, must safeguard quality and ethical standards and ensure proper handling of allegations of research misconduct.

Derived from the international and European declarations and legislation, the Ethics Review by the European Commission is based on a list of ethical issues. Whilst this list is not exhaustive, it helps to define the ethical issues a proposal might raise. The most important ethical issues are *privacy and data protection, informed consent, research on human embryos and foetuses, dual use, animal research and research involving developing countries.* Other ethical issues that should be taken into consideration are *scientific misconduct* (such as fabrication, falsification and plagiarism) and the possible *environmental impact* of the proposed research.

1. Data Protection and Privacy

Laid down as principles in the *Charter of Fundamental Rights*[22] and the *Treaty on the Functioning of the European Union*[23], privacy and data protection are fundamental rights which need to be protected at all time. **Privacy** can mean many different things in different contexts. Not all people have the same notion of the right to privacy, but most people want to maintain control over personal information and personal communications. If personal information is disclosed, we expect this information to be treated confidentially.

Data protection is meant to guarantee our right to privacy. Data protection refers to the technical framework and security measures designed to guarantee that all personal data are safe from unforeseen, unintended or malevolent use. Data protection therefore includes both measure with regard to access to data and the conservation of data. Also measures to assure the accuracy of the data can be included in a data protection strategy.

In the context of research, privacy issues arise whenever data relating to persons are collected and stored, in digital form or otherwise. The main challenge for research is to use and share the data, and at the same time protect all identifiable information to guarantee personal privacy. The personal data needed in research can include health information, genetic information, information on behaviour such as criminal records, financial information, travel records, information on religious beliefs and sexual orientation or ethnic identification records.

The *Data Protection Directive*[24] contains a number of key principles for the handling of personal data. This directive provides the framework for the regulation of data protection and privacy issues in the Member States. When the collection and processing of data is part of the planned research, applicants need to identify the applicable local or national legal requirements and the competent authorities to provide the necessary authorizations. A good overview of the implementation of *Data Protection Directive* by the member states can be found on the website of DG Justice under 'Data Protection.'[25] Please note that recently, the European Commission made an official proposal[26] to amend the current

PROPORTIONALITY

Are all the data collected really necessary to conduct the research? Often, more data are collected than necessary for the research purpose, raising the question of proportionality. For example, when conducting a survey the full identity of participants is registered when only some basic demographic information would suffice. Personal data collection must be adequate and relevant. The principle of proportionality is also important in other domains. The Ethics Review will verify the necessity to work with children or vulnerable adults or use animals in the experiments. One should always search for alternatives and the methods used must be proportional to the research objectives.

ANONYMISATION, CODIFICATION AND IDENTIFIABLE INFORMATION.

When dealing with privacy and data protection issues, it is important to correctly distinguish between the following categories of data: When personal data are collected, processed and stored, these data can remain **identifiable**, they can be **codified** or completely **anonymised**. Anonymised data are data that cannot be linked back to the individual. Codified data are data where the most obvious identifiers such as names and addresses are replaced with an indirect system of identification, usually through codes. It remains possible to link the indirect identifiers with names and addresses. For each category of data, different rules might apply.

EXPECTATIONS

What is expected with regards to privacy and data protection? For the Ethics Review, it is important that all relevant regulations and guidelines are followed and that the application is fully documented and prepared to meet all the requirements.

The application should provide an overview of the research activities where collection, processing or transfers of data are involved, including a detailed description of the procedures (e.g. informed consent) to comply with the relevant legislation.

All copies of the necessary national and local authorizations and approvals for all relevant research activities need to be provided. If authorizations or approvals aren't in place yet, a timeframe can be included explaining when approvals and authorizations will be requested or are expected to be granted. If no approvals or authorizations are required, this should also be explained.

Data Protection Directive, so changes in the regulatory framework are to be expected in the near future.[27]

When preparing a proposal to receive funding from the 7th Framework Programme, one should pay very careful attention to privacy and data compliance. In the Ethics Review, it is expected that proposals adequately deal with these issues and clearly show how compliance with all regulations will be assured. Apart from the strict regulatory obligations, it is important to demonstrate the awareness that privacy and data protection are issues which need to be addressed and that a strategy and methodology are developed and implemented.

Further reading & Legal framework:

- Ethical Review in FP7: Data protection and privacy ethical guidelines[28]
- European Textbook on Ethics in Research: Chapter 4: Privacy and confidentiality[29]
- Treaty on the Functioning of the European Union, article 16[30]
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[31]
- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[32]
- UNESCO International Declaration on Human Genetic Data[33]

Although the specifics of an informed consent procedure can vary according to the nature of the research and the needs of the research subjects involved, certain information should be provided to the research subjects before they participate:

- The purposes of the research and information about what will happen with the results of the research.
- The experimental procedures and a detailed description of the involvement of the participants, including the expected duration, and all the relevant procedures.
- All foreseeable risks or discomforts expected to occur for the research subjects during and after their participation.
- All benefits to the participants or to others which may reasonably be expected to occur.
- The insurance guarantees for the participants during and after participation and information on the foreseen treatments and compensations. Alternative procedures or treatments that might be advantageous to the participant need to be disclosed.
- Procedures in case of incidental findings
- A description of the procedures adopted to guarantee the participant's privacy: the levels of confidentiality, the measures to protect the data, the duration of the storage of the data and what will happen with the data or samples at the end of the research.
- Contact details for researchers who can be contacted at any time to answer pertinent questions about the research and the participant's rights and that can be contacted in the event of a research-related injury.
- A clear statement that the participation is voluntary, that the refusal to participate will involve no penalty or loss of benefits to which the participant would otherwise be entitled and that the participant may decide, at any time, to discontinue participation without penalty.
- Information about the organisation and funding of the research project.

2. Informed Consent

Declared one of the most pivotal principles in research ethics in many international conventions and guidelines[34], informed consent is meant to guarantee the voluntary participation in research and is probably the most important procedure to address privacy issues in research. Informed consent consists of three components: adequate information, voluntariness and competence. This implies that, prior to consenting to participation, participants should be clearly informed of the research goals, possible adverse events, possibilities to refuse participation or withdraw from the research, at any time, and without consequences. Research participants must also be competent to understand the information and should be fully aware of the consequences of their consent. Although informed consent is often seen in the context of clinical research, this principle is important for all types of research, including the social sciences.

Informed consent is required in when the research involves the participation of human beings, when the research uses human genetic material or biological samples and when the research involves personal data collection. In some cases, the 'traditional' informed consent procedure might not be sufficient to ensure that the rights and interests of the research subjects are fully respected. It is very important to take into account people's autonomy and vulnerability when deciding on how to organise the consent procedure. Some categories of people require special attention:

- Children[35]
- Vulnerable adults (elderly, prisoners, mentally deficient persons, severely injured patients …)
- People with certain cultural or traditional background: In some communities, the notion of individuality is lacking, written agreements do not exist, or women are not permitted to act autonomously. Strategies must be developed to address these issues with respect for the specificities of the situation.

The way participants are informed is a critical part of the informed consent process. When participants are informed, it is crucial that they fully realize the impact of the research for themselves and for society. Numerous anthropological studies have pointed out that participants rarely recall what they agreed upon when signing an informed consent form. A more interactive approach can address this issue. Good examples are making a presentation of the research project or conducting interviews with the participants to ensure that they understand all the issues at stake. Researchers might forget to explain what will happen with the research data and/or samples at the end of the research. If the data or samples are retained for further research this needs to be included in the consent procedure.

Further reading & Legal framework:

- Ethics Review in FP7: Guidance for Applicants: Informed Consent[36]
- European Textbook on Ethics in Research: Chapter 2: Consent and Chapter 3: Vulnerable and non-competent subjects[37]
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use[38]
- Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products[39]
- Ethical Considerations for Clinical Trials on Medicinal Products Conducted with the Paediatric Population: Recommendations of the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use[40]

3. Research on human embryo's and foetuses

Since the development of the techniques, the use of human embryos and foetuses for stem cell research is high on the political and ethical agenda. Research with human embryonic stem cells (hESC) gives the prospect to address medical needs, but at the same time raises fundamental ethical questions because research implies the use and destruction of human embryos. These fundamental ethical questions touch upon basic beliefs about the intrinsic value of life and our place in the universe: When does human life start? If an embryo is a human being, can it be destructed for the purpose of research? If hESC research is allowed, which conditions and procedures should apply? Can we allow the production of embryos for the purpose of research or can only spare embryos from IVF treatments be used? For all these questions, the answers vary according to one's beliefs and world views.

Because of the inherent pluralism of Europe, the acceptability and the conditions for the conduct of hESC research are not everywhere the same. In the context of the 7th Framework Programme the diversity in national regulations is addressed as follows:

"Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved. Any application for financing for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approval(s) that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member State(s) involved."[41]

Consequently, no research will be funded that is not allowed in all Member States, and no research will be funded in a Member State where such research is forbidden.[42]

Three field of research are explicitly excluded from the 7th Framework Programme[43]:

- Research activities aiming at human cloning for reproductive purposes.
- Research activities intended to modify the genetic heritage of human beings which could make such changes heritable.
- Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Because hESC research is such a sensitive issue, all research proposals involving hESC are closely monitored from beginning to end:

- All proposals are assessed in the Member State(s) where the research will take place. If the research is not authorized by the Member State(s) relevant bodies, the proposal cannot be funded.
- The scientific evaluation of the research proposal assesses the necessity of using human embryonic stem cells to achieve the research objectives.

- Proposals involving the use of human embryonic stem cells or foetal samples will always be automatically referred to an Ethics Review Panel, ensuring an independent ethical assessment on the European level.

For a more details on the specific provisions about hESC research please consult:

- *Statements of the Commission (Re Article 6)* added to *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)*[44]

- *Annex A "Ethics Review Procedures"* of the *Commission Decision of 28 February 2011 amending Decision C (2008) 4617 related to the rules for proposals submission, evaluation, selection and award procedures for indirect actions such as the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) and under the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007-2011)*[45]

Further reading & Legal framework:

- UNESCO Universal Declaration on the Human Genome and the Human Rights[46]

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[47]

- European Textbook on Ethics in Research: Chapter 8: Ethical Issues in the New Biotechnologies[48]

4. Dual Use

Dual use is a term often used in politics and diplomacy to refer to technology which can be used for both peaceful and military aims. In the context of research, dual use is to be understood as potential misuse of research. This means that the research activities involve or generate materials, methods or knowledge that could be misused.

- Research that, based on current understanding, can be reasonably anticipated to provide knowledge which could be misused for criminal or terrorist purposes.
- Research involving human, animal and plant pathogens, toxic chemicals, and radioactive materials that, when misused, could cause severe harm to humans, animals, plants or the environment.
- Research which uses classified information, materials or techniques or uses other dangerous or restricted materials.

"A dual-use dilemma is an ethical dilemma (…) since it is about promoting the good in the context of the potential for also causing harm. (…) It is an ethical dilemma for the researcher not because he or she is aiming at anything other than a good outcome; (…) Rather, the dilemma arises for the researcher because of the potential actions of others."[49]

For example, following the definition of the National Science Advisory Board for Biosecurity in the USA, bio-medical dual-use research is research which may enhance the virulence of microorganisms causing diseases; diminish the immunity of the host; enhance the transmissibility of the pathogens (enhance the contagiousness); alter (enlarge) the host range of the pathogen; render a vaccine ineffective; confer resistance to life-saving antibiotics; prevent diagnosis of infection or detection of a pathogen; enable eventual weaponization, severity of disease/symptoms or mass casualty.[50]

The phenomenon is not new, but the existence of weapons of mass destruction, the increase in international terrorism and the introduction of the concepts of bio-warfare and bioterrorism increased the importance of the concept of dual-use. In the past, the concept of dual use focussed on the proliferation of nuclear weapons, in the 21th century, the focus shifted to pathogenic organisms and viruses.

The possible dual use of new technologies and new scientific results creates ethical problems for the scientist and the scientific community, especially with regard to how to define the responsibility to prevent such dual use. European research funding is only possible for research with an exclusive focus on civil applications. This does not mean that dual use research is excluded from the 7th Framework Programme, but special measures need to be taken to ensure that the potential for misuse is adequately addressed and managed.

Applicants are expected to develop a comprehensive approach: A detailed strategy addressing the specifics of the situation, putting the necessary safeguards in place.

1. **Awareness –** Project applicant should be sufficiently aware of the potential risks (the direct risks for the participants and the risks for the society as a whole). Possible measures can be an ex-ante biosecurity assessment, an early flagging system for biosecurity and biosafety problems and education and training.

2. **A strategy –** Project applicants should develop appropriate and detailed procedures to deal with dangerous or restricted materials or information. Biosecurity and biosafety risk management procedures should comply with relevant standards.[1] These procedures can include access controls, assignment of confidentiality levels, the effective control and monitoring of all procedures and the reporting of near misses.

3. **Independent expertise –** Expertise on biosecurity and dual use should be included in the project management structure or in an independent ethics advisory board. It is the role of experts to oversee and assist in the creation of a comprehensive risk management system.

4. **Dissemination, communication and exploitation of the results –** Can the research results be shared with a wider public? What are the risks and possible consequences? How would the public opinion react? Independent experts can assist in the development of a strategy.

Further reading & Legal framework:

- Guidance document: A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research[51]
- WHO Biorisk management: Laboratory biosecurity guidance[52]
- Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items[53] and Annex I of Regulation (EU) No 388/2012 of the European Parliament and of the Council of 19 April 2012[54]
- European Textbook on Ethics in Research: Chapter 7: Science and Society: Dual use[55]
- Ethical and Philosophical Consideration of the Dual-Use Dilemma in the Biological Sciences by S. Miller and M.J. Selgelid[56]

5. Animal Research

Animal testing or animal research refers to the use of animals in experiments. The latest Commission report estimates that over 12 million animals are used for experimental or other scientific purposes in Europe each year. The most common used animals for these purposes are rodents, rabbits, mice and rats.[58]

A first important document protecting the animals used in experiments is the *European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes,* adopted in 1986.[59] At the European level, the *Directive on the Protection of Animals*[60] is meant to ensure the protection of animals used in experiments or for other scientific purposes. The directive sets standards for control on the use of laboratory animals, housing and care of the animals and for the training of the personnel involved in the animal testing.[61] Special rules apply for endangered species and non-human primates.[62]

Apart from setting standards, the directive aims at reducing the numbers of animals used for experiments, following the concept of the "Three Rs."

To realize compliance with the three principles, animal research must be systematically and thoroughly evaluated, requiring the assessment of pain, distress and lasting harm. For the Ethics Review organised by the European Commission, the researcher should provide all the details of the species (and strains) used, justify why they are used, explain why the anticipated benefits of the research justify the use of animals and why methods avoiding the use of animals cannot be used. All the planned measures to comply with the 'three Rs' should be indicated, in particular the procedures to alleviate or minimize the suffering of animals.

Specific rules and conditions for the conduct of animal studies (authorization procedures, inspection, etc.) are established by national law. National authorities are responsible for the implementation of the *Directive on the Protection of Animals*.[63] Keep in mind that this directive allows for the member states to adopt stricter national measures.[64]

THREE RS[57]

The three Rs represent three fundamental principles for conducting research on animals.

1. **Reduction** = methods should be used that enable the researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.
2. **Replacement** = non-animal methods are preferred above animal methods whenever it is possible to achieve the same scientific aim.
3. **Refinement** = all methods used for the research should alleviate or minimize the potential pain, suffering and distress and enhance the animal welfare for the animals still used.

Further reading & Legal framework:

- European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes[65]
- Consolidated Version of the Treaty on the Functioning of the European Union, article 13[66]
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes[67]

6. Research Involving Developing Countries

A particular situation arises when research is conducted in or in collaboration with non-EU countries. In the first place, all activities conducted beyond the borders of the European Union must comply with the general objectives of the Union's external action.[68] Secondly, it is not because research is conducted beyond these borders that European standards for research no longer apply.

Special attention is required with regards to developing countries and emerging economies. Collaboration with developing countries can raise ethical concerns. The overall level of development of a certain country and the conduct of research with potentially vulnerable people, demand attention for the specific characteristics of the situation. Developing countries are often disproportionally burdened by diseases, poverty, high levels of illiteracy and basic health care infrastructure and resources are often lacking. Special measures can ensure that the rights and interest of all participants are adequately protected and that the benefits of the research are equally shared.

- The research needs to comply with all the relevant European legislation, national legislation and with relevant accepted international standards.
- International research projects must be beneficial for all stakeholders, with emphasis on benefits for the research participants and their communities. Special initiatives to support local communities (e.g. provide access to basic health care and the benefits generated by the research), can help achieving this goal.
- If local resources are used, this should be adequately compensated.
- Potentially vulnerable populations need to be able to provide **genuine** informed consent. This requires taking into account potential cultural differences, economic and linguistic barriers and levels of education and illiteracy.
- Although adequate scientific and ethics infrastructure might not be available, the relevant local and independent ethics approvals need to be provided.

Further reading & Legal framework:

- UNESCO's Declaration on Science and the Use of Scientific Knowledge[69]
- Nuffield Council on Bioethics: The Ethics of Research Related to Healthcare in Developing Countries.[70]
- Ethics Review in FP7: Ethics in research and international cooperation[71]
- European Textbook on Ethics in Research: Chapter 6: Justice in Research: Research in developing countries[72]
- Ethical and Regulatory Challenges to Science and Research Policy at the Global Level: Chapter 3: Scientific-Technological Divides and Benefit Sharing[73]

Conclusions

The 7th Framework Programme is a research programme that promotes excellence and innovation. While respecting the freedom of research, the programme is designed to ensure that all research is conducted with respect for fundamental ethical principles and aims for the highest ethical standards.

The most important and common ethical issues in research are privacy and data protection, the involvement of children, patients or other vulnerable people, the use of human embryonic stem cells, adequate informed consent, the potential dual use of research, research on animals and non-human primates and research involving developing countries. Other issues, such as the potential environmental impact of research activities, can also be of importance and should not be ignored.

Although many ethical issues are codified using legal instruments, research ethics is much more than defining the difference between legal and illegal. Research ethics requires an independent evaluation of the research activities and its possible consequences. It is a matter of awareness and looking beyond the research objectives, to consequences for everyone involved and the possible impact on society as a whole. The Ethics Review procedure organised by the European Commission is designed to help scientists and researchers achieving this.

The further development of responsible research and innovation activities is of crucial importance for the future. Striving for responsible research and innovation is not only necessary to address specific ethical problems, but to avoid corrosive effects on research and innovation in general. Policy initiatives and legislation can help to ensure the integrity of research, but the attitudes and behaviour of scientists and researchers are as important as the institutional framework.

Three Tips to be more ethically prepared

Try to integrate ethical and societal expertise into your research projects

While everyone feels that they know right from wrong, sometimes researchers get too close to the work they are doing, and would benefit from someone who can look at their work from another angle. A research project that engages with an independent ethics expert, or an ethics panel that can provide insight and advice, generally tends to address ethical issues or societal obstacles. Multidisciplinary expertise will always add value to research both in opening up potential new research applications and in preventing negative societal reactions. For example, a synthetic biology research project on biofuel catalysts could benefit from a forest management expert to better understand the societal concerns about biodiversity loss from biofuels harvesting. Or, in cases where human samples are taken and stored, an ethicist will design and implement an informed consent process and a data protection system that can also reassure and keep human subjects involved.

Use existing codes of conduct for researchers

It is rarely the case that researchers act improperly. Unfortunately, a few well-publicised instances have created an elevated public fear and distrust of scientists. The public wants the benefits of research and wants to trust science so by articulating a code of conduct, how researchers should behave, the non-scientific community can be reassured that the research process is being managed responsibly. While codes have been expressed in many past activities and much of it is based on common sense, the mere presence of a code on your research project serves as a benchmark for the research community. This in itself can reassure the general public. As many projects have partners from different countries, expressing the code and comparing its elements could have a learning effect for researchers.

Do not hesitate to seek advice

Ethics panels are made up of individuals from different backgrounds in order to provide a multidisciplinary assessment and recommendations from a broad range of societal interests. Sometimes the conclusions of an ethical review may be difficult to understand. The European Commission operates on the principles of openness and engagement. If any conclusions are unclear or contain vocabulary that may seem ambivalent, researchers should not feel inhibited from asking for clarification or guidance. This document, in itself, is recognition that sometimes the advice from ethical panels is not altogether clear. Remember one of the first sentences of this booklet: points raised in ethical reviews are not meant to be punishments or attempts to interfere with your research. Rather, they are requests for safeguards to ensure that the public perception of research remains positive, within the remit of the law and in line with national, European and international ethics guidelines. The Commission is here to work with you so when in doubt, seek further advice.

Twelve Golden Rules to Ethical Research Conduct

You must ensure that your research:

1. Respects the integrity and dignity of persons (that this intrinsic worth protects them from being used for greater perceived benefits)
2. Follows the "Do no harm" principle. Any risks must be clearly communicated to subjects involved
3. Recognises the rights of individuals to privacy, personal data protection and freedom of movement
4. Honours the requirement of informed consent and continuous dialogue with research subjects
5. Treats animals with respect and works under humane conditions before, during and after the research
6. Designs animal research in accordance with the 3 Rs: Replacement, Reduction, Refinement
7. Respects the principle of proportionality: not imposing more than is necessary on your subjects or going beyond stated objectives (mission creep)
8. Treats societal concerns seriously - a researcher's first obligation is to listen to the public and engage with them in constructive dialogue, transparently, honestly and with integrity
9. Tries to prevent being openly available for misuse or malignant dual use by terrorists or military organisations
10. Recognises the wholeness of an individual and that any modification (genetic or technological) does not interfere with this principle
11. Respects biodiversity and does not impose irreversible change that threatens the environment or ecological balance
12. Builds on the understanding that any benefits are for the good of society, and any widely shared expressions of concern about threats from your research must be considered (with the acceptance that perhaps certain research practices might have to be abandoned)

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Researchers have the opportunity to be part of the Seventh Framework Program, a research programme that promotes excellence and innovation, and which respects freedom of research whilst ensuring the respect of fundamental ethical principles. Ethics must be given the highest priority in EU funded research as an integral part of research, permeating every area of research and it is only by getting the ethics rights that research excellence can be achieved. This publication presents the Ethics Review procedure of the European Commission in details: the objectives, the relevant legislation, the composition of Ethics Review panels. As for methodology, it defines ethical issues – informed consent, data protection and privacy, research on human embryos, animals, dual use and developing countries –, gives practical advice to researchers and explains via case studies. The moral from this publication is: do not forget research ethics.

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