Annex 5: 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 FP7[21] 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 Union[22] and take into account opinions of the European Group on Ethics in Science and New Technologies (EGE)[23].

Article 15 of the FP7 draft rules of participation[24] 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 Union[25] 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 Convention[26]. 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.[27] 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.[28]

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.

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[21] Decision 1982/2006/EC: Official Journal L412 of 18/12/06
[22] http://www.europarl.europa.eu/charter/default_en.htm
[23] 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
[24] Official Journal L391 of 30/12/06
[25] The Charter of Fundamental Rights of the European Union - http://www.europarl.europa.eu/charter/pdf/text_en.pdf
[26] http://conventions.coe.int/treaty/en/Treaties/Html/005.htm
[27] Opinion 10 of EGE - The Ethical Aspects of the 5th Framework Programme , http://ec.europa.eu/european_group_ethics/docs/opinion10_en.pdf
[28] Opinion 20 of EGE – Ethical Aspects of ICT Implants in the Human Body - http://ec.europa.eu/european_group_ethics/docs/avis20_en.pdf

2.2 Privacy and informed consent

The right to privacy and data protection is a fundamental right[29] and therefore applicable to ICT research.

Researchers must be aware that volunteers[30] have the right to remain anonymous[31]. Researchers must comply with Data Protection legislation[32] 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[3].

The majority of European citizens view personal privacy as an important issue. Research, for example, on RFID[33] and ICT for healthcare[34], 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 beings[35]. Thus ICT research involving animals should conform to the ethical principles of replacement, reduction, refinement and minimisation of suffering[3].

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 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 currently sensitive areas

3.1 ICT implants[36] 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.

[29] The Charter of Fundamental Rights of the European Union - http://www.europarl.europa.eu/charter/pdf/text_en.pdf
[30] "Volunteers" is used to describe all those who are the subjects of research observations, experiments, tests etc.
[31] Opinion 10 of EGE - The Ethical Aspects of the 5th Framework Programme , http://ec.europa.eu/european_group_ethics/docs/opinion10_en.pdf
[32] National legislation transposing Directive 95/46/EC - http://ec.europa.eu/justice_home/fsj/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf
[33] 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.htm
[34] Opinion 13 of EGE - Ethical Issues of Healthcare in The Information Society.- http://ec.europa.eu/european_group_ethics/docs/avis13_en.pdf
[35] 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
[36] Opinion 20 of EGE – Ethical Aspects of ICT Implants in the Human Body - http://ec.europa.eu/european_group_ethics/docs/avis20_en.pdf

- 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.[37]
- 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 eHealth[38] and genetics

Personal health data must be treated as 'sensitive personal data'[39]. 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[1].
- 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[40].

- 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[4].
- 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.

[37] 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

[38] Opinion 13 of EGE - Ethical Issues of Healthcare in The Information Society.- http://ec.europa.eu/european_group_ethics/docs/avis13_en.pdf

[39] Directive 95/46/EC - http://ec.europa.eu/justice_home/fsj/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf

[40] COM (2004) 338 final - http://ec.europa.eu/prelex/rech_simple.cfm?CL=en