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# Inventory of ethical laws, which apply (at national and EC level) during behavioural experimental studies

## Deliverable 2.1. of Task Force 2

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## 1 Introduction

The main objective of Activity 2.2. (TF 2) “**Respect of national and EC legislations on ethical rules**” is to produce a detailed inventory of the ethical laws which apply, at the national and EC levels, during experimental studies using human subjects in biomedical and behavioural research, to produce reports on the conditions of applications of these rules during behavioural experimental studies jointly executed by network partners, and to disseminate information on ethical rules to network researchers through special lectures during workshops and through the HUMANIST web site.

## 2 Theory of ethics

Anzenbacher (2001) defines ethics as "1. a system of moral principles; 2. the rules of conduct recognized in respect to a particular class of human actions or a particular group, culture, etc." The same reference defines ethics as distinction between right and wrong, concerning the principles of the right conduct.

In another words, ethics provides the framework whereby individuals can distinguish right from wrong attitudes and behaviors in themselves and in others. For professional individuals such as researchers in the transport area, application of this framework constitutes ethical practise of the profession. Ethical practice is essential to the well-being of the public, to the maintenance of respect for research. Ethics is the discipline that investigates and creates theories about the nature of right and wrong. As a branch of philosophy, ethics also pays attention to substantive conceptions of moral goodness, duty, obligation, freedom and virtue. More broadly, ethics involves the study of how we ought to conduct – and in our case – how to treat the individuals involved in our research studies.

### 2.1 *Ethical Issues*

#### Principles of Ethics

#### Research Ethics

Philosophical Platform	Research with Animals
Informed Consent	Research with Human Subjects
Participant 's Privacy	Research Integrity/Misconduct
Confidentiality of Information	Conflicts of Interest
<u>Social Policy and Values</u>	Confidentiality/Data Handling
Codes of Ethics	Ethical Standards in Research
	Record Keeping in Research
	Research Regulations
	Research Mentoring
	Intellectual Property
	Authorship
	Citations
	Data Ownership
	Misconduct and Fraud

## 2.2 Rules and regulations

The process of ethical reasoning is intended not only to provide solutions to difficult moral problems, but also to clarify the issues themselves. This includes analysing key terms (“informed consent,” “conflict of interest,” “fraud”); identifying shared assumptions (rigorous attention to procedures of acquiring and analysing primary data, appropriate mentoring of trainees) and points of controversy or conflict (criteria for inclusion as an author).

Thus at a minimum, training in responsible conduct of research should include practice in identifying and *analysing ethical situations*. Standardly, this involves working through a variety of case studies, either actual or hypothetical, to determine what ought to be done. The aim here is to identify the interests of the relevantly affected parties, the available lines of action, the likely benefits and harms of each, and the competing norms and values at issue. Effectively used, the case study approach can help in developing a range of skills that contribute to moving discussion of complex ethical issues beyond deadlock and towards a working consensus.

Training may also include some exposure to the discipline of ethics, in particular to that branch of ethical theory known as **normative ethics**. Normative ethics seeks to establish norms for right and wrong behaviour using principles of varying levels of generality, for instance principles of fairness, cooperation and honesty (Anzenbacher, 2001).

Although they may have only indirect application to areas such as human subjects research or research misconduct, contemporary work in moral theory is a fundamental resource for getting clearer about important ethical considerations.

In resolving ethical dilemmas, researchers do not have to start from scratch. Rules and regulations have been developed by various professions (psychologists, lawyers, doctors etc.) to codify minimal requirements for the responsible conduct of research. These provide a necessary starting place for any program of instruction.

### 2.3 *Key principles in ethics*

- **respect for the personality** and his or her autonomy, dignity and self-determination
- **beneficence**: a commitment to maximize potential benefit and minimize possible risks

These principles are generally relevant to the evaluation of the ethics of the research.

## 3 **Ethical Codes**

Ethical codes provide guidance to researchers in research involving human subjects. Some examples follow.

### 3.1 *Declaration of Helsinki*

The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. The fundamental inventory of ethical rules in the health area contains basic message that:

- the doctor (or researcher) always deals in the interest of the patient
- interest of the research and science shouldn't be put above the interest of the participant
- in research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society
- participant can withdraw (give up) without sanctions
- the necessary condition is the informed consent; it supposed that the participant has mental and decision capacity and voluntary decision making.

The participant has to understand the plan and process of the research, its assumed risks and benefits.

- it is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

### 3.2 *The Belmont Report*

The Belmont Report includes ethical principles and guidelines for the protection of human subjects of research, and was passed by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research in April 1979 in the United States. One of the charges of the Commission was to identify three basic ethical principles that should underlie the conduct of biomedical and behavioural research involving human subjects and to develop guidelines, which should be followed to assure that such research is conducted in accordance with those principles:

- Respect for Persons
- Beneficence
- Justice

**1. Respect for Persons.** Respect for persons incorporates at least two ethical conceptions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

**2. Beneficence.** Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

**3. Justice.** Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

### *3.3 Universal Declaration of Human rights*

Universal declaration of Human Rights is a declaration adopted by the United Nations General Assembly, December 1948, outlining basic human rights. **Human rights** (natural rights) are rights which some hold to be **inalienable** and belonging to all humans; according to natural law. Such rights are thought, by proponents, to be necessary for freedom and the maintenance of a reasonable quality of life. Inalienable rights cannot be bestowed, granted, limited, bartered away, or sold away. Inalienable rights can only be secured or violated. Human rights can be divided into two categories; positive and negative human rights. Every negative human right can be expressed as a positive human right, but not vice versa. For example, the right of a newborn to a caring parent can only be expressed positively.

### 3.4 Code of conduct by EFPA – European Federation Of Psychologists' Associations

European psychologists developed a valid and reliable body of knowledge based on research and applied that knowledge to psychological processes and human behaviour in variety of contexts.

EFPA has a responsibility to ensure that the ethical codes of its member associations are in accord with the following fundamental principles which are intended to provide a general philosophy and guidance to cover all situations encountered by professional psychologists.

#### **Ethical Principles:**

- Respect for a Persons Rights and Dignity:

Psychologists accord appropriate respect to and promote the development of the fundamental rights, dignity and worth of all people. They respect the rights of individuals to privacy confidentiality, self-determination and autonomy consistent with the psychologist's other professional obligations and with the law.

- Competence:

Psychologists strive to maintain high standards of competence in their work.

- Responsibility:

Psychologists are aware of the professional and scientific responsibilities to their clients, to the community and to the society in which they work and live. They avoid doing harm and are responsible for their actions, and assure themselves, as far as possible, that their services are not misused.

- Integrity:

Psychologists seek to promote integrity in the science, teaching and practice of psychology and in these activities are honest, fair and respectful of others.

- Respect for Person's Rights and Dignity includes:

#### **General respect:**

1. Awareness of and respect for the knowledge, insight, experience and areas of expertise of clients, relevant third parties, colleagues, students and the general public.

2. Awareness of individual cultural and role differences including those due to disability, gender, sexual orientation, race, ethnicity, national origin, age, religion, language and socio-economic status.
3. Avoidance of practices which are the result of unfair bias and may lead to unjust discrimination.

### **Privacy and Confidentiality**

1. Restriction of seeking and giving out information to only that required for the professional purpose.
2. Adequate storage and handling of information and records, in any form, to ensure confidentiality, including taking reasonable safeguards to make data anonymous when appropriate, and restricting access to reports and records to those who have a legitimate need to know.
3. Obligation that clients and others that have a professional relationship are aware of the limitations under the law of the maintenance of confidentiality.

### **Informed Consent and Freedom of Consent**

Clarification and continued discussion of the professional actions, procedures and probable consequences of the psychologist's actions to ensure that a client provides informed consent before and during psychological intervention.

#### *3.5 Ethical Principles of Psychologists and Code of Conduct (by APA)*

The American Psychological Association's Ethics Code applies the psychologist's activities that are part of their scientific, educational or professional roles and psychologists.

Principle A: Beneficence

Principle B: Responsibility

Principle C: Integrity

Principle D: Justice

Principle E: Respect for People's Rights and Dignity

Respecting dignity and worth of all people, the rights of individuals to privacy, confidentiality and self-determination:

Respect on cultural, individual and role differences, including those based on age, gender, gender identity, race, ethnicity, culture, national origin, religion, sexual orientation, disability, language and socio-economic status.

**Institutional Approval; Informed Consent to Research:**

Psychologists inform participants about the purpose of the research, about expected duration and procedures, about their right to decline to participate and withdraw from research once participation has begun, and about the limits of confidentiality.

Psychologists provide opportunity for participants to obtain appropriate information about the nature, results and conclusions of the research.

Researchers do not fabricate data and do not present portions of another's work as their own.

### *3.6 Human Research Ethic Committee – National Health and Medical Research Council (Australia)*

**Ethical Committee** should provide the participants of the research the opportunity to express their doubts and complaints concerning the ethics of the research. Where initial investigations reveal a situation that requires further investigation and review, the following procedures are recommended: invite the researcher to explain the situation to the committee. Having considered the matter, the committee may:

- stop the project, require amendments to the original research
- allow the project continue without amendment

Serious research misconduct:

- falsification
- it includes failure to follow established protocols if this results in unreasonable risk or harm to human beings, other vertebrates, or the environment.
- does not include honest error or honest differences in design, execution, interpretation, judgment in evaluating research methods or results of misconduct unrelated to the research process.

Sanction:

- stopping the project, negative consequences for researchers in terms of their ability to publish articles and obtain further funding for research. There may also be financial consequences if grants have to be returned to funding bodies.

#### Conflicts of Interest:

- no member of an ethics committee should be involved in research in which he or she has any interest, including personal involvement or participation, financial interest in the outcome.

#### Institutional Approval:

- foreseeable consequences of declining or withdrawing  
foreseeable factors that may be expected to influence their willingness to participate such as

- potential risks or discomfort
- prospective research benefits
- limits of confidentiality

Researchers provide a prompt opportunity for participants to obtain appropriate information about the nature, results and conclusions of the research

### *3.7 Science and Society in Europe*

The European Commission aims to promote responsible research in Europe and to keep the rapidly advancing progress in science in harmony with the ethical values of all Europeans. The information is available on [www.eu.int/comm/research/science-society/ethics/legislation\\_en.html](http://www.eu.int/comm/research/science-society/ethics/legislation_en.html).

The purpose of this web page is to guide researchers towards the most important reference texts in the area of ethics in research. It also gives access to a series of opinions of the European Group on Ethics (EGE) that are relevant to research activities.

### 3.8 Ethical Legislation and Conventions

#### 3.8.1 EU Legislation

- Charter of the Fundamental Rights of the European Union (signed in Nice, December 2000; 2000/C 364/01)
- 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
- 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 clinic trials on medicinal products for human use
- Council Directive 83/570/EEC of 26 October 1983 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation laid down by law, regulation or administrative action relating to proprietary medicinal products
- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions
- Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.
- Ethical rules of the Sixth Framework Programme

#### Ethical rules of the Sixth Framework Programme:

- Article 3 of the FP6 states that “*All researchers activities carried out under the Sixth Framework Programme must be carried out in compliance with fundamental ethical principles.*”
- in order to implement this article the European Commission has introduced an ethical review for proposals raising sensitive ethical issues into the evaluation process
- the Commission considers sensitive ethical issues to be those which:

- involve human beings
- use human tissues, in particular embryonic and foetal tissue
- use animals
- data production
- ETHICAL REVIEW PANEL is composed of independent experts of different disciplines such as law, sociology, psychology, philosophy and ethics, medicine, molecular biology and veterinary science and these experts are bound to the EC requirements concerning conflict of interest and confidentiality
- Ethical Review Panel does not replace a local ethics committee or local authority approval, but checks to find out whether approval has been given

Participants in research projects must conform to current legislation and regulations in the countries where the research will be carried out.

They have to follow the **Guide for Proposers Checklist** - crucial information for the Sixth Framework Programme applicants who have identified sensitive ethical issues (further information is given at the science and ethics website at [http://europa.eu.int/comm/research/science-society/ethics\\_en.html](http://europa.eu.int/comm/research/science-society/ethics_en.html)).

### 3.8.2 International conventions and declarations

Participants should respect the following international conventions and declarations:

- Helsinki Declaration in the latest version (Scotland, October 2000), World Medical Association
- Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on April 1997
- Universal Declaration on the human genome and human rights adopted by UNESCO, 11 November 1997
- UN Convention on the Rights of the Child

### 3.9 *Privacy and protection of personal data*

The developments of information technology facilitating the ready collection, holding, manipulation, disclosure and transfer of vast amounts of personal data represents a possible threat to the individual's privacy and confidentiality of personal data.

### 3.9.1 Privacy

The protection of privacy with respect to personal data had attracted much attention since 1970's. Statutory control was considered necessary to ensure proper protection of personal data privacy. Apart from being a privacy issue, the protection of personal data also has implications for financial and economic activities. An increasing number of countries are enacting legislative provisions that impose restrictions on the free flow of personal data to places that do not have adequate protection for personal data.

The key issue is personal data processing. It is defined as each operation in which researchers (administrators) conduct systematically with personal data (gathering, saving, making available, using, searching, passing, dissemination, publishing, interchanging or liquidation). The administrator is every person who determines the aim and means of personal data processing.

In behavioural research, respect for privacy and confidentiality is a key concept in the ethics of the research with human participants. Researchers are responsible for protecting of the privacy of volunteers and they should to inform them about what may be done with their data, for example the rules of sharing (Mates, 2004).

Applicants should describe the procedure for obtaining informed consent of persons and describe the procedures for protecting the confidentiality of such personal data. Where data are to be shared with other stakeholders the persons whose data are collected should give a specific consent.

Applicants should also describe the process of encoding or anonymisation.

The informed consent (see in ANNEX 2) has to be signed.

### 3.9.2 Confidentiality

Accordingly the document approved by the Commission on 23 October 2003 – Decision C the Commission and the contractor undertake to preserve the confidentiality of any document, information, knowledge, pre-existing know-how or other material communicated to them in relation to the execution of the project, and which has been identified as confidential in relation to the execution of the project. The confidentiality of any document, information or other material, the disclosure of

which could harm, interfere with or otherwise limit the effective protection of their intellectual property rights, must be maintained during the life of the project.

#### 4 **Ethical rules within NoE – Checklist of Ethical Conduct**

The purpose of this checklist is to summarize the key points that we have to consider if we do research with humans. Some ethical principles from the codes stated above are included.

According the Science and Ethics in Europe researchers are requested to fill this table concerning sensitive ethical issue (this table is copied from the Science and Society in Europe; *Crucial information for the Sixth Framework Programme Applicants* ([http://europa.eu.int/comm/research/science-society/ethics/rules\\_en.html](http://europa.eu.int/comm/research/science-society/ethics/rules_en.html)))

##### A. Specification of the issues identified:

Please indicate whether the proposal involves	Yes	No	UNCERTAIN
· Research on human beings			
<input type="checkbox"/> Persons not able to give consent			
<input type="checkbox"/> Children			
<input type="checkbox"/> Adult healthy volunteers			
· Human biological samples			
<input type="checkbox"/> Human foetal tissue/cells			
<input type="checkbox"/> Human embryonic stem cells			
· Human embryos			
· Human genetic information			
· Other personal data			
<input type="checkbox"/> Sensitive data about health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction			
· Animals (any species)			
<input type="checkbox"/> Non- human primates			
<input type="checkbox"/> Transgenic small laboratory animals			
<input type="checkbox"/> Transgenic farm animals			
<input type="checkbox"/> Cloning of farm animals			
· Research involving developing countries (e.g. clinical trials, use of human and animal genetic resources...)			
· Dual use			

##### Applicants are requested to confirm that the proposed research does not involve:

- Research activity aimed at human cloning for reproductive purposes,
- Research activity intended to modify the genetic heritage of human beings which could make such changes heritable \*

- Research activity 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.

\* Research relating to cancer treatment of the gonads can be financed.

HUMANIST researcher should carefully explain to the participant (and to reach a subject's informed consent:

- the purpose of the research
- the likely benefits of the research for the participant
- any risks associated with the research
- the arrangements for the protection of confidentiality and privacy throughout the research activity
- the likelihood of any complications from the research, including pain
- that participation in the research is voluntary and that the participant may withdraw participation at any time

Research furthermore has to:

1. treat the participants with respect to their autonomy and dignity
2. realize that interest of the research is subordinated the interest of the participant (primacy of protection of research participants is not overridden by the social value or contribution to knowledge)
3. must not falsify, fabricate and present another's work as his own work
4. must not jeopardize health, security, autonomy and dignity of the participant
5. must not cause harms on the environment and animals
6. must not exploit personal data of the participants; in case that these data are shared another research groups, the participant must give them his or her consent
7. each research should follow the regulations of his country and respect:
  - a) Charter of European Fundamental Rights
  - b) 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
  - c) Convention of Europe Council on human rights and biomedicine
  - d) Convention of children's right of UN

e) Declaration on human genome and human rights of UNESCO

**It should be also noted that all participants in the project pilots would be healthy, holders of a valid driving licence and volunteers.**

**They will have to sign an Informed Consent form before the test realisation.**

**In case they would like to stop the test, they will be able to do so without explaining the reason and without having any financial or other penalty.**

As the participants of the Sixth Framework Programme they 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.

## **5 Analysis of the questionnaires on ethical rules**

Since that each country has its own ethical laws and guidelines and the principles can vary and we can expect local modifications, we need to analyse the local guidelines concerning the ethical conduct of research that is practised by our partners in the different countries. That is why we have sent the questionnaire on ethical rules (in ANNEX 1) to our partners.

The following partners gave feedback of the questionnaires:

- BIVV (Belgium)
- CDV (Czech Republic)
- CUT (Germany)
- FACTUM (Austria)
- IfaDo (Germany)
- INRETS (France)
- NTUA (Greece)
- TNO (The Netherlands)
- TRL (England)
- VTI (Sweden)
- VTT (Finland)

We also created an Informed Consent Template that has to be used as a guarantee of basic ethical conduct in research. We comprised the observations of our partners to these templates (see in Annex 2).

We recommend this template for partners whose national ethical rules or internal codex don't include a similar template.

**Results of the analysis**

Country	Partners	National laws on protection of personal data	National laws on clinical tests	National association guidelines	Internal guidelines	Difference between psychology and medical sciences	Ethical controlling body	Internal ethical committee	Tools of controlling
Austria	Factum			Psychologist association			YES fo health matters	NO	
Belgium	BIVV					YES	related to universities	NO	Initial approval
Czech republic	CDV	YES		Psychologist association	YES	YES		NO	Internal audit
Denmark	DTF								
EC	JRC								
England	TRL	NO	NO	Psychologist association	YES		related to the health authorities	NO	Internal audit
Finland	VTT	NO	NO						
France	INRETS	YES	YES			NO	related to the health authorities	YES	Initial approval
France	Eurisco								
Germany	Bast								
Germany	Cut			Psychologist association			related to German association of psychologists		
Germany	Ifado			Psychologist association			related to German association of psychologists	YES	Initial approval
Greece	NTUA	YES		Market and opinion research companies association			a national body	NO	
Greece	ICCS								
Greece	HIT								
Norway	TOI								

Country	Partners	National laws on protection of personal data	National laws on clinical tests	National association guidelines	Internal guidelines	Difference between psychology and medical sciences	Ethical controlling body	Internal ethical committee	Tools of controlling
Portugal	UTL								
Spain	UPM								
Sweden	VTI		YES			NO	Related to the health authorities	No but in the phase of setting up one	
Netherlands	TNO		YES		YES	NO	Related to the health authorities	YES	Internal audit
Netherlands	SWOV								

**BIVV:**

*Title of the study (providing for HUMANIST):* “Driving with Low vision (On-Road Peripheral Prism) – Engineering Approaches to Low Vision Rehabilitation”

*Ethical guideline:* every protocol needs approval from Medical Ethical Committee of Universities involved

*Ethical Committee:* Universities (departments) have their own ethical committees (e.g. separate for psychology and medical sciences). Hence if you cooperate with university, you need approval from their ethical committee.

Each committee mostly has their own forms to be filled in and submitted.

*Ethical controlling body:* it is again a matter of institutions (i.e. universities). Researchers do not start before they have formal approval. But after this, no real control is exerted. The committee might contact the researcher after the expiry date to check the study has finished or is continued and a new approval is needed.

**CDV:**

*Ethical guideline:* The basic document of CDV – Research Code. there is stated that the researcher is obligated to keep the ethics of his/her work and to respect the authorship of the texts with clear reference to a relevant source. Psychologists have the ethical code of Bohemia-Moravia Psychologists’ Association, but the rules are not binding, just in the level of recommendations.

*Legislation:* Zákon o ochraně osobních údajů 101/2000 Sb. (Act for protection of personal data). There exist an Authority for protection of personal data and its inspectors are permitted to control the gaining and processing of personal data.

*Ethical controlling body:* No official controlling body. This exist for area of medicine (Czech Medical Chamber).

*Tools of controlling:* Internal audit

**CUT:**

*Ethical guideline:* Ethical rules of the DGPs (Deutsche Gesellschaft für Psychologie e.V. – German Association for Psychology, registered association) and the BDP (Berufsverband Deutscher Psychologinnen und Psychologen e.V. – Professional Institution of German Psychologists, registered association).

These ethical rules are binding rules for psychologists in their professionalism as well as in all life situations. They represent criteria against which professional activities of psychologists are validated and enable sanctions in the case of noncompliance.

*Legislation:* see above (ethical rules consider for example following issues: job title, secrecy, recording/storage of data, scientific work, standards for research on humans, information and adhesion of client/patients.. etc.

*Ethical controlling body:* The ethical commission of the DGPs is an independent organ of this association, which proves and assesses the ethical and legal acceptance of psychological research projects and their implementations. The ethical commission comments at the request of the person responsible for the project on the ethical defensibility of the aims and the procedures of the project. If the planned project is rejected by the ethical commission, it has to be modified.

*Tools of controlling:* By compliance with the ethical rules of DGPs and BDP, since we are all psychologists.

**FACTUM:**

*The title of the study:* Effects of ACC on driver behaviour (Analysing behaviour-adaptation phenomena due to equipping the car with Acc (Autonomous Cruise Control))

*Ethical guideline:* The Austrian Psychologists' Association's Ethical guidelines, issued together with the Austrian Department of Health, valid for all work.

For health psychologists – guidelines by the Chamber of Labour

- supervision of Department of Transport

*Ethical Controlling body:*

In the case of diagnostics and rehabilitation; for other work in the area it is more a “matter of honour” without disciplinary power.

*Ethical committee in the organization:* No

*Tools of Controlling:* according to the principles imposed by the Psychologists' Association's Guidelines and all the other guidelines mentioned above.

This control is on a voluntary basic, but for instance, giving away names of test-persons would cause reactions in the media, and the sponsoring of further projects would be endangered.

**IfaDo:**

*The title of the study:* Psychophysiological measurement of mental load induced by information provided by driver assistance systems (Evaluation of different information provision methods with event-related potentials)

*Ethical guideline:* Ethical guidelines are usually provided by the relevant professional associations, e. g. for a psychological experiment the ethical guidelines of the German Psychological Associations DGP and BDP would apply (available at <http://www.dgps.de/dgps/kommissionen/ethik/003.php4>)

*Legislation:* German laws include ethical rules at an implicit level, e.g. the first articles of the Grundgesetz (Basic Law).

*Ethical controlling body:* No

*Ethical Committee in the organization:* Yes

*Tools of controlling:* Research programs/experiments touching ethical issues have to be approved by the ethical committee of IfaDo.

**INRETS:**

*Title of the study:* - research on driver's behaviour

- study of the impact of on-board systems on driver's behaviour
- study of the usability and the acceptability of on-board systems

*Ethical guideline:* No

*Legislation:* In France, there are two legislations concerning researches with human subjects. The first one is related to the protection of individuals with regard to the processing of personal data and concerns any process of research likely to produce personal data collection (surveys and experiments using human subject as well). The second one is more particularly related to the protection of volunteers included in biomedical and behavioural research: it is the law of December 20<sup>th</sup>, 1998 modified, said law Huriet-Sérusclat. Following the entry into force of the European directive of April 4<sup>th</sup>, 2001 relating to the European harmonization as regards clinical tests, this law is currently revised.

*Controlling body:* Within the framework of application of the Law Huriet-Serusclet, Consultative Committees of protection of person in biomedical research (CCPPRB) were created. They bring together doctors, pharmacists, nurses, dentists, psychologists and lawyers.

For any research, the investigator must consult the CCPPRB on which he depends. The committee gives its opinion on the conditions of validity of the research concerning protection of person, in particular the protection of the human subjects, their information before and during the duration of research and the methods of collection of their consent (the consent must be free, enlightened and express), the allowances possibly due, the general relevance of the project and the balance between the aims expected and the means implemented as well as the qualification of the investigators. The new text resulting from the transposition of the European directive in French right, envisages to replace the current system of declaration of research by a system of authorization.

*Ethical committee in the organization:* The Consultative Committee INRETS on biomedical and behavioural research (CCIERBC) was created in January 1994 to

apply the law Huriet-Sérusclat. Each protocol of research including human subjects is presented at the CCIERBC which determines if the research is or not in the area of application of the law. The distinction will be done:

- according to whether the subject is observed in the natural context of his (her) activity or he (she) is observed within the framework of a experimental protocol
- According to whether the aim of the research is to improve knowledge on human behaviour, or that its aim is to study the acceptability of a technological system
- According to the level of instrumentation of the subject

If the research is in the area of application of the law, the CDCIERBC can assist the researcher for the constitution of the report of presentation at the CCPPRB. The CCIERBC is in charge to propose to the Director of INRETS to be the promoter of the research.

The general principles of the law are followed even for the experiments which are not in the area of application of the law:

- a civil liability insurance is subscribed
- before any research, the researcher must collect the consent of the subject to participate to the experiment
- if personal data are computerized, an authorization must be requested from the National Commission of Informatics and Freedoms (CNIL)

If the research is in the area of application of the law, the subjects must have a medical examination before their participation to the experiment.

*Tools of controlling:* Control is before and not during or after the research. All the documents relating to the research must be kept during 10 years.

### **NTUA:**

*Ethical guideline:* The Greek association in which several such companies are members is the “ASSOCIATION OF Greek Market and Opinion Research Companies – SADEA ([www.sedea.gr](http://www.sedea.gr)). This association provides the guidelines for undertaking questionnaires, in accordance with the international ESOMAR (World Association of Opinion and Marketing Research Professionals). The guidelines

involve several issues such as the customer and respondents rights, and are in accordance with the Greek and international legislation.

*Legislation:* The Greek legislation that applies is 2472/97 involving the protection of personal data. As for the international legislation, projects should comply with the EU legislation (directive 95/45/EC of the EU Parliament and of the Council of 24.10.1995).

*Ethical controlling body:* The national body: Hellenic Data Protection authority ([www.dpa.gr](http://www.dpa.gr))

Additionally, SEDEA is also an ethical controlling body but only for surveys carried out by its member companies.

*Ethical committee in the organization:* No

*Tools of controlling:* Generally, the responsible body is the Hellenic Data Protection Authority. Questionnaire surveys involve a free market and no permission for their implementation is needed. However, in cases where the rights of human subjects are not respected the respondents may appeal to the Hellenic Data Protection Authority. The companies-members of SEDEA that undertake the research may be monitored by the controlling body SEDEA.

## **TNO:**

*Study:* All types of human factors study, including those on driving behaviour in lab, simulator, or instrumented vehicles.

*Ethical guideline:* Internal TNO "Standard Operating Procedure"

*National legislation:* Law on Medical Research which is applicable to human factors research

*Ethical controlling body:* National Committee which guards over regional Commissions; TNO is under a regional Commission (METC) that covers the relevant aspects of research primarily in a number of associated Academic Hospitals

*Ethical Committee in the organization:* TCPE; decides on protocols and gives its judgment in individual cases, and that assists the individual researcher in dealing with the METC

*Tools of controlling:* Internal standard procedures – informed consent form for subjects. These procedures should be taken into account in a Project Proposal. The Proposal is then taken to:

- 1) Head of Department. If there is anything non-standard, the Proposal is taken to:
- 2) The Director and the TCPE. They may then decide to take it to:
- 3) The METC (The Regional Committee). Treatment by the METC will take at least 3 months and cost 2-3 000 Euro.

**TRL:**

*Ethical guideline:* The British Psychological Society, Code of Conduct, Ethical Principles & Guidelines November 2000

*National legislation:* No

*Ethical controlling body:* Surrey Health Authority. There are many ethics committees belonging to Universities and Health Authorities.

*Ethical committee within the organization:* No

*Tools of controlling:* The procedures for dealing with participants involved in the study are collated in a study plan which is audited by the Quality auditor. The study plan includes information provided to the participant, consent forms, adverse event forms, instructions to participants, the method being applied and everything the participant will be required to do.

**VTI:**

*The title of the study:* “The effect of alcohol on driver behaviour”

*Ethical guideline:* No

Legislation: Since January 2004 the Swedish research ethics review system is regulated by law “Lag (2003:460) om etikprovning av forskning som avser människor”. This legislation takes into account both the European convention on human rights and biomedicine and the directive 2001/20EC 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.

*Ethical board:* <http://www.forskningsetikprovning.se/>

*Ethical committee within organization:* No

*Ethical committee in the organization:* No, but VTI has the ambition to have one, and it is in the phase of setting up one.

*Controlling of ethical rules:*

All research that involves sensitive personal information, physical incision, physical or psychical influence, or biological human samples as well as research that involves physical incision or biological samples from corpses have to be reviewed for ethics by the regional ethical board according to the law. The review is undertaken within six separate Regional ethical review boards involving at least two separate units for review. Each unit includes ten experienced scientists and five lay persons and is chaired by an experienced judge all elected by the government. The Central Ethical Review Board is responsible for supervision of the law except the supervision provided by the Medicinal Products Agency and the National Board of Health and Welfare and the Swedish Data Inspection Board. Appeals on decisions taken by a Regional ethical review board can be made to the Central Ethical Review Board.

**VTT:**

*The title of the study:* HASTE (Human machine interface and the safety of traffic in Europe) is to develop methodologies and guidelines for the assessment of IVIS. The study includes field experiments involving test drivers.

*Ethical guidelines:* rules for protection of individual data; not giving any kind of data to the third party, not reporting the data in reports.

Everyone who takes part of e.g. roadside interviews must have a “road safety certificate” (two days course)-

The driver of the instrumented vehicle is always responsible in case of an accident; however he or she is always informed before the test that he/she is responsible and his/her primary task is to drive safely and the secondary task (e.g. use of navigation device) must be interrupted if it is too dangerous to be conducted at a specific time.

**6 Conclusions**

The general standards and rules for the ethical conduct of research were described. For creating the ethical checklist of NoE HUMANIST we included ethical principles from *Helsinki Declaration, Belmont Report, Code of Conduct by EPFA, Ethical Code by APA, Human Research Ethics Committee in Australia and Science and Society in Europe*.

We also created an Informed Consent Template that has to be used as a guarantee of basic ethical conduct in research. We comprised the observations of our partners to these templates. The condition of producing the inventory of ethical laws was the questionnaire for each organization.

**After analysing the questionnaires we may say that:***Regarding professional ethical codex or guideline*

- In case of CDV, CUT, IfaDo, Factum, NTUA, and TRL the ethical rules are provided by the relevant professional associations (The Bohemia-Moravia Psychologists Association, The German Psychological Association, The Austrian Psychologists Association, The Association of Greek Market and Opinion Research Companies, The British Psychological Society).

- In case of CDV and TNO there are internal documents treating the ethical rules (Research Code at CDV, TNO “Standard Operating Procedure”).

*Regarding the national legislation on ethics research*

- In Austria, Belgium, England and Finland there is no national legislation on ethics.
- German laws include ethical rules at implicit level (the first articles of the Grundgesetz – Basic Law).
- In Netherlands there is a Law on Medical Research which is applicable to human factors research.
- in France there are two legislations concerning researches with human subjects; one is related to the protection of individuals with regard to the processing of personal data, the second one is related to the protection of volunteers included in biomedical and behavioural research.
- In Sweden there is the law on research ethics since January 2004.
- Greece and Czech Republic follow national laws on protection of personal data.

*Regarding the Ethical controlling body*

- In Belgium, England, France, Netherlands and Sweden the ethical controlling body depends of health authorities.
- In Germany, it is related to the psychologist association.
- At NTUA (Greece) the responsible body is Hellenic Data Protection Authority and SEDEA.

*Regarding the Ethical Committee in the institution*

- INRETS (France) has a CCIERBC (determines if researches are or not in the area of application of the national law of protection of volunteers included in biomedical and behavioural research and assists researchers for the constitution of their report for the regional commission CCPPRB).
- TNO (Netherlands) has a TCPE (decides on protocols and gives its judgment in individual cases, and assist the individual researcher in dealing with regional Commission METC).
- IfaDo (Germany) has its Ethical Committee of IfaDo.
- VTI (Sweden) is in phase of setting up one.

*Regarding the tools of controlling the ethical rules*

- CDV, TNO and TRL have a quality audit.
- Generally, the ethical controlling body gives an approval before the beginning of experiment and there is not a control during and after the research.

Every addressed country has its own way of following ethical rules in research involving human subjects. We assume that the national laws provide a basic guarantee for ethical conduct, but the internal codes and existence of ethical committees in organizations or universal codes outside the institution serve also as a very important tool for following ethics of our work.

## 7 References

Anzenbacher, A.: Úvod do etiky. Akademia, Praha 2001.

Code of conduct by EFPA – European Federation of Psychologists' Associations

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

Mates, P.: Ochrana osobních dat v profesionálním psychologickém postupu. Západočeská univerzita, Plzeň 2004.

The Belmont Report – Ethical Principles and Guidelines for the Protection of Human Subjects of Research

World Medical Association Declaration of Helsinki

Universal Declaration of Human Rights

[http://europa.eu.int/comm/research/science-society/ethic/rules\\_en.html](http://europa.eu.int/comm/research/science-society/ethic/rules_en.html)

[http://www.nhmrc.gov.au/hrecbook/02\\_ethics/13.htm](http://www.nhmrc.gov.au/hrecbook/02_ethics/13.htm)

<http://www.apa.org/ethics/code2002.html>

[www.onlineethics.org/codes/NSPEcode.html](http://www.onlineethics.org/codes/NSPEcode.html)

**ANNEX 1: Inform Consent Template**

## Information Society Technologies (IST)

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### HUMAN centred design for Information Society Technologies

<b>TF 2 (Deliverable 2.1.) Informed Consent Template</b>
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**Project acronym:** HUMANIST

**Project full title:** HUMAN centred design for Information Society Technologies

**Proposal/Contract no.:** 507420

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**Summary:** Template for providing informed consent to persons taking part in studies within HUMANIST

**Status:** preliminary draft

**Contact:** Iva Hanzlíková, CDV

**TF 2 leader:** TNO

**Issue date: July 9, 2004**

### HUMANIST Informed Consent Template

The aim of this template is to guarantee the basic level of ethics in the research by making sure if the researchers and the subject in research understand the objectives of the study and are informed about its possible risks and other important things that are preconditions of the ethical conduct in research.

A. *This part would be filled **by the researcher** for each study.*

a) Title of the study:

.....  
.....  
.....

b) Names of the researchers responsible for this study:

.....  
.....  
.....

c) The purpose of the study:

.....  
.....  
.....

d) Who will be involved in this study (specify the group of participants):

.....  
.....  
.....

Subject's name: .....

Date: .....

B. This part will be filled by the research subject of each study.

Subject's name

.....

I was informed about the organization that is doing the research and about the aim of the research.

YES

NO

I was informed about the possible risks connected to the study – possible advantages and disadvantages and risks verbally or in a written form by the test leader.

*Please circle the acceptable alternative.*

YES

NO

I was informed about the duration of the experiment.

YES

NO

My questions related to the study have been answered in a sufficient way and I have understood all the information.

YES

NO

I had enough time for my decision.

YES

NO

Mr/Ms/Miss.....informed me about the study and its possible risks.

I understand that I am free to withdraw from the study anytime, without having to state a reason and without penalty.

YES

NO

I fully agree to be involved in this study.

YES

NO

I was informed that the confidentiality of my personal data is guaranteed and my personal data will be anonymised.

YES

NO

If case of doubts and uncertainty I will contact Mr/Ms/Miss

.....

Name\* (in block letters):

.....

Date and signature:

.....

THANK YOU VERY MUCH FOR YOUR CO-OPERATION.

**ANNEX 2: Questionnaire on ethical rules applying during studies with human subjects**

# Information Society Technologies (IST)



## **HUMAN centred design for Information Society Technologies**

<b>TF 2 (Deliverable 2.1.) Inventory of ethical rules within HUMANIST -Questionnaire</b>
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**Project acronym:** HUMANIST

**Project full title:** HUMAN centred design for Information Society Technologies

**Proposal/Contract no.:** 507420

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**Summary:** Questionnaire for the identification of ethical rules applying during behavioral studies within project HUMANIST

**Status:** Preliminary draft

**Contact:** Iva Hanzlíková, CDV

**TF 2 leader:** TNO

**Issue date: July 9, 2004**

**QUESTIONNAIRE ON ETHICAL RULES APPLYING DURING STUDIES WITH HUMAN SUBJECTS**

(all HUMANIST partners have to fill out)

1. The title and brief description of the study:

.....  
.....  
.....

2. Does the study involve humans?

*(Please circle the acceptable alternative)*

YES

If NO, no further questions are requested.

2. If yes, do you follow any ethical guidelines for the research?

YES

NO

Please indicate the name and character of the guideline, and the organization providing it.

.....  
.....  
.....  
.....

3. Is there an international or national legislation, which you must follow when doing research with human subjects?

YES

NO

If yes, please provide the details.

.....  
.....  
.....  
.....

4. Is there an ethical controlling body in your country?

YES

NO

If yes, please provide the details.

.....  
.....  
.....

5. Is there an ethical committee within your organization?

YES

NO

If yes, please provide the details.

.....  
.....  
.....

6. How are the ethical rules within your studies involving human subjects controlled?

.....  
.....  
.....

THANK YOU VERY MUCH FOR YOUR CO-OPERATION.