Competitiveness and Innovation Framework Programme (CIP)

INDEPENDENT

ICT Enabled Service Integration for Independent Living

D9.5 Ethics and Data Protection Framework

WP9: Management

Version control

Version	Date	Changes made	by	Sent to
0.1	25/05/2010	Draft	Empirica	MKC
0.2	15/06/2010	Revised draft	MKC	All
0.3	23/07/2010	Final draft	MKC	Peer review
0.4	13/08/2010	Revised final draft	Empirica	MKC
0.5	17/09/2010	Revised final draft	MKC	Empirica
0.6	25/10/2010	Revised final draft	MKC	Empirica
1.0	12/11/2010	Final	Empirica	CEC

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1. Introduction

The INDEPENDENT project has the aim to define, deliver and pilot a multiplatform digital infrastructure supporting coordinated cross-sector delivery of sufficient and timely support, thereby effectively preventing or at least slowing the way many older people today inexorably slip towards the edges of safe independent living. By adopting a coherent approach towards ethics and data protection across all pilot sites involved, the project sets out to provide a solid basis for ethical service innovation in the independent living domain across different jurisdictions, thereby reinforcing basic European values and the European social model.

This document presents the INDEPENDENT Ethics and Data Protection Framework (D9.5). It aims at providing operationally useful guidance to the project consortium on how appropriate safeguards are to be achieved against relevant ethical and data protection issues that are of relevance to this project. There has however not yet been any overall compilation and analysis of ethical issues as they apply in this field. Appropriate guidance materials that could be used for the purposes of the project is thus not available "off the shelf", despite the fact that ethical issues are frequently alluded to in the policy and practice discourses on ICT-enabled independent living solutions. There has been some work on defining the ethics that can guide research in the area and some on the ethics that can guide practitioners but such efforts have generally been partial. The ethics and data protection framework adopted for the purposes of the INDEPENDENT project therefore relies on various value frameworks potentially relevant to the project, including both binding ones such as legislation and non-binding ones such as voluntary codes of conduct.

An important aspect deserving attention here is that ethical considerations are not always 'black-or-white' and that dilemmas can often arise. In addition, even for a given group, such as older persons offered technology to support independent living, the issue of what is good may depend on the specifics of each individual circumstance. Therefore, whilst universal ethical principles have value, their interpretation and application in any specific context is often not straightforward. Thus 'cookbook' type guidelines that can be applied throughout the various stages of the project are difficult to define in advance.

The current document therefore aims at not just presenting 'how to do' guidance but also the wider picture against which the project's ethics and data protection framework has been developed. It is hoped that that this will enable appropriate interpretation and application of ethical principles throughout the project's life cycle. The remainder of this document comprises of three core parts which are:

a. The following Chapter 2 identifies ethical and data protection requirements deserving attention throughout the project's life cycle, and provides operational guidance on how the project team may best go about meeting these respectively.

b. Chapter 3 describes how ethics and data protection management will be implemented throughout the project's life cycle.

c. Finally, various materials are annexed to the main report. This includes generic consent forms to be adapted to the various activities within which individuals are to be involved throughout the project's life cycle (Annex 1). Also the various value frameworks – both binding and non-binding ones - that have informed the development of the more operational guidance are presented (Annex II). Last but not least, a compilation of currently available information on how to achieve age-friendly and accessible technology design is provided (Annex III)

2. The INDEPENDENT ethics and data protection framework

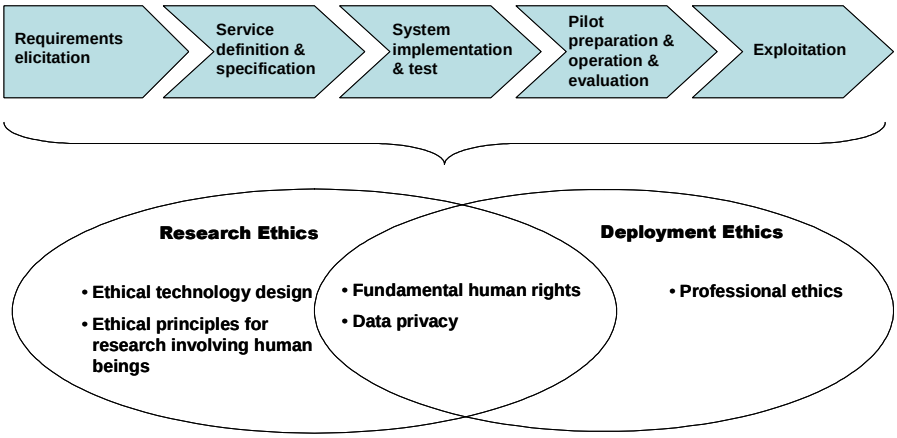
2.1 Conceptual approach

In general, ethics have relevance to all human activities and endeavours. When it comes to ICT-enabled forms of support directed towards older people, the combination of the inherent properties of ICT applications with relevance to this field (e.g. monitoring and automation) and the vulnerabilities and needs of older people (e.g. frailty, diminished capacity to protect one's own interests, and risk of social isolation) has however led to a considerable amount of ethical concern and attention in particular.[1] Ethics here are about what the involved stakeholders 'should' do as the right thing, for the good of older people and those who may be collaterally affected (such as family members) as well as for the common good more generally.

There is a potentially very wide ranging set of issues relating to ethics and data protection which arise along the overall project's life cycle, being a typical project funded under the EU's CIP programme. At a generic level two main ethical perspectives can be discerned which deserve attention in the framework of the INDEPENDENT project. On the one hand, a range of ethical issues arise when it comes to ensuring that piloting and evaluation activities to be conducted with in the project do indeed follow commonly accepted ethical practice. Here, guidance can be obtained from existing discourses on ethics in research fields that have relevance to the project, such medical research, social research and RTD. On the other hand, ethical issues arising in relation to the deployment of mainstream support services deserve attention as well, e.g. when it comes to preparing and planning service rollout beyond the immediate project duration. Also, there are ethical concerns that cut across both the research and deployment perspectives, e.g. when it comes to engaging with individuals independent whether these are test users or mainstream service clients. As summarised in the graph below, the INDEPENDENT ethics and data protection framework address all three areas of ethical concern. This is discussed in the following subsections.

[1] The EGE (European Group on Ethics in Science and New Technologies) opinion on Ethical Issues of Healthcare in the Information Society (1999; Opinion 13) reflects on such concerns and lists the following applying to the area of health care, but which are equally relevant today for the application of ICTs in support of independent living more generally: the pervasiveness of a technology which many people do not understand; the lack of transparency that may be brought to the work of healthcare professionals and its effects on the doctor/patient relationship; the difficulty in respecting privacy and confidentiality when third parties may have a strong interest in getting access to electronically recorded and stored personal health data; the difficulty in ensuring the security of shared personal health data and the lack of adequate infrastructure in certain regions and the absence of computer literacy in certain sections of the population which may reinforce existing inequalities.

Exhibit 1 Ethical Perspectives of Relevance to INDEPENDENT



Ethical technology design

One set of ethical issues are related directly to the technologies and their design, in particular, whether they are compatible with changes in the physical, sensory and cognitive capacities associated with age. Lack of age-friendliness of ICT design is an important barrier to equality of access and opportunity for older people, and thus has been discussed as an important ethical concern. This shares much in common with the more general principle of eAccessibility, which includes accessibility for people with disabilities, whether young or old. The prevalence of disability increases significantly amongst the older age groups and, even when not classified as having a disability, many older people experience age-related changes that require attention in the design of ICT's. There is currently quite a lot of guidance material to help ensure that ICT products and services are designed to meet the needs of particular groups. Most emphasis has been placed on the needs linked to specific disabilities but much less attention has been given to more general age-related needs as well.

Operational issues

INDEPENDENT service addresses older people in need of support and professional and non-professional carers as well. User friendly design in general and age friendly design in particular is to be achieved as appropriate, thereby taking account of the fact that the project relies on the utilisation of existing technologies rather than technologies hat are newly to be developed. This is to be achieved by concrete means including user consultations - as enshrined in the project's work plan at an early stage (e.g. requirements elicitation and service definition) - and a review of existing guidance materials when it comes to design related user requirements as (see D1.1)

Ethical principles for research involving human beings

The so called Belmont Report (1979) has for the first time made a distinction in the domain of medical ethics between 'research' and 'practice'. For the most part, the term 'practice' refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioural practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalised knowledge (expressed, for example, in theories, principles, and statements of relationships).

Being a pilot project cutting across established domain boundaries, a challenging issue for INDEPENDENT concerns what is (or should) be considered to fall within the 'medical' and 'social' domains, respectively, when it comes to ethics and data protection. This is important because ethical perspectives, regulations and practices vary considerably within the different domains. In general, there has tended to be a lot more visibility and regulation/codification in the medical field than the social field, even if the former has in practice been a lot more arbitrary and less consistent than might be expected. For instance almost all European countries have by now put regulative procedures in place concerning ethics approval of clinical research involving human beings. But even within the 'medical' domain, there is blurring between what is a 'clinical' intervention as opposed to more collateral interventions linked to healthcare needs in a wider sense.[2] Also, ethics approval practices concerning medical research vary widely across countries and in the intervention and practices in the social care domain which is typically much more loosely conceptualised and regulated.

Although INDEPENDENT is not a classical research project in the sense of the Belmont Report, the general principles set out in the report can be analogously applied to those activities within the project that involve more research type working techniques, e.g. user focus groups and field evaluation of pilot services.

Operational issues

The Belmont Report is still relevant today and its formulation of the basic principles for the domain of involving human subjects in research can be used as a practical starting point for considering what kind of dimensions of research ethics are important for INDEPENDENT. These principles include respect for persons; beneficence (do no harm, maximize possible benefits) and justice. Also, national regulation concerning ethical approval of research including human beings will be adhered to as far as these apply to piloting activities to be conducted within the project.

Fundamental human rights

The concept of human rights refers to basic rights and freedoms to which all humans are entitled. It has been formalised through the Universal Declaration of Human Rights adopted by the General Assembly of the United Nations in 1948. In the European Union, the concept of fundamental rights provides a basic value framework to guide ethics related policy development and implementation at the European policy level as well as in the Member States. Fundamental rights need to be respected at all stages of the projects life cycle, and supported by the service development/piloting techniques/practices to be applied within the project respectively (e.g. in relation to initial requirement elicitation, prototype testing, field testing). Beyond this, there is a risk – at least potentially - that the fundamental interest of the individual may be violated by diverging interests of other stake holders that may be involved in INDEPENDENT service development and/or deployment, e.g. economic ones.

Operational issues

The question "what is good for the individual" is to be adopted as a general principle guiding the project at the operational level when it comes to ensuring that fundamental rights are respected throughout it's life cycle. To this end, commonly accepted ethical principles including respect for people, beneficence and justice will be adhered to when it comes to involving

[2] Hemminki, E. (2005): "Research ethics committees: agents of research policy?", Health Res Policy Syst. 3: 6.

individuals (e.g. older end users, professional users, researchers) in project activities.. Where situations arise involving potentially conflicting rights (as in, for example, the case of people with dementia and their carers), every effort will be made to facilitate all parties to participate in the decision-making process on an equal basis.

Professional ethics

Professional ethics enshrined in codes of practice have up to now mainly emerged in the healthcare domain. Here, the main focus historically has been on the doctor-patient relationship, that is, on the duty of the doctor towards the presenting patient. Principles that have commonly been applied in medical ethics for many years include autonomy (the patient has the right to refuse or choose their treatment), beneficence (the practitioner should act in the best interest of the patient), non-malfeasance (do no harm), justice (fairness and equality in who gets treatment), dignity (the patient and the person treating the patient have the right to dignity), and truthfulness and honesty (including informed consent). In more recent times, other professions such as community nurses and paramedical professions, e.g. occupational therapists, also have an important role in assessing needs, making referrals and implementing ICT-based solutions and services for independent living and homecare, and codes of ethics in these fields are thus also of relevance to INDEPENDENT as well.

Operational issues

INDEPENDENT aims to piloting ICT-enabled cross-sectoral service delivery to older people in need of care and support. This concerns both medical professions and non-medical professions. Although there is no overarching ethical framework that could be applied by INDEPENDENT in relation to the various professions that will be involved in piloting activities, the project will rely upon any professional ethics codes and guidelines that do potentially exist in the six pilot sites.

Data Privacy

In modern societies, the interest in the right of privacy particularly increased with the advent of information technology. Today, all European Member States have put some kind of data protection legislation in place which sets out specific rules covering the handling of electronic data. This may include a general law that governs the collection, use and dissemination of personal information by both the public and private sectors. It may also include sectoral laws governing data protection in relation to specific domains such as health care, employment and so on. In general, data protection provisions tend to describe personal information as data that are afforded protection at every step from collection to storage and dissemination. Basic principles that have frequently been enshrined into legislation include that personal data are obtained fairly (e.g. not violating informational self-determination) and lawfully (e.g. consent-based); that they are used only for the original specified purpose; that they are adequate, relevant and not excessive to purpose; that they are accurate and up to date as well as accessible to the subject and that they are kept secure and destroyed after its purpose is completed.

Operational issues

As INDEPENDENT aims at cross-sectoral service delivery, different legislative/regulative data protection frameworks may deserve attention. A review of national data protection regulation/legislation will be conducted across the six pilot sites countries and project activities at each pilot site will

comply with these respectively. Moreover, general data protection guidelines have been prepared by the project to help pilot sites to comply with European and national legislation.

2.2 INDEPENDENT Project guidelines

1.1.1 General principles

In the following, more operational guidance is provided on how the ethical perspectives discussed above will be adhered to within the INDEPENDENT project. This starts with a summary given in the table below, followed by more specific guidelines to be adopted for the purposes of the project. In the following subsections, more specific guidance is provided on how compliance with the ethics and data protection requirements summarised in the table above is to be achieved within the project.

Theme	Key issues	Operational guidance
Ethical technology design	Accessible and age-friendly design is to be achieved to the greatest extent possible, thereby taking account of the fact that the project relies on the utilisation of existing technologies rather than technologies that are newly designed/developed.	Accessibility/usability issues are to be considered in all project activities concerning requirements capture (e.g. WP1) and service/system design (WP 2,3,4) to the extent possible at each stage of the project. A compilation of existing guidance material on accessible and age-friendly technology design is to be generated and used as appropriate (see Annex 3)
Ethical research practices	The basic principles for involving human subjects in medical research (Belmond Report) are to be adhered to in relation to all project activities involving end users, namely respect for persons; beneficence and justice.	Applications of the general principles to the conduct of the project's work plan includes: • informed consent (see further below), including conditions for information provision (comprehension, voluntariness), • assessment of risks and benefits (recognizing the fact that risks and benefits of piloting activities may affect individual subjects, families of the individual subjects) and • selection of subjects (fair procedures and outcomes in the selection of subjects participating in piloting activities) As far as required by national regulation/legislation, the pilot sites will seek ethical approval of the planned piloting activities from relevant ethics committees.
Fundamental human rights	Fundamental human rights need to be respected at all stages of the projects life cycle, and supported by the piloting techniques/practices to be applied within the project respectively	The question "what is good for the individual" is to be adopted as a general principle guiding the project at the operational level when it comes to ensuring that fundamental rights are respected throughout it's life cycle. To this end, commonly accepted ethical principles including respect for persons, beneficence and justice will be adhered to when it comes to involving individuals (e.g. older

		end users, professional users, researchers) in project activities. Where situations arise involving potentially conflicting rights (as in, for example, the case of people with dementia and their carers), every effort will be made to facilitate all parties to participate in the decision-making process on an equal basis.
Professional ethics	Professional ethics enshrined in codes of practice may have emerged in relations to different professions potentially involved in INDEPENDENT services	A compilation of ethical codes of practice as they exist in the pilot site countries is to be compiled (see 2.3) Pilot sites are to adhere to existing ethics codes as far as they have relevance to the activities they conduct in the framework of INDEPENDENT (e.g. piloting activities)
Data protection	Data privacy is to be guaranteed during all stages of the project according to European and national standards.	A review of national data protection regulation/legislation will be conducted across the six pilot sites countries and project activities at each pilot site will comply with these respectively (see p. 12). Pilot sites are to adhere to general data protection guidelines prepared by the project in elation to piloting/evaluation activities (see below)

1.1.2 Specific guidance on beneficence and non-malfeasance

The following principles should be considered in relation to project activities involving end users:

- The evaluation/piloting of INDEPENDENT services should be scientifically sound and the purpose should be to contribute to knowledge;
- The evaluation/piloting of INDEPENDENT services should be undertaken and supervised by those who are appropriately qualified and experienced;
- The importance of the objective should be in proportion to the inherent risk to the subject;
- The evaluation/piloting of INDEPENDENT services should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others;
- Evaluation/piloting of INDEPENDENT services should not be undertaken where the hazards involved are not believed to be predictable;
- Adequate facilities and procedures should be in place to deal with any potential hazards.

1.1.3 Specific guidance on informed consent

The following principles should be considered in relation to achieving informed consent from users participating in the project:

- Each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the research and any discomfort it may entail;
- Any documentation given to potential participants should be comprehensible and there should be an opportunity for them to raise any issues of concern;

- Consent should be required in writing and records of consent should be maintained;
- Potential participants must be informed that they are free to withdraw consent to participation at any time;
- There should be a procedure for making complaints and participants should be made aware of this;
- All participants should be volunteers. Considerable care should be taken where consent is sought from those in a dependent position and it should be made clear that refusal to participate will not lead to any adverse consequences. For example, clients of care service providers must be assured that any decision not to participate will not prejudice or affect in any way the services they currently receive;
- Any inducement offered to participants should be declared and should be in accordance with appropriate guidelines;
- Consent must be obtained from a legal guardian in the case of minors or any others who do not have the legal competence to give informed consent.

Some project participants may be unable to consent. In such a case, other safeguards need to be in place. There may be many reasons why an individual may not be able to provide consent. If this happens the assessor should consider the following.

- Is there a legitimate need to use Assisted Living Technology due to the level of risk?
- Is this the least restrictive intervention possible at this time?
- Are the wishes of the adult being considered in the broader sense e.g. has the person previously expressed a wish to stay at home but cannot do so safely without this equipment.
- Whenever possible the consent of the person should be sought.
- Where possible, the element of control should be with the person.

All decisions made on behalf of the adult with impaired capacity must:

- Benefit the adult.
- Take account of the adult's wishes, if these can be ascertained.
- Take accounts of the views of relevant others, as far as it is reasonable and practicable to do so.
- Restrict the adult's freedom as little as possible while still achieving the desired benefit.
- Encourage the adult to use existing skills or develop new skills.

1.1.4 Specific guidance on data privacy

All pilot sites are to follow a common data protection protocol as follows:

- Only research/other personnel within the participating organisations should be granted access to data.
- All data must be made to be anonymous.
- Only summaries of the quantitative data should be available. Excerpts (e.g. quotations) from the qualitative data may be included in any results section of any report or academic publication.

- Participants must be treated with respect at all times and their anonymity protected. Pseudonyms or codes must be used to replace any identifiers within the data. Every quotation must be made anonymous using e.g. a pseudonym.
- Quotations from interviews may included in reports and publications arising from the research
- If participants wish to talk to interviewers about sensitive issues which they wish to remain confidential, interviewers must not use what they hear in this context in any part of the research.
- Personal paper based details of participants must be kept in locked filing cabinets.
- Transcription must be made anonymous
- Data (transcripts, audio and video recordings) will be kept in locked cabinets.
- Interview/focus group recording, transcription and analysis: It is essential that data is made to appear anonymous. Reference numbers must be used to identify tapes, transcriptions and data analyses.
- All information that could be used to identify the participant (names, address, and personal details) must be separated from the data permanently before analysis.
- Reports must only contain selected passages of interview transcripts and must not publish transcripts in their entirety. All quotations will be made anonymous.
- Video recordings of persons will also be separated from identifiers permanently and will not be used publicly.

Beyond this generic protocol, each pilot site must comply with national data protection legislation/regulation.

2.3 National legislation & regulation

The first phase of the project included an investigation of legislation and regulation, both on the national and regional governance levels, which is likely to have a bearing on the design and implementation of the pilot scenarios described in the previous chapter.

In view of the immature nature of the INDEPENDENT service domain as a self-standing field of ICT implementation, it may not come as a surprise that no dedicated legal and regulatory framework has emerged in this domain as of today. Nevertheless, a number of policy/regulatory fields have relevance for ICT-enabled services directed towards the well being and independent living of older people. Together they provide a rather dispersed and patchy frame of reference for legal and regulatory guidance for the various actors involved, in particular when it comes to developing services that cut across existing domain boundaries such as social care and medical care. In general, various fields of legislation/regulation deserve attention here, wherein the situation varies from country to country, i.e. pilot site to pilot site:

- Data protection and data privacy
- Liability
- Licensing and quality control
- Patient rights
- Ethics approval

- Sectoral / organizational codes of practices, guidelines and quality standards

Exhibit 2 provides an overview of individual pieces of legislation/regulation that have been identified in relation to these legislative/regulative fields at the European and national governance levels. These are then described in more detail in the subsequent sections.

Exhibit 2: Overview legal and regulatory aspects of potential relevance to the service scenarios to be piloted

Legislative/regulatory dimension	Governance level	Legislation / regulation of potential relevance
Data protection & data privacy	EU	- Directive 95/46/EC (Data Protection Directive): on the protection of individuals with the regard to the processing of personal data and the free movement of such data . - Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector.
	Geldrop(NL)	- Law on protection of personal data (WBP: Wet Bescherming Persoonsgegevens) - Legislation on the use of the Citizen Service Number (BSN) in healthcare - Electronic health record (EHR) - The Medical Treatment Act (Wet Behandelingsovereenkomst (WGBO)
	Trikala(GR)	- The Hellenic Data Protection Authority (HDPA)
	Malaga(ES)	- Personal Data Protection Law(1999) ORGANIC LAW 15/1999 of 13 December on the Protection of Personal Data(Organic law 15/99). - Safety of medical information 41/2002 - Royal Decree 994/1999
	Hull(UK), Milton Keynes(UK)	- UK Data Protection Act 1998 - Health and Social Care Act 2001
	Dublin(IE)	- Data Protection Amendment ACT 2003
Liability	EU	- Directive 2000/31/EC (known as the e-commerce directive) - Directive 85/374/EEC Product Liability - COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices - Diagnostic in vitro devices (DIR 98/79) EC
	Trikala(GR)	- Medical Devices, Greek Law: ΔΥ7/οικ2480/ΦΕΚ679Β'/13-9-94 (to be replaced on 21-3-2010 by : ΔΥ8δ/Γ.Π.οικ130648/ΦΕΚ 2198Β/02-10-2009) - Diagnostic in vitro devices, Greek law : ΔΥ8δ/οικ3607/892/ΦΕΚ 1060Β'/10-8-01)
Licensing & quality control	EU	- Directive 2005/36/EC on the recognition of professional qualifications
	Gelderop(NL)	- Law Occupations in Individual Healtcare - Wet Beroepen in de Individuele Gezondheidszorg (BIG) - Quality of Healthcare institutions act (Kwalitetswet Zorginstellingen) and Medical treatment act (Wet Geneeskundige Behandelovereenkomst)
	Malaga(ES)	- Health Andalusia Region Law (1998 May)
	Hull(UK), Milton Keynes(UK)	- Health and Social Care Act 2001
Patient Rights	EU	- -The European Charter of Fundamental Human Rights - -The European Convention on Human Rights and Biomedicine

Legislative/regulatory dimension	Governance level	Legislation / regulation of potential relevance
	Malaga(ES)	- Equal opportunity, no discrimination and universal accessibility of handicapped people: Independent living / accessibility 51/2003 - Health Andalusia Region Law (1998 May) - Vital Individual Wish Law (2003 October) - Decree (2003 may) - Decree (1996 may) - Palliative Care Integral Plan (2008) - Dependency Situation Integral Plan(2008)
	Hull(UK), Milton Keynes(UK)	- Mental Capacity Act 2005 - Fair Access to Care Services (FACS)
Ethics approval	EU	- Directive 2001/20/EC The Clinical Trials Directive
	Geldrop(NL)	- The Medical Research Involving Human Subjects Act (WMO)
	Malaga(ES)	- Public Health Act 14/1986 - A network of Research Ethics Committees (CEICs) has been established according to the Real Decreto 223/2004
	Hull(UK), Milton Keynes(UK)	- National Research Ethics Service (NHS) - United Kingdom Ethics Committee Authority (UKECA)
	Dublin(IE)	- The Ethics Committees Supervisory Body (ECSB)
Sectoral/ organizational codes of practice and guidelines	Hull(UK)	- Government Connect initiative - Clinical governance policies of both the community and acute NHS trusts - Nursing and Midwifery Council Code - Final evaluation report from the 3 pilot sites for the Whole Systems Demonstrator Action Network - The current PASA system for procuring Telehealth and Telecare equipment - Strategic Health Authority in Yorkshire and the Humber - Policy (DH (2008) 1 entitled 'Transforming Adult Social Care'
	Milton Keynes(UK)	- Social Care Services - UK Local Authority best practice and policy - Social Care Service provision
	Dublin(IE)	- IS0 9001 - Telecare Service Association (TSA) standard

1.1.5 Data protection

Legislation and regulation concerning the protection of personal data is of central relevance for the services to be developed and piloted within the project. In general, the recognition of privacy is deeply rooted in the history of modern societies and interest in the right of privacy particularly increased with the advent of information technology. Today, all European Member States have put some kind of data protection legislation in place which sets out specific rules covering the handling of electronic data. This may include a general law that governs the collection, use and dissemination of personal information by both the public and private sectors. It may also include sectoral laws governing data protection in relation to specific domains such as health care, social care and so on.

In general, data protection provisions tend to describe personal information as data that are afforded protection at every step from collection to storage and dissemination. Basic principles

that have frequently been enshrined into legislation include that personal data are obtained fairly (e.g. not violating informational self-determination) and lawfully (e.g. consent-based); that they are used only for the original specified purpose; that they are adequate, relevant and not excessive to purpose; that they are accurate and up to date as well as accessible to the subject and that they are kept secure and destroyed after its purpose is completed.

Regulatory / legislative framework at the European governance level

The European Data Protection Directive

The EU Data Protection Directive 95/46/EC (DPD) complement fundamental rights in the area of personal data protection. Personal data are defined as "any information relating to an identified or identifiable natural person ("data subject"); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity;" (art. 2 a).

By adopting the Data Protection Directive of 1995 (Directive 95/46/EC) the European Union set legally binding rules for the protection of individuals with regard to the processing of personal data. Through this regulation basic principles for processing personal data have been stipulated which have to be followed in all Member States:

- **Transparency:** The data subject has the right to be informed when his or her personal data are being processed. The controller must provide his or her name and address, the purpose of processing, the recipients of the data and all other information required to ensure the processing is fair. (art. 10 and 11). Data may be processed only under the following circumstances (art. 7):
    - when the data subject has given his or her consent
    - when the processing is necessary for the performance of or the entering into a contract
    - when processing is necessary for compliance with a legal obligation
    - when processing is necessary in order to protect the vital interests of the data subject
    - when processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data are disclosed
    - when processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject

  The data subject has the right to access all data processed about him or her. The data subject even has the right to demand the rectification, deletion or blocking of data that is incomplete, inaccurate or isn't being processed in compliance with the data protection rules. (art. 12)

- **Legitimate purpose:** Personal data can only be processed for specified explicit and legitimate purposes and may not be processed further in a way incompatible with those purposes. (art. 6 b)
- **Proportionality:** Personal data may be processed only insofar as it is adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed. The data must be accurate and, where necessary, kept up to date; every

reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified; The data should not be kept in a form which permits identification of data subjects for longer than is necessary for the purposes for which the data were collected or for which they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use. (art. 6) When sensitive personal data (including religious beliefs, political opinions, health, sexual orientation, race, membership of past organisations) are being processed, extra restrictions apply. (art. 8)

Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector.

The Data Protection Directive of 1995 was complemented in 2002 (Directive 2002/58/EC), with particular respect to the processing of personal data in the electronic communication sector. It applies to all matters which are not specifically covered by the 1995 Directive. The main provision made in the 2002 Directive concerns the duty of electronic communication providers is to ensure security of services (art. 4). This obligation also includes the duty to inform subscribers whenever there is a particular risk, such as a virus or other malware attack (art. 4.2). Another provision concerns maintenance of confidentiality of information. Here the addressees are Member States, who should prohibit listening, tapping, storage or other kinds of interception or surveillance of communication and related traffic unless the users have given their consent or specific conditions (art. 15.1) have been fulfilled.

National level regulation/legislation potentially relevant to the pilot site in the Netherlands

Law on protection of personal data (Wet Bescherming Persoonsgegevens)

This law provides rules and privacy criteria for healthcare providers to keep and process personal data. It exists since 2001, when it replaced the old law of personal registrations (WPR). WBP protects the person of whom the data concerns and the duties of the parties who use the data. According to WBP personal data is data that contains information relating to a real person and that person is identifiable. The legislation actually applies to 'paper' records, but also offers an adequate legislative framework for a digital record. The law further states that the usage of data should be based on an informed consent of the person and that it should be given by free will. In article 25 a code of conduct for the use of personal data in research is offered. The purpose is to support Dutch universities that conduct scientific research. (VSNU, 2005).

Legislation on the use of the Citizen Service Number (BSN) in healthcare

This legislation regulates the use of a national identification number in the healthcare sector in a way that enables medical data to be uniquely linked to one patient across multiple information systems. The law is currently being discussed in the Dutch parliament. If it will be accepted it means that healthcare workers and organizations will be obliged to enter the BSN in their records, confirm that it belongs to the person in question, and to use it in the electronic exchange of data.

Electronic health record (EHR)

Recently, this legislation has been subject to much attention and discussion in the Netherlands. The aim of the legislation is to address issues, such as security, data quality, authorization and access (by the patient amongst others), standardization and the actual use of the EHR. According to the Ministry of Health, Welfare and Sport the EHR should regulate at least:

- (mandatory) connection of healthcare providers with the National Switch Point;
- electronic availability of patient data via the National Switch Point;
- secure and reliable information exchange via the National Switch Point.

The National Switch Point is the traffic control tower behind the secure electronic exchange of up-to-date patient data throughout the Netherlands. It was established on January 31 2006 to promote safe and fast communication between care organizations across the country (Ministry of Health, Welfare and Sport, 2006).

The Medical Treatment Act (Wet Behandelingsovereenkomst (WGBO))

This law regulates which parties are authorized to access the Electronic Health Record (HER). The patient has the right to access his/her own EHR. The health providers (e.g., GP, specialist, pharmacy) who are involved in the patient's treatment have access to the patient's EHR. There are some authorization exceptions. These persons can access the EHR of another person: curator, mentor, parents of children under 12 years old, parents of children between 12-16 years old (together with the child), and a representative. There are some additional rules:

- Healthcare professionals can access the EHR when presently involved in the patient's treatment and only when it is needed for the treatment.
- Healthcare providers always need consent to access the EHR.
- Access to the EHR is limited to specific categories of health care professionals. GP's, pharmacies, and specialists can access the data about the medication provided by the pharmacists. GP's on GP posts can request a summary of the EHR from the patient's GP. Other healthcare providers (physiotherapists, psychologists, company doctors, and insurers) cannot view the medical data.
- The patient can prevent access to his/her EHR data.
- The clinician needs a special card (UZI-pas) to access the EHR.
- The Medical Treatment Act states that a patient cannot make changes in the EHR. However, the clinician can edit, add, hide and delete medical data from the EHR on the patient's request.

National level regulation/legislation potentially relevant to the pilot site in Greece

The Hellenic Data Protection Authority (HDPA)

The Hellenic Data Protection Authority (HDPA) is the responsible authority for the protection of personal data. It grants permissions to the various legal entities to deal with the personal data of Greek citizens in accordance with the following laws: Law 2472/1997, Protection of Individuals with regard to the Processing of Personal Data. Law 3471/2006, Protection of personal data and privacy in the electronic telecommunications sector and amendment of law 2472/1997.

The mission of the Hellenic Data Protection Authority is to supervise the implementation of Act

2472/97, Article 15 of which establishes the Authority. Article 19(1) sets out the powers of the authority. Among the powers are the following: 1) 19(1)(a): It shall issue instructions for the purpose of a uniform application of the rules pertaining to the protection of individuals against the processing of personal data. 2)19(1)(b): It shall call on and assist trade unions and other associations of legal and natural persons keeping personal data files in the preparation of codes of conduct for the more effective protection of the right to privacy and in general the rights and fundamental liberties of all natural persons active in their field. 3) 19(1)(c): It shall address recommendations and instructions to Controllers or to their representatives, if any, and shall publicise them, at its discretion. It shall deliver opinions with respect to any rules relating to the processing and protection of personal data.

National level regulation/legislation potentially relevant to the pilot site in Spain

Personal Data Protection Law(1999) ORGANIC LAW 15/1999 of 13 December on the Protection of Personal Data(Organic law 15/99)

The protection of personal data is enshrined in the Spanish Constitution through Article 18.4 which requires that the law shall restrict the use of informatics in order to protect the honour and the personal and family privacy of Spanish citizens, as well as the full exercise of their rights. This provision was further developed by Organic Law 5/1992 on the Regulation of the Automatic Processing of Personal Data, as amended by Organic Law 15/1999 on the Protection of Personal Data. This law corresponds to European legislation. Article 7 deals with data related to information on testing of health in particular. In the Royal Decree 1720/2007, the Rule Development of Personal Data Protection Law is approved. This Decree aims at regulating possible risks of Personal data treatment.

Safety of medical information 41/2002

In law 41/2002 the safety of medical information is set out. It states that: "Health Centres must establish an active and diligent mechanism to safeguard medical records"

Royal Decree 994/199

This law might also be relevant as a legislation dealing with safety and security of medical and personal data. It states that databases that contain medical and personal data must be given maximum security.

National level regulation/legislation potentially relevant to the pilot sites in the United Kingdom

The Data Protection Act of 1998

The EU Data Protection Directive (DPD) was transposed into national legislation by the Data Protection Act of 1998. The act stipulates general rules for processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information. In part IV, section 30 the rules around personal data consisting of information as to the physical or mental health of the subject are set (Opsi, 1998).

Vital signs data is classified as "sensitive personal data" (section 1). "Data protection principles" are set out in Schedule 1 (section 4). As in DPD, "Processing" includes any storage ("holding") or transmission; the data do not have to be manipulated for their use to qualify as "processing". Schedule 1 specifies the first such data protection principle, for the case of sensitive personal data, as "1 Personal data ... shall not be processed unless ... at least one of the conditions in Schedule 2 is met, and ... at least one of the conditions in Schedule 3 is also met."

Schedule 2 allows processing under at least three circumstances relevant to INDEPENDENT; processing is allowed if

- The data subject has given his consent to the processing.
- The processing is necessary ... for the performance of a contract to which the data subject is a party, or ...

- ... in order to protect the vital interests of the data subject."

Schedule 3 allows processing if consent is obtained i.e. if "1 The data subject has given his explicit consent to the processing of the personal data. " but also where "8 (1) The processing is necessary for medical purposes and is undertaken by (a) a health professional, or (b) a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional.... ". . Medical purposes" includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services. "

So in summary, the Act allows transmission and storage of vital signs and therefore vital signs triage by anyone, given the client's consent (Schedule 2 paragraph 1 and Schedule 3 paragraph 1) is allowed. It seems also possible (but probably no advantage) to have a contract with a client which includes care for medical purposes and to apply Schedule 2 paragraph 2 and Schedule 3 paragraph 8.

Schedule 2 also allows processing if "6 (1) ... necessary for ... legitimate interests pursued by the data controller ... except where the processing is unwarranted" and allows the Secretary of State to specify what this means.. Also, though section 57 seems to outlaw (a contract of) consent to use of any health record or extract of this, this applies only when the client himself has obtained the data from elsewhere, and so is not relevant (Opsi, 1998).

Health and Social Care Act 2001

This act deals with the law around the National Health Service in the United Kingdom. In part one the National Health Service is covered, whereas part four focus on the laws around social care. This law also contains rules for handling patient information and is therefore complementary to the Data Protection Act. (Opsi, 2001)

National level regulation/legislation potentially relevant to the pilot site in Ireland

Data Protection Amendment ACT of 2003

The primary purpose of the Data Protection (Amendment) Act 2003 is to give effect to the provisions of Directive 95/46/EC. The most significant change is the broadening of the definition of data to include manual data in structured filing systems. Being a service provider means that project participants fall into the category of Data Controllers which brings significant legal responsibilities in relation to protection of data.

1.1.6 Liability

While data protection is covered quite extensively in European law, liability is a field in European law that is still under development. However, EU legislation applicable to telecare and telemedicine services may be covered by the e-Commerce Directive, as these services may be regarded as information society services. Mover, the EU Directive for medical devices 92/42/EEC could is of potential relevance to INDEPENDENT from the perspective of liability related provisions. It entails provisions on the quality and standards medical devices have to comply with.

Regulatory / legislative framework at the European governance level

Directive 2000/31/EC (e-commerce directive)

The e-Commerce Directive defines rules for the provision of Information Society Services, both within and between Member States. It may also apply to telecare and telehealth. For business-to-business (professional-to-professional) services, such as tele-radiology, the country of origin principle applies: the service offered by the professional must comply with the rules of the Member State of establishment. In the case of business-to-consumer activities (which might be relevant to tele-monitoring services) the contractual obligations are exempted from the country of origin principle: the service might need to comply with the rules of the recipient's country. Definition of medical or other sectoral legislation of potential relevance to INDEPENDENT may be the responsibility of the Member States. As a general principle, for instance the classification of telemedicine services as a medical act should ensure that these meet the same level of requirements than equivalent non-telemedicine services (e.g. tele-radiology vs. radiology). This principle ensures that adequately regulated health services are not replaced by less regulated telemedicine services and it avoids discrimination between providers of the same service which would be incompatible with the e-Commerce Directive.

The general lack of legal clarity in legislative fields that are of potential relevance to INDEPENDENT such as telehealth has been recognized by the Commission of the European communities. According to their communication to the European Parliament (2008, 689): "on telemedicine for the benefit of patients, healthcare systems and society", the lack of legal clarity especially with regard to licensing, accreditation and registration of telemedicine services and professionals as well as liability, reimbursement and jurisdiction is evident. Only a few member states have clear legal frameworks in these areas. However, actions are being taken to analyze and support member states in sharing information on national legislative frameworks relevant to telemedicine.

Directive 85/374/EEC Product Liability

Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products is a directive of the Council of the European Union that created a regime of strict liability for defective products.

Articles 1 to 12 create a scheme of strict product liability for damage arising from defective products. This liability is in addition to any existing rights that consumers enjoy under domestic law (article 13).

This Directive seeks to protect victims and promote improvements in product safety within the internal market through a regulatory framework which is as consistent as possible and based on a fair apportionment of the risks inherent in modern production.

DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

The Council Directive 93/42/EEC covers the placing on the market and putting into service of Medical Devices (MHRA, 2008). By medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

From the first of January 2008 a new safety standard, the European Harmonised Standard (ETSI EN 300 220-2 V2.1.2) came into effect. The standard affects telecare/social alarm equipment that receives radio transmissions from telecare devices (This, 2008). This kind of equipment needs to carry a CE marking to be legally sold in the European Union. The standard ensures that signals from personal radio are picked up reliably and therefore ensuring the safety of service users (PublicTechnology.net, 2008).

Directive 98/79 on in vitro diagnostic medical devices

This directive describes the demands that are placed by the European Union on the use of in vitro medical devices. 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

National level regulation/legislation potentially relevant to the pilot site in Greece

Medical Devices, Greek Law: ΔΥ7/οικ2480/ΦΕΚ679Β'/13-9-94 (to be replaced on 21-3-2010 by : ΔΥ8δ/Γ.Π.οικ130648/ΦΕΚ 2198Β/02-10-2009)

Telehealth devices are included in the Medical Devices and certain Directives refer to them. These Directives have been included in the Greek legislation: Medical devices (Dir 93/42) EC Mark - Medical devices (93/42 Directive) are classified under 4 classes with specific modalities to evaluate the conformity. Greek Law: ΔΥ7/οικ2480/ΦΕΚ679Β'/13-9-94 (to be replaced on 21-3-2010 by : ΔΥ8δ/Γ.Π.οικ130648/ΦΕΚ 2198Β/02-10-2009)

- Class I, Low potential Risk (reusable surgical instruments, non invasive medical devices)
- Class IIa, Moderate potential Risk (Contact lenses, Single use surgical instrument, short term invasive medical devices)
- Class IIb, High potential Risk (Long term invasive / implantable medical devices)
- Class III, Critical potential Risk (long term implantable medical devices in contact with central circulatory system and nervous system, absorbable medical devices, mammary implant, joint implants)

Diagnostic in vitro devices, Greek law : ΔΥ8δ/οικ3607/892/ΦΕΚ 1060Β'/10-8-01)

In vitro diagnostic devices are classified under 5 classes with specific modalities to evaluate the conformity.

- List A
- List B
- Device for performance evaluation
- Auto-diagnostic devices
- Other in vitro diagnostic devices

1.1.7 Licensing and quality control

Legislation and regulation concerning professional qualifications and licensing are of potential relevance to INDEPENDENT, for instance as far as care personnel is concerned. The latter is covered on the European governance level by dedicated Directives, with impacts on existing national regulation/legislation respectively.

Regulatory / legislative framework at the European governance level

Directive 2005/36/EC on the recognition of professional qualifications

This directive applies to all European Union (EU) Member State nationals wishing to practice a regulated profession, on either a self-employed or employed basis, in a Member State other than that in which they obtained their professional qualifications.

This directive is a response to the 2001 Stockholm European Council's recommendations calling on the Commission to design a more uniform, transparent and flexible system with the aim of achieving the Lisbon strategy objectives.

The directive brings together in a single text the three directives on the general system for the recognition of professional qualifications (recognition of diplomas, certificates and other evidence of higher education of long duration; recognition of other diplomas, certificates and other evidence of other professional education and training; and the mechanism for the recognition of qualifications for crafts, trades and certain services).

It also consolidates twelve sectoral directives covering the professions of doctor, nurse (Directive 77/452/EEC), dental practitioner (Directive 78/686/EEC), veterinary surgeon (Directive 78/1026/EEC), midwife (Directive 80/154/EEC), architect and pharmacist (mutual recognition of diplomas in pharmacy and qualifications in pharmacy).

There are two main European legal instruments covering the mutual recognition of professional qualifications: Directive 89/48/EEC and Directive 92/51/EEC.

Directive 89/48/EEC covers the mutual recognition of qualifications in recognized professions that require a University degree or equivalent. Directive 92/51/EEC covers the mutual recognition of qualifications in professions regulated below degree level.

They mean that any form of work other than those covered by the Transitional Measures Directive (Directive 99/42/EC, covering crafts and trades people such as hairdressers and construction workers) or the Sectoral Directives (dental practice, medicine, nursing, pharmacy, veterinary practice, Engineering, and architecture - this was the original method of achieving mutual recognition but proved too slow) that would normally be restricted in a member state to people who had gained a professional qualification in that member state are also open to nationals of the EU (and the other three states) that have gained a similar professional qualification in another member state.

The Directives referred to above have been consolidated under Directive 2005/36/EC. This was due to be transposed by Member States in October 2007.

National level regulation/legislation potentially relevant to the pilot site in the Netherlands

Law Occupations in Individual Healthcare - Wet Beroepen in de Individuele Gezondheidszorg (BIG)

This law regulates licensing of the occupations in the healthcare domain such as medical doctors, dentists, pharmacists, psychologists, psychotherapists, physiotherapists, midwives and nurses. It states that there should be a register of such professionals . It also describes which tasks each of the occupations is allowed to carry out.

Quality of Healthcare institutions act (Kwalitetswet Zorginstellingen) and Medical treatment act (Wet Geneeskundige Behandelovereenkomst)

The Quality of Healthcare institutions act includes provisions on responsibilities of care providers and the use of modern tools in health care. The Medical treatment act requires healthcare providers to keep a record of the patients.

National level regulation/legislation potentially relevant to the pilot site in Spain

Health Andalusia Region Law (1998 May)

This Law has three main goals: Health protection for all citizens in Andalusia Region, definition of all the citizens' rights and responsibilities and regulation of all medical public and private activities.

National level regulation/legislation potentially relevant to the pilot sites in the United Kingdom

Health and Social Care Act 2001

This Act is intended to deliver many of the aspects of the NHS Plan and the Government's response to the Royal Commission on Long Term Care that requires changes to primary legislation. Its purpose is to improve the performance of the NHS, provide better protection for patients through a faster, more effective and fair system for regulating practitioners, provide better protection around the use of patient information, strengthen the way the public and patients are involved in the way the NHS works, modernize pharmacy and prescribing services, extend direct payments for social services users and provide a fairer system of funding for long term care including measures to reduce the need to sell one's home on entering residential care.

1.1.8 Patient Rights

Beyond protection of personal data more generally, there is growing international consensus that users of health related services in particular have a fundamental right to privacy, to the confidentiality of their medical information, to consent to or to refuse treatment, and to be

informed about relevant risk to them of medical procedures. Against this background, many countries have put dedicated legislation on patient rights in place with a view to providing legal and moral guidance to relevant actors respectively. The rights guaranteed under such legislation vary in different jurisdictions, often depending upon prevailing cultural and social norms. Different models of the patient-physician relationship have been developed, and these have informed the particular rights to which patients are entitled. Although such provisions do not tend to be specifically geared towards the inherent properties of ICT-enabled service provision such as telecare, their basic principles would seem to be applicable to the latter as well.

Regulatory / legislative framework at the European governance level

The European Charter of Fundamental Human Rights

The Charter of Fundamental Rights of the European Union (2000/C 364/01) includes three articles that potentially concern INDEPENDENT.

The first one is article 8 which covers the area of protection of personal data. This will be important as (medical) data transfer concerning the end-users will most likely be part of the services that INDEPENDENT offers. The following is stated in the article:

- 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 25 deals with end-users and "recognizes and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life". The next article, number 26, deals with integration of persons with disabilities. The article states that: "The Union recognizes and respects the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community". This is applicable for the chronic disease management in particular.

The fundamental rights of health care are included in article 35, which states that: "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."

The European Convention on Human Rights and Biomedicine

The European Convention on Human Rights and Biomedicine provides a general value framework for dealing with patients nationally, institutionally and across borders. It was adopted by the Committee of Ministers of the Council of Europe on 19 November 1996 and entered into force on 1 December 1999 after signature of the first five countries. Currently 13 countries have ratified the Convention. Other than suggested by its title, the Convention does not just contain dispositions regarding bio medics related themes such as the human genome, scientific research, and organ and tissue removal. As a whole, it intends to provide a common

framework for the protection of human rights and dignity in both longstanding and developing areas concerning the application of biology and medicine more generally. It aims at guaranteeing everyone's rights and fundamental freedoms and, in particular, their integrity and to secure the dignity and identity of human beings in this sphere.

In relation to patient rights, the convention sets out a number of rules that are instructive to the ICT telehealth/telecare domain from an ethics related perspective:

- An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. The person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time (art. 5).
- When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned (art.8).
- The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account (art. 9).
- Everyone has the right to respect for private life in relation to information about his or health (art. 10.1).
- Everyone is entitled to know any information collected about his or health (art. 10.2). Also, the wishes of individuals not to be so informed shall be observed.
- Exceptionally a doctor may withhold information from the patient for therapeutic reasons. This is called the "therapeutic exception" or "therapeutic necessity" (art 10.3)
- Countries that have ratified the convention shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice (art 23)
- The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law (art. 24)

A recent Communication of the European Commission on telemedicine (COM((2008)) 689) has however highlighted the current lack of European-wide guidelines on ethical issues that tend to arise with the wider deployment of telemedicine and tele-monitoring in particular, e.g. due to the way in which the patient-doctor relationship is affected. The Commission has therefore welcomed that health professionals and patient organisations have signalled their intention to commonly work towards European-wide guidelines to address these issues. Beyond this, the importance of privacy and security related aspects as major components of building trust and confidence in telemedicine systems has been highlighted. It should however be noted that the European Union's competences are generally limited when it comes to regulating service provision in the health care sector, as the responsibility for the organisation, provision and funding of their healthcare systems generally rests with the Member States.

National level regulation/legislation potentially relevant to the pilot site in Spain

Equal opportunity, no discrimination and universal accessibility of handicapped people: Independent living / accessibility 51/2003

This law recognizes and respects the right of people with disabilities to benefit from measures designed to ensure their independence and accessibility.

Health Andalusia Region Law (1998 May)

This Law has three main goals: Health protection for all citizens in Andalusia Region, definition of all the citizens' rights and responsibilities and regulation of all medical public and private activities.

Vital Individual Wish Law (2003 October)

This Law recognizes the citizen's rights concerning the complementary medical test for diagnosis, therapeutic treatments, artificial life support, CPR (cardio pulmonary resuscitation), etc and gives them support to their wishes, which should be collected in an official format issued by the Regional Health Ministry. This Law recognizes how any citizen in the Andalusia Region can decide about medical diagnosis, therapeutics treatments, etc. in relation with their lives.

Decree (2003 may)

This Decree recognizes citizen's rights who have an interest in a second medical opinion about their medical process, even if it is in a different Andalusia Province than where they live.

Decree (1996 may)

This Decree allows citizens to choose their primary health doctor and specialist doctor at the place they live.

Palliative Care Integral Plan (2008)

This Plan is to those citizens who need palliative care in Andalusia Region.

Dependency Situation Integral Plan(2008)

This Plan is to those citizens who are under a dependency situation.

National level regulation/legislation potentially relevant to the pilot sites in the United Kingdom

Mental Capacity Act 2005

The Mental Capacity Act and the respective Code of practice are potentially relevant to INDEPENDENT if users lack mental capacity of some sort. This act is obviously meant to protect people who lack mental capacity. The act empowers the subjects to make decisions whenever

possible, and protect people who lack this capacity. (Opsi, 2005)

Fair Access to Care Services (FACS)

This system of accessing adult social care services is based on national eligibility criteria set by the government. The government has introduced a countrywide set of criteria, which Medway and all other councils now follow when assessing who is eligible for support – they are known as the Fair Access to Care Services (FACS) Eligibility Criteria and have been designed to ensure fair access to care services. The eligibility criteria look at who is most in need of assistance immediately or in the short, medium or longer term. The criteria are divided into four bands depending on an individual's needs. The eligibility bands are: critical, substantial, moderate, low.

Full details of the FACS eligibility criteria are available at

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4009653

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1.1.9 Ethics approval of research

As in the case of patient rights in health care provision, there has been an increasing interest in protecting the rights of individuals participating in research more generally and in medical research in particular.

Apart from existing regulation on Clinical trials the European Union has given ethical aspects a prominent place on its RTD agenda more generally. More specifically, all the research activities carried out under the European Union's Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles (Decision N° 1982/2006/EC, art. 6 (1§)).

Regulatory / legislative framework at the European governance level

Directive 2001/20/EC The Clinical Trials Directive

An EU Directive on Clinical Trials of 2001 requires Member States to have in place a system of ethical review of research projects that would inspire confidence in the conduct of clinical research throughout Europe. With this Directive, the European Union (EU) envisioned a harmonization of research ethics committees (REC's) across Europe, including the time taken to assess a trial proposal and the kinds of issues a committee should take into account.

However, ethical review procedures that are in place in the individual countries differ in many aspects. In general, they are directed towards ensuring that the conduct of clinical trials is compliant with basic principles of the protection of human rights and the dignity of the human being. Again, ethical review systems concerning clinical research do not tend to be geared towards ICT telecare/telehealth trials in particular, but basic ethical principals applied in relation to clinical trials more generally would in principle seem to be applicable to telehealth/telecare trials as well.

National level regulation/legislation potentially relevant to the pilot site in the Netherlands

The Medical Research Involving Human Subjects Act (WMO)

The Medical Research Involving Human Subjects Act (WMO) of 1999 stipulates two types of committees involved in the assessment of research protocols involving humans - the METCs and the Central Committee on Research Involving Human Subjects (CCMO). Beyond these bodies, Hospital Ethics Committees (HECs) started appearing at the beginning of the 1980s, and today many public hospitals and nursing homes have established such a committee. They are not regulated by legislation and put their focus of activity on reviewing clinical ethics.

Studies are subjects to this regulation if they meet the following two criteria:

- It is medical/scientific research
- People are subjected to procedures or are required to follow rules of behaviour

The question that the research addresses is a key element for deciding if it falls under the WMO. Also if the study involves any form of invasion of the integrity or if a questionnaire takes a long time to fill in or includes questions that are personal, embarrassing or intimate it falls under WMO. Studies using drugs is always subject to the act. (WMO, 1999)

The committee of the CCMO (Central Committee on research involving human subjects) make sure that the subjects are protected in medical research. (CCMO, 2008)

National level regulation/legislation potentially relevant to the pilot site in Spain

Public Health Act 14/1986

Ethical aspects about patient care and research are covered in this law. According to the law, the subject of the research should be informed about plan, purpose, methods and risks. This is similar to the Helsinki declaration.

A network of Research Ethics Committees (CEICs) has been established according to the Real Decreto 223/2004

A network of Research Ethics Committees (CEICs) has been established according to the Real Decreto 223/2004. A Coordinator Centre for CEICs provides a general contact point to get further information on of the CEIC network and relevant procedures. The Health Authorities in the 17 Autonomous Regions hold the competence to accredited CEICs. In some regions, a single regional Committee exists whereas in others many have been established.

National level regulation/legislation potentially relevant to the pilot sites in the United Kingdom

National Research Ethics Service (NHS)

In the UK, the National Research Ethics Service (NHS) sets out the guidelines for research projects. Their goal is to: "maintain a UK-wide system of ethical review that protects the safety,

dignity and well being of research participants, whilst facilitating and promoting ethical research within the NHS" (NHS, 2008). The Committee is mainly concerned with clinical and medical research. Projects with such a research component that is involving patients have to seek approval from research ethics committees. As mentioned earlier, INDEPENDENT must also take care to ensure that there is no conflict with Fair Access to Care Services (FACS). FACS is a priority system that social services apply to people seeking help. It is intended to deliver a fair allocation system between people living in the same area. (Department of Health, 2008)

United Kingdom Ethics Committee Authority (UKECA)

Ethics committees with the competence to review clinical trials of investigational medicinal products must be recognized by the United Kingdom Ethics Committee Authority (UKECA). Research studies other than these are reviewed by NHS Research Ethics Committees (RECs), which are established under policy from the relevant Health Departments in each of the four UK countries.

National level regulation/legislation potentially relevant to the pilot sites in Ireland

The Ethics Committees Supervisory Body (ECSB)

The Ethics Committees Supervisory Body (ECSB), currently the Minister for Health, approves ethics committees that have the competence to review clinical trials of investigational medicinal products (IMPs). When recognizing an ethics committee, the Supervisory Board must specify whether it may act for all areas within the Republic of Ireland and the description or class of clinical trials for which the committee may act. Recognized committees may be established at various types of bodies such as hospitals, universities, the Irish College of General Practitioners and the local Health Services Executive. Moreover, the Department of Enterprise, Trade and Employment has established the Irish Council for Bioethics as an autonomous body that has issued Operational Procedures for Research Ethics Committees. Although these guidelines have no statutory status, they seem to be generally supported by recognized ethics committees.

2.4 Sectoral codes of practice, guidelines and quality standards

Beyond legislation and regulation identified above, there are various sectoral/occupational codes of practice, guidelines and quality standards that are potentially of relevance to the project. These may relate to local and/or national actors and are presented in the following according o pilot sites.

Hull (UK)

Government Connect initiative

Specific elements of the project may require ethical approval through the Local Research Ethics Committee (LREC). In the case of the Lifeline development this will be reviewed in the context of the new Government Connect initiative. Obligatory staff training will begin in May 2010.

Clinical governance policies of both the community and acute NHS trusts

All developments related to telehealth and tele-kiosks will need to satisfy the clinical governance policies of both the community and acute NHS trusts.

Nursing and Midwifery Council Code

Established in 2002, the Nursing & Midwifery Council (NMC) is a statutory body set up by the Parliament of the United Kingdom through the Nursing and Midwifery Order 2001. The NMC is the UK regulator for nursing and midwifery professions with a stated aim to safeguard the health and well being of the public. The NMC maintains a register of all nurses, midwives and specialist community public health nurses eligible to practise within the UK and by setting and reviewing standards for their education, training, conduct and performance. The NMC also investigates allegations of impaired fitness to practise (i.e. where these standards are not met). All healthcare practitioners involved with the project will have to practice within the boundaries of their professional codes.

Final evaluation report from the 3 pilot sites for the Whole Systems Demonstrator Action Network

The Lifeline Service has been in operation for years and complies with national and international regulations. Codes of practice for any further roll out of assistive technology will be influenced by the final evaluation report from the 3 pilot sites for the Whole Systems Demonstrator Action Network (Hull is a partner) due to come out in Sept.2010 which marks the end of the pilots.

Strategic Health Authority in Yorkshire and the Humber

The Strategic Health Authority in Yorkshire and the Humber is developing a telehealth strategy, and this may have some synergies with the INDEPENDENT work, in addition to identifying possible funding streams for associated work. There is a strong opportunity to roll out a successful tele-kiosk programme across the entire Yorkshire and Humber region.

Policy (DH (2008) 1 entitled 'Transforming Adult Social Care'

The Department of Health issues a policy (DH (2008) 1entitled 'Transforming Adult Social Care' It states; by 2010/11 councils will have made significant steps towards redesigning and reshaping their social care services, with the majority having most of the core components of a personalised systems in place. Telecare is one of those core components. The Head of service is updating the Council's Scrutiny Committee at 6 monthly intervals on progress. The work carried as part of the INDEPENDENT project is featured in those reports.

Telecare Service Association (TSA) standard

TSA aims to promote and support the telecare industry and highlight the benefits of telecare for consumers. The TSA has almost 300 members, primarily from Local Authorities, Registered Social Landlords and private sector suppliers. TSA members give support to the majority of the 1.5 million service users who benefit from telecare in the UK.

TSA works closely with the Government and devolved authorities. In England TSA played a pivotal role in the Telecare Policy Collaborative which resulted in the development of the 'Building Telecare in England' strategy published in 2005. TSA is also helping the Welsh Assembly to deliver its Telecare Strategy and works with the Scottish Executive in the delivery of its Telecare Development Programme.

Milton Keynes (UK)

UK Local Authority best practice and policy

UK Local Authority best practice and policy will operate. This means any commissioning should adhere to local policies (best value is proved etc). Records will be maintained for review and service transparency (while observing Data Protection requirements). The service outcomes will be recorded and reported to central government under the Councils response on Care Quality Commission matters/targets.

Dublin (IE)

IS0 9001

ISO 9000 is a family of standards for quality management systems. ISO 9000 is maintained by ISO, the International Organization for Standardization and is administered by accreditation and certification bodies. The rules are updated, as the requirements motivate changes over time. Some of the requirements in ISO 9001:2008 (which is one of the standards in the ISO 9000 family) include:

- a set of procedures that cover all key processes in the business;
- monitoring processes to ensure they are effective;
- keeping adequate records;
- checking output for defects, with appropriate and corrective action where necessary;
- regularly reviewing individual processes and the quality system itself for effectiveness; and
- facilitating continual improvement

A company or organization that has been independently audited and certified to be in conformance with ISO 9001 may publicly state that it is "ISO 9001 certified" or "ISO 9001 registered". Certification to an ISO 9001 standard does not guarantee any quality of end products and services; rather, it certifies that formalized business processes are being applied.

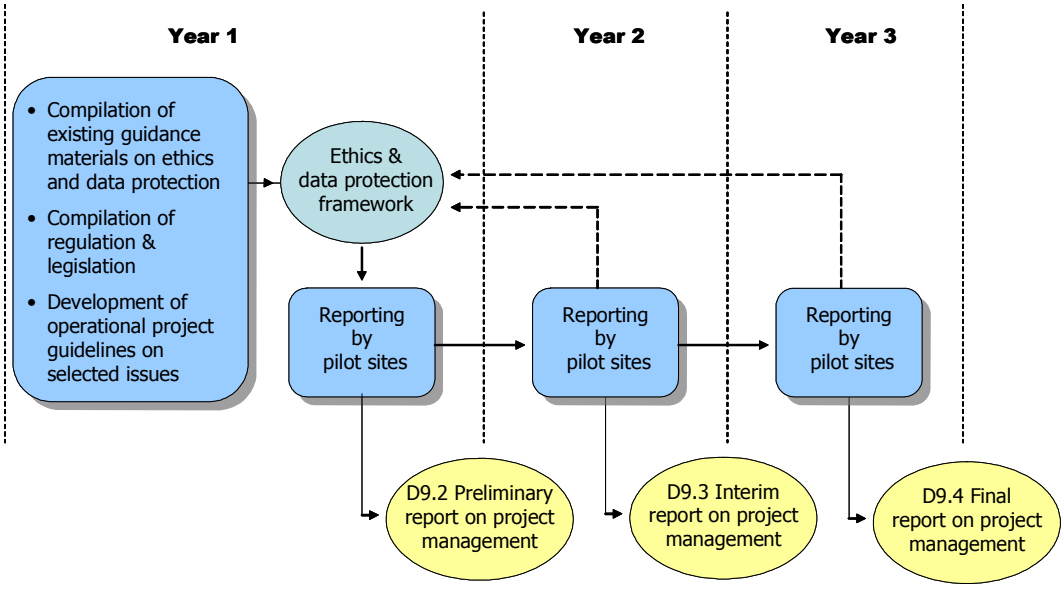
Telecare Service Association (TSA) standard

The TSA Guidelines produced for the UK have also been voluntarily adopted by telecare providers in the Republic of Ireland.

3. Ethics and data protection management

As graphically summarised below (Exhibit 3) ethics and data protection management activities during the first year will focus to a large extent on analysing ethics and data protection requirements that are to be applied to the project, and on developing operationally useful guidance in terms of the INDEPENDENT ethics and data protection framework presented throughout this document. Each pilot site is to report annually on activities and measures undertaken to comply with ethics and data protection requirements set out in this framework. As mentioned in the beginning, although ethical issues are frequently alluded to in the policy and practice discourses on ICT and ageing, definite "cook book" type guidelines in this field are not easy to define, particularly when it comes to the piloting of ICT enabled services cutting across existing domain boundaries – e.g. healthcare and social care - as in the case of the INDEPENDENT project. Experiences gained by the project participants throughout the project's life cycle will therefore be critically reflected upon and fed back into the current framework as the project progresses.

Exhibit 3 INDEPENDENT Ethics & Data Protection Management Road Map



Annex I:
Generic consent forms

Consent Form Template - Anonymous data

I understand that my participation in The Independent project will involve [*provide brief description of what is required, e.g. ...completing two questionnaires about my attitudes toward controversial issues which will require approximately 20 minutes of my time.*].

I understand that participation in this study is entirely voluntary and that I can withdraw from the study at any time without giving a reason.

I understand that I am free to ask any questions at any time. I am free to withdraw or discuss my concerns with [*name*].

I understand that the information provided by me will be held totally anonymously, so that it is impossible to trace this information back to me individually. I understand that this information may be retained indefinitely.

I also understand that at the end of the study I will be provided with additional information and feedback about the purpose of the study.

I, _____(NAME) consent to participate in the study conducted by [*name*]

Signed:

Date:

Consent Form Template- Confidential data

I understand that my participation in The Independent project will involve [*provide brief description of what is required, e.g., ...completing two questionnaires about my attitudes toward controversial issues which will require approximately 20 minutes of my time.*].

I understand that participation in this study is entirely voluntary and that I can withdraw from the study at any time without giving a reason and without penalty.

I understand that I am free to ask any questions at any time. I am free to withdraw or discuss my concerns with [*name*].

[select one of the two following paragraphs depending on design]:

I understand that the information provided by me will be held confidentially, such that only the [*name(s) of researchers where applicable*] can trace this information back to me individually. The information will be retained for up to [*state amount of time data will be held*] when it will be deleted/destroyed. I understand that I can ask for the information I provide to be deleted/destroyed at any time and I can have access to the information at any time.

OR IF DATA IS TO BE EVENTUALLY ANONYMISED:

I understand that the information provided by me will be held confidentially, such that only the Experimenter and [*name(s) of other researchers where applicable*] can trace this information back to me individually. I understand that my data will be anonymised [*state when this will happen, for example at the end of the study or on a specific date*] and that after this point no-one will be able to trace my information back to me. The information will be retained for up to [*state amount of time data will be held*] when it will be deleted/destroyed. I understand that I can ask for the information I provide to be deleted/destroyed at any time up until the data has been anonymised and I can have access to the information up until the data has been anonymised.

I also understand that at the end of the study I will be provided with additional information and feedback about the purpose of the study.

I, _____(NAME) consent to participate in the study conducted by [*name*]

Signed:

Date:

Annex II: International value frameworks informing INDEPENDENT

Fundamental human rights

The European Union Charter of Fundamental Rights which was adopted in 2000 has set out in a single text, for the first time in the European Union's history, the whole range of civil, political, economic and social rights of European citizens and all persons resident in the EU. These human rights are enshrined in the EU Reform Treaty signed in Lisbon in December 2007 which indicates a set of human values stated in the ECFR. The principle aspects of the ECFR with potential relevance to the development and piloting of INDEPENDENT services include the following aspect in particular:

- Article 1 - Human dignity: Human dignity is inviolable. It must be respected and protected.
- Article 3 - Right to the integrity of the person: Everyone has the right to respect for his or her physical and mental integrity.
- Article 4 - Prohibition of torture and inhuman or degrading treatment or punishment: No one shall be subjected to torture or to inhuman or degrading treatment or punishment.
- Article 6 - Right to liberty and security: Everyone has the right to liberty and security of person.
- 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.

Implications for INDEPENDENT

The fundamental rights enshrined in the articles listed above need to be respected at all stages of the projects life cycle, and supported by the service development/piloting techniques/practices to be applied within the project respectively (e.g. in relation to initial requirement elicitation, prototype testing, field testing). Beyond this, together these articles point to the general risk that the fundamental interest of the individual may be violated by diverging interest of other stake holders that may be involved in INDEPENDENT service development and/or deployment, e.g. economic ones. The question "what is good for the individual" is therefore to be adopted as a general principle guiding the project at the operational level when it comes to ensuring that fundamental rights are respected throughout it's life cycle. To this end, commonly accepted principles (e.g. in the medical field) will be adhered to when it comes to involving individuals (e.g. older end users, professional users, researchers) in project activities:

- Autonomy: Decisions and choices of grown-up persons involved in the project, e.g. pilot users, are to be respected and not interfered with;
- Non-maleficence: The project is to avoid doing harm and harming other persons through its activities;

- Justice: The project is to seek a fair distribution of benefits and burdens across persons involved, e.g. when it comes to the redistribution of scarce resources.

Data privacy and security

By adopting the Data Protection Directive of 1995 (Directive 95/46/EC) the European Union set legally binding rules for the protection of individuals with regard to the processing of personal data. Through this regulation basic principles for processing personal data have been stipulated which have to be followed in all Member States:

- Transparency: The data subject has the right to be informed when his personal data are being processed. The controller must provide his name and address, the purpose of processing, the recipients of the data and all other information required to ensure the processing is fair. (art. 10 and 11). Data may be processed only under the following circumstances (art. 7):
    - when the data subject has given his consent
    - when the processing is necessary for the performance of or the entering into a contract
    - when processing is necessary for compliance with a legal obligation
    - when processing is necessary in order to protect the vital interests of the data subject
    - when processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data are disclosed
    - when processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject

The data subject has the right to access all data processed about him. The data subject even has the right to demand the rectification, deletion or blocking of data that is incomplete, inaccurate or isn't being processed in compliance with the data protection rules. (art. 12)

- Legitimate purpose: Personal data can only be processed for specified explicit and legitimate purposes and may not be processed further in a way incompatible with those purposes. (art. 6 b)
- Proportionality: Personal data may be processed only insofar as it is adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed. The data must be accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified; The data shouldn't be kept in a form which permits identification of data subjects for longer than is necessary for the purposes for which the data were collected or for which they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use. (art. 6) When sensitive personal data (can be: religious beliefs, political opinions, health, sexual orientation, race, membership of past organisations) are being processed, extra restrictions apply. (art. 8)

Relevance to INDEPENDENT

Application of Data Protection Directive of 1995 (Directive 95/46/EC) should be uniform throughout the consortium as implemented in each partner counties local implementation of the legislation. This must be adhered to at all times and data subjects must give consent for data to be collected

Research and technology development

The so-called Clinical Trials Directive of 2001 (Directive 2001/20/EC) provides regulative and administrative provisions relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. The term "good clinical practice" refers to a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects in the European Union's Member States (art. 1.2). A subsequent Directive (Directive 2005/28/EC) lays down principles and more detailed guidelines for good clinical practice. Here, a number of basic principles to be followed by every trial that fall within the scope of the Clinical Trail Directive are set out as follows (art. 2):

- The rights, safety and well being of the trial subjects shall prevail over the interests of science and society.
- Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his tasks.
- Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.
- The necessary procedures to secure the quality of every aspect of the trials shall be complied with.

Moreover, clinical trials shall be conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, as adopted by the General Assembly of the World Medical Association in 1996 (art. 3). The latter provides a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. It is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs. Amongst others the Declaration highlights that it is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. Other participants in medical research involving human subjects are however encouraged to adopt these principles as well. It is also highlighted that some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.

With a view to enforcing compliance with the rules set out in the Clinical Trial Directive of 2003, Member States are required to implement Ethics Committees. In relation to each trial that falls within the scope of the Directive, among other things, they have the duty to express an opinion on the clinical trial protocol, the suitability of the investigators involved in the trial and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.

More generally the European Union has stipulated that all research activities carried out under its Seventh Framework Programme shall now be carried out in compliance with fundamental

ethical principles (Decision N° 1982/2006/EC, art. 6 (1§)). One of the tasks of a dedicated Governance and Ethics Unit is to analyse, through ethics reviews, whether these values are respected in research activities funded by the European Commission (E. Pauwels, 2007). Ethics Reviews now form an integral part of research proposal evaluation procedure undertaken by the European Commission. They are intended to ensure that all research activities carried out under the Framework Programme are conducted in compliance with fundamental ethical principles. Key principles that apply in this context derive from the European Charter of Fundamental Rights (Council of Europe, 1996), in particular:

- The right to the integrity of the person (art. 3):
    - 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:
        (a) the free and informed consent of the person concerned, according to the procedures laid down by law,
        (b) the prohibition of eugenic practices, in particular those aiming at the selection of persons,
        (c) the prohibition on making the human body and its parts as such a source of financial gain,
        (d) the prohibition of the reproductive cloning of human beings.
- Protection of personal data (art. 8)
    - 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.
- Freedom of the arts and sciences (art. 13)
    - The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

As highlighted by the Commission (Jelena Jakulj, 2008), ethics is context-dependent and consequently definitive mathematical outcomes are rare. Therefore, each research proposal is requested to take the time to consider the benefit/burden balance of each research task at hand, as well as the impact of the research, not only in terms of scientific advancement (publications, patents etc.), but also in terms of human dignity, and social and cultural impact. When it comes to informed consent in particular, some general principles should be applied:

- Only persons able to freely understand a question should give consent. This excludes vulnerable persons (prisoners, mentally-deficient persons, severely injured patients, very young children, etc.). However, to avoid any loss of opportunities for these persons, legal frameworks should guarantee their participation (notion of surrogate legal/ therapeutic representative).

Relevance to INDEPENDENT

Funded under the EU's CIP program, clearly the INDEPENDENT project is not a RTD project , nor can it be considered a clinical trial. However, key principles described above would seem to be applicable to the specification and piloting of the INDEPENDENT services as well, in particular as they relate to the concept of fundamental human rights described earlier. Where any RTD methods and techniques are to be applied (e.g. focus groups, prototype testing, trial evaluation) these will have to comply with the above principles. Research protocols and consent forms will be developed respectively (draft consent form templates for both anonymous and confidential data that have been developed during the early stages of the project are for instance presented in Annex 1.)

Annex III: Compilation of information on user friendly technology design

Making technologies age-friendly

The first thing to consider when designing for older adults are their needs and limitations. According to Fisk et al. (2004) there are two main themes in the design recommendations:

1. capitalising on the knowledge and capabilities of the user group

2. providing environmental support for the limitations of the user group.

Fehler! Verweisquelle konnte nicht gefunden werden. shows some generally accepted principles that can serve as an initial starting point for system designers. In order to make a system as optimal as possible for older people (and other groups) the principles of compatibility, consistency, error recovery, feedback, individualisation, memory, structure and workload must be incorporated in the design. For example, understanding the labels that users have for functions, the ways in which they organise information, their expectations about how systems work, and their experience with similar systems will all contribute to the development of systems that are usable by that population.

Exhibit 4: Principles for optimising human-computer interactions (Fisk, 2004)

Principle	Description	Examples
Compatibility	System design should be compatible with user expectations	A knob turned clockwise results in an increase in something; counter-clockwise results in a decrease
Consistency	Location of items should be the same across screens; similar functions should act the same throughout the system	Save or home button should be in the same location on every screen; cancel button should always result in the same action
Error recovery	Expect users to make errors and make recovery easy	Provide an "undo" option and meaningful error messages
Feedback	Results of actions should be clear	Provide status information such as an hourglass to indicate processing
Individualisation	Enable the user to tailor the system to individual capabilities and preferences	Flexibility in display characteristics such as size of icons; more than one option to perform a task (e.g., menu versus control keys)
Memory	The user's memory should not be overloaded; memory aids should be provided	Do not require multiple meaningless steps to perform an action (CTRL-F-Q-L-R); provide labels to support memory
Structure	Provide structure to support performance	System layout chart; site map; organised displays
Workload	Reduce information processing requirements of user	Organise displays and highlight critical information to reduce need for scanning

General factors of usability

Nielsen (2003) defines usability as follows: '…a quality attribute that assesses how easy user interfaces are to use'. He goes on to describe five quality components to define usability: learn-ability, efficiency, memorability, errors, and satisfaction.

The learn-ability factor concerns how easy it is to learn to use the device. Efficiency determines the amount of resources to be invested in order to achieve the intended goal. The less the invested resource, e.g. time, the higher the efficiency. Efficiency also refers to the capability for matching functions provided by the product with the needs of the users to produce acceptable product performance without inducing frustration, fatigue, and dissatisfaction. The memorability component of usability indicates that the operation of a device should be easy to remember, thereby minimising the effort required to relearn how to use the device following periods of non-use. Errors are generally much more easily identifiable from products with computer interfaces, where error messages are signalled to the user. However, in a broader context errors can be construed as user actions that do not accomplish the desired goal. In any case, errors resulting from interacting with the product should be minimal, and if they do occur the user should be able to easily recover from them. Finally, the satisfaction component addresses the experience the user has in interacting with the product, that is, the experience should be satisfying (Fisk, 2004).

The International Organisation of Standardisation sets out seven general ergonomic principles (DIN EN ISO 9241, part 10), which should be adopted in the design of any dialogue to make it more effective, efficient and satisfying to use.

1. Suitability for the task: A dialogue is suitable for the task when it supports the user in the effective and efficient completion of the task.

- Is the interface software easy to use?
- Is the format of input and output appropriate to the given tasks and user requirements?
- Does the dialogue support the affordability of the task?)

2. Self-descriptiveness: A dialogue is self-descriptive when each dialogue step is immediately comprehensible through feedback from the system or is explained to the user on request.

- Does the interface software give useful information about the possible functions?
- Is there enough feedback or explanation about necessary and illegal actions?
- Are explanations available without having to ask for them?
- Are the expressions and symbols easy to understand?

3. Controllability: A dialogue is controllable when the user is able to initiate and control the direction and pace of the interaction until the point at which the goals have been met.

- Does the user have control how to proceed in the dialogue?
- Is the way that input and output data are represented under the control of the user?

4. Conformity with user expectations: A dialogue conforms with user expectations when it is consistent and corresponds to the user characteristics, such as task knowledge, education and experience, and to commonly accepted conventions.

- Is the behaviour and appearance of the user interface software consistent?
- Does the system give immediate feedback on user input whenever the user expects it?

- Does the system give information if an input action was successful?

5. Error Tolerance: A dialogue is error tolerant if, despite evident errors in input, the intended result may be achieved with either no or minimal corrective action having to be taken.

- Do small errors have serious consequences?
- Does the application assist the user in detecting and avoiding errors in input?
- Is it possible to correct wrong inputs easily?

6. Suitability for individualisation: A dialogue is capable of individualisation when the interface software can be modified to suit the task needs, individual preferences and skills of the user.

- Is it possible to adapt the functions, actions to the user's individual needs?
- Can the user choose among different formats of system output according to personal preferences?
- Can the user choose among different ways of task solving according to personal preferences

7. Suitability for learning: a dialogue is suitable for learning when it supports and guides the user in learning to use the system

- Does the application require a lot of time for learning?
- Does the system encourage the user to try out new functions?
- Is it necessary to remember a lot of details?

These guidelines frame usability as a property of a human-machine system. Usability is a combination of interrelated factors or dimensions, and each of the above mentioned factors or dimensions are of different importance, not only from task-to-task or domain-to-domain but also across different age groups. Usability for older people determines successful interaction with technology. For each interaction device the aspects addressed above must be thoroughly investigated.

it should try to get methodology for priority definition of usability factors by the user, bottom-up priority.

Usability and accessibility of telecare equipment and services

The European Telecommunications Standards Institute published a paper (ETSI, 2007) providing a synopsis of user experience guidelines applicable to the research, design, development and deployment of telecare services. This comprehensive document focuses on the guidelines grouped according to three main themes: trust; usability and accessibility; and service provisioning, all addressed using a user-centric approach. The usability and accessibility aspects considered are those applicable to users who directly interact with the telecare equipment. Users may face difficulties when using telecare equipment, either because of limited ICT proficiency or due to physical, cognitive or sensory issues. Telecare services may be provided through different types of generic ICT applications: fixed and mobile phones, TV sets and their remote controls, personal computers, Laptops, PDAs, and so on. This trend may affect interaction with telecare devices. On the other hand other specific pieces of equipment, such as medical or biometric devices, may be part of the telecare system. Available guidelines in this field are mainly related to enhancing the usability of medical devices to minimise the risk of

human error. Additional guidelines refer to accessibility and usability of general ICT products and services. The following list presents a selection of guidelines provided by the ETSI document in relation to usability and accessibility.

Generic guidelines:

A telecare system's output should be perceivable by users. Important information, such as alarms or loss of critical functions, should be effectively notified to users.

Telecare equipment should require a minimum of effort and time to achieve the desired goal. Furthermore, it should be easy for users to raise alarms in an emergency situation.

The operation of telecare equipment should be understandable to all users.

Assistive technologies should be usable in conjunction with telecare equipment. Telecare equipment should allow both direct use, and use by means of assistive technologies.

Telecare equipment and services should support adaptation to clients' abilities and preferences, as well as to the context of use (e.g., when roaming).

Consistency and standardised elements among user interfaces should be promoted in related telecare equipment and services, also when roaming (if supported).

Research, design and development guidelines:

A Telecare system's output should be made available through multiple modalities (auditory, tactile and visual). Users should be allowed to select one or more output modalities, as well as their specific characteristics (e.g. volume, brightness, contrast). Information on active output modalities and their characteristics should be provided.

The information generated through the different modalities of a telecare system should be equivalent.

Brightness and contrast of visual signals should be adjustable. Their value range should allow visual signals to be perceived under various conditions of ambient illumination; the size of visual symbols (e.g. text, icons) should be adjustable; Information should not be provided relying only on colour; image quality should be sufficient to perceive sign language correctly, see.

Location and function controls of telecare equipment should be easily identifiable by users.

The telecare equipment should provide users with multimodal feedback, see, in order to: acknowledge user interaction with telecare equipment, such as the use of input controls, or the engagement of external connectors (e.g. medical sensor, power cord, PC card, USB connector, etc.) and inform on the progress of a telecare service that has been requested by the user.

Feedback should be presented without any perceptible delay. Visual or tactile feedback should occur at the same location as the control, or in a common place, standard for the whole telecare system.

Guidelines for the design of input devices

Fisk et al. (2004) enumerate the following guidelines for input devices designers:

- Select good default values or develop profiles that could be selected based on different age groups (children, adults, seniors). Do not assume that flexible interfaces will result in optimal choice of parameters by users.
- Match the input device with the task demands.

- Prefer trackball to mouse for novices if the interface requires double-clicking; consider default interfaces that do not require double-clicking.
- Prefer direct (light pen, touch screen) to indirect (mouse, trackball, joystick) positioning devices for pure pointing and clicking tasks, particularly when the input device is not large (e.g., hand-held computer).
- Prefer indirect devices if users are experienced and the task requires combined keyboard entry and device use, the extent of movement for a direct device is large (e.g., 19 inch monitor), or the task requires precise selection.
- Prefer speech recognition control and input when individuals are very restricted in manual dexterity and the ambient noise level in the environment is low. Prefer CRT to LCD displays when precise colour matching is needed.
- For keypad input, use large keys with clear markings (adequate contrast for text or symbol to background) and appropriate inter-key spacing.
- Provide for the possibility of both tactile and auditory feedback with keypads. This situation occurs with many microwave ovens that emit beeps on key press and can be coded in software for computer keyboards.
- Permit alternatives for navigation with a visual cursor for those with moderate tremor, such as arrow key movement.

Guidelines for characteristics of output devices

Fisk et al. (2004) mention the following guidelines for output devices designers:

- Select the output device with the higher contrast between characters and background. For example, choosing between an LCD and CRT, an important consideration is to select based on best contrast ratio for the ambient light conditions. a 4-letter word this approximates the width of your thumb at arm's length.
- Keep visual output screens adequately shielded from glare.
- Provide an adaptive (adjustable) display when feasible and provide instruction to the user about how to change screen resolution.
- consider advising an older user to set the resolution of their computer display to 800 x 600 pixels or lower (640 x 480 pixels) to enhance access to small icons typical in today's software interfaces.
- Use built-in controls (e.g., Microsoft Windows accessibility functions available through Control Panel settings) or special purpose software.
- Permit adjustability of output intensity and frequency of sounds.
- For important visual warning messages, repetitively flash the information rather than have it come on and stay on. However, make sure that the flashing is not so fast as to impede reading of the message.
- Prefer tactile output devices for simple signalling (e.g., using moderate to high frequency vibration ~250 Hz) when auditory and visual output would be difficult to process (noisy environments, glare situations) or would be disruptive to performance of the user or nearby personnel.
- For important auditory warnings, select output (e.g., speaker) systems that emit sounds in the 500-1000 Hz frequency range and repeat the message until acknowledged.

- Older users are easily distracted by extraneous design detail or background noise. That is why graphics need to be carefully selected for relevance rather than decoration. Multi-media approaches and the more flamboyant Web pages may disadvantage older users. (Fisk et al., 2004).

Screens and touch screens

Touch screens

To help older people and those with hand tremors, active fields should be as large as possible and separated by a 'dead area'. There should be high contrast between touch areas, text and background colour to ensure that the older adults are able to read the text presented (Gill, 2004). Try to achieve at least 50:1 contrast (e.g., black text to white background, measured from solid black and solid white areas); for transmission displays prefer LCDs rather than CRTs when screen size is held constant because of the generally higher contrast ratio on backlit LCDs.

Luminance meter readings taken near the screen on a white and black patch on a typical LCD monitor are 140/.8 = 175, and from a CRT monitor 71/1.5 = 47 (Fisk et al., 2004). Colourful patterns, pictures or watermarks in the background may interfere with the readability of text. Therefore, the use of solid, light backgrounds with dark text will make the text easier to read by older adults (Fisk et al., 2004; Echt in Morrell et al., 2003, Gill, 2004). Consider providing white on black text when using CRT displays for those with significant visual impairments (Fisk et al., 2004). Screens should be positioned so that they are shaded from overhead lighting or sunlight which will reflect glare (Gill, 2004).

Touch screens can either be triggered by insertion or withdrawal of the fingertip. With the latter system, it would be possible for the user to pass their fingertip over the screen and get speech output describing the active area being touched at the time. Then the system is only triggered by withdrawing the fingertip from over an active area (Gill, 2004).

It is already possible to increase the size of the characters on the screen for individuals who require this facility. This can be done by selecting this option from a menu or, preferably, by storing this information on the customer's card. With touch screen systems, it could be arranged that holding one's finger in the bottom right corner for at least two seconds indicates that one would like larger characters on the screen. Screens should be as large as possible so that larger text can be used. Larger screens also allow more space to position text and active areas (Gill, 2004).

To use a touch screen from a user-propelled wheelchair, the height of the active areas should be between 800mm and 1200mm for most users. Also, the screen should be perpendicular to the line of sight. If the terminal is also to be used comfortably by standing users, this may involve using two screens or a variable height screen. A recessed space beneath the terminal will make it easier for a person in a wheelchair to get as close as possible to a screen (Gill, 2004).

Visual displays

Visual display screens are common in most electronic devices, appearing in everything from phone devices e.g., to provide caller ID information), to electronic thermometers, to microwave ovens. A variety of display elements are used in these devices, from passive liquid crystal displays (LCDs) to light emitting diodes (LEDs). There are a large number of factors that determine whether reading the screen will be difficult or easy for disabled or older persons (Gill,

2004).

Light levels in homes for reading materials are typically in the 30 cd/m2 range, compared to 100 cd/m2 found in offices. Ensuring good contrast for output sources becomes critical in these environments. Consider substituting active or fluorescing for passive LCDs or provide backlighting for LCDs when they are intended for home use. For portable devices that will be used both indoors and outdoors, consider trans-reflective displays, such as those found on second generation palm-top computing devices and personal digital assistants (Fisk et al., 2004).

Sunlight can degrade the view-ability of the display for all users. The screen should be shielded from direct or reflected sunlight or other bright light sources. The display should be viewable from the eye level of a person sitting in a wheelchair. People with low vision should not be prevented from getting their faces close to the screen (Gill, 2004).

The conflicting requirements of tall pedestrian users and short wheelchair users can lead to a significant group of users having parallax problems when lining up the function keys with the displayed option. Lines on the user-interface leading from the key to the surface of the display can alleviate this problem (Gill, 2004).

Good standards of legibility help all users, but for many people with low vision the issue is fundamental to being able to read information and prompts on displays. Many screens are too small and too dark to display information in a way that can be clearly seen. This is also true for the screens on mobile phones, larger screens and clear graphics, with strong contrast between the characters and the background all help improve legibility. Adjustment of the size of text should be allowed (Gill, 2004).

Gill (2004) provides a checklist of the guidelines:

1. Have you allowed for red/green and blue/yellow colour blindness?

2. Is the screen protected from glare?

3. Is the screen readable from a wheelchair?

4. Can the user adjust the angle of the display?

5. Can the user get close to the screen?

6. Can the user increase the character size?

7. Have you used a legible typeface?

8. Is the text on a plain background?

9. Have you used scrolling or flashing text?

10. Have you minimised parallax?

11. Is the language selectable?

12. Have you used standard icons?

Interactive television

Many older people are reluctant to use personal computers but would be prepared to use interactive television to obtain information (e.g. about local council services). However, if their initial experience is poor, they may be reluctant to try using interactive television in the future. Television is extensively used by older persons throughout the day as a major source of leisure time activity and as compensation for reduced social interactions - almost four hours a day, on

average (Wahl and Mollenkopf, 2003). It is therefore very important for designers to realise that interactive television is not the same as a personal computer and therefore its design must be treated differently. In comparison to computer screens, most people view television a long distance from their screens.

To be able to operate interactive television controls, the legibility of features on the screen must be as clear as possible. The requirements to operate remote control handsets have become more complex. In particular, pressing buttons on the remote control whilst watching the screen becomes difficult for older viewers with presbyopia (age-related long sightedness), as the ability of the eye to focus at different distances decreases. With the increase in television functions, more buttons are required on handsets that are already very full. This leaves less room for text labels, which are often already too small. Integrating smart card and digital technology together would enable people with special requirements to configure a system to meet their needs.

Mobile phone handsets could replace the remote control for televisions and recorders. Many of the new mobile phones have larger screens. Devices such as this could provide an interactive channel (for services such as tele-shopping) while connecting to the television using wireless systems such as Bluetooth. Text when displayed on a television screen is made up of multi-coloured pixels, which tends to soften the appearance of text. To ensure that interactive television is easy to use, it is important that typefaces chosen to display text are suited to the medium and that they are used in ways that ensure maximum readability. Tiresias Screenfont is a typeface that was specifically designed for subtitling on digital television (Gill, 2004).

Keypads and remote control devices

Keypads

There are currently two common layouts for numeric keys; the telephone layout and the calculator layout. A standard layout for keypads is essential for blind people. It is recommended that the telephone layout be used exclusively on public access terminals Consistency in the layout of keypads is essential for blind users and highly desirable for other users. It is also important to set out the keys in a way that makes it easy to distinguish between the main numerical keys and other function keys. Variation in the size, shape and position of function keys will help differentiation. Colour should not be the only distinguishing feature between keys, since red/green colour blindness is not uncommon; if possible, the keys should have different shapes and be marked with symbols.

Enlarged keys enable persons with poor dexterity to press the correct key; the spacing between the keys is as important as the size of the keys themselves. A concave shape to the keys will also help fingers to stay in place. Guarded or recessed keys can help a person who has difficulty in making precise finger movements (Gill, 2004).

Some devices have buttons that have more than one function, and some involve time delays to allow audible responses to be heard. If no consideration is given to the needs of people with disabilities then even a simple operation sequence can be unworkable and leave people excluded. In the ideal world, systems will automatically learn from the way the user controls a system, and modify the user interface to optimally meet their needs (Gill, 2004).

Function keys should be clearly separated from the numeric keys. When command keys are vertically arranged, 'cancel' should be the uppermost key and 'enter' the lowest. When the command keys are horizontally arranged, 'cancel' should be located the furthest left, 'enter' the furthest right. It is better to position the command keys to the right of the numeric keys, since

they are then less likely to be inadvertently touched when entering numerals. Where command keys are positioned beneath the numerical keys they may be a problem to visually impaired persons because they are likely to be pressed accidentally when entering numbers. Command keys should be as large as possible so that the words on them can be larger and thus easier to read (Gill, 2004).

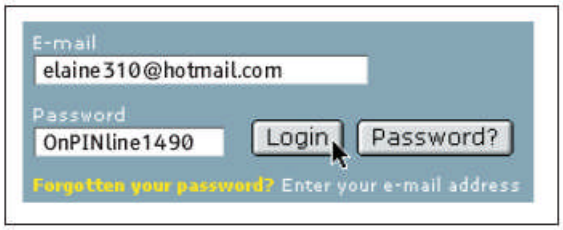
Visual markings on the keys should be characters at least 4 mm high and should have good contrast with the colour of the key (e.g. white characters on matt black keys). On numeric keypads which also include up to 4 alphabetic characters, the size of the alphabetic characters should be as large as possible without affecting the legibility of the numerals (NB for most users, the legibility of the numerals is more important than the legibility of the alphabetic characters); the spacing between the alphabetic characters is as important as the size of the character, since it is the characters which are being read and not a word.

The optimum spacing of keys on a mobile phone handset or remote control will depend on whether the user uses a thumb or finger to press the keys. Teenagers tend to use their thumbs, but many older people prefer to use a finger; this has implications for the optimum spacing between keys (Gill, 2004). Ideally keys should be internally illuminated when the terminal is waiting for input from that keypad. One implication is that completion of keystrokes may be uncertain for those pressing keys gingerly and hence it might be useful to supplement the usual minimal tactile feedback of a key press with an auditory signal (Fisk et al., 2004). Tactile indication can be provided by a gradual increase in the force, followed by a sharp decrease in the force required to actuate the key, and a subsequent increase in force beyond this point for cushioning (Gill, 2004).

Typefaces and legibility

Many older people have difficulties reading standard text even with spectacles and good illumination. To help with this problem choosing a clear typeface will be very important in helping ensure the best levels of legibility for any application. Text set with sans serif typeface has been found to be read more easily by older adults, (Grabinger and Osman-Jouchoux in Morrell et al., 2003; Hawthorn, 2000) and also preferred by them (Ellis and Kurniawan in Morrell et al., 2003). Decorative and cursive fonts (e.g. gothic) should be avoided (Fisk et al., 2004). Sans serif typefaces include Helvetica, Arial and Univers (Morrell et al, 2003). For people with low vision some numerals such as 6, 8, and 9 can look very similar. In some typefaces characters such as the lower case 'l', the numeral '1' or an upper case 'I' can be difficult to distinguish. Increasingly, password and email addresses use a combination of letters and numbers. For such applications it is essential to use a typeface which clearly differentiates numerals and letters (Gill, 2004). In some applications where the context does not make the meaning obvious, it is essential to be able to differentiate the zero and the capital 'O'. In this case it may be necessary to use a cancelled zero. The Tiresias fonts include this optional feature (**Fehler! Verweisquelle konnte nicht gefunden werden.**).

Exhibit 5: Tiresias font example



The RNIB Scientific Research Unit (http://www.tiresias.org/sru.htm) has produced a range of

typefaces for applications where legibility is important. Tiresias Screenfont was designed for subtitling on UK digital television. Tiresias PCfont is a typeface designed to display clearly on screen based systems. When a typeface is generated on a screen, the character shapes are created on a grid of fine lines or pixels. Because most traditional typefaces were designed for reproduction on paper rather than screens their subtle shapes are often distorted on screen.

Tiresias Infofont has been designed for use on information labels and controls to help improve legibility. The characters and letterforms have been designed for a reading distance of 30-100 cm. This typeface has been used for applications such as fire notices and labels in museums. Tiresias Signfont is a bolder typeface, but has characters that have been designed to maintain open shapes that provide maximum readability at longer distances. Tiresias LPfont is a large print typeface designed for use in publications. Large print publications should be designed to specifically help with reading problems, and should not be just an enlarged version of ordinary print. Tiresias Keyfont has been specifically developed for use on the keypads of ATMs, chip and PIN terminals, telephones, ticket machines, domestic appliances, computers, office equipment and remote control pads (Gill, 2004).

Most findings demonstrate (Fisk et al., 2004; Hartley in Morrell et al., 2003) that type size should be increased to maximize text legibility. Performance has been shown to increase on paper tasks when a 12- 14 point size is employed; many older adults seem to prefer these sizes of type relative to smaller sizes, they also benefit from short line lengths (Ellis and Kurniawan, 2000; Hawthorn, 2000). On web pages designer should avoid style sheets that prevent people from increasing font size with their browser software (Fisk et al., 2004). Type should be intense enough to be read easily. The use of a medium or bold form of a typeface will meet this qualification (Hartley in Morrell et al., 2003).

Capital and lower-case letters bodies of text set entirely in capital letters are difficult to read and slow down the reader (Fisk et al., 2004; Hartley in Morrell et al., 2003). Text set in upper- and lower-case letters and increases reading speed (Carter et al., Conover in Morrell et al., 2003). Body text should be in upper- and lower-case letters, all capital letters and italics should only be used for headlines and underlining for links (Morrell et al, 2003). However, UPPERCASE TEXT attracts more attention than lower case in mixed case situations. The preferred way to present text to older adults to increase comprehension is to format as left-justified (Morrell et al., 2003, Hawthorn 2000). Scrolling text is difficult to process and should be avoided (Fisk et al., 2004).

To optimise perception of information by older people ensure that the demands made on their somewhat noisy perceptual systems are minimized. A good heuristic for optimizing perception of information is to increase signal strength and reduce noise sources. Another is to provide redundant channels. For instance, in the case of text, boosting signal strength involves choosing a legible font (type, size) and increasing the contrast between text and background. The latter can often be accomplished by boosting light levels. Diminishing noise involves isolating important text from its surroundings, usually by enhancing it (e.g., putting text in bold) (Fisk et al., 2004) or by avoiding patterned backgrounds that make reading noticeably harder for older adults. Moving text should also be avoided, since it is important to give older users ample time to read the text. Designs should use only simple, highly relevant graphics and avoid decorative animation and pictures, wallpaper patterns and flashing text (Hawthorn, 2000). Colour shadings that convey information should be distinct and avoid blue–green tones. We should not expect older users to detect small movements and so should find more obvious ways of indicating changes.

Labels, icons and symbols

Icons and other symbolic displays can be effective ways to convey information if the older adult is already familiar with the meaning of the icon or symbol. Research on perception of traffic signs indicates that as long as the symbols are well designed (do not require the ability to process high frequency spatial information, that is, acuity for fine detail) they can be processed as or more effectively than text messages. However they also become useful only after an opportunity to learn their meaning. Older adults can be expected to take longer to learn arbitrary symbol sets and to be less likely to remember them. Some icons used in current software packages are ambiguous and the symbols give little indication of their meaning – this defeats the utility of the icon. Icons and symbols must also be easily discriminable (Fisk et al., 2004).

Text and icons must be clear, not too small and have sufficient contrast to help people with impaired vision. The position of labels with text or icons is crucial for an unfamiliar user with impaired vision. Labels are often positioned in a way that they are obscured from the user's view when the controls are being operated. The problem is particularly common when the control panel is at an acute angle to the user's line of sight or at an inappropriate distance. Allowance should be made for the 10% of the population who are left-handed. Many people with low vision like to get their face close to the control panel to read the labels, or use face-mounted or hand-held magnifiers (Gill, 2004).

The selection of labels for menus is also relevant to the issue of compatibility. The user's label for the task must correspond to the menu label for that task. The use of jargon or unfamiliar terms may be especially problematic for older adults because the need to decipher the terms and determine which one matches their goal adds extra demands to the task and may overload their working memory capabilities. Help and instructions must be provided in non-technical language, possibly suggested by older, novice computer users (Gregor & Dickinson, 2006). Similarly, text on buttons should be as descriptive as possible, e.g., "send message" rather than "send", making the outcome of a user's action more predictable.

However, the general organization of well-learned information is comparable across age groups and well maintained into old age. Designers should capitalize on older adults' knowledge base to select the most compatible labels. The label selection process may reveal a natural (i.e., learned) organisational structure that would inform the depth versus breadth decision as well (Fisk et al., 2004).

Controls

Regardless of which technologies are used, the user interface is likely to be one of the most important features. This in itself is a design challenge. As can be seen from the current design of television controls, a consistent and easy to understand interface has yet to be developed. For a blind person it may not be obvious where the controls are located if they are not in a standard position. It is important that controls are grouped in a logical manner, and that they can be differentiated by shape, size and colour as well as position. The layout of controls should reflect the sequence of operation (e.g. left to right, or top to bottom). Consistency of layout is essential for users not familiar with a particular terminal. Controls which change the relative, rather than absolute, values often cause problems for people with low vision. A blind person may find it difficult to judge where a slider switch is positioned in relation to the upper and lower limits of the scale. A person with decreased manual dexterity may find it difficult to operate a control which has to be moved from side to side (Gill, 2004). Some additional product

review criteria regarding controls that involve upper body dexterity and mobility issues (Gutman, 2003):

- Do controls allow activation by persons with low grip strength?
- Are controls knobs a minimum of 25 mm in diameter?
- Are touch pad activators a minimum of 12 mm square?
- Are C- or U-shaped handles installed when straightforward pulling movements are required?

When the same control is used for a number of different functions, older users can easily become confused. Often it is preferable to have a larger number of buttons laid out in a logical manner rather than use multifunction controls (Gill, 2004).

Wireless systems

Bluetooth is one example of a short-range wireless technology that can link appliances and devices together, so that control and communication can be managed remotely. It offers a number of very interesting and important applications for people with disabilities. Small devices that have tiny knobs – mobile phones, hearing aids, pocket calculators etc. – could be controlled from a separate keypad, appropriate to the user's needs, connected via a Bluetooth link. This is of great significance because the mobile phone itself could replace the remote control for televisions and video recorders. It can provide an interactive channel (for services such as tele-shopping) while connecting to the television via Bluetooth (Gill, 2004). The use of wireless systems, such as Bluetooth or ZigBee, could also dramatically decrease the cost of installing smart systems in an existing home. Wireless systems also simplify the process of modifying the system when the user's needs change or a new resident takes over the accommodation. To provide sufficient support to give an older person confidence to continue to live independently may only involve a modest investment, which later can be re-used for another individual (Gill, 2004).

Menus and interactive voice response

Menus (e.g. phone menus) are also quite difficult to operate for older people. People with hearing and (age-related) cognitive impairments are especially deprived in this (Gill, 2004; Mayhorn et al., 2004). Older adults that use these kinds of menus to communicate with the bank, state and other civic services are required to store and process the menu options while attempting to make navigational decisions. If the structure of the menu systems is very broad such that a large number of options must be considered, older adults may find themselves forgetting the content of the options because their working memory capacity is exceeded (Mayhorn et al., 2004, Fisk et al., 2004). For visually presented menus however the broadness of structure reduces demands on memory, but increases the need for visual scanning (Fisk et al., 2004). The solution is reducing the number of menu options at each level of menu hierarchy. Another way is placing the most commonly requested menu items first and with that reducing the need to inhibit unwanted options (Mayhorn et al., 2004). Older adults would also benefit from a graphic display of the available options in a telephone menu system (Fisk et al., 2004).

In the speed of menu option presentation another factor which must be considered is reduced processing speed related to age-related memory decline. Slower speed of menu will give older people more time to process all the available options (Mayhorn et al., 2004). Gill (2004) also suggests prolonging the time given for the user to respond and stresses the problematic one-

piece phones, where the keypad is integral with the headset and makes it difficult for the user to simultaneously listen and press keys.

Another factor that needs to be considered is that older adults have more difficulty processing menu information when the speech is compressed (e.g. at 20%). Designers of these systems often compress speech at higher rates to maximize efficiency, however this may place older adults at a disadvantage (e.g., they may need to repeat the menu more often). The same is true for speech rate of messages on telephone answering machines. This is an increasingly important issue as we rely on use of these systems to convey important information such as reminders of doctor's appointments or medication reminders. Television and radio announcer speech rates for newscasts are a good standard to emulate (Fisk et al., 2004). To summarise the recommendations for integrated voice response are the following (Gill, 2004):

- Allow for users who need extra time to respond to prompts;
- Avoid broad menus;
- Provide a means of access to a human operator;
- Provide a recovery route from error;
- Provide different audio feedback for valid and invalid key presses;
- Provide a consistent and predictable user interface;
- Avoid compressed speech;
- Use consistent terminology;
- Keep user IDs to no more than 8 digits;
- Do not require that the same information is entered more than once;
- Provide users with the facility to repeat the audio output;
- Place the most commonly requested menu items first;
- Provide context-sensitive help.

Colours

Colours such as red and blue are commonly used to distinguish hot and cold for example. However, status should not be indicated by colour alone since a significant portion of the male population has problems distinguishing red/green or blue/yellow. In addition older adults are prone to decreased sensitivity to colour particularly for yellow and blue/green combinations (Echt in Morrell et al., 2003). Therefore avoid signalling important information using short wavelength (blue-violet-green) contrasts (Fisk et al., 2004); these combinations can be used in decorative graphic elements as long as their use does not require discrimination for the understanding of the graphic (Morrell et al., 2003). References to colours in text should be avoided in general because they may not be detectable to all readers, especially individuals who are colour blind (Hartley and Harris in Morrell et al., 2003). People with retinitis pigmentosa often have difficulty reading red displays (Gill, 2004).

Audiovisual input and output

To compensate for losses in hearing acuity, older adults may need to use context to interpret

speech. Studies have shown that relative to the young, older adults make more use of semantic context (such as degree of predictability of a target word) to facilitate speech recognition (Scialfa et al., 2004; Fisk et al., 2004). Having good structure (e.g., grammar) in spoken (and written) texts can help older adults differentially. In speech, increased signal strength can be promoted by regulating speech characteristics to match listener needs. For instance, pausing after important grammatical boundaries (phrases, ends of sentences) when speaking may be particularly helpful (Fisk et al., 2004). However it is important that clear speech does not devolve to 'elderspeak' (Kemper and Lacal in Scialfa et al., 2004), a semantically simplified and effectively patronizing communicative style that is offensive to many older listeners and detracts from speech comprehension.

Another important issue is the slower rate of processing for older adults. This has implications for the use of compressed and speeded speech (Fisk et al., 2004). Namely, people with a hearing impairment often have difficulties in understanding synthetic speech output since it tends to have less redundancy than natural speech. However brief spoken messages might be useful as optional replacements for the current provision of fly-over hints to give brief names or explanations of buttons and other features of an interface. It is possible that interfaces of this sort could extend the number of years during which users are able to make use of applications (Hawthorn, 2000). The facility to repeat a message is also frequently essential rather than just desirable (Gill, 2004).

If information is confidential, then speech output should be to an earphone (e.g. telephone handset). For situations with poor viewing conditions (e.g. low illumination or high vibration) audio output can provide another modality of information dissemination or provide more redundancy. Audio messages are most appropriate when an immediate response is required with less reliance on referral to the message at a later date.

Other guidelines for audio output (Fisk et al., 2004; Gill, 2004, Hawthorn, 2000):

- Messages should be simple and short.
- Keep speech rates to 140 words per minute or less.
- Match voice characteristics to the situation. Prefer male voices to female voices for announcements. Prefer female to male to get attention. Older individuals may find female voices harder to follow than male voices because of the overall higher pitch.
- Avoid artificial (synthesized) speech messages that do not closely imitate natural speech for prompts or fixed messages (e.g. next stop on a tram), error or help messages, output of contents of screen.
- Provide user control of volume of audio output. It is important to provide instructions regarding how to make volume adjustments.

For acoustic signals to attract attention, use a frequency between 300Hz and 3000Hz. Other sources recommend 500 to 2000 Hz and intensities at least 60 dB at the ear of the listener. Huey et al. (in Hawthorn, 2000) found hat a beep that swept a range of frequencies including the 500–1000 range was reasonably effective, according to Hawthorn (2000) older adults miss attention getting sounds with peaks over 2500 Hz. Commercially available telephone bells and smoke alarms tend to have intensity peaks around 4000 Hz which are effective for younger users but these sounds are missed by older users. Fisk also warns against using frequencies above 4000 Hz as many older men have difficulty hearing sounds in the 8000+ Hz frequency range even at very high sound levels (90 dB). It would therefore be unwise to signal a dangerous situation using that frequency range. If sound location must be signalled with high frequency sound sources (fundamental frequency >2000 Hz), use longer duration (> 0.5 s)

sounds. Minimise background noise and reverberation. For example, use sound absorbing materials on walls, floors and ceilings. Provide wireless headphone sets to older listeners in public settings. Avoid background music during spoken language (e.g., in movie or television segments). Speech input keying is a useful means of providing a hands-free facility for users with reliable voice, and may be valuable even where full hands-free operation is not necessary (e.g. when hand tremor interferes with manual keying). Speech input is also useful for dyslexic users who can read aloud and simultaneously enter keys thus avoiding short-term memory problems. A sensitive microphone will help people with quiet voices or with restricted neck and chest movement that makes speaking difficult. It is also important for the user to be able to adjust the sensitivity of the microphone so that it can be used by either a person with a weak voice or a normal voice. Amplification of the microphone should be user controlled and should automatically reset for the next user (Gill, 2004).

Voice control can be beneficial in situations where more than one task is performed simultaneously which require both hand and/or eye co-ordination. Its limitations include technological constraints which limit the vocabulary size and speed of accurate processing. Feedback of a mistake may interrupt other activities. Accuracy of voice recognition systems deteriorates significantly if there is background noise. Accuracy is improved by allowing a limited choice of commands which should include common alternatives such as 'start' or 'begin'(Gill, 2004).

- Other guidelines for audio input (Gill, 2004):
- Minimise background noise.
- Ensure that the microphone can be used by people in wheelchairs as well as by people standing in front of the terminal.
- Provide alternative method of input for people with speech impairment (or with a strong accent).
- Provide recognition feedback after each input.
- Provide opportunity for the user to undo incorrect inputs.

Combining audio and visual signals

When feasible try to provide multiple channels for important information, such as speech and visual signs (Fisk et al., 2004). Designers should consider engaging alternative sensory systems by providing redundant channels for those who have severe visual and hearing impairments. An example for warnings would be using sound and vibration in addition to visual signals. Screen phones that provide both auditory and visual text information help older adults interact successfully with telephone menu systems. Visual ringing signal is on the other hand essential for people who are deaf. Visual signals incorporated in the terminal are often not easily seen and are mainly of use as a reminder of line status. An interface should be provided so that external lights or a vibrating pager can be triggered by the phone (Gill, 2004). Consider providing parallel visual and auditory presentation of language (e.g., using speech recognition or closed caption text for public addresses).

Video telephony

Video phones have been slow to make significant market penetration. This is attributable to the low bandwidth available to most domestic consumers. For deaf users, a video phone could transmit sign language with a modest picture quality, but greater bandwidth is needed for lip reading (Gill, 2004). Screen phones may expand the utility of telephones for many IADL in the

future, making it possible for nurses to provide technical support over the phone. The ability to see the person on the other end of the telephone provides an added measure of cognitive support for older adults by allowing them to both see and hear the person providing the instruction (Liu and Park, 2003).